

SANOFI-AVENTIS  
Form 20-F  
March 12, 2010  
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, 2009

OR

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

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

For the transition period from            to

Commission File Number: 001-31368

**Sanofi-Aventis**

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

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, Senior Vice President Legal Affairs and General Counsel

174, avenue de France, 75013 Paris, France. Fax: 011 + 33 1 53 77 43 03

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

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

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

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

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

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

common stock as of December 31, 2009 was:

Ordinary shares: 1,318,479,052

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

of the Securities Act.

YES  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

Edgar Filing: SANOFI-AVENTIS - Form 20-F

requirements for the past 90 days.

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, 2009.

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

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

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

trademarks used or that may be or have been used under license by sanofi-aventis and /or its affiliates, such as Actonel<sup>®</sup>, Optinate<sup>®</sup> and Acrel<sup>®</sup>, trademarks of Warner Chilcott, Copaxone<sup>®</sup>, a trademark of Teva Pharmaceutical Industries, Mutagrip<sup>®</sup>, a trademark of Institut Pasteur, TroVax<sup>®</sup>, a trademark of Oxford BioMedica, Gardasil<sup>®</sup> a trademark of Merck & Co., Inc., BiTE<sup>®</sup>, a trademark of Micromet AG, and Xyzal<sup>®</sup>, a trademark shared by UCB and GlaxoSmithKline;

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, StarLink<sup>®</sup>, Liberty Link<sup>®</sup> and Liberty<sup>®</sup> trademarks of Bayer AG; and

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

The data relative to market shares and ranking information presented in particular in Item 4. Information on the Company B. Business Overview Markets Marketing and distribution are based on sales data from IMS Health MIDAS (IMS), retail and hospital, for calendar year 2009, in constant euros (unless otherwise indicated).

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

## **Table of Contents**

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

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

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

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

projections of operating revenues, net income, business net income, earnings per share, business earnings per share, capital expenditures, cost savings, restructuring costs, positive or negative synergies, dividends, capital structure or other financial items or ratios;

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

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

statements of assumptions underlying such statements.

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

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

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

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

product liability claims;

our ability to renew our product portfolio;

the increasingly challenging regulatory environment for the pharmaceutical industry;

uncertainties over the pricing and reimbursement of pharmaceutical products;

fluctuations in currency exchange rates; and

slowdown of global economic growth.

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

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

**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>	4
Item 4.	<u>Information on the Company</u>	14
	<u>A. History and Development of the Company</u>	15
	<u>B. Business Overview</u>	16
	<u>C. Organizational Structure</u>	67
	<u>D. Property, Plant and Equipment</u>	68
Item 4A.	<u>Unresolved Staff Comments</u>	70
Item 5.	<u>Operating and Financial Review and Prospects</u>	71
Item 6.	<u>Directors, Senior Management and Employees</u>	113
	<u>A. Directors and Senior Management</u>	113
	<u>B. Compensation</u>	128
	<u>C. Board Practices</u>	137
	<u>D. Employees</u>	140
	<u>E. Share Ownership</u>	142
Item 7.	<u>Major Shareholders and Related Party Transactions</u>	147
	<u>A. Major Shareholders</u>	147
	<u>B. Related Party Transactions</u>	148
	<u>C. Interests of Experts and Counsel</u>	149
Item 8.	<u>Financial Information</u>	150
	<u>A. Consolidated Financial Statements and Other Financial Information</u>	150
	<u>B. Significant Changes</u>	151
Item 9.	<u>The Offer and Listing</u>	152
	<u>A. Offer and Listing Details</u>	152
	<u>B. Plan of Distribution</u>	153
	<u>C. Markets</u>	153
	<u>D. Selling Shareholders</u>	155
	<u>E. Dilution</u>	155
	<u>F. Expenses of the Issue</u>	155
Item 10.	<u>Additional Information</u>	156
	<u>A. Share Capital</u>	156
	<u>B. Memorandum and Articles of Association</u>	156
	<u>C. Material Contracts</u>	171
	<u>D. Exchange Controls</u>	171
	<u>E. Taxation</u>	171
	<u>F. Dividends and Paying Agents</u>	177
	<u>G. Statement by Experts</u>	177
	<u>H. Documents on Display</u>	177
	<u>I. Subsidiary Information</u>	177
Item 11.	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	177
Item 12.	<u>Description of Securities other than Equity Securities</u>	181
<u>Part II</u>		
Item 13.	<u>Defaults, Dividend Arrearages and Delinquencies</u>	184
Item 14.	<u>Material Modifications to the Rights of Security Holders</u>	184
Item 15.	<u>Controls and Procedures</u>	184
Item 16.	<u>[Reserved]</u>	185
Item 16A.	<u>Audit Committee Financial Expert</u>	185
Item 16B.	<u>Code of Ethics</u>	185



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

Item 16C.	<u>Principal Accountants Fees and Services</u>	185
Item 16D.	<u>Exemptions from the Listing Standards for Audit Committees</u>	185
Item 16E.	<u>Purchases of Equity Securities by the Issuer and Affiliated Purchasers</u>	185
Item 16F.	<u>Change in Registrant's Certifying Accountant</u>	185
Item 16G.	<u>Corporate Governance</u>	185
<u>Part III</u>		
Item 17.	<u>Financial Statements</u>	187
Item 18.	<u>Financial Statements</u>	187
Item 19.	<u>Exhibits</u>	187

**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 OF SELECTED FINANCIAL DATA**

The tables below set forth selected consolidated financial data for sanofi-aventis. These financial data are derived from the sanofi-aventis consolidated financial statements. The sanofi-aventis consolidated financial statements for the years ended December 31, 2009, 2008 and 2007 are included in Item 18 of this annual report.

The consolidated financial statements of sanofi-aventis for the years ended December 31, 2009, 2008 and 2007 have been prepared in compliance with IFRS issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union. The term IFRS refers collectively to international accounting and financial reporting standards (IAS and IFRS) and to interpretations of the interpretations committees (SIC and IFRIC).

Sanofi-aventis reports its financial results in euros.

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

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

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

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

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

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

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

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

**Table of Contents****SELECTED EXCHANGE RATE INFORMATION**

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2005 through February 2010 expressed in U.S. dollar per euro. The information concerning the U.S. dollar exchange rate is based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York (the Noon Buying Rate). We provide the exchange rates below solely for your convenience. We do not represent that euros were, could have been, or could be, converted into U.S. dollars at these rates or at any other rate. For information regarding the effect of currency fluctuations on our results of operations, see Item 5. Operating and Financial Review and Prospects and Item 11. Quantitative and Qualitative Disclosures about Market Risk.

	<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>			
2005	1.18	1.24	1.35	1.17
2006	1.32	1.27	1.33	1.19
2007	1.46	1.38	1.49	1.29
2008	1.39	1.47	1.60	1.24
2009	1.43	1.40	1.51	1.25
Last 6 months				
2009				
September	1.46	1.46	1.48	1.42
October	1.48	1.48	1.50	1.45
November	1.50	1.49	1.51	1.47
December	1.43	1.46	1.51	1.42
2010				
January	1.39	1.43	1.45	1.39
February	1.37	1.37	1.40	1.35
March <sup>(2)</sup>	1.36	1.36	1.37	1.35

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

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

On March 10, 2010 the European Central Bank Rate was 1.3610 per euro.

***B. Capitalization and Indebtedness***

N/A

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

N/A

## **Table of Contents**

### ***D. Risk Factors***

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

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

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

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

Through patent and other proprietary rights, we hold exclusivity rights for a number of our research-based products. However, the patent protection that we are able to obtain varies from product to product and country to country and may not be sufficient, including to maintain product exclusivity. Furthermore we are involved in litigation worldwide to enforce certain of these patent rights against generics and proposed generics (see Note D.22.b) to our consolidated financial statements included in this annual report at Item 18 for additional information). Moreover, patent rights are limited in time and do not always provide effective protection for our products: competitors may successfully avoid patents through design innovation, we may not hold sufficient evidence of infringement to bring suit, or our infringement claim may not result in a decision that our rights are valid, enforceable or infringed.

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

Finally, our successful assertion of a given patent against one competing product is not necessarily predictive of our future success or failure in asserting the same patent against a second competing product because of such factors as possible differences in the formulations of the competing products, intervening developments in law or jurisprudence, or inconsistent judgments. Moreover, patents differ from country to country and a successful result in one country may not predict success in another country because of local variations in the patents and differences in national law or legal systems.

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

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

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

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

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

## **Table of Contents**

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

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

Product liability is a significant business risk for us, notably in the United States where product liability claims can be particularly costly. The Group's recent acquisitions may increase product liability exposure (see The diversification of the Group's business exposes us to additional risks below). Substantial damage awards have been made in certain jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. Not all possible side effects of a product can be anticipated based on preapproval clinical studies involving only several hundred to several thousand patients. Routine review and analysis of the continually growing body of post-marketing safety surveillance and clinical trials provide additional information for example, potential evidence of rare, population-specific or long-term adverse reactions or of drug interactions that were not observed in preapproval clinical studies and may cause product labeling to evolve, restriction of therapeutic indications and potentially even the suspension or withdrawal of a product. See Item 19. Exhibits 99.1 Report of the Chairman of the Board of Directors for 2009 for further discussion of these issues. Several pharmaceutical companies have recalled or withdrawn products from the market because of actual or suspected adverse reactions to their products, and currently face significant product liability claims. We are currently defending a number of product liability claims (see Note D.22.a) to the consolidated financial statements included at Item 18 of this annual report) and there can be no assurance that the Group will be successful in defending against these claims or will not face additional claims in the future.

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

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

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

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

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



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

## **Table of Contents**

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

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

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

### **Changes in the laws or regulations that apply to us could affect the Group's business, results of operations and financial condition.**

Governmental authorities are increasingly looking to facilitate generic competition to existing products through new regulatory proposals intended to or resulting in, within the major markets, changes to the scope of patent rights or data exclusivity rules.

This new competitive environment and potential regulatory changes may further limit the exclusivity enjoyed by innovative products on the market and directly impact pricing and reimbursement levels, which may adversely affect our business and future results. See Item 4. Information on the Company B. Business Overview Competition and Regulation .

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

For more information regarding risks related to changes in environmental rules and regulations, see Environmental Risks of our Industrial Activities Environmental liabilities and compliance costs may have a significant adverse effect on our results of operations below.

## **Risks Relating to Our Business**

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

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products to take the place of products facing expiration of patent and regulatory data exclusivity or

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

competition from new products that are perceived as being superior. In 2009, we spent 4,583 million on research and development, amounting to approximately 15.6% of our net sales.

The research and development process typically takes from 10 to 15 years from discovery to commercial product launch. This process is conducted in various stages in order to test, along with other features, the effectiveness and safety of a product. There can be no assurance that any of these compounds will be proven safe or effective. See Item 4. Information on the Company B. Business Overview Pharmaceutical Research & Development and Vaccines Research and Development . Accordingly, there is a substantial risk at each stage of development that we will not achieve our goals of safety and/or effectiveness and that we will have to abandon a product in which we have invested substantial amounts, including in late stage development (Phase III). Our ongoing investments in new product launches and research and development for future products could therefore result in increased costs without a proportionate increase in revenues. Furthermore each regulatory authority may impose its own requirements in order to grant a license to market the product, including requiring local clinical studies, and may delay or refuse to grant approval, even though a product has already been approved in another country. Finally, obtaining regulatory marketing approval is not a guarantee that the product will achieve commercial success.

## **Table of Contents**

As a complement to its portfolio of products, sanofi-aventis pursues a strategy of acquisitions, in-licensing and partnerships in order to develop new growth opportunities. The implementation of this strategy depends on our ability to identify business development opportunities at a reasonable cost and under acceptable conditions of financing. Moreover, entering into these in-licensing or partnership agreements generally requires the payment of significant milestones well before the relevant products are possibly placed on the market without any assurance that such investments will ultimately become profitable in the long term. Because of the active competition among pharmaceutical groups for such business development opportunities, there can be no assurance of our success in completing these transactions when such opportunities are identified.

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

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

### **We may lose market share to competing low-cost remedies or generic brands if they are perceived to be superior products.**

We are faced with intense competition from generic products and brand-name drugs. Doctors or patients may choose these products over ours if they perceive them to be safer, more reliable, more effective, easier to administer or less expensive, which could cause our revenues to decline and affect our results of operations.

### **The diversification of the Group's business exposes us to additional risks.**

We have undertaken to transform our Group by implementing a strategy that includes pursuing external growth opportunities to meet the challenges that we have identified for the future. The inability to quickly or efficiently integrate newly acquired activities or businesses, or integration costs that are higher than anticipated, could delay our growth objectives and prevent us from achieving expected synergies. Moreover, we may miscalculate the risks associated with these entities at the time they are acquired or not have the means to evaluate them properly. It may take a considerable amount of time and be difficult to implement a risk analysis after the acquisition is completed due to lack of historical data. As a result, risk management and the coverage of such risks, particularly through insurance policies, may prove to be insufficient or ill-adapted.

In addition to pursuing our objective to become a global and diversified leader within the health industry, we are exposed to a number of new risks inherent in sectors in which, in the past, we have been either less active or entirely inactive. As an example, we have increased exposure to the animal health business. The contribution of our animal health business to the Group's income may be adversely affected by a number of risks including some which are specific to this business: i.e., the outbreak of an epidemic or pandemic that could kill large numbers of animals, and the effect of reduced veterinary expenditures during an economic crisis. In some of these sectors the margins are lower than in the traditional pharmaceutical business. Moreover, the nature, scope and level of losses that may be sustained or caused by these new businesses may differ from the types of product liability claims that we have handled in the past (See Product liability claims could adversely affect our business, results of operations and financial condition above), and thus our current risk management and insurance coverage may not be adapted to such losses. These risks could affect our business, results of operations or financial condition.

**The globalization of the Group's business exposes us to increased risks.**

The significant expansion of our activities in emerging markets may further expose us to more volatile economic conditions, political instability, competition from companies that are already well established in these

## **Table of Contents**

markets, the inability to adequately respond to the unique characteristics of these markets, particularly with respect to their regulatory frameworks, difficulties in recruiting qualified personnel, potential exchange controls, weaker intellectual property protection, higher crime levels (particularly with respect to counterfeit products (see Risks Relating to Our Business Counterfeit products could harm our business below)), corruption and fraud. Any difficulties in adapting to these markets could impair our ability to take advantage of these growth opportunities and could affect our business, results of operations or financial condition.

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

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

Health authorities, in particular the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have imposed increasingly burdensome requirements on pharmaceutical companies, particularly in terms of the volume of data needed to demonstrate a product's efficacy and safety. Marketed products are also subject to continual review even after regulatory approval. See Item 19. Exhibit 99.1 Report of the Chairman of the Board of Directors for 2009 for a further discussion of these issues. Later discovery of previously undetected problems may result in marketing restrictions or the suspension or withdrawal of the product, as well as an increased risk of litigation for both pharmaceutical and animal health products.

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

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

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

price controls imposed by governments in many countries;

removal of a number of drugs from government reimbursement schemes;

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

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

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

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

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

## **Table of Contents**

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

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

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

We market some of our products in collaboration with other pharmaceutical companies. For example, we currently have major collaborative arrangements with Bristol-Myers Squibb (BMS) for the marketing of Plavix<sup>®</sup> and Aprovel<sup>®</sup> in the United States and several other countries, with Warner Chilcott 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 ; our major alliances are detailed under Main pharmaceutical products . When we market our products through collaboration arrangements, we are subject to the risk that certain decisions, such as the establishment of budgets and promotion strategies, are subject to the control of our collaboration partners, and that deadlocks may adversely affect the activities conducted through the collaboration arrangements. For example, our alliances with BMS are subject to the operational management of BMS in some countries, including the United States. Any conflicts that we may have with our partners may affect the marketing of certain of our products. Such difficulties may cause a decline in our revenues and affect our results of operations.

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

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

<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**

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

Third parties supply us with a substantial portion of our raw materials, active ingredients and medical devices, which exposes us to the risk of a supply interruption in the event that these suppliers experience financial difficulties or are unable to manufacture a sufficient supply of our products meeting Group quality standards. It also increases the risk of quality issues, even with the most scrupulously selected suppliers. For example, in 2008 we recalled a limited number of batches of Lovenox<sup>®</sup> and wrote down significant unused inventory following the discovery of quality issues at a Chinese supplier of raw materials. If disruptions or quality concerns were to arise in the third-party supply of raw materials, active ingredients or medical devices, this could adversely affect our ability to sell our products in the quantities demanded by the market and could damage our reputation and relationships with our customers. See also [Item 4. Information on the Company B. Business Overview Production and Raw Materials](#) for a description of these outsourcing arrangements. The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, delay the launch of new products and adversely affect our operating results and financial condition above. Even though we aim to have backup sources of supply whenever possible, including by manufacturing backup supplies of our principal active ingredients at a second or third facility when practicable, we cannot be certain they will be sufficient if our principal sources become unavailable. Switching sources and manufacturing facilities may require significant time. Some raw materials essential to the manufacture of our products are not widely available from sources we consider reliable; for example, we have approved only a limited number of suppliers of heparins for use in the manufacture of Lovenox<sup>®</sup>. Heparin purchase prices can also fluctuate. See [Item 4. Information on the Company B. Business Overview Production and Raw Materials](#) for a description of these outsourcing arrangements. Any of these factors could adversely affect our business, operating results or financial condition.

### **Counterfeit versions of the Group's products could harm our business.**

The drug supply has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. To distributors and users, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and could harm the business of companies such as sanofi-aventis. Additionally, it is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. If a Group product were the subject of counterfeits, the Group could incur substantial reputational and financial harm. See [Item 4. Information on the Company B. Business Overview Competition](#).

### **Use of biologically derived ingredients may face resistance from patients or the purchasers of these products, which could adversely affect sales and cause us to incur substantial costs.**

In line with industry practice, we manufacture our vaccines and many of our prescription pharmaceutical products with ingredients derived from animal or plant tissue. We subject our products incorporating these ingredients to extensive tests and believe them to be safe. There have been instances in the past where the use of biologically derived ingredients by sanofi-aventis or its competitors has been alleged to be an actual or theoretical source of harm, including infection or allergic reaction, or instances where production facilities have been subject to prolonged periods of closure because of possible contamination. Such allegations have on occasion led to damage claims and increased resistance on the part of patients to such ingredients. A substantial claim of harm caused by a product incorporating biologically derived ingredients or a contamination event could lead us to incur potentially substantial costs as a result of, among other things, litigation of claims, product recalls, adoption of additional safety measures, manufacturing delays, investment in patient education, and development of synthetic substitutes for ingredients of biological origin. Such claims could also generate patient resistance, with a corresponding adverse effect on sales and results of operations.

## **Table of Contents**

### **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. This risk is accentuated by the current worldwide financial crisis. The United States, which is our largest market in terms of sales, poses particular client credit risk issues, because of the concentrated distribution system in which approximately 78% of our consolidated U.S. pharmaceutical sales were accounted for by just three wholesalers. In addition, the Group's three main customers represent 22% of our total revenues. We are also exposed to large wholesalers in other markets, particularly in Europe. An inability of one or more of these wholesalers to honor their debts to us could adversely affect our financial condition (see Note D.34. to our consolidated financial statements included at Item 18 of this annual report).

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

Our future funding obligations for our main defined-benefit pension plans depend on changes in the future performance of assets held in trust for these plans, the interest rates used to determine funding levels (or company liabilities), actuarial data and experience, inflation trends, the level of benefits provided for by the plans, as well as changes in laws and regulations. Adverse changes in those factors could increase our unfunded obligations under such plans, which would require more funds to be contributed and hence negatively affect our cash flow and results (see Note D.18.1 to our consolidated financial statements included at Item 18 of this annual report).

### **Environmental Risks of Our Industrial Activities**

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

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

fires and/or explosions from inflammable substances;

storage tank leaks and ruptures; and

discharges or releases of toxic or hazardous substances.

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

the shutdown of affected facilities; and

the imposition of civil or criminal penalties.

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

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

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

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

that we currently own or operate;

that we formerly owned or operated; or

where waste from our operations was disposed.

<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 and by Notes D.10. and D.34. to our consolidated financial statements included at Item 18 of this annual report.

---

## **Table of Contents**

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

Furthermore, we are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former sanofi-aventis subsidiaries have been named as potentially responsible parties or the equivalent under the U.S. Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (also known as Superfund), and similar statutes in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligation, we and/or our subsidiaries may retain responsibility for environmental liabilities at some of the sites of our predecessor companies, or our subsidiaries that we demerged, divested or may divest. We have disputes outstanding, for example, with Rhodia, over costs related to environmental liabilities regarding certain sites no longer owned by the Group. An adverse outcome in such disputes might have a significant adverse effect on our operating results. See Note D.22.e) to the consolidated financial statements included at Item 18 of this annual report.

Environmental regulations are evolving (i.e., in Europe, REACH, SEVESO, IPPC, the Waste Framework Directive, the Emission Trading Scheme Directive, the Water Framework Directive and the Directive on Taxation of Energy Products and Electricity and several other regulations aiming at preventing global warming). Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to our Group and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants, site restoration and compliance costs to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures as well as other costs and liabilities, thereby adversely affecting our business, results of operations or financial condition. For more detailed information on environmental issues, see Item 4. Information on the Company B. Business Overview Health, Safety and Environment (HSE).

### **Risks Related to Financial Markets<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 2009, approximately 32% of our net sales were realized in the United States. While we incur expenses in those currencies, the impact of currency exchange rates on these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate and when technically feasible, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations or financial condition. For more information concerning our exchange rate exposure, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

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

As of December 31, 2009, the Group's net debt amounted to 4.1 billion. In addition to debt outstanding, the Group has contracted a number of credit lines and put into place commercial paper and medium term note programs with the aim of providing liquidity. See Item 11. Quantitative

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

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

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

## **Table of Contents**

sources of financing, including under programs currently in place, or less favorable conditions. While liquidity conditions in the financial markets have improved somewhat in recent months, they could deteriorate once again, in which case our sources of financing could be substantially reduced, and we might find it difficult to refinance existing debt or to incur new debt on terms that we would consider to be commercially reasonable.

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

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

Holders of ADSs face exchange rate risk. Our ADSs trade in U.S. dollars and our shares trade in euros. The value of the ADSs and our shares could fluctuate as the exchange rates between these currencies fluctuate. If and when we do pay dividends, they would be denominated in euros. Fluctuations in the exchange rate between the euro and the U.S. dollar will affect the U.S. dollar amounts received by owners of ADSs upon conversion by the depository of cash dividends, if any. Moreover, these fluctuations may affect the U.S. dollar price of the ADSs on the New York Stock Exchange (NYSE), whether or not we pay dividends in addition to the amounts, if any, that a holder would receive upon our liquidation or upon the sale of assets, merger, tender offer or similar transactions denominated in euros or any foreign currency other than U.S. dollars.

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

Holders of ADSs may have more difficulty exercising their rights as a shareholder than if they directly held shares. For example, if we offer new shares and they have the right to subscribe for a portion of them, the depository 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 depository how to vote their shares. Because of this extra procedural step involving the depository, the process for exercising voting rights will take longer for holders of ADSs than for holders of shares. ADSs for which the depository does not receive timely voting instructions will not be voted at any meeting.

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

As of December 31, 2009, Total and L Oréal, our two largest shareholders, held approximately 7.33% and 8.97% of our issued share capital, respectively, accounting for approximately 12.36% and approximately 15.32%, respectively, of the voting rights (excluding treasury shares) of sanofi-aventis. See Item 7. Major Shareholders and Related Party Transactions A. Major Shareholders. Affiliates of each of these shareholders are currently serving on our Board of Directors. To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, Total and L Oréal will remain in a position to exert heightened influence in the election of the directors and officers of sanofi-aventis and in other corporate actions that require shareholders' approval.

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

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

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



---

## **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 2009, our net sales amounted to 29,306 million. Based on 2009 sales, we are the fourth largest pharmaceutical group in the world and the second largest pharmaceutical group in Europe (source: IMS sales 2009). Sanofi-aventis is the parent of a consolidated group of companies. A list of the principal subsidiaries included in this consolidation is shown at Note F. to our consolidated financial statements included at Item 18 of this annual report.

Our business includes two main activities: pharmaceuticals, and human vaccines through sanofi pasteur. The Group is also present in animal health products through Merial Limited ( Merial ).

In our pharmaceutical activity, which generated net sales of 25,823 million in 2009, we specialize in the following therapeutic areas:

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

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

*Thrombosis and Cardiovascular:* our thrombosis medicines include two leading drugs in their categories: Plavix<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. Our cardiovascular medicines include Multaq<sup>®</sup>, a new anti-arrhythmic agent launched in the United States and a few other markets in 2009 and indicated for patients with atrial fibrillation, and two major hypertension treatments: Aprovel<sup>®</sup>/CoAprovel<sup>®</sup> and Tritace<sup>®</sup>;

*Other therapeutic areas are:*

*Central Nervous System ( CNS ):* our major CNS medicines include Stilnox<sup>®</sup>/Ambien<sup>®</sup> CR, a sleep disorder 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 anti-histamine, 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 in Consumer Health Care ( CHC ) and other prescription drugs including generics.

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

We are a world leader in the vaccines industry. Our net sales amounted to 3,483 million in 2009, with leading vaccines in five areas:

Pediatric combination vaccines providing protection against diseases such as pertussis, diphtheria, tetanus, and *Haemophilus influenzae* type b infections. Our main products are Daptacel<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 in both hemispheres, as well as Intanza<sup>®</sup>/IDflu<sup>®</sup> (the first intradermal influenza vaccine, approved in Europe in February 2009), and Fluzone<sup>®</sup> High Dose IM, approved in the U.S. in December 2009. Additionally, we manufactured and distributed: an A(H1N1) pandemic influenza vaccine in the United States; Panenza, another A(H1N1) pandemic influenza vaccine approved in several countries outside the United States, including in Europe; and pre-pandemic influenza vaccines (including H5N1 vaccines), as part of the global pandemic efforts in both our French and U.S. facilities;

---

**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 U.S. in 2005), Adacel Polio<sup>®</sup>, Decavac<sup>®</sup>, Repevax<sup>®</sup> and Revaxis<sup>®</sup>;

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

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

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

Our animal health activity is managed through Merial, formerly a joint venture in which we and Merck & Co., Inc. ( Merck ) each held 50%. On September 17, 2009 we acquired Merck's interest in Merial. On March 8, 2010, sanofi-aventis exercised its contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial to form an animal health joint venture that would be equally owned by the new Merck and sanofi-aventis. In addition to execution of final agreements, formation of the new animal health joint venture remains subject to approval by the relevant competition authorities and other closing conditions (for more information see Item 8 B. Significant Changes Merial and Notes D.1 and D.8.1 to our consolidated financial statements included at Item 18 of this annual report). Merial is one of the world's leading animal healthcare companies dedicated to the research, development, manufacture and delivery of innovative pharmaceuticals and vaccines used by veterinarians, farmers and pet owners. Its net sales for 2009 (which are not included in the Group's 2009 net sales) amounted to \$2,554 million. The company's top-selling products include Frontline<sup>®</sup>, a topical anti-parasitic flea and tick brand for dogs and cats, Heartgard<sup>®</sup>, a parasiticide for control of heartworm in companion animals as well as Ivomec<sup>®</sup>, a parasiticide for the control of internal and external parasites in livestock.

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

A drug can be referred to either by its international non-proprietary name (INN), or by its brand name, which is normally exclusive to the company that markets it. In most cases, our brand names, which may vary from country to country, are protected by trademark registrations. In general, we have chosen in this annual report to refer to our products by the brand names that we use in France, except for Allegra<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) and Multaq<sup>®</sup> (not yet sold in France);

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

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

We present our consolidated net sales for our leading products sold directly and through alliances. As regards the products sold through our alliance with BMS, we also present the aggregate worldwide sales of Plavix<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 our main telephone number is +33 1 53 77 40 00. Our principal U.S. subsidiary's office is located at 55 Corporate Drive, Bridgewater, NJ 08807; Telephone: +1 (908) 981-5000.

(1) Worldwide excluding North America and Europe.

## **Table of Contents**

We are present in approximately 110 countries on five continents with about 105,000 employees at year end 2009, not including an additional 5,600 employees of Merial. Our legacy companies, Sanofi-Synthélabo (formed by a merger between Sanofi and Synthélabo in 1999) and Aventis (formed by the combination of Rhône-Poulenc and Hoechst also in 1999), bring to the Group more than a century of experience in the pharmaceutical industry.

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

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

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

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

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

Merial was founded in 1997 as a combination of the animal health activities of Rhône-Poulenc and Merck. Merial was a joint venture in which we and Merck each held 50%. On September 17, 2009, sanofi-aventis acquired Merck's 50% interest in Merial and Merial is now a wholly-owned subsidiary of sanofi-aventis. On March 8, 2010, sanofi-aventis exercised its contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial to form an animal health joint venture that would be equally owned by the new Merck and sanofi-aventis. Formation of the new animal health joint venture remains subject to approval by the relevant competition authorities and other closing conditions (for more information see Item 8 B. Significant Changes Merial and Notes D.1 and D.8.1 to our consolidated financial statements included at Item 18 of this annual report).

The Prague-based branded generics group Zentiva was acquired by sanofi-aventis through a tender offer completed on March 11, 2009.

On February 9, 2010 Sanofi-aventis successfully completed its tender offer for all outstanding shares of common stock of Chattem, Inc., ( Chattem ) a leading U.S. consumer healthcare company. Immediately following the tender offer, sanofi-aventis held approximately 97% of Chattem's outstanding shares, and acquired the remaining shares in a short form merger on March 10, 2010.

***B. Business Overview***

**Strategy**

Sanofi-aventis is a diversified global healthcare leader with a number of core strengths: a strong and long-established presence in emerging markets <sup>(1)</sup>, a portfolio of diabetes drugs including the biggest selling insulin in the world: Lantus<sup>®</sup>, a market-leading position in vaccines, a broad range of consumer health care products and research that is increasingly focused on biological products, allied with a track record of adapting cost structures and a solid financial position.

<sup>(1)</sup> Worldwide excluding United States, Canada, Western Europe (France, Germany, UK, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxemburg, Portugal, the Netherlands, Austria, Switzerland, Ireland, Finland, Norway, Iceland, Sweden and Denmark), Japan, Australia and New Zealand.

---

## **Table of Contents**

Like most pharmaceutical companies, we are facing competition from generics for several of our major products, in an environment subject to cost containment pressures from both third party payers and healthcare authorities as well as tougher regulatory hurdles. We have decided to respond to these major challenges by developing our platforms for growth.

Throughout 2009, we have been engaged in a wide-ranging transformation program designed to secure sources of sustainable growth. Our strategy focuses on three key themes:

### **Increasing innovation in Research & Development ( R&D )**

We conducted a complete and objective review of our research portfolio in 2009, in order to reassess the allocation of resources. This review led to a rationalization of our portfolio, targeting the most promising projects. In February 2010, 60% of our development portfolio consisted of biological products and vaccines. We also redefined our decision-making processes so that new commercial potential and the scope for value creation are better integrated into our development choices. The ongoing reorganization of our R&D is intended to help us become more flexible and innovative, with some of our existing resources being reallocated to external collaborations. In line with this policy, we have signed a number of alliance and licensing agreements with partners including Kyowa Hakko Kirin Co. Ltd ( Kyowa Hakko Kirin ), Exelixis, Inc. ( Exelixis ), Merrimack Pharmaceuticals, Inc. ( Merrimack ), Wellstat Therapeutics Corporation ( Wellstat ), Micromet, Inc. ( Micromet ), and Alopexx Pharmaceuticals LLC ( Alopexx ). These agreements are designed to give us access to new technologies, or to broaden or strengthen our existing fields of research. We have also signed additional agreements with Regeneron Pharmaceuticals, Inc. to broaden and extend our existing collaboration on the research, development and commercialization of fully human therapeutic monoclonal antibodies. In February 2010, 55% of our development portfolio consisted of projects originated by external R&D. Finally, we have made progress on our objective of offering more products that add value for patients: for example Multaq<sup>®</sup>, which in 2009 was launched in the United States and approved in the European Union.

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

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

### **Exploring external growth opportunities**

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

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

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



## **Table of Contents**

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

Our sound financial position should give us significant potential to create value via external growth opportunities, with the aim of securing a return on investment in excess of our cost of capital.

## **Pharmaceutical Products**

### **Main Pharmaceutical Products**

Within our Pharmaceuticals business, we focus on the following therapeutic areas: diabetes, oncology, thrombosis & cardiovascular, central nervous system and internal medicine.

The sections that follow provide additional information on the indications and market position of these products in their principal markets. The Group's intellectual property relating to its pharmaceutical products is material to our operations and is described at Patents, Intellectual Property and other Rights below. As disclosed in Note D.22.b to our consolidated financial statements included at Item 18 of this annual report, we are involved in significant litigation concerning the patent protection of a number of these products.

**Table of Contents**

The following table sets forth the net sales of our best selling pharmaceutical products for the year ended December 31, 2009. These products are major contributors to public health.

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

Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

## **Table of Contents**

### ***Diabetes***

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

### **Lantus<sup>®</sup>**

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

Lantus<sup>®</sup> is a well established treatment with 24 million patient-years exposure since 2000. Over 70,000 patients throughout the world have been involved in Lantus<sup>®</sup> clinical trials.

Lantus<sup>®</sup> can be administered subcutaneously using syringes or specific pens including the Lantus<sup>®</sup> SoloSTAR<sup>®</sup> disposable pen and the new KlikSTAR<sup>®</sup> reusable pen:

Lantus<sup>®</sup> SoloSTAR<sup>®</sup> is a pre-filled disposable pen available in over 50 countries worldwide. It is the only disposable pen that combines a low injection force, up to 80 units per injection and ease-of-use. In 2007, it was awarded a GOOD DESIGN Award by the Chicago Athenaeum Museum of Architecture and Design; and

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

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

Versus detemir:

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

Versus NPH (Neutral Protamine Hagedorn):

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

- A 5-year large randomized study comparing Lantus® with NPH confirmed findings from short-term studies of lower risk of hypoglycemia with Lantus® vs NPH (Rosenstock IDF 2009); and
- In October 2009, the FDA approved the inclusion in the Lantus® labeling of favorable results from this 5-year study comparing the effect of Lantus® with that of NPH insulin on the progression of retinopathy in patients with type 2 diabetes.

### Versus Premixes:

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

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

## **Table of Contents**

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

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

In September 2009, we announced an action plan to provide methodologically robust research that will contribute to the scientific resolution of the debate over insulin safety, including insulin analogs and Lantus<sup>®</sup>. The research program encompasses both pre-clinical and clinical programs involving human insulin and insulin glargine and is designed to generate more information on whether there is any association between cancer and insulin use and to assess if there is any difference in risk between insulin glargine and other insulins. The plan is structured to yield short-term and longer-term results. Three epidemiological studies are planned (two retrospective cohort studies and one case-control study). We expect to complete the two retrospective cohort studies and analyze their results in time for scientific presentations at medical conferences in 2012. We aim to present the results of the case-control study in 2013. We are also conducting pre-clinical studies that for which we expect to have results in 2010 and in 2011.

The American Diabetes Association ( ADA ) and European Association for the Study of Diabetes ( EASD ) have maintained their 2008 treatment recommendations for type 2 diabetes. As a reminder, these guidelines further established basal insulins such as Lantus<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 treatment recommendations reinforce the timely use of basal insulin as a core therapy for type 2 diabetes.

Lantus<sup>®</sup> is the number-one sold insulin in the world in both sales and units (source: IMS, 2009 sales) and is available in over 70 countries worldwide. The three leading countries for sales of Lantus<sup>®</sup> are the United States, France and Germany.

## **Apidra<sup>®</sup>**

Apidra<sup>®</sup> (insulin glulisine) is a rapid-acting analog of human insulin. Apidra<sup>®</sup> is indicated for the treatment of adults with type 1 and in type 2 diabetes for supplementary glycemic control. Apidra<sup>®</sup> has a more rapid onset and shorter duration of action than fast-acting human insulin and can be associated with long-acting insulins such as Lantus<sup>®</sup> for supplementary glycemic control at mealtime.

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

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

Apidra<sup>®</sup> can be administered subcutaneously using syringes or specific pens including the Apidra<sup>®</sup> SoloSTAR<sup>®</sup> disposable pen and the new KlikSTAR<sup>®</sup> reusable pen:

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

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

Apidra<sup>®</sup> was launched in Germany in 2004, in other European countries in 2005, in the United States in 2006, and in Canada and Japan in 2009. Apidra<sup>®</sup> is now available in over 26 countries worldwide. The top three countries contributing to sales of Apidra<sup>®</sup> are the United States, Germany and Italy.

## **Table of Contents**

### **Amaryl®/Amarel®/Solosa®**

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

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

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

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

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

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

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

### ***Oncology***

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

### **Taxotere®**



Taxotere<sup>®</sup> (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<sup>®</sup> promotes their assembly and blocks their disassembly, thereby preventing many cancer cells from dividing and resulting in death in some cancer cells.

Taxotere<sup>®</sup> 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<sup>®</sup> 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.

## **Table of Contents**

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

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

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

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

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

## **Eloxatine®**

Eloxatine® (oxaliplatin) is a platinum-based cytotoxic agent. Eloxatine® combined with infusional (given through bloodstream) administration of two other chemotherapy drugs, 5-fluorouracil/leucovorin (the FOLFOX regimen) is approved by the FDA for adjuvant treatment of people with stage III colon cancer who have had their primary (original) tumors surgically removed. This approval was based on evidence of an improvement in disease-free survival after four years.

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

Increase overall survival rates by 5.5% when the recommended dose of 12 cycles of therapy is completed; and

Reduce the risk of colon cancer coming back.

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

Significantly prolonged survival;

Significantly shrank tumors; and

Significantly delayed cancer progression.

Following the end of the Eloxatine<sup>®</sup> European regulatory data exclusivity in April 2006, a number of oxaliplatin generics have received marketing authorization and have been launched throughout Europe. With regard to the United States market, in August and September 2009, a number of oxaliplatin generics received final marketing authorization from the FDA and have since been launched.

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

## Table of Contents

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

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

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

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

**Aflibercept** (the VEGF Trap, anti-angiogenesis agent; solid tumors; Phase III). VEGF (Vascular Endothelial Growth Factor) Trap is being developed under an alliance with Regeneron Pharmaceuticals, Inc. Aflibercept is a novel anti-angiogenesis agent that acts as a decoy receptor or Trap for circulating VEGF. Three Phase III studies in combination with chemotherapy in patients with several solid tumors are ongoing in the following indications: in first-line advanced prostate cancer (with Taxotere<sup>®</sup> /prednisone: VENICE study) and in second-line non-small cell lung cancer (with Taxotere<sup>®</sup>: VITAL study), both of which are now fully enrolled; and in second-line metastatic colorectal cancer (with FOLFIRI; VELOUR study) where about 95% of the patients have been recruited. A fourth study, in first-line metastatic pancreas cancer with gemcitabine, was stopped in September 2009 based on the recommendation of an Independent Data Monitoring Committee ( IDMC ). As part of a planned interim efficacy analysis, the IDMC determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine as it was unlikely to demonstrate superiority *versus* gemcitabine alone. Additional exploratory studies in earlier stage disease or other indications are being conducted either by sanofi-aventis and Regeneron or in collaboration with the U.S. National Cancer Institute;

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

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

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

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

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

## **Table of Contents**

### ***Thrombosis and Cardiovascular***

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

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<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup> and Tritace<sup>®</sup>/Triatec<sup>®</sup>/Delix<sup>®</sup>/Altace<sup>®</sup>.

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

### **Lovenox<sup>®</sup>/Clexane<sup>®</sup>**

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

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

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

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

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

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

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

### **Plavix<sup>®</sup> / Iscover<sup>®</sup>**

Plavix<sup>®</sup> (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<sup>®</sup> is indicated for the secondary prevention of atherothrombosis regardless of the location of the arteries initially affected (heart, brain, lower limbs). This

## **Table of Contents**

indication is supported by the results of the landmark CAPRIE trial, including almost 20,000 patients. CAPRIE demonstrated the superior efficacy of Plavix® over acetylsalicylic acid (ASA, the active ingredient of Aspirin®), with a comparable safety profile.

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

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

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

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

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

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

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

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



Plavix® is marketed in over 115 countries. The marketing of Plavix® is organized through our alliance with BMS (see Alliance with BMS below).

Sales of Plavix® in Japan are consolidated by sanofi-aventis and are outside the scope of our alliance with BMS. In 2009, Plavix® obtained the highest level recommendation in the Japanese stroke and ACS guidelines.

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

#### **Aprovel®/Avapro®/Karvea®**

Aprovel® (irbesartan) is an anti-hypertensive belonging to the class of angiotensin II receptor antagonists. These highly effective and well tolerated antagonists act by blocking the effect of angiotensin II, the hormone

## **Table of Contents**

responsible for blood vessel contraction, thereby enabling blood pressure to return to normal. In addition to Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>, we also market CoAprovel<sup>®</sup>/Avalide<sup>®</sup>/Karvezide<sup>®</sup>, a fixed dose combination of irbesartan and hydrochlorothiazide ( HCTZ ), a diuretic that increases the excretion of water and sodium by the kidneys and provides an additional blood pressure lowering effect. These products achieve control of blood pressure in over 80% of patients, with a very good safety profile.

Aprovel<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> is indicated in patients whose blood pressure is not adequately controlled with a monotherapy, but also as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals (in the United States only).

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

Aprovel<sup>®</sup> and CoAprovel<sup>®</sup> are marketed in more than 80 countries. The marketing of Aprovel<sup>®</sup> and CoAprovel<sup>®</sup> is organized through an alliance with BMS (see Alliance with BMS below).

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

Irbesartan generics in monotherapy are marketed in Spain and Portugal.

### **Alliance with BMS**

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

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

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

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

*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 Daiippon Sumitomo Pharma Co. Ltd since June 2008. The BMS alliance does not cover rights to Plavix<sup>®</sup> in Japan; sales of Plavix<sup>®</sup> in Japan are consolidated by sanofi-aventis.

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

We use the co-promotion system for most of the countries of Western Europe for Aprovel<sup>®</sup> and Plavix<sup>®</sup> and for certain Asian countries for Plavix<sup>®</sup>;

## **Table of Contents**

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>; and

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), 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<sup>®</sup> and Aprovel<sup>®</sup> and in Colombia only for Plavix<sup>®</sup>; and

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

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

The financial impact of our principal alliances on our financial condition or income is significant and is described under Item 5. Operating and Financial Review and Prospects Financial Presentation of Alliances , and see Item 3. Key Information D. Risk Factors We rely on third parties for the marketing of some of our products for more information relating to risks in connection with our alliance agreements.

### **Tritace<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.

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<sup>®</sup> is the only ACE inhibitor approved for the prevention of stroke, myocardial infarction and death in these patients and has the broadest spectrum of indications among ACE inhibitors for the treatment of cardiovascular diseases.

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

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

### **Multaq<sup>®</sup>**

Multaq<sup>®</sup> (dronedarone) is a multichannel blocker with both rhythm (prevention of atrial fibrillation recurrences) and rate (decrease of ventricular rate) controlling properties and additional effects (anti-hypertensive, vasodilatory). It is the first and only anti-arrhythmic drug to have shown a significant reduction in cardiovascular hospitalization or death in patients with Atrial Fibrillation ( AF ) / Atrial flutter ( AFL ). Multaqa convenient fixed dose regimen of twice daily 400 mg tablets to be taken with morning and evening meals. Treatment with Multaqa<sup>®</sup> does not require a loading dose and can be initiated in an outpatient setting with minimal monitoring. The most common adverse reactions are diarrhea, nausea, vomiting, abdominal pain, asthenia (weakness) and cutaneous rash.

## **Table of Contents**

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

In the United States, Multaq<sup>®</sup> is indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent AF or AFL, with a recent episode of AF/AFL and associated cardiovascular risk factors.

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

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

In Europe, Multaq<sup>®</sup> is indicated in adult clinically stable patients with a history of or with current non-permanent AF to prevent recurrence of AF or to lower ventricular rate.

The use of Multaq<sup>®</sup> in unstable patients with New York Heart Association class III and class IV heart failure is contraindicated.

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

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

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

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

**Otamixaban** (direct factor Xa inhibitor, interventional cardiology; Phase III initiation). Otamixaban is an injectable, selective direct inhibitor of coagulation factor Xa. It is a synthetic small molecule. Otamixaban exhibits a fast on- and off-set of action. A Phase III

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

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

**Celivarone** (anti-arrhythmic; Phase IIb). Based upon the results of a previous trial, a new Phase II study in patients fitted with an implantable cardioverter/defibrillator is ongoing; and

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

## **Table of Contents**

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

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

#### **Stilnox<sup>®</sup>/Ambien<sup>®</sup>/Myslee<sup>®</sup>**

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

Stilnox<sup>®</sup> is available in 5 mg and 10 mg tablets. Stilnox<sup>®</sup> rapidly induces sleep that is qualitatively close to natural sleep and devoid of certain side effects that are characteristic of the benzodiazepine class as a whole. Its action lasts for a minimum of six hours, and it is generally well tolerated, allowing the patient to awaken with a reduced risk of impaired attention, decreased alertness or memory lapses throughout the day. The risk of dependence is minimal when Stilnox<sup>®</sup> is used at the recommended dosage and duration of use. Stilnox<sup>®</sup> 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<sup>®</sup> CR in 6.25 mg and 12.5 mg tablets. Ambien<sup>®</sup> CR is marketed only in the United States.

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

The top three markets contributing to sales of Stilnox<sup>®</sup> in 2009 (either immediate or controlled release formulations) are the United States, Japan and Italy. Generic zolpidem tartrate has been available in Europe since 2004. In the United States, generics of the immediate release formulation of Ambien<sup>®</sup> have been available since 2007.

#### **Copaxone<sup>®</sup>**

Copaxone<sup>®</sup> (glatiramer acetate) is a non-interferon immunomodulating agent indicated for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis. Copaxone<sup>®</sup> 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<sup>®</sup> is more effective than placebo at two years, but also that it has a clinical efficacy over 15 years both in reducing relapses and progression of disability. A significant effect on lesions has also been confirmed by nuclear magnetic resonance imaging.



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

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

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

#### **Alliance with Teva**

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

## **Table of Contents**

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 records product sales or shares certain marketing expenses with respect to the United States and Canada and, until March 31, 2010, will receive from Teva a royalty of 25% of sales in these markets.

Under the terms of our agreement, the Copaxone<sup>®</sup> business in countries other than the U.S. and Canada will be transferred to Teva over a period running from the third quarter of 2009 to the first quarter of 2012 at the latest, depending on the country. Following the transfer, sanofi-aventis will receive from Teva a royalty of 6% for a period of two years, on a country-by-country basis. In September 2009, the Copaxone<sup>®</sup> business was transferred to Teva in Switzerland and Lichtenstein. See Item 3. Key Information D. Risk Factors We rely on third parties for the marketing of some of our products, for more information relating to risks in connection with our alliance agreements.

## **Depakine<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, and long years of experience have shown that it is effective for all types of epileptic seizures and epileptic syndromes, and is generally well tolerated. Consequently, Depakine<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. Depakine<sup>®</sup> is recommended as a first-line treatment in these indications by international guidelines such as the guidelines of the World Federation of Societies of Biological Psychiatry Guidelines 2009, the Canadian Network for Mood and Anxiety Treatments 2009, and the British Association for Psychopharmacology 2009.

We provide a wide range of formulations of Depakine<sup>®</sup> enabling it to be adapted 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®, including both indications, are the United Kingdom, France and Italy.

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

**Teriflunomide** (orally active dihydroorotate dehydrogenase inhibitor, multiple sclerosis; Phase III). An extensive Phase III monotherapy development program in relapsing forms of multiple sclerosis is ongoing, with results of the first pivotal study expected to be released in October 2010. In a Phase II adjunctive therapy study, teriflunomide, when added to background stable therapy with interferon (IFN-beta) showed acceptable tolerance and significant improvements of the disease (measured by magnetic resonance imaging -MRI);

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

## **Table of Contents**

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

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

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

### ***Internal Medicine***

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

### **Allegra®/Telfast®**

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

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

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

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

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

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

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

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

### **Nasacort<sup>®</sup>**

Nasacort<sup>®</sup>AQ Spray (NAQ) (triamcinolone acetonide) is an unscented, water-based metered-dose pump spray formulation unit containing a microcrystalline suspension of triamcinolone acetonide in an aqueous medium that was launched in 1996. Previously indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children six years of age and older, Nasacort<sup>®</sup> AQ received an additional approval for the seasonal and annual treatment of pediatric patients between the ages of two and five years from the FDA in September 2008. NAQ is an intranasal corticosteroid, which is recommended in treatment guidelines as first-line treatment for moderate to severe allergic rhinitis patients. NAQ offers significant relief from nasal allergy symptoms to patients, with no scent, alcohol or taste.

## **Table of Contents**

The top three countries contributing to Nasacort<sup>®</sup> AQ Spray sales in 2009 were the United States, France and Turkey. In settlement of patent litigation, Barr has been granted a license to sell a generic triamcinolone acetonide in the United States as early as 2011. See Note D.22.b) to our consolidated financial statements included at Item 18 of this annual report.

### **Xatral<sup>®</sup>/Uroxatral<sup>®</sup>**

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

Xatral<sup>®</sup> OD (extended release formulation) is active from the first dose, provides a rapid and lasting symptom relief and improves patient quality of life. Xatral<sup>®</sup> is the only alpha1-blocker showing no deleterious effect on ejaculation, as shown by the final results of the international ALF-LIFE trial. The once-daily formulation of Xatral<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. The top three countries contributing to sales of Xatral<sup>®</sup> in 2009 are the United States, Italy and France. Generic alfuzosin became available in most European countries in 2009.

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

Actonel<sup>®</sup> (risedronate sodium) belongs to the bisphosphonate class that helps to prevent osteoporotic fractures.

Actonel<sup>®</sup> is the only osteoporosis treatment that reduces the risk of both vertebral and non-vertebral fractures in as little as 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 end point (hip, wrist, humerus, clavicle, leg and pelvis).

Actonel<sup>®</sup> is available in various dosage strengths and combination forms to better suit patients' needs. According to dosage form, Actonel<sup>®</sup> is indicated for the treatment of post-menopausal osteoporosis, osteoporosis in men, or Paget's disease.

Actonel<sup>®</sup> is marketed in more than 75 countries through an alliance with Warner Chilcott (see Alliance with Warner Chilcott below). In Japan, Actonel<sup>®</sup> is marketed by Eisai.

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

### **Alliance with Warner Chilcott**

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

We originally in-licensed Actonel<sup>®</sup> from Procter & Gamble ( P&G ) and entered into an alliance agreement with P&G in April 1997 for the co-development and marketing of Actonel<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 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.

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

---

## Table of Contents

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

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

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

*Co-marketing territory:* each company markets the products independently under its own brand name. This territory currently includes only Italy. In Italy, the product is sold under the brand name Actonel<sup>®</sup> by WCRX 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 WCRX, and under the brand name Actonel<sup>®</sup> by sanofi-aventis;

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

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

The financial impact of our principal alliances on our financial condition or income is significant and is described under Item 5. Operating and Financial Review and Prospects Financial Presentation of Alliances . See Item 3.D. Risk factors We rely on third parties for the marketing of some of our products for more information relating to risk in connection with our alliance agreements.

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

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

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

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



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

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

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

## **Table of Contents**

### **Ophthalmology**

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

Oxford BioMedica has entered into a new collaboration with sanofi-aventis to develop novel gene-based medicines, utilizing LentiVector® gene delivery technology, for the treatment of ocular disease. The new agreement covers four Lentivector-based product candidates for different ophthalmologic indications such as wet age-related macular degeneration, Stargardt disease, Usher syndrome and corneal graft rejection.

### **Consumer Health Care ( CHC )**

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

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

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

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

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

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

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

## **Table of Contents**

### **Generics**

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

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

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

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

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

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

### **Vaccines Products**

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

Sanofi Pasteur is a world leader in the vaccine industry in terms of sales. In the United States and Canada, sanofi pasteur is the market leader in the segments where we compete (source: based on internal estimates).

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

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

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

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

**Table of Contents**

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

( million)	2009 Net Sales
Influenza Vaccines *	1,062
Polio/Pertussis/Hib Vaccines	968
Meningitis/Pneumonia Vaccines	538
Adult Booster Vaccines	406
Travel and Other Endemic Vaccines	313
Other Vaccines	196
<b>Total Human Vaccines</b>	<b>3,483</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. 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 ( Hib ) 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>, a vaccine protecting against five diseases (pertussis, diphtheria, tetanus, polio and *Haemophilus influenzae* type b), was launched in the United States in 2008 and has been approved in ten countries.

Pediacel<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 ). The worldwide polio eradication initiative led by the World Health Organization (WHO) and UNICEF has positioned sanofi pasteur as a global preferred partner with both OPV and eIPV vaccines.

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

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

---

## **Table of Contents**

### **Influenza Vaccines**

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines. Sales of the influenza vaccines Fluzone® and Vaxigrip®/Mutagrip® have more than tripled since 1995 and annual supply reached more than 180 million doses in 2009 to better meet increasing demand. We expect the global demand for influenza vaccines to continue to grow within the next decade, due to an increased disease awareness as a result of the A(H1N1) influenza pandemic, and wider government immunization recommendations.

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

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

In December 2009, the FDA approved sanofi pasteur's supplemental Biologics License Application (sBLA) for licensure of Fluzone® High-Dose (Influenza Virus Vaccine). This new vaccine, for adults 65 years of age and older, will be available to health-care providers for administration during the third quarter of 2010 in preparation for the 2010-2011 influenza season. The Fluzone® High-Dose vaccine was specifically designed to generate a more robust immune response in people 65 years of age or older. This age group which typically shows a weaker immune response, has proven to respond better to the Fluzone® High-Dose product.

In September 2009, the FDA approved the company's supplemental Biologics License Application for licensure of its Influenza A(H1N1) 2009 Monovalent Vaccine, marking an important milestone in the pandemic fight. The U.S. licensed vaccine is an inactivated influenza virus vaccine indicated for active immunization of adults and children six months of age and older against influenza caused by the A(H1N1) 2009 virus. Sanofi Pasteur provides the only influenza vaccine licensed in the United States for populations as young as six months of age.

In 2009, sanofi pasteur received A(H1N1) orders from the U.S. Department of Health and Human Services ( HHS ), totaling 87 million doses. We began shipping the first doses of vaccine to the U.S. government ( HHS ) on September 29, 2009.

In November 2009, Panenza® (our non-adjuvanted vaccine) was registered by the *Agence Française de Sécurité Sanitaire des Produits de Santé*. The vaccine was made available to the French authorities, and vaccination began in France in November 2009. Panenza® is also registered in Spain, Luxemburg, Germany, Brazil, Hong Kong, Slovakia, Thailand, Tunisia and Turkey. Sanofi Pasteur submitted the final registration file for our adjuvanted vaccine (Humenza ) to the EMA in January 2010; following the positive opinion from the CHMP, we expect regulatory approval during the first half of 2010.



**Adult and Adolescent Boosters**

The incidence of pertussis (whooping cough) is on the rise globally, affecting children, adolescents and adults (Source: WHO publication WER 2005). Its resurgence, combined with an increased awareness of the dangers of vaccine-preventable diseases in general, has led to higher sales of this product group in recent years. Adacel<sup>®</sup>, the first trivalent adolescent and adult booster against diphtheria, tetanus and pertussis, was licensed and launched in the United States in 2005. Adacel<sup>®</sup> has since 2004, been the standard of care in Canada where most provinces provide routine adolescent immunization. This product plays an important role in efforts to better

## **Table of Contents**

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

### **Meningitis and pneumonia vaccines**

Sanofi Pasteur is at the forefront of the development of vaccines to prevent meningitis. Sanofi Pasteur introduced Menactra<sup>®</sup>, the first conjugate quadrivalent vaccine against meningococcal meningitis, arguably the deadliest form of meningitis in the world. In 2009, sales of Menactra<sup>®</sup> continued to grow in the United States following the implementation of the recommendations of the Advisory Committee on Immunization Practices (ACIP) for routine vaccination of pre-adolescents (11-12 years old), adolescents at high school entry (15 years old) and college freshmen living in dormitories. In October 2007, the FDA granted sanofi pasteur licensure to expand the indication of Menactra<sup>®</sup> to children two years through 10 years of age. Menactra<sup>®</sup> is now indicated for people ages 2-55 years in the United States and in Canada. Additional submission for infants aged 9-12 months is expected in the United States in 2010. Sanofi Pasteur has also begun launching Menactra<sup>®</sup> in other countries. Use of meningococcal meningitis vaccines is expected to grow significantly through anticipated future use in multiple segments of the population.

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

### **Travel and Endemic Vaccines**

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

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

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

### **Other vaccines**

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

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

**Animal Health: Merial**

Merial is one of the world's leading animal healthcare companies dedicated to the research, development, manufacture and delivery of innovative pharmaceuticals and vaccines used by veterinarians, farmers and pet owners (Source: Vetnosis September 2009). Its net sales for 2009 amounted to U.S.\$2,554 million.

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

## **Table of Contents**

Plough Animal Health business with Merial to form an animal health joint venture that would be equally owned by the new Merck and sanofi-aventis. In addition to the execution of final agreements, formation of the new animal health joint venture remains subject to approval by the relevant competition authorities and other closing conditions (for more information see Item 8 B. Significant Changes Merial and Notes D.1 and D.8.1 to our consolidated financial statements included at Item 18 of this annual report).

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

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

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

For regulatory exclusivity, in Europe, similar to human pharmaceutical products, there is an eight-year data exclusivity and a 10-year marketing exclusivity for veterinary medicinal products. In the United States, there is a 10-year data exclusivity for products approved by the Environmental Protection Agency and an additional 5 years during which a generic applicant has to compensate the originator if it cites its data. For FDA approved veterinary medicinal products a regulatory exclusivity period of 5 years is granted for a new chemical entity and 3 years for a previously approved active ingredient. No data exclusivity exists at present for veterinary vaccines in the United States.

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

Merial operates through a network of 16 production sites, with major sites located in France, the United States, Brazil and China. The major R&D sites are located in France and in the United States. Merial employs approximately 5,600 employees worldwide.

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

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

## **Pharmaceutical Research & Development ( R&D )**

Since the start of 2009, sanofi-aventis has been engaged in a wide-ranging transformation program designed to overcome the challenges facing the pharmaceutical industry. R&D is the first priority of this program. The rapid developments in the scientific environment, which are bringing about a veritable revolution in biopharmaceutical research, especially in biology, have generated profound and continuous change in the pharmaceutical environment. To anticipate the consequences of these changes and to maintain its innovative capacities, sanofi-aventis intends to set in place the most effective R&D organization in the pharmaceutical industry by 2013. The new R&D approach aims to foster greater creativity and innovation, while remaining fully focused on patient needs. Streamlined organizational structures are designed to make R&D more flexible and entrepreneurial and hence better adapted to overcome future challenges.

## **Table of Contents**

### **Organization**

The resulting structure is focused on addressing patient needs, and not on therapeutic indications *per se*.

The new R&D organization is composed of three different types of units:

Entrepreneurial Units: Divisions, Therapeutic Strategic Units ( TSU ) and Distinct Project Units ( DPU ) focused on patient needs and driving value in collaboration with the external academic and biotech communities. Two global divisions have been created – Diabetes and Oncology – to further strengthen the Group’s position in these two areas. Five TSUs have been formed with a focus on major pathophysiologies, pressing public health needs (aging) or major geographic areas (Asia Pacific); DPUs have been created to drive projects outside the areas covered by the Divisions and TSUs. In addition, an exploratory unit will deliver early innovation, exploring and incubating new ideas, new technologies and new methodology.

Five Scientific core platforms provide expert scientific support throughout the organization and operate as internal state-of-the-art service providers to the Entrepreneurial Units.

Enabling and Support functions are being realigned to support the new structure and governance arrangements.

This new model will foster a strategy of openness with closer cooperation between sanofi-aventis researchers and external partners, and a more reactive and flexible organization that promotes the emergence of innovation and the grouping of researchers in stronger centers of expertise (oncology, diabetes, aging, etc ). Implementation of this new structure is ongoing.

In line with this approach, a number of alliances and acquisitions were entered into during 2009 with companies including Bipar, Merrimack, Wellstat and Exelixis. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

### **Portfolio**

During 2009, R&D undertook a rigorous and comprehensive portfolio review. The projects were assessed using six key criteria. These criteria allow management to rapidly understand how the portfolio performs in terms of innovation, unmet medical needs, risk and value. They can be summarized as follows:

Science: level of innovation, level of safety, quality and reliability of the scientific data;

Execution: likelihood of development and manufacturing success;

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

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

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

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

Financials: predicted return on investment for the project.

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

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

**Table of Contents**

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

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

**Main changes in Diabetes/Other Metabolic Disorders portfolio**

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

One late Phase project was halted:

AVE5530 in hypercholesterolemia for insufficient benefit for the patient

The following approvals were obtained from the health authorities:

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



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

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

### **Main changes in Oncology portfolio**

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

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

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

## **Table of Contents**

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

Late phase projects which were terminated:

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

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

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

AVE1642 was stopped due to lack of differentiation versus competitive environment

The following approvals were obtained from the health authorities:

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

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

## **Main Change in Thrombosis and Cardiovascular portfolio**

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

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

Late phase projects which were terminated:

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

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

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

### Approvals from health authorities

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

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

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

### Main Change in Central Nervous System portfolio

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

## **Table of Contents**

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

Late phase projects which were terminated:

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

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

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

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

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

## **Main changes in Internal Medicine portfolio**

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

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

Approvals from health authorities:

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

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

## **Ophthalmology portfolio**

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

**Other discovery/ development partnerships**

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

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

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

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

**Vaccines Research and Development**

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

**Table of Contents***Portfolio*

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

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

<sup>(1)</sup> Flu=Influenza.

<sup>(2)</sup> D=Diphtheria, T=Tetanus, Hib=*Haemophilus influenzae* b, HepB=Hepatitis B, P=Pertussis.

\* New targets

**Project highlights****Influenza**

To sustain our global leadership in the development of influenza vaccine, our R&D efforts are focused on innovative approaches for assessing new formulations and alternate delivery systems. We remain actively engaged in pandemic preparedness activities, as evidenced by our response to the H1N1 pandemic in 2009.

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

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

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

## **Table of Contents**

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

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

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

**Pediace1®** A regulatory submission was filed in December 2009 for licensing in the rest of Europe of this pentavalent pediatric vaccine that is the standard of care in the United Kingdom and the Netherlands for protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b disease.

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

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

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

## **Meningitis Program**

*Neisseria meningitidis* is a leading cause of meningitis in the United States, Europe and elsewhere, affecting infants and children as well as adolescents. The primary focus of several ongoing projects related to Menactra® is to decrease the age at which one can first receive this vaccine.

**Menactra® Infant/Toddler (9-12 months)** This project is aimed at lowering the age of administration below twelve months of age. Three pivotal clinical studies have been completed to support the 9-12 month indication. No safety concerns were identified and the vaccine was immunogenic for the four serotypes (A, C, Y, W-135). In 2009, the FDA requested supplemental testing to be completed prior to regulatory filing. This testing is ongoing and a regulatory submission to the FDA for licensure in the United States is planned for the first half of 2010.



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

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

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

### **Pneumococcal Vaccine Program**

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

## **Table of Contents**

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

### **Rabies Vaccine**

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

**Rabies mAb Post Exposure Prophylaxis** This product consists of two rabies monoclonal antibodies (MABs) that will be used in association with the rabies vaccine for post-exposure prophylaxis. It is being developed in collaboration with Crucell. The Phase II study in adolescents and children in the Philippines showed that the antibody combination was safe and well tolerated. Additional clinical trials are planned for 2010.

### **New Vaccine Targets**

**Dengue** Dengue fever has increasing epidemiological importance due to global socio-climatic changes. It is a major medical and economic burden in the endemic areas of Asia, Pacific, Latin America and Africa. It is also one of the leading causes of fever among travelers. Multiple approaches have been tested to develop a vaccine covering the dengue's four viral serotypes in order to prevent this disease and its severe complications (hemorrhagic fever). Results of a Phase II clinical trial in adults in the United States demonstrated proof of concept of the lead vaccine candidate that is based on the ChimeriVax technology. Sanofi Pasteur has maintained its relationship with the WHO and the Pediatric Dengue Vaccine Initiative, a program of the International Vaccine Institute funded by the Gates Foundation to make dengue a vaccine preventable disease and to accelerate vaccine introduction in pediatric populations where the disease is endemic through disease burden evaluation, vaccine advocacy and vaccine access. Sanofi Pasteur's dengue vaccine research program includes ongoing clinical studies (adults and children) in several countries in endemic regions: Mexico, Colombia, Honduras, Puerto Rico, Peru, the Philippines, Vietnam, Singapore, and Thailand.

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

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

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

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

**HIV** The Phase III clinical trial in Thailand involving more than 16,000 adult volunteers was completed in 2009. The trial was a collaboration between the U.S. Army, the National Institute of Allergy and Infectious Diseases of the National Institutes of Health ( NIH ), the Ministry of Public Health of Thailand, sanofi pasteur and VaxGen. The prime-boost combination of ALVAC<sup>®</sup> HIV (from sanofi pasteur) and AIDSVAX<sup>®</sup> B/E (from VaxGen) vaccines lowered the rate of HIV infection by 31.2% compared with placebo. This is the first concrete evidence, since the discovery of the HIV virus in 1983, that a vaccine against HIV is potentially feasible. Additional work is required to develop and test a vaccine suitable for licensure and worldwide use. Future research will be conducted through public-private partnerships.

## **Table of Contents**

**ACAM-Cdiff** *Clostridium difficile* is a major public health concern in North America and Europe. It is the leading cause in hospitals of infectious diarrhea in adults, particularly the elderly. The epidemiology of *C. difficile* associated disease (CDAD) has been increasing at an alarming rate since 2003, driven primarily by the emergence of a treatment resistant, highly virulent strain CD027. There is currently no vaccine available and the only vaccine candidate currently in development is ACAM- Cdiff. ACAM-Cdiff is a toxoid-based vaccine, based on a formalin-inactivated toxin principle similar to the tetanus and diphtheria toxoids used in licensed vaccines. This vaccine candidate has successfully completed Phase I clinical trials with more than 200 participants in which safety and immunogenicity were evaluated. In February 2009, a Phase II clinical trial in patients recently infected with *C. difficile* started in the United Kingdom. This trial was expanded to the United States in December 2009. While the target indication for the vaccine is prevention, this trial with recently infected patients aims to provide early proof-of-concept of a vaccine approach for the prevention of recurring infection.

## **Patents, Intellectual Property and Other Rights**

### **Patent Protection**

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

active ingredients;

pharmaceutical formulations;

product manufacturing processes;

intermediate chemical compounds;

therapeutic indications/methods of use;

delivery systems; and

enabling technologies, such as assays.

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

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

The protection a patent affords the related product depends upon the type of patent and its scope of coverage, and may also vary from country to country. In Europe for instance, applications for new patents may be submitted to the European Patent Office ( EPO ), an intergovernmental organization which centralizes filing and prosecution. As of December 2009, an EPO patent application may cover the 36 European Patent Convention member states, including all 27 member states of the European Union. The granted European Patent establishes corresponding national patents with uniform patent claims among the member states. However, some older patents were not approved through this centralized process, resulting in patents having claim terms for the same invention that differ by country. Additionally, a number of patents prosecuted through the EPO may pre-date the EP Convention accession of some current EP Convention member states, resulting in different treatment in those countries. See Note D.22.b) to the consolidated financial statements included in Item 18 of this annual report.

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

The expiration or loss of an active ingredient patent may result in significant competition from generic products and can result in a dramatic reduction in sales of the original branded product. See Item 3.D. Risk

---

**Table of Contents**

Factors Generic versions of some of our products may be approved for sale in one or more of their major markets. In some cases, it is possible to continue to obtain commercial benefits from product manufacturing trade secrets or other types of patents, such as patents on processes, intermediates, structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulin, have been historically relatively less reliant on patent protection and may in many cases have no patent coverage, although it is increasingly frequent for novel vaccines and insulins to be patent protected. See Focus on Biologics below.

One of the main limitations on our operations in some countries outside the United States and Europe is the lack of effective intellectual property protection or enforcement for our products. The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP) has required developing countries to amend their intellectual property laws to provide patent protection for pharmaceutical products since January 1, 2005 although it provides a limited number of developing countries an extension to 2016. While the situation has gradually improved, the lack of protection for intellectual property rights or the lack of robust enforcement of intellectual property rights poses difficulties in certain countries (see Item 3.D. Risk Factors The globalization of the Group's business exposes us to increased risks. ). Additionally, in recent years a number of countries faced with health crises have waived or threatened to waive intellectual property protection for specific products, for example through compulsory licensing.

**Regulatory Exclusivity**

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

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

In the European Union, regulatory exclusivity is available in two forms: data exclusivity and marketing exclusivity. Generic drug applications will not be accepted for review until eight years after the first marketing authorization (data exclusivity). This eight-year period is followed by a two-year period during which generics cannot be marketed (marketing exclusivity). The marketing exclusivity period can be extended to three years if, during the first eight-year period, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which are deemed to provide a significant clinical benefit over existing therapies. This is known as the 8+2+1 rule. While these exclusivities are intended to be applicable throughout the European Union, in a decentralized system, national authorities may act in ways that are inconsistent with EU regulatory exclusivity. For example, although European marketing exclusivity for clopidogrel expired in July 2008, in May 2008 the German Health authority BfArM had already registered a competitor's clopidogrel product based on a contested interpretation of the law. Furthermore, in 2006, the Polish and Bulgarian authorities registered generics of clopidogrel bisulfate based on these countries' contested position that EU marketing exclusivities need not be applied by individual countries where generics had been approved prior to their accession date.

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

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)

---

**Table of Contents**

containing a medicinal composition, or requiring a new route of administration) to eight years (for drugs containing a new chemical entity) to ten years (for orphan drugs or new drugs requiring pharmaco-epidemiological study).

**Pediatric Extension**

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

In the United States, the FDA may ask a company for pediatric studies if it has determined that information related to the use of the drugs in the pediatric population may produce health benefits. The FDA has invited us by written request to provide additional pediatric data on several of our main products. Under the Hatch-Waxman Act, timely provision of data meeting the FDA's requirements may result in the FDA extending regulatory exclusivity and patent life by six months, to the extent these protections have not already expired (the so-called pediatric exclusivity). The main products having received past FDA grants of pediatric exclusivity are Aprovel<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 regulation on pediatric medicines entered into force on January 26, 2007. This regulation provides for the progressive implementation in 2009 of pediatric research obligations with associated possible rewards including an extension of patent protection (for patented medicinal products) and regulatory exclusivity for pediatric marketing authorization (for off-patent medicinal products). For additional details, see Regulation below.

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

**Product Overview**

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



**Table of Contents**

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.

<p><b>U.S.</b> Compound: August 2014</p>	<p><b>Lantus® (insulin glargine)</b></p> <p><b>E.U.</b> Compound: November 2014 in most of EU; no compound patent in force in much of Eastern Europe</p> <p>Regulatory exclusivity until June 2010</p>	<p><b>Japan</b> Compound: November 2014</p> <p>Regulatory exclusivity: October 2011</p>
<p><b>U.S.</b> Compound: June 2018</p> <p>Later filed improvement patents: formulation March 2022 and January 2023</p> <p>Regulatory exclusivity: expired April 2009</p>	<p><b>Apidra® (insulin glulisine)</b></p> <p><b>E.U.</b> Compound: September 2019 in most of EU</p> <p>Regulatory exclusivity: September 2014</p>	<p><b>Japan</b> Compound: June 2018</p> <p>Later filed improvement patent: formulation March 2022</p> <p>Regulatory exclusivity: April 2017</p>
<p><b>U.S.</b> Compound: expired Genericized</p> <p><b>U.S.</b> Compound: May 2010</p> <p>Later filed improvement patents: formulation (2012 to 2013)</p>	<p><b>Amaryl® (glimepiride)</b></p> <p><b>E.U.</b> Compound: expired Genericized</p> <p><b>Taxotere® (docetaxel)</b></p> <p><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</p> <p>Later filed improvement patents: additional patent coverage (2012 to 2013)</p>	<p><b>Japan</b> Compound: expired</p> <p><b>Japan</b> Compound: June 2012</p> <p>Later filed improvement patents: formulation (2012 to 2013)</p>
<p><b>U.S.</b> Compound: expired</p> <p>Later filed improvement patents: coverage ranging through 2016</p> <p>Genericized</p>	<p><b>Eloxatine® (oxaliplatin)<sup>1</sup></b></p> <p><b>E.U.</b> Compound: expired</p> <p>Genericized</p>	<p><b>Japan</b> N/A</p>

<sup>1</sup> We do not own most Eloxatine® patents but license them from Debiopharm for marketing.

**Table of Contents**

	<b><i>Lovenox® (enoxaparin sodium)</i></b>	
<b>U.S.</b> Compound: no compound patent coverage	<b>E.U.</b> Compound: June 2011 in most of EU; exceptions: June 2010 in France, no compound patent in force in Germany, Spain, Portugal, Finland, Norway, Greece and much of Eastern Europe	<b>Japan</b> Compound: expired  Regulatory exclusivity: 2016
	<b><i>Plavix® (clopidogrel bisulfate)</i></b>	
<b>U.S.</b> Compound: November 2011	<b>E.U.</b> Compound: 2013 in most of EU; no compound patent in force in Spain, Portugal, Finland, Norway and much of Eastern Europe.  Genericized	<b>Japan</b> Compound: 2013  Regulatory exclusivity: 2014
	<b><i>Aprovel® (irbesartan)</i></b>	
<b>U.S.</b> Compound: September 2011	<b>E.U.</b> 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	<b>Japan</b> Compound: 2016
Later filed improvement patent: formulation (2015)	Later filed improvement patents: formulation coverage ranging through 2016	Later filed improvement patent: formulation (2021)  Regulatory exclusivity: 2016
	<b><i>Tritace® (ramipril)</i></b>	
<b>U.S.</b> N/A	<b>E.U.</b> Compound: expired  Genericized	<b>Japan</b> Compound: expired
	<b><i>Multaq® (dronedarone hydrochloride)</i></b>	
<b>U.S.</b> Compound: July 2011  (2016 if PTE petition is granted)	<b>E.U.</b> Compound: August 2011  (2016 if SPC is granted)	<b>Japan</b> Compound: August 2011
Later filed improvement patent: formulation (2018)	Later filed improvement patent: formulation (2018)	
Regulatory exclusivity: July 2014	Regulatory exclusivity: 2019	

**Table of Contents**

	<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
Later filed improvement patent: Ambien® CR formulation (2019)	Genericized	Later filed improvement patent: Ambien® CR formulation (2019)
		Regulatory exclusivity: September 2010 on all formulations
	<i>Copaxone® (glatiramer acetate)<sup>1</sup></i>	
<b>U.S.</b> Compound: 2014	<b>E.U.</b> Compound: 2015	<b>Japan</b> N/A
	<i>Depakine® (sodium valproate)</i>	
<b>U.S.</b> N/A	<b>E.U.</b> Compound: expired	<b>Japan</b> Compound: expired
	Later filed improvement patent: Depakine® Chronosphere® formulation (2017)	Later filed improvement patent: Depakine® Chronosphere® formulation (2017)
	<i>Allegra® (fexofenadine hydrochloride)</i>	
<b>U.S.</b> Compound: expired	<b>E.U.</b> Compound: expired	<b>Japan</b> Compound: expired
Later filed improvement patents: coverage ranging through 2017	Genericized	Later filed improvement patents: coverage ranging through 2016
Single entity form genericized, licensed generic D® -12 Hour form since November 2009 <sup>2</sup>		
	<i>Nasacort® (triamcinolone acetonide)</i>	
<b>U.S.</b> Compound: expired	<b>E.U.</b> Compound: expired	<b>Japan</b> Compound: expired
Later filed improvement patents: formulation and method of use 2016	Later filed improvement patent: formulation 2017	

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

Generic licensed as early as 2011<sup>2</sup>

### *Xatral® (alfuzosin hydrochloride)*

<b>U.S.</b>	<b>E.U.</b>	<b>Japan</b>
Compound: expired	Compound: expired	Compound: expired
Later filed improvement patent: formulation 2017	Later filed improvement patent: formulation 2017	Later filed improvement patent: formulation 2017

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

**Table of Contents**

	<i>Actonel® (risedronate sodium)<sup>1</sup></i>	
<b>U.S.</b>	<b>E.U.</b>	<b>Japan</b>
Compound: December 2013	Compound: December 2010 in Austria, Belgium, France, Germany, the Netherlands, the United Kingdom, Sweden, Switzerland and Italy; 2013 in Spain; expired elsewhere	N/A

Later filed improvement patents: coverage ranging through 2018

Later filed improvement patents: coverage ranging through 2018

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

As disclosed in Note D.22.b) to our consolidated financial statements included at Item 18 of this annual report, we are involved in significant litigations concerning the patent protection of a number of products.

We caution the reader that there can be no assurance that we will prevail when we assert a patent in litigation and that there may be instances in which the Group determines that it does not have a sufficient basis to assert one or more of the patents mentioned in this report, for example in cases where a competitor proposes a formulation not appearing to fall within the claims of our formulation patent, a salt or crystalline form not claimed by our composition of matter patent, or an indication not covered by our method of use patent. See Item 3.D. Risk Factors Generic versions of some of our products may be approved for sale in one or more of their major markets.

**Challenges to Patented Products**

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

In the European Union, a generic drug manufacturer may only reference the data of the regulatory file for the original approved product after data exclusivity has expired. However, there is no patent listing system in Europe comparable to the Orange Book, which would allow the patent holder to prevent the competent authorities from granting marketing approval by bringing patent infringement litigation prior to approval. As a

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

result, generic products may be approved for marketing following the expiration of marketing exclusivity without regard to the patent holder's rights.

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

## **Table of Contents**

Nevertheless, in most of these jurisdictions once the competing product is launched and in some jurisdictions, even prior to launch, (once launch is imminent), the patent holder can seek an injunction against such marketing if it believes its patents are infringed. See Note D.22.b) to our consolidated financial statements included at Item 18 of this annual report.

The accelerated ANDA-type procedures are potentially applicable to most, but not all, of the products we manufacture. See Focus on Biologics and Regulation below. We seek to defend our patent rights vigorously in these cases. Success or failure in the assertion of a given patent against one competing product is not necessarily predictive of the future success or failure in the assertion of the same patent or *a fortiori* the corresponding foreign patent against a second competing product due to factors such as possible differences in the formulations of the competing products, intervening developments in law or jurisprudence, local variations in the patents and differences in national patent law and legal systems. See Item 3.D. Risk Factors Generic versions of our products may be approved for sale in one or more of their major markets.

## **Trademarks**

Our products are sold around the world under trademarks that we consider to be of material importance in the aggregate. Our trademarks help to maintain the identity of our products and services, and protect the sustainability of our growth. It is our policy to register our trademarks with a strategy adapted to each product or service depending on their countries of commercialization: i.e. on a worldwide basis for worldwide products or services, or on a regional or local basis for regional or local products or services. Our trademarks are monitored and defended based on this policy and in order to prevent infringement and/ or unfair competition.

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

## **Production and Raw Materials**

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

We generally develop and manufacture the active ingredients that we use in our products. We have a general policy of producing the active ingredients for our principal products at our own plants in order to minimize our dependence on external manufacturers and control the product throughout the production cycle. In some cases however, we have outsourced certain production elements, especially as part of supply agreements entered into within the framework of plant divestitures. As a result, we outsource a portion of the production of the active ingredients used in Stilnox® and Xatral®, a part of the chemical activity linked with Lovenox® and certain formulations of various pharmaceutical products. Our main subcontractors are Patheon, Famar, Catalent, GSK-NDB, Haupt and Sofarimex. These subcontractors are required to follow our guidelines in terms of quality, logistics and other criteria. See Item 3.D. Risk Factors The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, delay the launch of new products and adversely affect our operating results and financial condition.



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

**Table of Contents**

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

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

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

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

The manufacturing and research operations of sanofi-aventis are subject to increasingly stringent health, safety and environmental laws and regulations. These laws and regulations are complex and rapidly changing, and sanofi-aventis invests the necessary sums in order to comply with them. This investment, which aims to respect health, safety and the environment, varies from year to year and totaled approximately 130 million in 2009.

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

Moreover, as for a number of companies involved in the pharmaceutical, chemical and agrochemical industries, soil and groundwater contamination has occurred at some Group sites in the past, and may still occur or be discovered at others. In the Group's case, such sites are mainly located in the United States, Germany, France, Hungary, Brazil, Italy and the United Kingdom. As part of a program of environmental audits conducted over the last few years, detailed assessments of the risk of soil and subsoil contamination have been carried out at current and former Group sites. In cooperation with national and local authorities, the Group constantly assesses the rehabilitation work required and this work has been implemented when appropriate. Long-term rehabilitation work has been completed or is in progress in Rochester, Cincinnati, Mount-Pleasant, East Palo Alto, Ambler and Portland in the United States; Frankfurt in Germany; Beaucaire, Valernes, Limay, Rousset and Vitry in France; Dagenham in the United Kingdom; Brindisi and Garessio in Italy; and on a number of sites divested to third parties and covered by contractual environmental guarantees granted by sanofi-aventis. Sanofi-aventis may also have potential liability for investigation and cleanup at several other sites. Provisions have been established for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. For example, in 2007 the State of New Jersey initiated a claim against Bayer CropScience seeking compensation for damages caused to natural resources ( NRD ) at a former Rhône-Poulenc site in the United States, resulting in indemnification claims by Bayer CropScience against the Group under contractual environmental guarantees granted at the time of Bayer's acquisition of the CropScience business. Rehabilitation studies and an NRD assessment are underway in a similar project in Portland, Oregon. Potential environmental contingencies arising from certain business divestitures are described in Note D.22.e) to the consolidated financial statements included at Item 18 of this annual report. In 2009, sanofi-aventis spent 38 million on rehabilitating sites previously contaminated by ground

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

pollution. During the year ended December 31, 2009, comprehensive review was carried out relating to the legacy of environmental pollution. In light of data collected during this review, the Group adjusted the provisions to approximately 695 million as at December 31, 2009.

## **Table of Contents**

Because of changes in environmental regulations governing site remediation the Group's provisions for remediation obligations may not be adequate due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques considered, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations of Aventis arising from its past involvement in the chemical and agrochemical industries, it is impossible to quantify the future impact of these laws and regulations with precision. See Item 3.D. Risk Factors Environmental Risks of Our Industrial Activity .

To our knowledge, the Group is not currently subject to liabilities for non-compliance with current HSE laws and regulations that could be expected to significantly jeopardize its activities, financial situation or operating income. We also believe that we are in substantial compliance with current HSE laws and regulations and that all the environmental permits required to operate our facilities have been obtained. Regular HSE audits (38 in 2009) are carried out by the Group in order to detect possible instances of non-compliance with regulations and to initiate corrective measures. Moreover, 89 loss prevention technical visits were carried out in 2009.

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

### ***Health***

From the development of compounds to the commercial launch of new drugs, sanofi-aventis research scientists continuously assess the effect of products on human health. This expertise is made available to employees through two committees responsible for chemical and biological risk assessment. The Group's COVALIS committee classifies all chemical and pharmaceutical products handled within the Group and establishes workplace exposure limits for each of them. The Group's TRIBIO Committee is responsible for classifying all biological agents according to their degree of pathogenicity, and applies rules for their containment and the preventive measures to be respected throughout the Group. See Item 3.D. Risk Factors Risks from the handling of hazardous materials could adversely affect our results of operations .

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

### ***Safety***

Sanofi-aventis has rigorous policies to identify and evaluate safety risks and to develop preventive safety measures, and methods for checking their efficacy. Additionally, sanofi-aventis invests in training that is designed to instill in all employees a sense of concern for safety, regardless of their duties. These policies are implemented on a worldwide scale to ensure the safety of all employees and to protect their health. Each project, whether in research, development or manufacturing, is subject to evaluation procedures, incorporating the chemical substance and process data communicated by the COVALIS and TRIBIO committees described above. The preventive measures are designed primarily to reduce the number and seriousness of work accidents and to minimize exposures involving permanent and temporary sanofi-aventis employees

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

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

## **Table of Contents**

thresholds). In accordance with French law on technological risk prevention, the French sites are also subject to heightened security inspections in light of the toxic or flammable materials stored on the sites and used in the operating processes.

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

Our laboratories that specialize in process safety testing, which are fully integrated into our chemical development activities, apply methods to obtain the physico-chemical parameters of manufactured chemical substances (intermediate chemical compounds and active ingredients) and apply models to measure the effect of potentially leachable substances in the event of a major accident. In these laboratories the parameters for qualifying hazardous reactions are also determined to define scale-up process conditions while transferring from development stage to industrial scale. All these data ensure the relevance of the risk assessments.

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

## ***Environment***

The main objectives of the environmental policy of sanofi-aventis are to implement clean manufacturing techniques, minimize the use of natural resources and reduce the environmental impact of its activities. In order to optimize and improve our environmental performance, sanofi-aventis is committed to progressively obtaining ISO 14001 certification. 39 manufacturing sites and three Research & Development sites are currently certified. This commitment is part of a strategy of continuous improvement practiced at all Group sites through the annual implementation of HSE progress plans. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and the environment. In 2008 and 2009, six of the Group's European sites are included in the scope of the European CO<sub>2</sub>Emissions Credit Trading Scheme aimed at helping to reach the targets set by the Kyoto protocol.

The recent efforts of the Group in terms of environmental protection have mainly targeted reductions in energy consumption, greenhouse gas emissions control, improvements in the performance of water treatment installations, reduction of volatile organic compound emissions, raw material savings and recycling, and reductions in waste materials or increases in the percentage being recycled. Since 2005 we have reduced carbon dioxide emissions caused by our sales representation car fleet by 14%, our direct carbon dioxide emissions by 11 % and our indirect emissions by 16% in terms of our activity level per unit produced.<sup>(1)</sup>

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

**Markets**

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

- (1) The CO<sub>2</sub> emissions variations per produced unit are calculated for each business and added proportionally to their contribution to the total. Each business defines a specific indicator of its activity (e.g., hours worked for vaccines, number of boxes produced for pharmacy). An important evolution in chemistry occurred this year regarding the production mix between chemical synthesis, fermentation and biotechnology. It was decided that from 2008, the added value would be considered as the new activity indicator instead of the quantity of API and isolated intermediates produced, which was previously used from 2005 to 2008.

## **Table of Contents**

The following market shares and ranking information is based on sales data from IMS Health MIDAS, retail and hospital, for 2009, in constant euros (unless otherwise indicated). For more information on market shares and ranking, see Presentation of Financial and Other Information at the beginning of this document.

## **Marketing and Distribution**

Sanofi-aventis has a commercial presence in approximately 110 countries, and our products are available in more than 170. Our main markets in terms of net sales are, respectively:

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

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

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

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

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

- Good performance by Plavix<sup>®</sup>, Myslee<sup>®</sup> and Allegra<sup>®</sup>;



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

- Approval of Lovenox<sup>®</sup> for the prevention of venous thromboembolic events after abdominal surgery; and
- Launch of Apidra<sup>®</sup> in June 2009.

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

A breakdown of our sales by geographic market is presented in Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2009 Compared with Year Ended December 31, 2008.

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

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

## **Table of Contents**

Our medical sales representatives, who work closely with healthcare professionals, use their expertise to promote and provide information on our drugs. They represent our values on a day-to-day basis and are required to adhere to a code of ethics. As of December 31, 2009, we have a global sales force of some 34,300 representatives, including approximately 11,100 in Europe, 7,100 in the United States, 3,200 in Japan and 3,600 in China.

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

Although we market most of our products with our own sales forces, we have entered into and continue to form partnerships to co-promote/co-market certain products in specific geographic areas. Our major alliances are detailed at [Main pharmaceutical products](#) above.

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

## **Competition**

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

There are four types of competition in the pharmaceutical market:

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

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

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

Competition between generic or biosimilar products.

We compete with other pharmaceutical companies in all major markets to develop innovative new products. We may develop new technologies and new patented products wholly in-house, but we also enter into collaborative R&D agreements in order to access new technologies. See Note D.21. to our consolidated financial statements included at Item 18 of this annual report.

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

In our Vaccines business, we compete primarily with Merck outside of Europe, GlaxoSmithKline, Wyeth (recently acquired by Pfizer) and Novartis. In selected market segments, sanofi pasteur competes with mid-size international players (such as CSL of Australia in the influenza market for the Southern Hemisphere). Sanofi Pasteur also competes with an increasing number of local manufacturers, which are raising their level of technical capability and quality standards to compete on more sophisticated antigens in their domestic markets and also in international donor markets.

## **Table of Contents**

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

Competition from producers of generics has increased sharply in response to healthcare cost containment measures and to the increased number of products for which patents have expired.

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

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

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

The WHO also estimates that 50% of sales over the Internet are of counterfeit drugs: their development has intensified in 2009.

A medical product is counterfeit when there is a false representation in relation to its identity (e.g. name, composition, strength, etc.) or source (e.g. manufacturer, country of manufacturing/origin, marketing authorization holder, etc.) or its background (e.g. filings and documentation related to its distribution channels). Sanofi-aventis is committed to being part of any efforts made to overcome drug counterfeiting and has implemented the following actions:

Intensification of close collaboration with international organizations and with customs and police to reinforce regulatory frameworks and to investigate suspected counterfeiters; and

Development of technologies to make drugs more difficult to copy through packaging protection programs and to ensure no direct traceability.

## **Regulation**

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

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

## Table of Contents

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

The International Conference on Harmonization ( ICH ) regulatory agencies (the three founder members being the European Union, Japan and the United States), plus Health Canada and Swissmedic as observers, all have high standards for pharmaceutical technical appraisal. Product approval usually takes one to two years, but depending on the country it can vary from six months to, in some cases, several years from the date of application. Factors such as the quality of data submitted, the degree of control exercised by the regulatory authority, the review procedures, the nature of the product and the condition to be treated, play a major role in the length of time a product is under review.

In recent years, intensive efforts have been made by the ICH area regulatory agencies to harmonize product development and regulatory submission requirements. An example of this is that many pharmaceutical companies are now able to prepare and submit a Common Technical Document ( CTD ) that can be used in different regions for a particular product with only local or regional adaptation. Electronic CTD is becoming the standard for submission.

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

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

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

The centralized procedure is mandatory for certain types of medicinal products and optional for others. An application is typically submitted to the EMA. The scientific evaluation of the application is carried out by the Committee for Medicinal Products for Human Use ( CHMP ) of the EMA, and a scientific opinion is prepared. The opinion is sent to the European Commission which adopts the final decision and grants a Community marketing authorization. Such a marketing authorization is valid throughout the Community and the drug may be marketed within all European Union member states.

If a company is seeking a national marketing authorization in more than one Member State, the mutual recognition or decentralised procedure is available to facilitate the granting of harmonized national authorizations across Member States. Both the decentralised and the mutual recognition procedures are based on the recognition by national competent authorities of a first assessment performed by the authorities of one member state.

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

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

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

Generic products are subject to a harmonized procedure in all countries of the European Union. A generic product contains the same active medicinal substance as an originator product. Generic applications are abridged: generic manufacturers only need to submit quality data and demonstrate that the generic drug is bioequivalent to the originator product *i.e.* that it works in essentially the same way in the patient's body, but there is no need to submit safety or efficacy data as regulatory authorities refer to the originator product's dossier. Generic

## Table of Contents

product applications can be filed and approved in the European Union only after the eight year data exclusivity period of the originator product has expired. Further, generic manufacturers can only market their generic products after a 10- or 11-year period from the date of approval of the originator product has elapsed.

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

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

A new regulatory framework has been implemented specifically covering Advanced Therapy Medicinal Products ( ATMPs ). This new legislation provides specific requirements for the approval, supervision, and pharmacovigilance of ATMPs. A new scientific committee – the Committee for Advanced Therapies ( CAT ) – has been established within the EMA to play a central role in the scientific assessment of ATMPs.

A new regulatory framework on variations to marketing authorizations is being implemented with a view to rendering the whole system for post-authorization activities simpler, clearer and more flexible without compromising public health.

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

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

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



In Japan, the regulatory authorities can require local development studies; they can also request bridging studies to verify that foreign clinical data are applicable to Japanese patients and require data to determine the appropriateness of the dosages for Japanese patients. These additional procedures have created a delay in the registration of some innovative products in Japan compared to the European Union and United States.

For animal health products, see [Animal Health: Merial](#) above.

## **Table of Contents**

### **Focus on Biologics**

Products are usually referred to as biologics when they are derived from plant or animal tissues (e.g., blood products) or manufactured within living cells (e.g., anti-bodies, insulins, vaccines). Most biologics are complex molecules or mixtures of molecules which are difficult to completely characterize. To characterize and determine the quality, these products require physico-chemical-biological testing, and an understanding of and control over the manufacturing process.

The concept of generics is not scientifically appropriate for biologics due to their complexity. It is the concept of biosimilar products that applies. A full comparison of the quality, safety and efficacy of the biosimilar product against the reference biological product should be undertaken and must include assessment of physical/chemical, biological, non-clinical and clinical similarity.

In the European Union, a regulatory framework for developing and evaluating biosimilar products has been in place since November 2005. The CHMP has issued several product/disease specific guidelines for biosimilar products. In March 2009, the CHMP adopted a guideline on pre-clinical and clinical development of biosimilars of low molecular weight heparins. This means that in Europe, a potential product candidate claiming to be biologically similar to Lovenox<sup>®</sup> must show therapeutic equivalence in terms of efficacy and safety in at least one adequately powered, randomized, double-blind, parallel group clinical trial. With respect to vaccines, the CHMP has taken the position that currently it is unlikely that these products may be characterized at the molecular level, and that each vaccine product must be evaluated on a case by case basis.

In Japan, guidelines defining the regulatory approval pathway for follow-on biologics were finalized in March 2009. These guidelines set out the requirements on preclinical and clinical data to be considered for the development of the new application category of biosimilars.

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

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

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

### **Pricing & Reimbursement**

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

---

## Table of Contents

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

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

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

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

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

## **Table of Contents**

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

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

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

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

## **Insurance and Risk Coverage**

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

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

Our captive insurance company, Carraig, participates in our coverage for various lines of insurance including excess property, stock and transit and product liability. Carraig is run under the supervision of the Irish regulatory authorities, is wholly owned by sanofi-aventis, and has sufficient resources to meet the risks that it covers. It sets premiums for Group entities at market rates. Claims are assessed using the traditional models applied by insurance and reinsurance companies, and the company's reserves are regularly checked and confirmed by independent actuaries.

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

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

can lead to a concentration of value in a single ship.

Our General Liability & Product Liability program has been renewed for all our subsidiaries worldwide wherever it was possible to do so, despite the increasing reluctance in the insurance and reinsurance market to cover product liability risks for large pharmaceutical groups. For several years, insurers have been reducing product liability cover because of the difficulty of insuring some products that have been subject to numerous claims. These products are excluded from the cover provided by insurers, and hence from the cover obtained by us on the insurance market. This applies to a few of our products, principally those described in Note D.22.a) to

**Table of Contents**

our consolidated financial statements included at Item 18 in this annual report. Because of these market conditions we have increased, year by year, the extent to which we self-insure.

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

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

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

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

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

**C. Organizational Structure**

Sanofi-aventis is the holding company of a consolidated group of subsidiaries. The table below sets forth our significant subsidiaries and affiliates as of December 31, 2009. For a complete list of our main consolidated subsidiaries, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

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

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

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

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



**Table of Contents**

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

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

In certain countries, sanofi-aventis carries out part of its business operations through ventures with local partners. In addition, the Group has signed worldwide alliances by which two of its products (Plavix® and Aprove1®) are marketed through an alliance with BMS (see Pharmaceutical Products – Main Pharmaceutical Products, above).

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

***D. Property, Plant and Equipment***

Our headquarters are located in Paris, France.

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

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

**Breakdown of sites by nature**

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

**Breakdown of the Group's sites between owned and leased**

Leased	68%
Owned	32%

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

## **Table of Contents**

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

Research and Development activities are housed at 25 sites:

11 sites in France , the largest in terms of surface area being in Vitry/Alfortville (approximately 110,000 sq.m), Montpellier (98,000 m<sup>2</sup>), Chilly/Longjumeau (77,000 m<sup>2</sup>) and Toulouse (38,000 m<sup>2</sup>);

5 sites in other European countries (Germany, United Kingdom, Hungary, Spain and Italy), the largest being in Frankfurt, Germany (84,000 m<sup>2</sup>);

6 sites in the United States, the largest being in Bridgewater, New Jersey, United States (111,000 m<sup>2</sup>);

In Japan, Research & Development is represented in Tokyo;

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

### **Industrial sites for the Pharmaceutical Activity**

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

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

France: Ambarès (Aprovel<sup>®</sup>, Depakine<sup>®</sup>, Multaq<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, Apidra<sup>®</sup>);

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

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

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

Japan: Kawagoe (Plavix®);

United States: Kansas City (Allegra®).

### **Sanofi Pasteur Sites**

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

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

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

### **Acquisitions, Capital Expenditures and Divestitures**

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

Because we intend to contribute Meril to a joint venture and consequently lose our exclusive control (see Note D.8.1 to our consolidated financial statements included at Item 18 of this annual report) we have not

\* Sites acquired in 2008 with Acambis.

## **Table of Contents**

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

The net book value of our property, plant and equipment at December 31, 2009 was 7,830 million. During 2009, we invested 1,353 million (see Note D.3. to the consolidated financial statements) in increasing capacity and improving productivity at our various production and R&D sites.

The Group's principal capital expenditures and divestments for the years 2007, 2008 and 2009 are set out in this annual report at Item 5. Operating and Financial Review and Prospects Divestments, Acquisitions and Liquidity and Capital Resources and in the notes to the consolidated financial statements (Note D.1., Note D.2. and Note D.4. to our consolidated financial statements included at Item 18 of this annual report).

Our principal investments in progress are described below:

In Europe, we continued to optimize our industrial facilities, in particular by investing in two new Lantus<sup>®</sup> production lines at the Frankfurt site and acquiring the Diabel manufacturing site from Pfizer to strengthen our insulin production capacity. The construction of syringe filling and packaging lines at Le Trait (France) increased our production capacity in Lovenox<sup>®</sup> and vaccines.

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

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

The Vaccines activity invested in the construction of a state-of-the art research facility in Toronto (Canada); the creation of a new vaccines campus in Neuville (France); the construction of formulation and filling facilities in Val de Reuil (France), of a bacteriological bulk facility in Marcy l'Étoile (France), and of bulk flu facilities in Shenzhen (China) and Ocoyoacac (Mexico); and the completion of bulk and filling facilities in Swiftwater (United States), mainly dedicated to influenza and meningitis vaccines.

Other investments related mainly to Research & Development sites.

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

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

N/A



## **Table of Contents**

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

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

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2009.

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

#### **2009 Overview**

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

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

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

Business net income totaled 8,629 million in 2009 (18.0% higher than in 2008) due to growth in our sales and control over operating costs, plus favorable trends in the U.S. dollar exchange rate over the period. Business earnings per share were 6.61, 18.2% up on the 2008 figure. Business net income and business earnings per share are non-GAAP financial measures which our management uses to monitor our operational performance, and which are defined at [Business Net Income](#), below.

Net income attributable to equity holders of the Company for 2009 was 5,265 million, up 36.7% from the 2008 figure.

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

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

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

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

(1) See definition below under Presentation of net sales



## **Table of Contents**

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

We have significantly reinforced our presence in Animal Health by acquiring the remaining 50% of Merial Limited not already held by us. On March 8, 2010, sanofi-aventis exercised its contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial to form an animal health joint venture that would be equally owned by the new Merck and sanofi-aventis. In addition to execution of final agreements, formation of the new animal health joint venture remains subject to approval by the relevant competition authorities and other closing conditions (for more information see Item 8 B. Significant Changes Merial and Notes D.1 and D.8.1 to our consolidated financial statements included at Item 18 of this annual report).

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

Our operations generate significant cash flow. We recorded 8,515 million of net cash provided by operating activities in 2009 compared to 8,523 million in 2008. During the course of 2009, we paid out 2.9 billion in dividends and funded part of the cost of our acquisitions by contracting new debt. In terms of financial position, we ended 2009 with our debt, net of cash and cash equivalents (meaning the sum of short-term debt and long-term debt less cash and cash equivalents) at 4.1 billion (2008: 1.8 billion). Debt, net of cash and cash equivalents, is a financial indicator that is used by management and investors to measure the Company's overall net indebtedness and to assess the Company's financing risk as measured by its gearing ratio (debt, net of cash and cash equivalents, to total equity). The gearing ratio stood at 8.5% at the end of 2009 versus 3.9% at the end of 2008. See Liquidity and Capital Resources Consolidated Balance Sheet and Debt below.

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

Our results of operations and financial condition for the years ended December 31, 2009, December 31, 2008 and December 31, 2007 have been significantly affected by our August 2004 acquisition of Aventis and certain subsequent transactions.

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

In order to isolate the impact of these and certain other items, we use as an evaluation tool a non-GAAP financial measure that we refer to as business net income. For a further discussion and definition of business net income, see Business Net Income below. For consistency of application of this principle, business net income also takes into account the impact of our subsequent acquisitions.

Business net income for the years ended December 31, 2009, 2008 and 2007 is presented in Business Net Income below.

**Sources of Revenues and Expenses**

*Revenue.* Revenue arising from the sale of goods is presented in the income statement under Net sales. Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Returns, discounts, incentives and rebates described above are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. See Note B.14. to our consolidated financial statements included at Item 18 of this annual report. We sell pharmaceutical products and human vaccines directly, through alliances, and through licensees throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. When we sell products through alliances, the revenues reflected in our consolidated financial statements are based on the overall level of sales of the products

## **Table of Contents**

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

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

*Operating Income.* Our operating income reflects our revenues, our cost of sales and the remainder of our operating expenses, the most significant of which are research and development expenses and selling and general expenses. We also present our operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals and litigation, which appears on the face of our financial statements in accordance with IFRS, and which reflects our operating income before the impact of a number of items that do not reflect the results of our current business activities. For our business segments, we also measure our results of operations through an indicator referred to as [Business Operating Income](#), which we describe below under [Segment Information](#) [Business Operating Income of Segments](#).

## **Segment Information**

### *Business Segments*

In accordance with IFRS 8, [Business Segments](#), we have defined our segments as [Pharmaceuticals](#) and [Human Vaccines \(Vaccines\)](#). Our other identified segments are categorized as [Other](#).

The [Pharmaceuticals](#) segment includes our research, development, production and sales activities relating to pharmaceutical products, including prescription, consumer health care and generic products. This segment also includes equity affiliates and joint ventures with pharmaceutical business activities, including in particular the entities that are majority-held by BMS. See [Financial Presentation of Alliances](#).

The [Vaccines](#) segment includes our research, development, production and sales activities relating to human vaccines. This segment also includes our Sanofi Pasteur MSD joint venture.

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

Inter-segment transactions are not significant.

*Business Operating Income of Segments*

We measure the results of operations of our business segments on the basis of Business Operating Income, a performance measure that we adopted in accordance with IFRS 8. Our chief operating decision-maker uses Business Operating Income to evaluate the performance of our operating managers and to allocate resources.

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

amortization of intangible assets is eliminated;

the share of profits and losses of associates is added and net income attributable to minority interests is deducted; and

other impacts associated with acquisitions (primarily, the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of purchase accounting on associates) are eliminated.

**Table of Contents**

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

( million)	2009			Total
	Pharmaceuticals	Vaccines	Other	
<b>Net sales</b>	<b>25,823</b>	<b>3,483</b>		<b>29,306</b>
Other revenues	1,412	31		1,443
Cost of sales	(6,527)	(1,326)		(7,853)
Research and development expenses	(4,091)	(491)	(1)	(4,583)
Selling and general expenses	(6,762)	(561)	(2)	(7,325)
Other operating income and expenses	387	(3)	1	385
Share of profit/loss of associates excluding Merial <sup>(1)</sup>	792	41	8	841
Share of profit/loss of Merial <sup>(1)</sup>			241	241
Net income attributable to minority interests	(426)	(1)		(427)
<b>Business operating income</b>	<b>10,608</b>	<b>1,173</b>	<b>247</b>	<b>12,028</b>

<sup>(1)</sup> Net of tax

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

<sup>(1)</sup> Net of tax

**Business Net Income**

In addition to net income, we use a non-GAAP financial measure that we refer to as **Business Net Income** to evaluate our Group's performance. Business net income, which is defined below, represents the aggregate business operating income of all of our business segments, less net financial expenses and the relevant income tax charges. We believe that this non-GAAP financial measure allows investors to understand the performance of our Group because it segregates the results of operations of our current business activities, as opposed to reflecting the impact of past transactions such as acquisitions.

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

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

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

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

Business net income is defined as Net income attributable to equity holders of the Company, determined under IFRS, excluding (i) amortization of intangible assets; (ii) impairment of intangible assets; (iii) other impacts associated with acquisitions (including impacts of acquisitions on associates); (iv) restructuring costs;

**Table of Contents**

gains and losses on disposals of non-current assets; costs or provisions associated with litigation; (v) the tax effect related to the items listed in (i) through (iv) as well as (vi) effects of major tax disputes, and (vii) the share of minority interests on (i) through (vi). Items listed in (iv) correspond to those reported in the line items Restructuring costs and Gains and losses on disposals, and litigation, which are defined in Note B.20. to our consolidated financial statements.

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

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

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

(2) Other items comprise:

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

(3) Other tax items comprise:

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

(4) This line item comprises: until September 17, 2009, amortization and impairment charged against the intangible assets of Merial; and from September 18, 2009 (i) the impact of the discontinuation of depreciation of the property, plant and equipment of Merial in accordance with IFRS 5 (see Note B.7. to our consolidated financial statements) and (ii) the expense arising from the workdown of inventories remeasured at fair value at acquisition date.

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

The most significant reconciliation items in the table above relate to the purchase accounting effect of our acquisitions, particularly the amortization and impairment of intangible assets such as acquired research and development. We believe that excluding these non-cash charges enhances an investor's understanding of our underlying economic performance because we do not consider that the excluded charges reflect the combined entity's ongoing operating performance. Rather, we believe that each of the excluded charges reflects the decision to acquire the businesses concerned.

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

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

charges to cost of sales resulting from the workdown of acquired inventory that was written up to fair value, net of tax;

charges related to the impairment of the goodwill; and

charges related to the amortization and impairment of intangible assets, net of tax and minority interests.



## Table of Contents

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

the elimination of charges related to the purchase accounting effect of our acquisitions (particularly amortization and impairment of definite-lived intangible assets) enhances the comparability of our ongoing operating performance relative to our peers in the pharmaceutical industry that carry these intangible assets (principally patents and trademarks) at low book values either because they are the result of in-house research and development that has already been expensed in prior periods or because they were acquired through business combinations that were accounted for as poolings-of-interest;

the elimination of selected items, such as the increase in cost of sales arising from the workdown of inventories remeasured at fair value, gains and losses on disposals of non-current assets and costs and provisions associated with major litigation, improves comparability from one period to the next; and

the elimination of integration and restructuring costs relating to our acquisitions and to the implementation of our transformation strategy enhances comparability because these costs are directly, and only, incurred in connection with the relevant acquisitions or transformation processes such as the rationalization of our research and development structures.

We remind investors, however, that business net income should not be considered in isolation from, or as a substitute for, net income attributable to equity holders of the Company reported in accordance with IFRS. In addition, we strongly encourage investors and potential investors not to rely on any single financial measure but to review our financial statements, including the notes thereto, and our other publicly filed reports, carefully and in their entirety.

There are material limitations associated with the use of business net income as compared to the use of IFRS net income attributable to equity holders of the Company in evaluating our performance, as described below:

The results presented by business net income cannot be achieved without incurring the following costs that the measure excludes:

*Amortization of intangible assets.* Business net income excludes the amortization charges related to intangible assets. Most of these amortization charges relate to intangible assets that we have acquired. Although amortization is a non-cash charge, it is important for investors to consider it because it represents an allocation in each reporting period of a portion of the purchase price that we paid for certain intangible assets that we have acquired through acquisitions. For example, in connection with our acquisition of Aventis in 2004, we paid an aggregate of 31,279 million for these amortizable intangible assets (which, in general, will be amortized over their useful lives, which represents an average amortization period of eight years) and 5,007 million for in-progress research & development. A large part of our revenues could not be generated without owning acquired intangible assets.

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

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

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

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

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

## **Table of Contents**

although the adjustments relating to the elimination of the effect of the purchase accounting treatment of the Aventis acquisition and other acquisitions represent non-cash charges, the adjustments relating to integration and restructuring costs represent significant cash charges in the periods immediately following the closing of the acquisition.

This Item 5 contains a discussion and analysis of business net income on the basis of consolidated financial data. Because our business net income is not a standardized measure, it may not be comparable with the non-GAAP financial measures of other companies using the same or a similar non-GAAP financial measure.

## **Presentation of Net Sales**

In the discussion below, we present our consolidated net sales for 2009, 2008 and 2007. We break down our net sales among various categories, such as by business segment, product and geographic region. We refer to our consolidated net sales as reported sales.

In addition to reported sales, we analyze non-GAAP financial measures designed to isolate the impact on our net sales of currency exchange rates and changes in group structure. In 2009, we changed our method of isolating these factors, so that the measures we use for purposes of comparing our net sales in 2009 and 2008 are not the same as the measures we use for purposes of comparing our net sales in 2008 and 2007. For the years ended December 31, 2009 and December 31, 2008, we adjust net sales for changes in exchange rates by applying the exchange rates used for the year ended December 31, 2008 to net sales for the year ended December 31, 2009. As more fully explained below, in our comparison of the years ended December 31, 2008 and December 31, 2007, we adjust net sales by applying exchange rates used for the year ended December 31, 2008 to the net sales for the year ended December 31, 2007. As a result, we use 2008 exchange rates for 2009 and for 2007. Using prior period exchange rates rather than current period exchange rates could modify the result of the calculations of our net sales at constant exchange rates, impacting the sales growth information presented below. This impact could be either positive or negative depending on the currency mix of our net sales for each year.

### *Years ended December 31, 2009 and 2008*

For the years ended December 31, 2009 and December 31, 2008, when we refer to changes in our net sales at constant exchange rates, we exclude the effect of exchange rates by recalculating net sales for the year ended December 31, 2009 using the exchange rates that were used for the year ended December 31, 2008. See Note B.2 to our consolidated financial statements for further information relating to the manner in which we translate into euros transactions recorded in other currencies.

When we refer to our net sales on a constant structure basis, we eliminate the effect of changes in structure by restating the net sales for the previous period (i.e., in this case 2008) as follows:

by including sales from an entity or with respect to product rights acquired in the current period for a portion of the previous period (i.e., 2008) equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we make the acquisition;

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

similarly, by excluding sales for a portion of the previous period (i.e., 2008) when we have sold an entity or rights to a product in the current period; and

for a change in consolidation method, by recalculating the previous period (i.e., 2008) on the basis of the method used for the current period.

A reconciliation of our reported net sales to our net sales at constant exchange rates and on a constant structure basis is provided at Results of Operations Year Ended December 31, 2009 Compared with Year Ended December 31, 2008 Net Sales below.

*Years ended December 31, 2008 and 2007*

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

## **Table of Contents**

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

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

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

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

## **Financial Presentation of Alliances**

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

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

### ***Alliance Arrangements with Bristol-Myers Squibb ( BMS )***

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

There are three principal marketing arrangements that are used:

*Co-marketing.* Under the co-marketing system, each company markets the products independently under its own brand names. We record our own sales and related costs in our consolidated financial statements.

*Exclusive Marketing.* Under the exclusive marketing system, one company has the exclusive right to market the products. We record our own sales and related costs in our consolidated financial statements.

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

*Co-promotion.* Under the co-promotion system, the products are marketed through the alliance arrangements (either by contractual arrangements or by separate entities) under a single brand name. The accounting treatment of the co-promotion arrangement depends upon who has majority ownership and operational management in that territory, as discussed below.

The alliance arrangements include two royalty streams that are applied on a worldwide basis (excluding Japan and other opt out countries), regardless of the marketing system and regardless of which company has majority ownership and operational management:

*Discovery Royalty.* As inventor of the two molecules, we earn an adjustable discovery royalty on all Aprovel<sup>®</sup> and Plavix<sup>®</sup> sold in alliance countries regardless of the marketing system. The discovery royalty is reflected in our consolidated income statement in Other revenues.

*Development Royalty.* In addition to the discovery royalty, we and BMS are each entitled to a development royalty related to certain know-how and other intellectual property in connection with sales of Aprovel<sup>®</sup> and Plavix<sup>®</sup>.

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.

---

## **Table of Contents**

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. Our alliance with BMS does not cover distribution rights to Plavix<sup>®</sup> in Japan, which is marketed by sanofi-aventis.

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

we use the co-promotion system for most of the countries in Western Europe for Aprovel<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), Scandinavia and Ireland.

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

we use the co-promotion system in the United States and Canada, where the products are sold through the alliances under the operational management of BMS. With respect to Avapro<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.

### ***Alliance arrangements with Warner Chilcott (previously with Procter & Gamble Pharmaceuticals)***

Our agreement with Warner Chilcott ( the Alliance Partner ) covers the worldwide development and marketing arrangements of Acto<sup>®</sup> except Japan for which we hold no rights. Until October 30, 2009, this agreement was between sanofi-aventis and Procter & Gamble Pharmaceuticals

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

(P&G). Since the sale by P&G of its pharmaceutical business to Warner Chilcott on October 30, 2009, Actonel® has been marketed in collaboration with Warner Chilcott. The local marketing arrangements may take various forms.

*Co-promotion*, whereby sales resources are pooled but only one of the two parties to the alliance agreement (sanofi-aventis or the Alliance Partner) invoices product sales. Co-promotion is carried out under contractual agreements and is not based on any specific legal entity. The Alliance Partner sells the product and incurs all of the related costs in the United States, Canada and France. This co-promotion scheme also included the Netherlands until March 31, 2008. We recognize our share of revenues under the agreement in our income statement as a component of operating income in the line item *Other operating income*. In the secondary co-promotion territories (the United Kingdom until December 31, 2008, Ireland, Sweden, Finland, Greece, Switzerland, Austria, Portugal and Australia), we sell the product and recognize all the revenues from sales of the product along with the corresponding expenses. The share due to the Alliance Partner is recognized in *Cost of sales*;



---

## **Table of Contents**

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

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

*sanofi-aventis only territories*: we have exclusive rights to sell the product in all other territories. We recognize all revenues and expenses from our own operations in our income statement, but in return for these exclusive rights pay the Alliance Partner a royalty based on actual sales. This royalty is recognized in Cost of sales .

## **Impact of Exchange Rates**

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in countries where the euro is not the local currency, our results of operations can be significantly affected by exchange rate movements between the euro and other currencies, primarily the U.S. dollar and, to a lesser extent, the British pound, the Japanese yen, and currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2009, we earned 32.2% of our net sales in the United States. A decrease in the value of the U.S. dollar against the euro has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively affects our operating income. A decrease in the value of the U.S. dollar has a particularly significant impact on our operating income, which is higher in the United States than elsewhere, and on the contribution to net income of our alliance with BMS in the United States, which is under the operational management of BMS, as described at Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb above.

For a description of positions entered into to manage operational exchange rate risks as well as our hedging policy, see Item 11. Quantitative and Qualitative Disclosures about Market Risk , and Item 3.D. Risk factors Fluctuations in currency exchange rates could adversely affect our results of operations and financial conditions .

## **Divestments**

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

## **Acquisitions**

The principal acquisitions during 2009 are described below:

On September 17, 2009, and further to the agreement signed on July 29, 2009, sanofi-aventis completed the acquisition of the interest held by Merck & Co., Inc. ( Merck ) in Merial Limited ( Merial ) for consideration of \$4 billion in cash. Founded in 1997, Merial was previously held jointly (50/50) by Merck and sanofi-aventis, and is now 100% held by sanofi-aventis. Merial is one of the world's leading animal health companies, with sales of \$2.6 billion in 2009. With effect from September 17, 2009, sanofi-aventis has held 100% of the shares of Merial and

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

has exercised exclusive control over the company. In accordance with IAS 27, Merial is accounted for by the full consolidation method in the consolidated financial statements of sanofi-aventis.

In connection with the agreement signed on July 29, 2009, sanofi-aventis also signed an option contract giving it the possibility, once the Merck/Schering-Plough merger is complete, to combine the Merck-owned Intervet/Schering-Plough Animal Health with Merial in a joint venture to be held 50/50 by Merck and sanofi-aventis. The terms of the option contract set a value of \$8 billion for Merial. The minimum total value received by Merck and its subsidiaries in consideration for the transfer of Intervet/Schering-Plough to the combined entity would be \$9.25 billion, comprising a minimum value of \$8.5 billion for Intervet/Schering-Plough (subject to potential upward revision after valuations performed by the two parties) and additional consideration of \$750 million. On completion of the valuation of Intervet/Schering-Plough and after taking account of certain adjustments customary in this type of transaction, a balancing payment would be made to establish 50/50 parity between Merck and sanofi-aventis in the combined entity.

## Table of Contents

Because of the high probability of the option being exercised as of year end 2009, Merial was treated as an asset held for sale or exchange pursuant to IFRS 5 as of December 31, 2009. On March 8, 2010, sanofi-aventis did in fact exercise its contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial. In addition to execution of final agreements, formation of the new animal health joint venture remains subject to approval by the relevant competition authorities and other closing conditions (for more information see Item 8 B. Significant Changes – Merial ). Detailed information about the impact of Merial on the consolidated financial statements of sanofi-aventis is provided in Note D.8. Assets held for sale or exchange to our consolidated financial statements included at Item 18 of this annual report.

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

On March 31, 2009, sanofi-aventis acquired Laboratorios Kendrick, one of Mexico s leading manufacturers of generics, with sales of approximately 26 million in 2008.

On April 27, 2009, sanofi-aventis acquired 100% of the shares of Medley, Brazil s third largest pharmaceutical company and a leading generics company, with net sales of approximately 160 million in 2008 (more than two thirds of which were in generics) and 163 million in 2009 since the acquisition date. The purchase price, based on a 500 million enterprise value, was 348 million inclusive of acquisition-related costs.

On April 27, 2009 sanofi-aventis acquired 100% of BiPar Sciences, Inc. ( BiPar ), a U.S. biopharmaceutical company developing novel tumor-selective approaches for the treatment of different types of cancers. BiPar is the leading company in the emerging field of DNA (deoxyribonucleic acid) repair using Poly ADP-Ribose Polymerase (PARP) inhibitors. The pivotal Phase III trial for BSI-201, BiPar s lead product candidate in metastatic triple negative breast cancer, started in July 2009. The purchase price is contingent on the achievement (regarded as probable) of milestones related to the development of BSI-201, and could reach \$500 million. See Notes D.1. and D.21. to our consolidated financial statements included at Item 18 of this annual report.

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

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

On November 30, 2009, sanofi-aventis completed the acquisition of Laboratoire Oenobiol, one of France s leading players in health and beauty dietary supplements.

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

The principal acquisitions during 2008 are described below:

On September 25, 2008, sanofi-aventis completed the acquisition of Acambis plc for £285 million. Acambis plc became Sanofi Pasteur Holding Ltd, a wholly-owned subsidiary of Sanofi Pasteur Holding SA. This company develops novel vaccines that address unmet medical needs or substantially improve current standards of care. Sanofi Pasteur and Acambis plc were already developing vaccines in a successful partnership of more than a decade: Acambis plc was conducting three of its major projects under exclusive collaboration agreements with sanofi pasteur, for vaccines against dengue, Japanese Encephalitis and West Nile virus. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

**Table of Contents**

On September 1, 2008, sanofi-aventis completed the acquisition of the Australian company Symbion CP Holdings Pty Ltd (Symbion Consumer) for AUD560 million. Symbion Consumer manufactures, markets and distributes nutraceuticals (vitamins and mineral supplements) and over the counter brands throughout Australia and New Zealand. Symbion Consumer has a portfolio of brands including Natures Own, Cenovis, Bio-organics, Golden Glow and Microgenics. In 2007, Symbion Consumer sales amounted to approximately AUD190 million. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

The principal acquisitions during 2007 are described below:

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

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

**Table of Contents****Results of Operations***Year Ended December 31, 2009 Compared with Year Ended December 31, 2008*

The consolidated income statements for the years ended December 31, 2009 and December 31, 2008 break down as follows:

<i>(under IFRS)</i>	<b>2009</b>	<b>as % of</b>	<b>2008</b>	<b>as % of</b>
<i>( million)</i>		<b>net sales</b>		<b>net sales</b>
<b>Net sales</b>	<b>29,306</b>	<b>100.0%</b>	<b>27,568</b>	<b>100.0%</b>
Other revenues	1,443	4.9%	1,249	4.5%
Cost of sales	(7,880)	(26.9%)	(7,337)	(26.6%)
<b>Gross profit</b>	<b>22,869</b>	<b>78.0%</b>	<b>21,480</b>	<b>77.9%</b>
Research & development expenses	(4,583)	(15.6%)	(4,575)	(16.6%)
Selling & general expenses	(7,325)	(25.0%)	(7,168)	(26.0%)
Other operating income	866		556	
Other operating expenses	(481)		(353)	
Amortization of intangibles	(3,528)		(3,483)	
<b>Operating income before restructuring, impairment of property, plant &amp; equipment and intangibles, gains &amp; losses on disposals, and litigation</b>	<b>7,818</b>	<b>26.7%</b>	<b>6,457</b>	<b>23.4%</b>
Restructuring costs	(1,080)		(585)	
Impairment of property, plant & equipment and intangibles	(372)		(1,554)	
Gains and losses on disposals, and litigation			76	
<b>Operating income</b>	<b>6,366</b>	<b>21.7%</b>	<b>4,394</b>	<b>15.9%</b>
Financial expenses	(324)		(335)	
Financial income	24		103	
<b>Income before tax and associates</b>	<b>6,066</b>	<b>20.7%</b>	<b>4,162</b>	<b>15.1%</b>
Income tax expense	(1,364)		(682)	
Share of profit/loss of associates	814		692	
<b>Net income excluding the held-for-exchange Merial business <sup>(1)</sup></b>	<b>5,516</b>	<b>18.8%</b>	<b>4,172</b>	<b>15.1%</b>
Net income from the held-for-exchange Merial business <sup>(1)</sup>	175		120	
<b>Net income</b>	<b>5,691</b>	<b>19.4%</b>	<b>4,292</b>	<b>15.6%</b>
- attributable to minority interests	426		441	
<b>- attributable to equity holders of the Company</b>	<b>5,265</b>	<b>18.0%</b>	<b>3,851</b>	<b>14.0%</b>
Average number of shares outstanding (million)	1,305.9		1,309.3	
Basic earnings per share (in euros)	4.03		2.94	

<sup>(1)</sup> Reported separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations). For the other disclosures required under IFRS 5, refer to Note D.8. to our consolidated financial statements included at Item 18 of this annual report.

*Net Sales*

Net sales for the year ended December 31, 2009 amounted to 29,306 million, an increase of 6.3% versus 2008. Exchange rate movements had a favorable effect of 1.0 point, mainly reflecting the appreciation in the U.S. dollar against the euro. At constant exchange rates and after taking

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

account of changes in structure (mainly the consolidation of Zentiva and Medley from the second quarter of 2009, and the reversion of Copaxone® to Teva in North America effective April 1, 2008), net sales rose by 5.3%. Excluding changes in structure and at constant exchange rates, organic net sales growth was 4.0%.

**Table of Contents**

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2009 and December 31, 2008 to our net sales at constant exchange rates and net sales on a constant structure basis.

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

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

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

*Net Sales by Product Pharmaceuticals*

Net sales generated by our Pharmaceuticals business in 2009 were 25,823 million, an increase of 3.7% at constant exchange rates and of 4.5% on a reported basis.

Net sales of our flagship products (see table below) advanced by 4.6% at constant exchange rates to 13,278 million, representing 51.4% of Pharmaceuticals net sales, versus 50.5% in 2008. This growth rate was adversely affected by competition from generics of Eloxatine® in the United States and Europe; without this effect, growth in Pharmaceuticals net sales would have been 2.2 points higher in 2009 (at constant exchange rates).

Net sales of the other products in our portfolio fell by 6.0% at constant exchange rates to 6,078 million, compared with 6,484 million in 2008. At constant exchange rates, net sales of these products were down 9.7% in Europe, at 3,283 million; up 1.2% in the United States, at 610 million; and down 1.5% in the Other Countries region, at 2,185 million.

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



Our Consumer Health Care business achieved net sales growth of 26.8% in 2009 at constant exchange rates, to 1,430 million. This includes the consolidation of Symbion Consumer (now sanofi-aventis Healthcare Holdings Pty Limited), with effect from September 1, 2008; of Zentiva's consumer health care products, with effect from April 1, 2009; and of Oenobiol, with effect from December 1, 2009. On a constant structure basis and at constant exchange rates, the growth rate was 8.1%.

In 2009, net sales for our Generics business increased almost threefold (by 198% at constant exchange rates) to 1,012 million, boosted by the consolidation of Zentiva and Kendrick (each from April 1) and Medley (from May 1). On a constant structure basis and at constant exchange rates, the growth rate was 8.7%.

**Table of Contents**

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

( million)

Product	Indication	2009 Reported	2008 Reported	Change on a reported basis (%)	Change at constant exchange rates (%)	Change on a constant structure basis and at constant exchange rates (%)
Lantus®	Diabetes	3,080	2,450	+25.7%	+22.5%	+22.5%
Lovenox®	Thrombosis	3,043	2,738	+11.1%	+8.8%	+8.8%
Plavix®	Atherothrombosis	2,623	2,609*	+0.5%	+0.2%	+0.2%
Taxotere®	Breast, Non small cell lung, Prostate, Gastric, Head and neck cancers	2,177	2,033	+7.1%	+6.1%	+6.1%
Aprovel®/CoAprovel®	Hypertension	1,236	1,202	+2.8%	+4.7%	+4.7%
Eloxatine®	Colorectal cancer	957	1,345*	-28.8%	-34.7%	-34.7%
Apidra®	Diabetes	137	98	+39.8%	+38.8%	+38.8%
Multaq®	Atrial fibrillation	25				
<b>Sub-total flagship products</b>		<b>13,278</b>	<b>12,475</b>	<b>+6.4%</b>	<b>+4.6%</b>	<b>+4.6%</b>
Stilnox®/Ambien®/Myslee®	Sleep disorders	873	822*	+6.2%	-1.3%	-1.3%
Allegra®	Allergic rhinitis, Urticaria	731	666*	+9.8%	-2.6%	-2.6%
Copaxone®	Multiple sclerosis	467	622	-24.9%	-23.8%	+20.6%
Tritace®	Hypertension, Congestive heart failure, Nephropathy	429	491*	-12.6%	-9.2%	-9.2%
Amaryl®	Diabetes	416	379*	+9.8%	+4.2%	+4.2%
Depakine®	Epilepsy	329	322*	+2.2%	+7.1%	+7.1%
Xatral®	Benign prostatic hypertrophy	296	319*	-7.2%	-8.5%	-8.5%
Actonel®	Osteoporosis, Paget's disease	264	330	-20.0%	-17.6%	-7.5%
Nasacort®	Allergic rhinitis	220	240	-8.3%	-11.7%	-11.7%
Other products		6,078	6,484	-6.3%	-6.0%	-2.5%
Consumer Health Care		1,430	1,203	+18.9%	+26.8%	+8.1%
Generics		1,012	354	+185.9%	+198.0%	+8.7%
<b>Total Pharmaceuticals</b>		<b>25,823</b>	<b>24,707</b>	<b>+4.5%</b>	<b>+3.7%</b>	<b>+2.3%</b>

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

**Table of Contents**

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

( million)

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

*Flagship Products <sup>(1)</sup>*

Net sales of **Lantus®**, the world's leading insulin brand (source: IMS 2009 sales), rose by 22.5% (at constant exchange rates) to 3,080 million in 2009, driven largely by the SoloSTAR® injection pen. Growth was strong across all three geographic regions at 23.6% in the United States, 12.2% in Europe and 42.8% in the Other Countries region (all at constant exchange rates). In the Other Countries region, the performance of Lantus® is particularly high in China, Japan and Mexico, with respective growth rates at constant exchange rates of 113.7%, 81.6% and 48.2%.

Net sales of the rapid-acting analog of human insulin **Apidra®** were 137 million, up 38.8% (at constant exchange rates), boosted by the launch of Apidra® SoloSTAR® in the United States.

**Lovenox®**, the leader in anti-thrombotics in the U.S., Germany, France, Italy, Spain, and the United Kingdom (source: IMS 2009 sales), achieved net sales growth of 8.8% in 2009 (at constant exchange rates) to 3,043 million, driven by double-digit growth in Europe (up 13.7% at constant exchange rates, at 890 million) and in the Other Countries region (up 14.8% at constant exchange rates, at 331 million). In the United States, net sales increased by 5.3% to 1,822 million.

**Taxotere®** posted growth of 6.1% in 2009 at constant exchange rates to 2,177 million, driven by its use in adjuvant breast cancer treatment and in prostate cancer. Growth was good across all three geographic regions at 7.1% in Europe, 5.3% in the United States and 5.1% in the Other Countries region (all at constant exchange rates). In Japan, the product made further advances, with net sales rising by 9.5% to 129 million, in particular due to the prostate cancer indication approved in the second half of 2008.

**Eloxatine**<sup>®</sup> saw net sales fall by 34.7% at constant exchange rates in 2009 to 957 million, due to ongoing genericization in Europe and competition from a number of generics in the United States during the second half of the year.

Net sales of the hypnotic **Stilnox**<sup>®</sup>/**Ambien**<sup>®</sup>/**Myslee**<sup>®</sup> fell by 1.3% at constant exchange rates. In the United States, **Ambien CR**<sup>®</sup> reported growth of 0.9% at constant exchange rates, to 497 million. In Japan, net sales of **Myslee**<sup>®</sup>, the leading hypnotic on the market (source: IMS 2009 sales), totaled 194 million, an increase of 15.2% at constant exchange rates.

(1) Sales of **Plavix**<sup>®</sup> and **Aprovel**<sup>®</sup> are discussed below under Worldwide Presence of **Plavix**<sup>®</sup> and **Aprovel**<sup>®</sup>.

**Table of Contents**

**Allegra**<sup>®</sup> saw net sales fall by 2.6% at constant exchange rates in 2009 to 731 million, reflecting the arrival of Allegra<sup>®</sup> D 12 generics in the United States in the fourth quarter of 2009 (which follows the settlement of the U.S. patent infringement suit related to Barr's proposed generic version) and ongoing genericization in Europe. In 2009, sales decreased respectively by 15.9% and 20% (at constant exchange rates) in the U.S. and Europe. The product recorded further growth in Japan, with sales up 15.2% at constant exchange rates, at 334 million.

The end of commercialization of **Copaxone**<sup>®</sup> by sanofi-aventis in North America effective April 1, 2008 resulted in a 23.8% drop in consolidated net sales of this product in 2009 (at constant exchange rates), to 467 million.

**Multaq**<sup>®</sup> was launched in the United States during the third quarter of 2009. Sales of the product in 2009 amounted to 25 million.

*Net Sales Human Vaccines (Vaccines)*

In 2009, our Vaccines business generated consolidated net sales of 3,483 million, up 19.2% at constant exchange rates and 21.7% on a reported basis. The main growth drivers were Pentacel<sup>®</sup> and A(H1N1) influenza vaccines. Growth at constant exchange rates was robust across all three geographic regions, at 19.1% in the United States (to 2,098 million), 15.9% in Europe (to 448 million) and 20.8% in the Other Countries region (to 937 million). Excluding the impact of sales of pandemic influenza vaccines (A(H1N1) and H5N1), net sales growth was 7.1% (at constant exchange rates).

Polio/Pertussis/Hib vaccines achieved growth of 22.8% at constant exchange rates to 968 million, reflecting the success of **Pentacel**<sup>®</sup> (the first 5-in-1 pediatric combination vaccine against diphtheria, tetanus, pertussis, polio and *haemophilus influenzae* type b licensed in the United States in June 2008), which posted net sales of 343 million in 2009 versus 84 million in 2008.

Net sales of **influenza vaccines** rose by 46.7% at constant exchange rates to 1,062 million, mainly due to the shipment during 2009 of batches of vaccines against the A(H1N1) influenza virus for a total amount of 440 million, including 301 million in the United States.

Meningitis/pneumonia vaccines achieved net sales of 538 million, up 6.1% at constant exchange rates, largely as a result of good growth in sales of vaccines against pneumococcal infections. Net sales of **Menactra**<sup>®</sup> (quadrivalent meningococcal meningitis vaccine) increased by 1.1% at constant exchange rates to 445 million.

Net sales of adult booster vaccines fell by 3.0% at constant exchange rates to 406 million. Net sales of **Adacel**<sup>®</sup> (adult and adolescent tetanus/diphtheria/pertussis booster vaccine) were 267 million, down 1.2% at constant exchange rates.

Shantha, consolidated from September 1, 2009, contributed net sales of 17 million in 2009.

The following table presents the 2009 sales of our Vaccines activity by range of products:

<i>( million)</i>	<b>2009 Reported</b>	<b>2008 Reported</b>	<b>Change on a reported basis (%)</b>	<b>Change at constant exchange rates (%)</b>
Influenza Vaccines* (including Vaxigrip® and Fluzone® )	1,062	736	+44.3%	+46.7%**
Polio/Pertussis/Hib Vaccines (including Pentacel® and Pentaxim® )	968	768	+26.0%	+22.8%
Meningitis/Pneumonia Vaccines (including Menactra®)	538	472	+14.0%	+6.1%
Adult Booster Vaccines (including Adacel®)	406	399	+1.8%	-3.0%
Travel and Other Endemic Vaccines	313	309	+1.3%	0.0%
Other Vaccines	196	177	+10.7%	+6.8%
<b>Total Vaccines</b>	<b>3,483</b>	<b>2,861</b>	<b>+21.7%</b>	<b>+19.2%</b>

\* Seasonal and pandemic influenza vaccines.

\*\* Change of -0.2% excluding pandemic flu (A(H1N1) and H5N1)

**Table of Contents**

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

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

\* Seasonal and pandemic influenza vaccines.

In addition to the Vaccines activity reflected in our consolidated net sales, sales at Sanofi Pasteur MSD, our joint venture with Merck & Co. in Western Europe, reached 1,132 million, a fall of 11.0% on a reported basis. Full-year net sales of Gardasil, a vaccine that prevents papillomavirus infections (a cause of cervical cancer), amounted to 395 million, compared with 584 million in 2008. This 32.4% decrease reflects extensive catch-up vaccination campaigns in 2008.

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

*Net Sales by Geographic Region*

We divide our sales geographically into three regions: Europe, the United States and other countries. The following table breaks down our 2009 and 2008 net sales by region:

( million)	2009 Reported	2008 Reported	Change on a reported basis (%)	Change at constant exchange rates (%)	Change on a constant structure basis and at constant exchange rates (%)
Europe	12,059	12,096	-0.3%	+3.2%	+0.3%
United States	9,426	8,609	+9.5%	+2.8%	+5.4%
Other countries	7,821	6,863	+14.0%	+12.1%	+9.1%
<b>Total</b>	<b>29,306</b>	<b>27,568</b>	<b>+6.3%</b>	<b>+5.3%</b>	<b>+4.0%</b>

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

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

In the United States, the end of commercialization of Copaxone<sup>®</sup> by sanofi-aventis effective April 1, 2008 and the genericization of Eloxatine<sup>®</sup> during the second half of 2009 slowed the pace of net sales growth to 2.8% (at constant exchange rates). Lantus<sup>®</sup> and Lovenox<sup>®</sup>, with net sales growth of 23.6% and 5.3% respectively (at constant exchange rates) were the principal growth drivers in Pharmaceuticals. Growth for the Vaccines business was boosted by sales of pandemic influenza vaccines (A(H1N1) and H5N1).

In the Other Countries region, net sales rose by 12.1% at constant exchange rates, due largely to the performance of the Vaccines business (up 20.8% at constant exchange rates) and to the dynamism of Latin America (up 15.7% at constant exchange rates), the Middle East (up 16.4% at constant exchange rates), China



**Table of Contents**

(up 28.8% at constant exchange rates), Russia (up 59.8% at constant exchange rates) and Japan. Net sales in Japan reached 1,844 million (up 10.7% at constant exchange rates), driven by the performances of Plavix<sup>®</sup>, Myslee<sup>®</sup> and Allegra<sup>®</sup>. Net sales in Latin America (1,913 million) were underpinned by good organic growth and by the acquisition of Medley in the second quarter of 2009.

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

*Worldwide Presence of Plavix<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 Alliance arrangements with Bristol-Myers Squibb above, with the exception of Plavix Japan which is outside the scope of the alliance.

The worldwide sales of these two products are an important indicator of the global market presence of these sanofi-aventis products, and we believe this information facilitates a financial statement user's understanding and analysis of our consolidated income statement, particularly in terms of understanding our overall profitability in relation to consolidated revenues, and also facilitates a user's ability to understand and assess the effectiveness of our research and development efforts.

Also, disclosing sales made by BMS of these two products enables the investor to have a clearer understanding of trends in different line items of our income statement, in particular the line items Other revenues where we book royalties received on those sales (see Other Revenues); Share of profit/loss of associates (see Share of Profit/Loss of Associates) where we record our share of profit/loss of entities included in the BMS Alliance and under BMS operational management; and Net income attributable to minority interests (see Net Income Attributable to Minority Interests) where we book the BMS share of profit/loss of entities included in the BMS Alliance and under our operational management.

The table below sets forth the worldwide sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup> in 2009 and 2008, by geographic region:

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

( million)	2009			2008			Change (%)
	sanofi-aventis <sup>(5)</sup>	BMS <sup>(3)</sup>	Total	sanofi-aventis <sup>(5)</sup>	BMS <sup>(3)</sup>	Total	
<b>Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup><sup>(4)</sup></b>							

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

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

(1) Plavix® is marketed under the trademarks Plavix® and Iscover®.

(2) Net sales of Plavix® consolidated by sanofi-aventis, excluding sales to BMS ( 311 million in 2009 and 282 million in 2008).

(3) Translated into euros by sanofi-aventis using the method described in Note B.2 Foreign currency translation to our consolidated financial statements included at Item 18 in this annual report.

(4) Aprovel® is marketed under the trademarks Aprovel®, Avapro® and Karvea®.

(5) Net sales of Aprovel® consolidated by sanofi-aventis, excluding sales to BMS ( 113 million in 2009 and 94 million in 2008).

**Table of Contents**

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

<i>( million)</i>	<b>2009</b>	<b>2008</b>	<b>Change at constant exchange rates (%)</b>
<b>Plavix®/Iscover®</b>			
Europe	1,604	1,833	-10.3%
United States	4,026	3,351	+12.8%
Other countries	1,152	959	+14.4%
<b>Total</b>	<b>6,782</b>	<b>6,143</b>	<b>+6.2%</b>
<b>Aproveil®/Avapro®/Karvea®</b>			
Europe	982	992	+0.8%
United States	524	499	-1.6%
Other countries	506	475	+7.2%
<b>Total</b>	<b>2,012</b>	<b>1,966</b>	<b>+1.7%</b>

In the United States, sales of Plavix®/Iscover® (consolidated by BMS) reported strong growth of 12.8% at constant exchange rates in 2009, reaching 4,026 million. In Europe, net sales of Plavix® were down 10.3% at constant exchange rates at 1,604 million due to the marketing of generics using alternative salts of clopidogrel, especially in the United Kingdom, Germany and France (where we launched our own generic version, Clopidogrel Winthrop®, in the fourth quarter of 2009). In Japan, Plavix® continued its success, with sales up 58.9% at constant exchange rates to 339 million.

In a competitive environment, 2009 worldwide sales of Aproveil®/Avapro®/Karvea® were 2,012 million, an increase of 1.7% at constant exchange rates. In Europe, the product is facing competition from generics in the monotherapy segment in Spain and Portugal, and recorded sales growth of 0.8% at constant exchange rates.

*Other Revenues*

Other revenues, which mainly comprise royalty income under licensing agreements contracted in connection with ongoing operations, amounted to 1,443 million in 2009 compared with 1,249 million in 2008.

Licensing revenues under the worldwide alliance with BMS on Plavix® and Aproveil® totaled 1,155 million in 2009, compared with 985 million in 2008 (up 17.3% on a reported basis), boosted by strong growth in sales of Plavix® in the United States and the favorable impact of trends in the exchange rate of the U.S. dollar against the euro.

*Gross Profit*

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

Gross profit for 2009 was 22,869 million (78.0% of net sales), versus 21,480 million in 2008 (77.9% of net sales).

The gross margin ratio for the Pharmaceuticals segment improved by 0.5 of a point, reflecting the rise in royalty income (impact: +0.6 of a point) and an unfavorable trend in the ratio of cost of sales to net sales (impact: -0.1 of a point). This trend was the net result of:

the favorable effect on net sales and other revenues of movements in the exchange rates of various currencies against the euro (mainly the rise in the U.S. dollar), which largely feeds through into gross profit because our cost of sales is largely incurred in the euro zone;

the favorable effect of the end of commercialization of Copaxone<sup>®</sup> by sanofi-aventis in North America, effective April 1, 2008;

a less favorable product mix due to the impact of acquisitions of companies that generate lower gross margins than we do (primarily on generics).

## **Table of Contents**

The gross margin ratio for the Vaccines segment was unchanged, with the effect of lower royalty income (impact: -0.5 of a point) offset by an improvement in the ratio of cost of sales to net sales (impact: +0.5 of a point) that was largely due to the appreciation of various currencies against the euro.

Consolidated gross profit was also impacted by the expense arising from the workdown during 2009 of inventories remeasured at fair value on completion of acquisitions (mainly Zentiva, impact 27 million or 0.1 of a point).

### *Research and Development Expenses*

Research and development expenses were 4,583 million (versus 4,575 million in 2008), representing 15.6% of net sales (versus 16.6% in 2008); they were down 1.4% year-on-year at constant exchange rates, but up 0.2% on a reported basis.

Cost savings were achieved in the Pharmaceuticals segment due to tight cost control and a reduction in clinical trial costs, reflecting the discontinuation of some projects following the portfolio review.

In the Vaccines segment, research and development expenses increased by 66 million, up 15.5%, in particular due to the consolidation of Acambis from October 1, 2008 and to clinical trials related to influenza vaccines in the light of the pandemic.

### *Selling and General Expenses*

Selling and general expenses totaled 7,325 million, compared with 7,168 million in the previous year, an increase of 2.2% (or 1.1% at constant exchange rates). The ratio of selling and general expenses to net sales improved from 26.0% in 2008 to 25.0%, mainly because of savings in marketing expenses (in particular, due to the transfer of commercialization of Copaxone® to Teva in North America in April 2008) and cost savings in Europe. The 2009 figure includes the expenses of companies consolidated for the first time during the year.

Selling and general expenses for the Vaccines segment rose by 7.9%. This increase was due primarily to the influenza pandemic, and to the consolidation of Acambis with effect from October 1, 2008.

### *Other Operating Income and Expenses*

Other operating income for 2009 came to 866 million (versus 556 million in 2008), and other operating expenses amounted to 481 million (versus 353 million in 2008).

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

The balance of other operating income and expenses represented net income of 385 million for 2009, compared with net income of 203 million for 2008. The 182 million increase was mainly due to the transfer of commercialization of Copaxone® to Teva in North America effective April 1, 2008. We are entitled to receive a 25% royalty of North American sales of Copaxone® over a two-year period from that date, and recognize this royalty income in Other operating income .

We also recognized gains on disposals relating to our ordinary operations of 56 million (compared with 24 million in 2008), and a net operating foreign exchange gain of 40 million (compared with a net foreign exchange loss of 94 million in 2008).

### *Amortization of Intangibles*

Amortization charged against intangible assets in 2009 amounted to 3,528 million, versus 3,483 million in the previous year. The increase was due mainly to trends in the exchange rate of the U.S. dollar against the euro and the acquisition of Zentiva.

These charges mainly relate to the amortization of intangible assets remeasured at fair value at the time of the Aventis acquisition ( 3,175 million in 2009, versus 3,298 million in 2008).

## **Table of Contents**

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

This line item came to 7,818 million in 2009, compared with 6,457 million in 2008.

### *Restructuring Costs*

Restructuring costs amounted to 1,080 million in 2009, compared with 585 million in 2008. In 2009, our restructuring costs related primarily to measures taken to improve innovation by transforming our Research & Development operations, and to streamline our organizational structures by adapting central support functions. These costs consist mainly of employee-related charges, arising from early retirement benefits and termination benefits under the announced voluntary redundancy plans. The 2009 charge also reflects, though to a lesser extent, ongoing measures to adapt our industrial facilities in Europe and to adjust our sales forces.

The restructuring costs recognized in 2008 related primarily to the adaptation of industrial facilities in France and to measures taken in response to the changing economic environment in various European countries, principally France and Spain.

### *Impairment of Property, Plant & Equipment and Intangibles*

Net impairment losses charged against property, plant and equipment and intangible assets amounted to 372 million in 2009, and related primarily to the impact of changes in the competitive environment and of generic approval dates on our products Benzaclin<sup>®</sup>, Nasacort<sup>®</sup> and Actonel<sup>®</sup>. This item also includes impairment losses of 28 million arising from the decision to discontinue the development of TroVa<sup>®</sup>, and from the withdrawal of our product Di-Antalvic<sup>®</sup> from the market in response to a decision by the European Medicines Agency (EMA). With the exception of Trovax<sup>®</sup>, all of these products were recognized as assets in 2004 upon the acquisition of Aventis.

In 2008, this line item showed impairment losses of 1,554 million charged against intangible assets due to the discontinuation of some research projects and to the genericization of some products marketed by the Group, originating mainly from Aventis. The main discontinued research projects were those relating to larotaxel and cabazitaxel (new taxane derivatives developed in breast cancer, 1,175 million) and the antihypertensive ilepatril ( 57 million), both of which were recognized as assets on the acquisition of Aventis; and the oral anti-cancer agent S-1, following termination of the agreement with Taiho Pharmaceutical for the development and commercialization of this product. In addition, an impairment loss of 114 million was charged in respect of Nasacort<sup>®</sup> (also recognized as an asset on the acquisition of Aventis in 2004) following the settlement agreement with Barr in the United States.

### *Gains and Losses on Disposals, and Litigation*

Sanofi-aventis did not make any major disposals in either 2009 or 2008.

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

In 2008, this item included 76 million of reversal of litigation provisions.

### *Operating Income*

Operating income for 2009 was 6,366 million, 44.9% higher than the 2008 figure of 4,394 million.

### *Financial Income and Expenses*

Net financial expense for 2009 was 300 million, compared to 232 million in 2008, an increase of 68 million.

Interest expense directly related to our net debt (short-term and long-term debt, net of cash and cash equivalents) amounted to 222 million, versus 183 million in 2008. Although the average level of net debt was lower in 2009 than in 2008, sanofi-aventis was adversely affected by lower interest rates on its cash deposits (which averaged 5.0 billion in 2009, compared with 2.4 billion in 2008).



## **Table of Contents**

In 2008, we tendered our shares in Millennium Pharmaceuticals, Inc (Millennium) to the public tender offer for Millennium by Takeda Pharmaceuticals Company Ltd. This transaction generated a 38 million gain.

Net financial foreign exchange losses for the year were 67 million, compared with 74 million in 2008.

### *Net Income before Tax and Associates*

Net income before tax and associates for 2009 was 6,066 million, 45.7% higher than the 2008 figure of 4,162 million.

### *Income Tax Expense*

The effective tax rate is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates, the share of profit/loss of Merial and net income attributable to minority interests.

The effective tax rate was 28.0% in 2009, compared to 29.0% in 2008, the reduction resulting directly from the entry into force in 2009 of a protocol to the tax treaty between France and the United States that abolished withholding tax between the two countries subject to certain conditions. During 2009, this protocol resulted in the reversal through the consolidated income statement of 106 million in deferred tax liabilities relating to the tax cost of distributions made out of the reserves of Group subsidiaries as of January 1, 2009.

The difference between the effective tax rate and the standard corporate income tax rate applicable in France for 2009 (34%) was mainly due to the impact of the reduced rate of income tax on royalties in France.

In 2008, this line item included a gain through the consolidated income statement of 221 million on reversals of tax provisions related to the settlement of tax audits.

### *Share of Profit/Loss of Associates*

Our share of the profits of associates was 814 million in 2009, versus 692 million in 2008. This item mainly comprises our share of after-tax profits from the territories managed by BMS under the Plavix® and Avapro® alliance, which increased by 26.0% year-on-year from 623 million in 2008 to 785 million in 2009. This increase was a direct result of the growth in sales of Plavix® in the United States (up 12.8% at constant exchange rates) and of the appreciation of the U.S. dollar against the euro (up 7.0%).

### *Net Income from the Held-for-Exchange Merial Business*

With effect from September 18, 2009, the date on which sanofi-aventis obtained exclusive control over Merial, the operations of this company have been accounted for using the full consolidation method. As of December 31, 2009, the results of Merial's operations are reported in the line item "Net income from the held-for-exchange Merial business", in accordance with IFRS 5 (refer to Note D.8. "Assets held for sale or exchange" to our consolidated financial statements). The net income of the Merial business for the year ended December 31, 2009 was 175 million, compared with 120 million in the previous year.

This growth was attributable to a strong operating performance by Merial and to the appreciation of the U.S. dollar against the euro. The figures cited above include 100% of the net income of Merial with effect from September 18, 2009, compared with 50% prior to that date. The 2009 figure also includes a net expense of 46 million relating to the workdown of inventories remeasured at fair value, as part of the provisional purchase price allocation on the acquisition of the 50% interest in Merial acquired in 2009.

*Net Income*

Net income (before minority interests) totaled 5,691 million in 2009, compared with 4,292 million in 2008.

**Table of Contents***Net Income Attributable to Minority Interests*

Net income attributable to minority interests for the year ended December 31, 2009 was 426 million, against 441 million for the previous year. This item includes the share of pre-tax income paid over to BMS from territories managed by sanofi-aventis (405 million in 2009, versus 422 million in 2008).

*Net Income Attributable to Equity Holders of the Company*

Net income attributable to equity holders of the Company amounted to 5,265 million in 2009, versus 3,851 million in 2008. Earnings per share (EPS) for 2009 were 4.03, up 37.1% on the 2008 earnings per share figure of 2.94, based on an average number of shares outstanding of 1,305.9 million in 2009 and 1,309.3 million in 2008.

On a diluted basis, earnings per share for 2009 were 4.03, up 37.1% on the 2008 earnings per share figure of 2.94, based on an average number of shares after dilution of 1,307.4 million in 2009 and 1,310.9 million in 2008.

*Business Operating Income*

Business operating income for 2009 was 12,028 million, compared to 10,391 million in 2008. The table below shows trends in business operating income by business segment for 2009 and 2008:

<i>( million)</i>	<b>2009</b>	<b>2008</b>
Pharmaceuticals	10,608	9,399
Vaccines	1,173	882
Other	247	110
<b>Business operating income</b>	<b>12,028</b>	<b>10,391</b>

*Business Net Income*

Business net income is a non-GAAP financial measure that we use to evaluate our Group's performance (see Item 5. Operating and Financial Review and Prospects Business Net Income above).

Business net income for 2009 was 8,629 million, versus 7,314 million in 2008, representing growth of 18.0%.



**Table of Contents**

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

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

(2) Other items comprise:

- gain on sale of Millennium shares	38
- reversal of provisions for major litigation	76

(3) Other tax items include:

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

(4) This line item comprises: until September 17, 2009, amortization and impairment charged against the intangible assets of Merial; and from September 18, 2009 (i) the impact of the discontinuation of depreciation of the property, plant and equipment of Merial in accordance with IFRS 5 (see Note B.7. to our consolidated financial statements) and (ii) the expense arising from the workdown of inventories remeasured at fair value at acquisition date.

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

Business net income for 2009 was 8,629 million, an increase of 18.0% on the 2008 figure of 7,314 million, and represented 29.4% of net sales compared with 26.5% in 2008. The increase was mainly due to our good operating performance, reflected in the increase in gross profit ( 22,869 million in 2009 versus 21,480 million in 2008).

*Business Earnings Per Share*

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding (see Business Net Income above).

Business earnings per share for 2009 were 6.61, up 18.2% on the 2008 business earnings per share figure of 5.59. The weighted average number of shares outstanding was 1,305.9 million in 2009 and 1,309.3 million in 2008. Diluted business earnings per share for 2009 were 6.60, up 18.3% on the 2008 diluted business earnings per share figure of 5.58. On a diluted basis, the weighted average number of shares outstanding was 1,307.4 million in 2009 and 1,310.9 million in 2008.

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

Business earnings per share for 2008 were up 6.7% on the 2007 business earnings per share figure of \$5.24, 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 1,346.9 million in 2007. Diluted business earnings per share for 2008 were up 7.1% on the 2007 diluted business earnings per share figure of \$5.21. On a diluted basis, the weighted average number of shares outstanding was 1,353.9 million in 2007.

**Table of Contents****Year Ended December 31, 2008 Compared with Year Ended December 31, 2007**

In the discussion that follows, we present our sales on a reported basis and on a comparable basis, isolating the impacts of changes in structure and changes in exchange rates. The method we use to do this is different from the method we use in comparing our results of operations for the years ended December 31, 2009 and 2008. See Presentation of Net Sales above for further details.

In addition, we did not classify any our products as flagship products until 2009, and as a result our management did not analyze the performance of those products as a group in 2008 compared to 2007 (although each of those products is analyzed individually below, with the exception of Multaq®, which was introduced on the market in 2009).

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		522	
Other operating expenses	(353)		(307)	
Amortization of intangibles	(3,483)		(3,654)	
<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)		(137)	
Impairment of property, plant & equipment and intangibles	(1,554)		(58)	
Gains and losses on disposals, and litigation	76			
<b>Operating income</b>	<b>4,394</b>	<b>15.9%</b>	<b>5,911</b>	<b>21.1%</b>
Financial expenses	(335)		(329)	
Financial income	103		190	
<b>Income before tax and associates</b>	<b>4,162</b>	<b>15.1%</b>	<b>5,772</b>	<b>20.6%</b>
Income tax expense	(682)		(687)	
Share of profit/loss of associates	692		446	
<b>Net income excluding the held-for-exchange Merial business <sup>(1)</sup></b>	<b>4,172</b>	<b>15.1%</b>	<b>5,531</b>	<b>19.7%</b>
Net income from the held-for-exchange Merial business <sup>(1)</sup>	120		151	
<b>Net income</b>	<b>4,292</b>	<b>15.6%</b>	<b>5,682</b>	<b>20.3%</b>
- attributable to minority interests	441		419	
<b>- attributable to equity holders of the Company</b>	<b>3,851</b>	<b>14.0%</b>	<b>5,263</b>	<b>18.8%</b>
Average number of shares outstanding (million)	1,309.3		1,346.9	
Basic earnings per share (in euros)	2.94		3.91	

<sup>(1)</sup> Reported separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations). For the other disclosures required under IFRS 5, refer to Note D.8. to our consolidated financial statements included at Item 18 of this annual report.

*Net Sales*

Net sales for the year ended December 31, 2008 were 27,568 million, up by 3.7% on a comparable basis versus 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.



**Table of Contents**

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

( million)	<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>

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 change (%)	Comparable basis change (%)
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 versus 66.0% 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) decreased growth by approximately 2.2 points (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.



**Table of Contents**

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

( million)

Product	Indication	2008	2007 Reported	2007 Comparable	Reported basis change (%)	Comparable basis change (%)
Lovenox®	Thrombosis	2,738	2,612	2,475	+4.8%	+10.6%
Plavix®	Atherothrombosis	2,616	2,424	2,368	+7.9%	+10.5%
Lantus®	Diabetes	2,450	2,031	1,918	+20.6%	+27.7%
Taxotere®	Breast, Non small cell lung, Prostate, Gastric, Head and neck cancers	2,033	1,874	1,796	+8.5%	+13.2%
Eloxatine®	Colorectal cancer	1,348	1,521	1,430	-11.4%	-5.7%
Aprovel®/CoAprovel®	Hypertension	1,202	1,080	1,053	+11.3%	+14.2%
Stilnox®/Ambien®/Myslee®	Sleep disorders	829	1,250	1,258	-33.7%	-34.1%
Allegra®	Allergic rhinitis, Urticaria	688	706	674	-2.5%	+2.1%
Copaxone®	Multiple sclerosis	622	1,177	520	-47.2%	+19.6%
Tritace®	Hypertension, Congestive heart failure, Nephropathy	513	741	734	-30.8%	-30.1%
Amaryl®	Diabetes	387	392	392	-1.3%	-1.3%
Xatral®	Benign prostatic hypertrophy	331	333	320	-0.6%	+3.4%
Actonel®	Osteoporosis, Paget's disease	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>

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

( million)

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

*Top 15 Products* <sup>(1)</sup>

Over 2008 as a whole, net sales of **Lovenox**<sup>®</sup>, the leader in anti-thrombotics in the U.S., Germany, France, Italy, Spain, and the United Kingdom (source: IMS 2009 sales), 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

(1) Sales of Plavix<sup>®</sup> and Aprove1<sup>®</sup> are discussed below under Worldwide Presence of Plavix<sup>®</sup> and Aprove1<sup>®</sup> below.

## Table of Contents

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 (source: IMS 2009 sales), 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.

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.

In the United States, net sales of **Eloxatine<sup>®</sup>** 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.

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 of 2008, 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<sup>®</sup> in Japan in December 2008.

**Table of Contents**

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	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.

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*

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

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® (especially in France) pared around 1.3 points off 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



**Table of Contents**

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 versus 66 million in 2007) and Mysoline® net sales reached 142 million in 2008, up 14.9% on a comparable basis).

*Worldwide Presence of Plavix® and Aprovel®*

Two of our leading products Plavix® and Aprovel® were discovered by sanofi-aventis and jointly developed with Bristol-Myers Squibb ( BMS ) under an alliance agreement. Worldwide, these products are sold by sanofi-aventis and/or BMS under the terms of this agreement which is described in Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb above, with the exception of Plavix Japan which is outside the scope of the alliance.

The worldwide sales of these two products are an important indicator of the global market presence of sanofi-aventis products, and we believe this information facilitates a financial statement user's understanding and analysis of our consolidated income statement, particularly in terms of understanding our overall profitability in relation to consolidated revenues, and also facilitates a user's ability to understand and assess the effectiveness of our research and development efforts.

Also, disclosing sales made by BMS of these two products enables the investor to have a clearer understanding of trends in different line items of our income statement, in particular the line items 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.

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>							

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

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).

**Table of Contents**

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

( million)	2008	2007	2007 Comparable	Comparable basis growth (%)
<b>Plavix<sup>®</sup>/Iscover<sup>®</sup></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<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup></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>

Full-year 2008 sales of **Plavix<sup>®</sup>** (clopidogrel bisulfate) in the United States (consolidated by BMS) were significantly 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.

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 (versus 66 million in 2007).

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

*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 BMS on Plavix<sup>®</sup> and Aprovel<sup>®</sup> 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<sup>®</sup> (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 million 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 in addition to, from April 1, 2008, the discontinuation by sanofi-aventis of commercialization of Copaxone<sup>®</sup> 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<sup>®</sup> IR in the United States as from April 1, 2007 and the weakening of the U.S. dollar against the euro.

## **Table of Contents**

### *Research and Development Expenses*

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

### *Other Operating Income and Expenses*

In 2008, we recorded other operating income of 556 million (as compared to 522 million in 2007) 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<sup>®</sup> 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 line item came to 6,457 million in 2008, compared with 6,106 million in 2007.

*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 and Portugal) and in the United States. In 2007, restructuring costs related to the ongoing adaptation plan in France and in Germany.

## **Table of Contents**

### *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 following 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) was impaired following the agreement 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 item comprised 76 million of reversals of provisions for litigation.

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

### *Operating Income*

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

### *Financial Income and Expenses*

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

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

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

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

*Income before Tax and Associates*

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

*Income Tax Expense*

The reported tax rate for 2008 was 16.4%, compared with 11.9% for 2007.

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



**Table of Contents**

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 692 million in 2008, compared with 446 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 ( 623 million in 2008, compared to 526 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.

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

*Net income from the Held-for-Exchange Merial Business*

Net income from the held-for-exchange Merial business totaled 120 million in 2008, compared with 151 million in 2007. It was penalized by the unfavorable trends in the euro/U.S. dollar exchange rate.

*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*

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

Net income attributable to equity holders of the Company for 2008 was 3,851 million, against 5,263 million for 2007. Earnings per share (EPS) were 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).

### *Business Operating Income*

Business operating income was 10,391 million in 2008, against 10,162 million in 2007.

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

<i>( million)</i>	<b>2008</b>	<b>2007</b>
Pharmaceuticals	9,399	9,084
Vaccines	882	869
Other	110	209
<b>Business operating income</b>	<b>10,391</b>	<b>10,162</b>

### **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 2009, part of the cost of our acquisitions was also funded

**Table of Contents**

by taking on debt. As of December 31, 2009, our debt, net of cash and cash equivalents, stood at 4,135 million (8.5% of our net equity) versus 1,780 million as of December 31, 2008 (3.9% of our net equity). See Note D.17. Debt, cash and cash equivalents to our consolidated financial statements included at Item 18 of this annual report.

***Consolidated Statement of Cash Flows***

The table below shows our summarized cash flows for the years ended December 31, 2009, 2008 and 2007:

<i>( million)</i>	<b>2009</b>	<b>2008</b>	<b>2007</b>
Net cash provided by / (used in) operating activities	8,515	8,523	7,106
Net cash provided by / (used in) investing activities	(7,287)	(2,154)	(1,716)
Net cash provided by / (used in) financing activities	(787)	(3,809)	(4,820)
Impact of exchange rates on cash and cash equivalents	25	(45)	(12)
<b>Net change in cash and cash equivalents (decrease) / increase</b>	<b>466</b>	<b>2,515</b>	<b>558</b>

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. Receipts of royalty payments also contribute to cash from operations.

**Net cash provided by operating activities** totaled 8,515 million in 2009, compared with 8,523 million in 2008. Operating cash flow before changes in working capital was 9,362 million (versus 8,524 million in 2008), reflecting our good operating performance.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect Operating income before restructuring, impairment of property, plant & equipment and intangibles, gains and losses on disposals, and litigation, which is discussed in detail above under Results of Operations Year Ended December 31, 2009 Compared with Year Ended December 31, 2008 and Results of Operations Year Ended December 31, 2008 Compared with Year Ended December 31, 2007. The principal difference is that operating cash flow before changes in working capital reflects our share of the profits and losses of associates, net of dividend and similar income received.

Our working capital requirements increased by 847 million in 2009, having been stable in 2008. This increase was due to the growth in our operations during 2009, reflected in higher levels of inventories (up 489 million) and trade receivables (up 429 million).

**Net cash used in investing activities** was 7,287 million in 2009, versus 2,154 million in 2008.

Acquisitions of property, plant and equipment and intangible assets totaled 1,785 million (compared with 1,606 million in 2008), and mainly comprised investments in industrial facilities and research sites, plus contractual payments for intangible rights (325 million in 2009, mainly related to licensing agreements).

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

Financial investments, net of cash acquired, totaled 5,568 million. These investments, valued at a total of 6,334 million inclusive of assumed debt, mainly comprised acquisitions of shares in Merial ( 2,829 million), Zentiva ( 1,752 million), Shantha ( 528 million), Medley ( 451 million) and BiPar ( 253 million). In 2008, financial investments net of cash acquired totaled 667 million, mainly comprising the acquisitions of the entire share capital of the U.K. company Acambis Plc ( 332 million) and of the Australian company Symbion CP Holdings Pty Ltd, now sanofi-aventis Healthcare Holdings Pty Limited ( 329 million).

After-tax proceeds from disposals ( 85 million) related mainly to disposals of intangible assets, some of which were required as conditions for clearance of our acquisition of Zentiva. In 2008, after-tax proceeds from disposals were 123 million, mostly arising from the May 2008 disposal of our shares in Millennium.

**Table of Contents**

**Net cash used in financing activities** amounted to 787 million, against 3,809 million in 2008. The 2009 figure includes a dividend payout of 2,872 million (versus 2,702 million in 2008), and additional external financing (net increase in short-term and long-term debt) of 1,923 million (versus 69 million in 2008). During 2009, we placed five bond issues for a total amount of 4.7 billion (refer to Note D.17. Debt, cash and cash equivalents to our consolidated financial statements). In 2008, we acquired 23.9 million of our own shares at a cost of 1,227 million under our share repurchase programs.

After the impact of exchange rates, the net change in cash and equivalents during 2009 was an increase of 466 million, compared with an increase of 2,515 million in 2008.

**Consolidated Balance Sheet and Debt**

Total assets stood at 80,049 million as of December 31, 2009, compared with 71,987 million as of December 31, 2008, an increase of 8,062 million.

Our **debt, net of cash and cash equivalents** as of December 31, 2009 was 4.1 billion, compared with 1.8 billion as of December 31, 2008. We define debt, net of cash and cash equivalents as short-term debt plus long-term debt, minus cash and cash equivalents.

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

( million)	2009	2008	2007
Debt	8,827	6,006	5,941
Cash and cash equivalents	(4,692)	(4,226)	(1,711)
<b>Debt, net of cash and cash equivalents</b>	<b>4,135</b>	<b>1,780</b>	<b>4,230</b>

The gearing ratio (debt, net of cash and cash equivalents, to total equity) rose from 3.9% at the end of 2008 to 8.5% at the end of 2009 (see Liquidity and Capital Resources above). For an analysis of our debt at December 31, 2009 and 2008 by type, maturity, interest rate and currency, see Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

The financing in place at December 31, 2009 at the level of the sanofi-aventis holding company 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.

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

**Total equity** stood at 48,446 million as of December 31, 2009, against 45,071 million a year earlier. The principal factors underlying this net increase in equity were:

reductions: the dividend of 2,872 million distributed to our shareholders out of our 2008 earnings, and the net movement in the cumulative translation adjustment arising from the appreciation of the euro against various currencies ( 295 million, relating primarily to the U.S. dollar); and

increases: net income attributable to equity holders of the Company for the year ended December 31, 2009 ( 5,265 million); the remeasurement of our existing equity interests in Zentiva ( 80 million) and in Merial ( 922 million), net of taxes; and changes in our share capital relating to share-based payment plans (exercise of stock options, and proceeds from the sale of treasury shares on exercise of stock options: total impact 166 million).

At December 31, 2009, we held 9.4 million of our shares as treasury shares representing 0.71% of our share capital and recorded as a deduction from shareholders' equity.

**Goodwill and intangible assets** represented a combined total of 43,480 million as of December 31, 2009, 57 million higher than at the previous year-end. The main underlying factors were:

increases: the impact of the acquisitions made in 2009 ( 1,882 million of goodwill and 2,206 million of intangible assets); and

reductions: amortization and impairment losses charged during the period ( 3,950 million).

---

## **Table of Contents**

**Provisions and other non-current liabilities** ( 8,311 million as of December 31, 2009) increased by 581 million year-on-year, due mainly to a 274 million net rise in provisions for pensions and other long-term employee benefits and a 239 million net increase in tax exposures. The impact of the first-time consolidation of companies acquired during 2009 (principally Zentiva and Medley) on the total net increase amounted to 250 million. Refer to Note D.18. to our consolidated financial statements for further information.

**Net deferred tax liabilities** ( 2,021 million as of December 31, 2009) were 727 million lower than at the previous year-end, largely as a result of the reversal of deferred tax liabilities relating to the remeasurement of acquired intangible assets ( 661 million). An additional factor was a 126 million reduction in deferred tax liabilities relating to the tax cost of distributions made from reserves, mainly as a direct result of the entry into force of a protocol to the tax treaty between France and the United States that abolished withholding tax between the two countries subject to certain conditions.

**Other current liabilities** ( 5,445 million) increased by 724 million, mainly as a result of the change in restructuring provisions (net increase of 449 million). For further details, see Note D.19. to our consolidated financial statements included at Item 18 of this annual report.

**Net assets held for sale or exchange** ( 4,909 million) mainly comprise the net assets of Merial, whose operations have been accounted for by the full consolidation method with effect from September 18, 2009 and presented in accordance with IFRS 5 (refer to Note D.8. Assets held for sale or exchange to our consolidated financial statements).

### ***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 2009, we held cash and cash equivalents amounting to 4,692 million, substantially all of which was held in euros (see Note D.13. to our consolidated financial statements). As at December 31, 2009, 430 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 2009, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position. Undrawn confirmed credit facilities amounted to a total of 12.3 billion at December 31, 2009. 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. Our contractual obligations and our other commercial commitments as of December 31, 2009 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 research and development collaboration agreements as well as the financial commitments related to BiPar, Fovea, Chattem and Merial. Note D.21. to our consolidated financial statements describes our principal contractual commitments in respect of divestments.

**Table of Contents**

The Group's contractual obligations and other commercial commitments (excluding those of Merial, see Note D.8.1. to our consolidated financial statements) are set forth in the table below:

<i>December 31, 2009</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	8,681	2,737	576	2,761	2,607
interest	1,437	312	452	337	336
net cash flows related to derivative instruments	(14)	51	(1)	(22)	(42)
Operating lease obligations	1,197	278	350	201	368
Irrevocable purchase commitments <sup>(2)</sup> :					
given	2,628	1,484	550	197	397
received	(297)	(203)	(33)	(13)	(48)
Commercial commitments	5,781	235	546	542	4,458
Commitments relating to business combinations	439	76	268	95	
Commitment related to Chattem offer	1,319	1,319			
Commitment related to the combination of Intervet/Schering Plough Animal Health and Merial <sup>(3)</sup>	694	694			
<b>Total contractual obligations and other commitments</b>	<b>21,865</b>	<b>6,983</b>	<b>2,708</b>	<b>4,098</b>	<b>8,076</b>
<b>Undrawn credit facilities<sup>(4)</sup></b>	<b>12,290</b>	<b>590</b>	<b>11,700</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.

(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) Estimated cash outflows related to the call option agreement described in Note D.1.

(4) For details of confirmed credit facilities, see Note D.17.c).

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.



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

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.

In December 2009, sanofi-aventis and the American biotechnology company Alopexx Pharmaceuticals LLC (Alopexx) signed a collaboration agreement and option for a license on a first-in-class human monoclonal antibody for the prevention and treatment of infections originating in the bacterium that causes plague and other serious infections. This new antibody is currently in preclinical development. We will finance part of the Phase I clinical trials and we have made an upfront payment to Alopexx. In addition, we will make milestone payments which could reach \$210 million, plus royalties on sales of commercialized products and additional milestone payments linked to sales performance.

---

**Table of Contents**

In October 2009, sanofi-aventis and Micromet signed a global collaboration and license agreement to develop a BiTE<sup>®</sup> antibody against an antigen present at the surface of carcinoma cells. BiTE<sup>®</sup> antibodies are novel therapeutic antibodies that activate patients' T cells to seek out and destroy cancer cells. Micromet will receive milestone payments of up to 162 million and royalties on worldwide product sales. Micromet will also receive additional milestone payments linked to sales milestones.

In October 2009, sanofi-aventis and Wellstat Therapeutics Corporation (Wellstat) signed a worldwide license agreement for PN2034, a novel first-in-class oral insulin sensitizer for the treatment of Type II Diabetes. As a sensitizer, PN2034 is expected to normalize and therefore enhance insulin action in the livers of diabetic patients. The compound is currently in Phase II clinical testing. Total milestone payments could reach \$310 million. Wellstat will also receive royalties on worldwide product sales, and additional milestones linked to sales performance.

At the end of September 2009, sanofi-aventis and Merrimack Pharmaceuticals Inc. (Merrimack) signed an exclusive worldwide collaboration and licensing agreement for the MM-121 molecule for the management of solid malignancies. MM-121 is a first-in-class fully human monoclonal antibody designed to block signaling of the ErbB3 (also known as HER3) receptor. MM-121 is presently in Phase I of clinical development. Merrimack will receive milestone payments that could reach \$410 million, plus royalties on worldwide product sales and additional milestone payments based on worldwide product sales. Merrimack will participate in the clinical development of MM-121.

In May 2009, sanofi-aventis signed a global license agreement in oncology with the biotechnology company Exelixis, Inc. (Exelixis) for the XL147 and XL765 molecules, and an exclusive collaboration agreement for the discovery of inhibitors of phosphoinositide-3 kinase (PI3K) for the management of malignant tumors. We have made an upfront cash payment to Exelixis, and could make milestone payments that could reach over \$1 billion in aggregate. In addition, Exelixis will be entitled to receive royalties on sales of commercialized products, and milestone payments linked to the sales performance of those products.

In May 2009, sanofi-aventis and Kyowa Hakko Kirin Co., Ltd (Kyowa Hakko Kirin) signed a collaboration and licensing agreement under which we obtained the worldwide rights to the anti-LIGHT fully human monoclonal antibody. This anti-LIGHT antibody is presently at preclinical development stage. It is expected to be first-in-class in the treatment of ulcerative colitis and Crohn's disease. Kyowa Hakko Kirin will receive milestone payments which could reach \$305 million. Kyowa Hakko Kirin will also be entitled to receive royalties and milestone payments linked to sales performance.

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 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. Dyax will also receive royalties on sales of antibody candidates.

In November 2007, sanofi-aventis signed a further collaboration agreement with Regeneron to discover, develop and commercialize fully-human therapeutic antibodies. This agreement was broadened and extended on November 10, 2009. From 2010 until 2017, we will increase our yearly financial commitment to Regeneron's antibody research program to \$160 million.

In September 2003, sanofi-aventis signed a collaboration agreement with Regeneron in oncology to develop the Vascular Endothelial Growth Factor (VEGF) Trap program. Under the terms of the agreement, development milestone payments and royalties on VEGF Trap sales are payable to Regeneron. Total milestone payments could reach \$350 million.

Sanofi-aventis has signed other collaboration agreements with laboratories or universities, under which total contingent payments over the next five years could reach around 129 million.

The main collaborative agreements in the Vaccines segment are described below:

Sanofi Pasteur has entered into a number of collaboration agreements with partners including Crucell, Intercell, Vactech, Maxigen, SSI and Syntiron, under which sanofi pasteur may be required to make total contingent payments of around 99 million over the next five years.

**Table of Contents**

In June 2009, we announced our intention to donate to the World Health Organization (WHO) 10% of our output of A(H1N1) influenza vaccine up to a maximum of 100 million doses to help developing countries deal with the influenza pandemic. This donation was a response to the 2009 influenza pandemic caused by the emergence of the new A(H1N1) influenza strain, and replaces a previous commitment made in 2008 in the context of the H5N1 pandemic threat. However, the 100 million dose donation will be based on A(H1N1) or H5N1 strains, or any other strain that could potentially create an influenza pandemic.

**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 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 .

**Goodwill impairment and intangible assets.** 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. Key assumptions related to goodwill impairment and intangible assets are the perpetual growth rate and the after tax discount rate. Any changes in key assumptions could result in an impairment charge. A



**Table of Contents**

sensitivity analysis to the key assumptions is performed and disclosed 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.

**Pensions and post-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. Pensions and post-retirement benefits key assumptions are the discount rate and the expected long term rate of return on plan assets.

Depending on the discount rate used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on equity because in applying IAS 19 (Employee Benefits), the Company has elected to recognize all actuarial gains and losses (including the impact of a change in discount rate) immediately through equity (SoRIE option). A sensitivity analysis to discount rate is performed in Note D.18.1. Provisions for pensions and other benefits to our consolidated financial statements included at Item 18 of this annual report.

Depending on the expected long term rate of return on plan assets used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings. A sensitivity analysis to expected long term rate of return is performed in Note D.18.1. Provisions for pensions and other benefits to our consolidated financial statements included at Item 18 of this annual report.

**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 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 temporary differences are expected to reverse. We do not recognize 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**

Jean-François Dehecq, the current Chairman of the Board of Directors, will reach the statutory age limit for the office of Chairman at the General Meeting of Shareholders scheduled to take place on May 17, 2010. On December 16, 2009, the Board of Directors stated its intention to name Serge Weinberg to succeed Jean-François Dehecq as non-executive Chairman of the sanofi-aventis Board of Directors. Such an appointment would maintain the Board of Directors' decision to separate the offices of Chairman and Chief Executive Officer that has been in place at sanofi-aventis since January 1, 2007.

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.

Because 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***

The Board of Directors Meeting of July 28, 2009 set limits on the powers of the Chief Executive Officer. The prior authorization of the Board of Directors is required for undertakings in the field of investments, acquisitions and divestments in the following cases:

- a 500 million cap for each undertaking pertaining to a previously approved strategy; and
- a 150 million cap for each undertaking pertaining to a non-previously approved strategy.

When the consideration payable to the contracting parties for such undertakings include potential installment payments which are subject to the achievement of results or objectives, such as the registration of one or several products, the caps are calculated by adding the various payments due from the signature of the contract until (and including) the filing of the first application to obtain a marketing authorization in the United States or in Europe.

***Board of Directors***

Sanofi-aventis is administered by a Board of Directors with sixteen members.

Since May 14, 2008, the terms of office of these directors have been staggered, such that in each year from 2010 to 2012 one-third of the Board will be required to seek re-election each year.

During its meeting on March 1, 2010, the Board discussed the issue of director independence. Out of the sixteen directors, seven were regarded as independent: Uwe Bicker, Jean-Marc Bruel, Lord Douro, Jean-René Fourtou, Claudie Haigneré, Klaus Pohle and Gérard Van Kemmel.

In 2009, half of the members of the Board of Directors were independent Directors until the resignation on November 24, 2009 of Gunter Thielen, an independent Director. Since his replacement by Serge Weinberg, the Board of Directors has had 7 independent Directors out of 16. This is a temporary situation, and the proportion of independent Directors will be revised in 2010 so that at least half of the Directors are independent.

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.



**Table of Contents**

No more than one-third of the serving members of our Board of Directors may be over 70 years of age.

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 as of December 31, 2009**

<b>Jean-François Dehecq</b>	Age	70
Chairman of the Board of Directors	Nationality	French
Director	First elected	May 1999
	Last reappointment	May 2008
	Term as director expires	2011
396,017 shares		

**Other directorships and appointments**

Chairman of Policy Committee of the French Strategic Investment Fund

Chairman of National Committee of Etats Généraux de l'Industrie since November 2009

Chairman of the Appointments and Governance Committee and the Strategy Committee of sanofi-aventis

Director of Air France and Veolia Environnement

Chairman of Association Nationale de la Recherche Technique

Chairman of the Board of Directors of ENSAM (Ecole Nationale Supérieure d'Arts et Métiers)

**Education and professional activities**

Degree from the *Ecole Nationale des Arts et Métiers*

1964-1965 Mathematics teacher

1965-1973 Various positions at Société Nationale des Pétroles d'Aquitaine (SNPA)

1973-2006 sanofi-aventis

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

Chief Executive Officer (1975), Chairman and Chief Executive Officer (1988-2006)

<b>Christopher Viehbacher</b>	Age	49
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		

### Other directorships and appointments

Chairman of the Executive Committee and the Management Committee of sanofi-aventis

Member of the Strategy Committee of sanofi-aventis

Director of Sanofi Pasteur Merieux since August 31, 2009

Member of the Board of Directors of Health Leadership Council (United States), PhRMA (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)

### Education and professional activities

Graduate in Commerce of the Queens University (Ontario-Canada); certified public accountant

Began his career at Price Waterhouse

1998-2008                      Various positions at the GSK group, including President Pharmaceutical Operations for North America

**Table of Contents**

<b>Uwe Bicker</b>	Age	<i>64</i>
Independent Director	Nationality	<i>German</i>
	First elected	<i>May 2008</i>
	Term expires	<i>2012</i>

300 shares

**Other directorships and appointments**

Member of the Strategy Committee of sanofi-aventis

Chairman of the Supervisory Board of Siemens Healthcare Diagnostics 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)

**Education and professional activities**

Doctorate in chemistry and in medicine

Honorary Doctorate, Klausenburg University

Honorary Senator, Heidelberg University

1975-1994            Various positions at Boehringer Mannheim GmbH (later Roche AG)

1994-2004           Various positions at Hoechst group

Since 1983           Professor at the Medical Faculty of Heidelberg

<b>Jean-Marc Bruel</b>	Age	<i>74</i>
Independent Director	Nationality	<i>French</i>
	First elected	<i>August 2004</i>
	Last reappointment	<i>May 2008</i>

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

Term expires *2010*

8,201 shares

### Other directorships and appointments

Director of Institut Curie and Villette Entreprise

Member of the Audit Committee of sanofi-aventis

### Education and professional activities

Degree from the *Ecole Centrale des Arts et Manufactures de Paris*

1964-1999 Various positions at the Rhône-Poulenc group, including Chief Executive Officer

1999-2004 Member of the Supervisory Board and of the Appointment and Compensation Committee of Aventis

### **Robert Castaigne**

Age *63*

Director

Nationality *French*

First elected *February 2000*

Last reappointment *May 2008*

Term expires *2010*

500 shares

### Other directorships and appointments

Director of Vinci, Société Générale since January 20, 2009, and Compagnie Nationale à Portefeuille (Belgium)

Member of the Audit Committee of sanofi-aventis, Société Générale and Compagnie Nationale à Portefeuille (Belgium)

Member of the Audit Committee and the Compensation Committee of Vinci

**Table of Contents**

Education and professional activities

Degree from the *Ecole Centrale de Lille* and the *Ecole Nationale Supérieure du Pétrole et des Moteurs*

Doctorate in economic sciences

1972-2008      Various positions at the Total Group, including Chief Financial Officer and member of the Executive Committee (June 1994 - May 2008)

<b>Patrick de La Chevardière</b>	Age	53
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.

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), and Total Capital since February 11, 2009

Education and professional activities

Degree from the *Ecole Centrale de Paris*

Studies at the *Ecole des Hautes Etudes Commerciales (HEC)*

Since 1982      Various positions at the Total group including Deputy Chief Financial Officer (September 2003) and then Chief Financial Officer (since June 2008)

<b>Thierry Desmarest</b>	Age	64
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 of Total S.A.

Director of L Air Liquide, Renault SA, Renault SAS, and Bombardier Inc. (Toronto Canada) since January 21, 2009

Member of the Supervisory Board of Areva

Chairman of the Appointments and Governance Committee of Total S.A.

Chairman of Fondation Total and l Ecole Polytechnique (Foundations)

Member of the Appointments Committee and the Compensation Committee of L Air Liquide

Member of the Compensation Committee of Renault SA

Member of the Board of Directors of AFEP and l Ecole Polytechnique

Member of the Compensation Committee, the Appointments and Governance Committee and the Strategy Committee of sanofi-aventis

Director of Musée du Louvre

Education and professional activities

Degree from the *Ecole Polytechnique* and the *Ecole Nationale Supérieure des Mines de Paris*

Since 1981                      Various positions at the Total group, including Chairman and Chief Executive Officer (1995- 2007) and Chairman of the Board of Directors of Total S.A. since February 14, 2007

**Table of Contents**

<b>Lord Douro</b>	Age	64
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), Abengoa Bioenergy (Spain) and GAM Worldwide (United Kingdom)

Advisor of Calyon (United Kingdom)

Member of the Appointments and Governance Committee of sanofi-aventis

Member of the Compensation Committee and the Appointments Committee of Pernod Ricard

Member of the Appointments Committee of Compagnie Financière Richemont AG (Switzerland)

**Education and professional activities**

Degree from Oxford University

1979-1989          Member of the European Parliament

1995-2000          Chairman of Sun Life & Provincial Holdings Plc

<b>Jean-René Fourtou</b>	Age	70
Independent Director	Nationality	<i>French</i>
	First elected	<i>August 2004</i>
	Last reappointment	<i>May 2008</i>
	Term expires	<i>2012</i>
4,457 shares		

**Other directorships and appointments**

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

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)

Member of the Compensation Committee, the Appointments and Governance Committee and the Strategy Committee of sanofi-aventis

### Education and professional activities

Degree from the *Ecole Polytechnique*

1963-1986	Various positions at the Bossard group, including Chairman and Chief Executive Officer (1977-1986)
1986-1999	Chairman and Chief Executive Officer of Rhône-Poulenc
1999-2004	Vice Chairman of the Management Board, Vice Chairman of the Supervisory Board and member of the Strategy Committee of Aventis
2002-2005	Chairman and Chief Executive Officer of Vivendi

<b>Claudie Haigneré</b>	Age	52
Independent Director	Nationality	<i>French</i>
	First elected	<i>May 2008</i>
	Term expires	<i>2012</i>
500 shares		

### Other directorships and appointments

Chairman of Universcience (Cité des Sciences and Palais de la Découverte) since February 16, 2010

Vice President of the IAA (International Academy of Astronautics)



**Table of Contents**

Director of France Telecom, 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

Member of the Appointments and Governance Committee of sanofi-aventis

Member of the Strategy Committee of France Telecom

**Education and professional activities**

Rheumatologist, doctorate in sciences majoring in neurosciences

Selected in 1985 by CNES (French National Space Center) as a candidate astronaut

1984-1992	Rheumatologist, Cochin Hospital (Paris)
1996	Scientific space mission to the MIR space station (Cassiopee Franco-Russian mission)
2001	Technical and scientific space mission to the International Space Station (Andromède mission)
2002-2004	Minister for Research and New Technologies in French government

<b>Igor Landau</b>	Age	65
Director	Nationality	<i>French</i>
	First elected	<i>August 2004</i>
	Last reappointment	<i>May 2008</i>
	Term expires	<i>2011</i>

12,116 shares

**Other directorships and appointments**

Chairman of the Supervisory Board of Adidas-Salomon (Germany) since May 2009

Director of HSBC France and INSEAD

Member of the Supervisory Board of Allianz AG (Germany)

**Education and professional activities**

Degree from the <i>Ecole des Hautes Etudes Commerciales</i> (HEC) and from INSEAD (Master of Business Administration)	
1968-1970	Chief Executive Officer of the German subsidiary of La Compagnie du Roneo (Frankfurt)
1971-1975	Management consultant at McKinsey (Paris)
1975-2004	Various positions at the Rhône-Poulenc group, including member of the Management Board of Aventis (1999-2002) and Chairman of the Management Board of Aventis (2002-2004)

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

<b>Christian Mulliez</b>	Age	49
Director	Nationality	<i>French</i>
	First elected	<i>June 2004</i>
	Last reappointment	<i>May 2008</i>
	Term expires	<i>2010</i>
1,295 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., The Body Shop International (United Kingdom) and Galderma Pharma (Switzerland, since December 2009)

### Education and professional activities

Degree from the *Ecole Supérieure des Sciences Economiques et Commerciales (ESSEC)*

1984-2002	Various positions at Synthélabo and then at Sanofi-Synthélabo, including Vice President Finance
Since 2003	Executive Vice President Administration and Finance L Oréal

**Table of Contents**

<b>Lindsay Owen-Jones</b>	Age	<i>64</i>
Director	Nationality	<i>British</i>
	First elected	<i>May 1999</i>
	Last reappointment	<i>May 2008</i>
	Term expires	<i>2012</i>
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.

Director of Ferrari S.p.A. (Italy)

Member of the Compensation Committee, the Appointments and Governance Committee and the Strategy Committee of sanofi-aventis

**Education and professional activities**

Bachelor of Arts (Hons) from Oxford University and degree from INSEAD

Since 1969 Various positions at the L Oréal group, including Chairman and Chief Executive Officer (1988-2006) and Chairman of the Board of Directors since April 25, 2006

<b>Klaus Pohle</b>	Age	<i>72</i>
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**

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

Chairman of the Audit Committee of sanofi-aventis

Director of Labelux Group GmbH (Austria)

Director and Chairman of the Audit Committee of Coty Inc., New York

### Education and professional activities

Doctorate in law from Frankfurt University

Masters in law from Harvard University

Professor of Business Administration at the Berlin Institute of Technology

1966-1980 Various positions at the BASF group

1981-2003 Deputy Chief Executive Officer and Chief Financial Officer of Schering AG

<b>Gérard Van Kemmel</b>	Age	70
Independent Director	Nationality	French
	First elected	May 2003
	Last reappointment	May 2007
	Term expires	2011

500 shares

### Other directorships and appointments

Director of Groupe Eurotunnel, Europacorp and Eurotunnel NRS Holders Company Limited (United Kingdom)

Chairman of the Compensation Committee of sanofi-aventis

Member of the Audit Committee and the Appointments and Governance Committee of sanofi-aventis

Member of the Audit Committee of Europacorp

### Education and professional activities

Graduate of the *Ecole des Hautes Etudes Commerciales (HEC)*

MBA degree from the Stanford Business School

**Table of Contents**

1966-1995	Various positions including President of Arthur Andersen and Andersen Consulting in France (1976-1995) and Chairman of the Board of Arthur Andersen Worldwide (1989-1994)
1996-1997	Advisor, French Finance Minister
1997-2006	Various positions at Cambridge Technology Partners (Chief Operating Officer) and at Novell (Chairman EMEA)

<b>Serge Weinberg</b>	Age	59
	Nationality	<i>French</i>
	First elected	<i>December 2009</i>
	Term expires	<i>May 2011</i>

1,500 shares acquired in February 2010

**Other directorships and appointments**

Chairman of Weinberg Capital Partners, Financière Piasa, Piasa Holding and Corum (Switzerland)

Director of Fnac, Piasa, Rothschild Concordia, Team Partners Group and VL Holding

Manager of Adoval, Alret and Maremma

Member of the Supervisory Committee of Amplitude group and Financière BFSA

Vice Chairman and Director of Financière Poinsetia and Financière Sasa

Vice Chairman of the Supervisory Board of Schneider Electric

Member of the Supervisory Board of Gucci Group (Netherlands), Rothschild et Cie, and Alfina since February 16, 2010

Weinberg Capital Partners representative on the Board of Alliance Industrie and Sasa Industrie

**Education and professional activities**

Graduate in law

Degree from the *Institut d Etudes Politiques*

Studies at the *ENA (Ecole Nationale d Administration)*

1976-1982	<i>Sous-Préfet</i> and then Chief of staff of the French Budget Minister (1981)
1982-1987	Deputy General Manager of FR3 (the French Television Channel) and then Chief Executive Officer of Havas Tourisme
1987-1990	Chief Executive Officer of Pallas Finance
1990-2005	Various positions at PPR group including Chairman of the Executive Board for 10 years

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

Gunter Thielen was an independent Director and member of the Compensation Committee of sanofi-aventis until November 24, 2009.

During 2009, the Board of Directors met ten times, with an overall attendance rate among Board members of more than 89%.

The Board of Directors meeting held on March 1, 2010 discussed the reappointment of five members of the Board of Directors whose terms of office expire at the end of the General Shareholders meeting to be held on May 17, 2010.

The Board of Directors decided to propose that the General Shareholders meeting reappoint Christopher Viehbacher, Robert Castaigne, Lord Douro and Christian Mulliez as Directors.

Jean-Marc Bruel is not seeking reappointment. The Board of Directors is proposing that the General Shareholders meeting appoint a new director: Catherine Bréchnignac.

Catherine Bréchnignac is a physicist, and holds a doctorate in science. She is currently Director of Research at the CNRS (the French national center for scientific research); the French Ambassador at large for science, technology and innovation; President of the French High Commission on Biotechnology; and President of the International Council for Science (ICSU). She was Director General of the CNRS from 1997 to 2000, and its President from 2006 to 2010. She is a member of the French Academy of Sciences and the French Academy of Technologies, and holds doctorates *honoris causa* from a number of universities. She is also a director of Renault, and an Officer of the *Légion d honneur* (Legion of Honor) and of the *Ordre National du Mérite* (National Order of Merit).

**Table of Contents**

Assuming shareholder approval, at the end of the General Shareholders meeting to be held on May 17, 2010, the new Board of Directors would consist of the following members (year term of office ends):

Jean-François Dehecq (2011)

Thierry Desmarest (2011)

Igor Landau (2011)

Gérard Van Kemmel (2011)

Serge Weinberg (2011)

Uwe Bicker (2012)

Patrick de La Chevardièrre (2012)

Jean-René Fourtou (2012)

Claudie Haigneré (2012)

Lindsay Owen-Jones (2012)

Klaus Pohle (2012)

Catherine Bréchnignac (2014)

Robert Castaigne (2014)

Lord Douro (2014)

Christian Mulliez (2014)

Christopher Viehbacher (2014)

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

Out of the sixteen Directors on the new Board, seven would be regarded as independent: Uwe Bicker, Catherine Bréchnac, Lord Douro, Jean-René Fourtou, Claudie Haigneré, Klaus Pohle and Gérard Van Kemmel.

### *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**, Executive Vice President Research & Development;

**Jérôme Contamine**, Executive Vice President Chief Financial Officer;

**Laurence Debroux**, Senior Vice President Chief Strategic Officer;

**Karen Linehan**, Senior Vice President Legal Affairs and General Counsel;

**Philippe Luscan**, Senior Vice President Industrial Affairs;

**Wayne Pisano**, Senior Vice President Vaccines;

**Roberto Pucci**, Senior Vice President Human Resources; and

**Hanspeter Spek**, President Global Operations.

### *Management Committee*

The Management Committee is chaired by the Chief Executive Officer.



**Table of Contents**

At the beginning of March 2010, the Management Committee comprised:

***Christopher Viehbacher***

**Chief Executive Officer**

Chairman of the Management Committee and the Executive Committee

Age: 49

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 1, 2008.

***Jean-François Brin***

Member of the Management Committee

**Senior Vice President Pharmaceutical Customer Solutions** since October 2009

Age: 45

Jean-François Brin, a Doctor of Medicine, has a degree in Clinical Pharmacology & Toxicology and also is a graduate of HEC (*Ecole des Hautes Etudes Commerciales*). In 1995, he started his career as a Sales Representative and then held various posts within the Marketing Division of Rhône-Poulenc Rorer, where he became Marketing Director Central Nervous System and Bone Metabolism. In 1999, he was appointed Sales Director in the Cardio-Diabetes Business Unit in the French affiliate, subsequently becoming Cardio-Thrombosis Business Unit Head. Jean-François Brin was appointed sanofi-aventis Thrombosis Franchise Head in 2004. In this post, he was responsible for defining long-term marketing and medical strategy and he chaired the Lovenox® Strategic Steering Committee. He was appointed to his present position in October 2009.

***Pierre Chancel***

Member of the Management Committee

**Senior Vice President Global Diabetes** since September 2009

Age: 53

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<sup>®</sup>. He was appointed Senior Vice President Global Marketing and Access in August 2004 and to his present position in September 2009.

***Olivier Charmeil***

Member of the Management Committee

**Senior Vice President Pharmaceutical Operations, Asia / Pacific & Japan**

Age: 47

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 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 has reported to Olivier Charmeil, as has Asia/Pacific & Japan Vaccines, since February 2009.

## **Table of Contents**

### ***Marc Cluzel***

Member of the Management Committee and the Executive Committee

**Executive Vice President Research & Development** since November 2009

Age: 54

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 Synthelabo) and Vice President, International Development in 2001 (retaining this position after the 2004 merger with Aventis). Marc Cluzel was appointed Senior Vice President Research & Development in January 2007 and to his current position in November 2009.

### ***Jérôme Contamine***

Member of the Management Committee and the Executive Committee

**Executive Vice President Chief Financial Officer** since March 16, 2009

Age: 52

Jérôme Contamine is a Graduate of *Ecole Polytechnique (X)* and ENSAE, the national statistics and economics engineering school, affiliated with the Ministry of Finance. He graduated from the ENA *Ecole Nationale d'Administration*. After 4 years at the *Cour des Comptes* as a Senior State General Auditor, he joined Elf Aquitaine in 1988, as advisor to the Chief Financial Officer, and became Group Finance Director & Treasurer in 1991. He became the General Manager of Elf Petroleum Norway in 1995, after being named Deputy Vice President of Elf Upstream Division for Europe and the U.S. In 1999, he was appointed member of the taskforce for integration with Total, in charge of the reorganization of the merged entity, TotalFinaElf, and became, in 2000, Vice President Europe and Central Asia, Upstream Division of Total. The same year, he joined Veolia Environnement as CFO and Deputy General Manager. In 2003, he became Senior Executive Vice President, Deputy General Manager, Chief Financial Officer of Veolia Environnement and Director of Valeo. He was appointed to his current position in March 2009.

### ***Laurence Debroux***

Member of the Management Committee and the Executive Committee

**Senior Vice President Chief Strategic Officer** since February 11, 2009

Age: 40

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.

***Belén Garijo***

Member of the Management Committee

**Senior Vice President Pharmaceutical Operations, Europe**

Age: 49

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 Spain in 2003 as Managing Director of the Group's Spanish subsidiary. She was appointed to her current position in July 2006.

***Gregory Irace***

Member of the Management Committee

**Senior Vice President Pharmaceutical Operations, United States and Canada**

Age: 51

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

## **Table of Contents**

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.

### ***Marie-Hélène Laimay***

Member of the Management Committee

#### **Senior Vice President Audit and Internal Control Assessment**

Age: 51

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

#### **President France since June 2009**

Age: 62

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, Chairman of sanofi-aventis France and to his current position in June 2009.

### ***Jean-Pierre Lehner***

Member of the Management Committee

#### **Senior Vice President Chief Medical Officer since February 11, 2009**

Age: 62

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 Corporate Social Responsibility** since October 2009

Age: 54

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

**Table of Contents**

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 Senior Vice President Human Resources in September 2008 and to his present position in October 2009.

***Karen Linehan***

Member of the Management Committee and the Executive Committee

**Senior Vice President Legal Affairs and General Counsel**

Age: 51

Karen Linehan graduated from Georgetown University with bachelor of arts and *juris doctorate* degrees. Prior to practicing law, she 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, Karen 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 and the Executive Committee

**Senior Vice President Industrial Affairs**

Age: 47

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 in September 2008.

***Antoine Ortolì***

Member of the Management Committee

**Senior Vice President Pharmaceutical Operations, Intercontinental**

Age: 56

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

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

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: 59

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 and the Executive Committee since November 2009

#### **Senior Vice President Vaccines**

Age: 55

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



**Table of Contents**

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 & Corporate Strategy. He was appointed Senior Vice President Vaccines in August 2007. Since November 2009, he has been a member of the Executive Committee.

***Roberto Pucci***

Member of the Management Committee and the Executive Committee

**Senior Vice President Human Resources** since October 2009

Age: 46

Roberto Pucci has a Law degree from the University of Lausanne, Switzerland. He started his career in 1985 at Coopers & Lybrand in Geneva, Switzerland as an external auditor. He then joined Hewlett-Packard (HP) in 1987, where he held various positions in Human Resources in Switzerland and Italy including HR Manager for the European Headquarters and Human Resources Director in Italy. In 1999, he became Director, Compensation & Benefits for Agilent Technologies, a spin off from HP, and was appointed Vice President Human Resources Europe in 2003. In 2005, he moved to the United States to join Case New Holland, a subsidiary of the Fiat Group, as Senior Vice President, Human Resources, and was appointed, in 2007, Executive Vice President, Human Resources for the Fiat Group in Turin, Italy. He was appointed to his present position in October 2009.

***Debasish Roychowdhury***

Member of the Management Committee

**Senior Vice President Global Oncology** since August 2009

Age: 48

Debasish Roychowdhury received his medical training and doctorate of Medicine from the All India Institute of Medical Sciences, New Delhi, and then moved to the United States in 1989 to specialize in internal medicine, hematology and oncology (at the University of California at San Francisco), and subsequently as faculty at the University of Cincinnati, where he directed a number of clinical programs. In 1999, he moved to Eli-Lilly's R&D Department to work in Oncology Clinical Research and later in Regulatory Affairs, and was appointed Vice President for Clinical Development at GlaxoSmithKline in 2005. In 2008, he was part of the team that created GSK's new Oncology R&D Unit, uniting all of the teams working on the subject. He was appointed to his present position in August 2009.

***Jean-Philippe Santoni***

Member of the Management Committee

**Senior Vice President Industrial Development and Innovation** since June 2009

Age: 55

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

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 Senior Vice President International Development in January 2007 and to his present position in June 2009.

### ***Hanspeter Spek***

Member of the Management Committee and the Executive Committee

**President Global Operations** since November 2009

Age: 60

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

**Table of Contents**

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 Executive Vice President Pharmaceutical Operations in August 2004 and to his present position in November 2009.

***Laure Thibaud***

Member of the Management Committee

**Senior Vice President Communications** since June 2009

Age: 51

Laure Thibaud started her career as a Public Relations consultant before working for Alain Afflelou as Communication Manager. In 1990, she joined the GSK Group, where she remained for 17 years during which she successively held the following positions: in France, Head of Public Relations and Director of Communications; in London, Vice President Communications Europe; and in Brussels, Vice President External Affairs Europe. From 2007, Laure Thibaud was global Executive Vice President Communications and Sustainable Development of the Axa Group. She was appointed to her current position in June 2009.

As of December 31, 2009, none of the members of the Management Committee had any principal business activities outside of sanofi-aventis.

**Composition of the Management Committee at the beginning of March 2010**

## **Table of Contents**

### **B. Compensation**

#### **Compensation and pension arrangements for corporate officers**

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; he plays 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. The overall compensation package is determined by the Board of Directors on the recommendation of the Compensation Committee.

Christopher Viehbacher has been the Chief Executive Officer since December 1, 2008. 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.

On March 2, 2009, 250,000 options to subscribe for shares were granted to Christopher Viehbacher: 200,000 in accordance with what was contemplated on the announcement of his appointment in September 2008 and 50,000 more as part of the 2009 stock option plan. All of his stock options are subject to a performance condition. The performance condition must be fulfilled each financial year preceding the exercise period (2009, 2010, 2011 and 2012), and requires the ratio of adjusted net income excluding selected items (which was a non-GAAP financial measure used until the end of 2009) to net sales to be at least 18%.

The Board of Directors decided that no performance shares would be awarded to executive Directors, members of the Executive Committee or members of the Management Committee in 2009.

Nevertheless, in line with the undertakings made to him on September 10, 2008, at the time of the announcement of his appointment as Chief Executive Officer effective December 1, 2008, an exception was made in favor of Christopher Viehbacher. On March 2, 2009, 65,000 performance shares were awarded to him as compensation for loss of the benefits to which he had been entitled from his previous employer. All of his performance shares are subject to a performance condition. The performance condition must be fulfilled each financial year preceding the exercise period (2009 and 2010), and requires the ratio of adjusted net income excluding selected items (which was a non-GAAP financial measure used until the end of 2009) to net sales to be at least 18%.

On March 1, 2010, the Board of Directors granted 275,000 options to subscribe for shares to Christopher Viehbacher. All of his stock options are subject to a performance condition. The performance condition must be fulfilled each financial year preceding the exercise period (2010, 2011, 2012 and 2013), and requires the ratio of business net income to net sales to be at least 18% (see Item 5. Operating and Financial Review and Prospects Sources of Revenues and Expenses Business Net Income ).

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Executive directors do not receive attendance fees in connection with their role as directors or members of Board committees of sanofi-aventis.

**Table of Contents****Jean-François Dehecq****Compensation, options and shares awarded to Jean-François Dehecq**

(in euros)	2008	2009
Compensation payable for the year (details provided in the table below)	2,279,853	2,279,995
Value of stock subscription options awarded during the year	0	0
Value of performance shares awarded during the year	0	0
<b>Total</b>	<b>2,279,853</b>	<b>2,279,995</b>

**Compensation payable and paid to Jean-François Dehecq**

(in euros)	2008		2009	
	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>	975,000	910,000	975,000	975,000
Exceptional compensation	0	0	0	0
Attendance fees	0	0	0	0
Benefits in kind	4,853	4,853	4,995	4,995
<b>Total</b>	<b>2,279,853</b>	<b>2,214,853</b>	<b>2,279,995</b>	<b>2,279,995</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.

For 2009, the variable compensation of Jean-François Dehecq 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 (which was a non-GAAP financial measure used until the end of 2009).

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

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 the high-level interests of the Group.

The variable compensation may represent between 60% and 75% of his fixed compensation.

Taking into account the abovementioned criteria, the performance of the Company and the input of the Chairman of the Board of Directors during 2009, the Board of Directors set the variable compensation of Jean-François Dehecq for 2009 at 975,000, i.e., 75% of the fixed portion of his compensation.

His variable compensation is to be paid in 2010.

No stock options and no shares were granted in 2009. The basic characteristics of previously granted options are set out in the table below.

For 2010, the fixed compensation and the terms and conditions of the variable compensation of Jean-François Dehecq have been maintained on a *pro rata* basis for the remainder of his term as Chairman of the Board of Directors.

**Table of Contents****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 12/31/2009	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>

As of December 31, 2009, 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 2009.

**Pension arrangements for Jean-François Dehecq**

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.

Based on the assumptions used in the actuarial valuation of this plan, in terms of salary increases, employee turnover and life expectancy, 82 executives are potentially eligible for this plan.

Effective October 1, 2008, this plan was closed to any new eligible executive following the harmonization of the top-up defined-benefit pension plans of the French subsidiaries of the Aventis Group (including the Vaccine Division) and the Sanofi-Synthélabo Group, which merged in 2005. Nevertheless, a totally identical plan, the sanofi-aventis plan, replaced it. It is offered to all executives within the meaning of the AGIRC regime (*Association Générale des Institutions de Retraite des Cadres*, i.e. a confederation of executive pension funds) of sanofi-aventis and its French subsidiaries, extended to corporate officers, including Christopher Viehbacher (see below). Approximately 400 executives are potentially eligible for this regime, almost all being active executives.

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 (PASS) applicable in the year in which the rights vest. The annuity varies according to length of service (capped at 25



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

years) and supplements the compulsory industry schemes, subject to a cap equal to 52% of final salary on the total pension from all sources.

In accordance with the common rules of the French compulsory pension schemes (social security, *Association pour le Régime de Retraite Complémentaire des salariés*, ARRCO, i.e. a confederation of employee pension funds, and AGIRC), Jean-François Dehecq, who is over 65 years old, may, provided that he ceases to exercise his duties, decide at any time to receive these compulsory pension benefits and fix the date of vesting. The application for compulsory pension benefits may only be made by the beneficiary, who may then subsequently request the vesting of the collective top-up defined-benefit pension plan in accordance with the plan rules.

**Table of Contents**

Taking into account the final salary caps specified in the plan rules (60 x PASS, i.e. 2,077,200 for 2010), the length of service (25 years), and the rate (37.5%), if Jean-François Dehecq elects to receive all of his pension benefits at the end of his current term of office, the maximum annuity (gross amount before taxes) deriving from the top-up defined-benefit pension plan would be 778,950, in addition to the annuities due under the compulsory legal regimes.

**Christopher Viehbacher**

Christopher Viehbacher took office as Chief Executive Officer on December 1, 2008.

**Compensation, options and shares awarded to Christopher Viehbacher**

(in euros)	2008	2009
Compensation payable for the year (details provided in the table below) <sup>(1)</sup>	100,000	3,669,973
Value of stock subscription options awarded during the year <sup>(2)</sup>	0	1,237,500
Value of performance shares awarded during the year <sup>(3)</sup>	0	2,221,700
<b>Total</b>	<b>100,000</b>	<b>7,129,173</b>

(1) For 2008, fixed compensation corresponds to December 2008.

(2) Valued at date of grant using the Black & Scholes method.

(3) Valued at date of grant. The value is the difference between the quoted market price of the share on the award date and the dividends to be paid over the next three years.

**Compensation payable and paid to Christopher Viehbacher**

(in euros)	2008		2009	
	Payable	Paid	Payable	Paid
Fixed compensation <sup>(1)</sup>	100,000	100,000	1,200,000	1,200,000
Variable compensation <sup>(2)</sup>	0	0	2,400,000	0
Exceptional compensation <sup>(3)</sup>	2,200,000	0	0	2,200,000
Attendance fees	0	0	0	0
Benefits in kind	6,016	6,016	69,973	69,973
<b>Total</b>	<b>2,306,016</b>	<b>106,016</b>	<b>3,669,973</b>	<b>3,469,973</b>

The amounts reported are gross amounts before taxes.

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

- (1) Fixed compensation payable in respect of a given year is paid during that year. For 2008, fixed compensation corresponds to December 2008.
- (2) Variable compensation in respect of a given year is determined and paid at the start of the following year
- (3) Exceptional compensation corresponds to an indemnity payable upon his starting to hold office.

The amount reported for benefits in kind relates primarily, pending the relocation of his family to France, to payment of his housing costs and the cost of healthcare cover for his family in the United States. The amount reported for benefits in kind also relates to a company car.

The fixed compensation of Christopher Viehbacher for 2009 was maintained at 1,200,000.

The variable compensation of Christopher Viehbacher was based half on quantitative criteria and half on qualitative criteria.

The quantitative criteria included 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 earnings per share excluding selected items (which was a non-GAAP financial measure used until the end of 2009). These criteria were assessed by reference to the performances of the leading global pharmaceutical companies.

**Table of Contents**

The qualitative criteria related 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 could represent between 0% and 200% of his fixed compensation. In case of exceptional performance, it could exceed 200% of the fixed compensation.

Taking into account the above mentioned criteria, the performance of the Company and the input of Christopher Viehbacher during 2009, the Board of Directors fixed his variable compensation for 2009 at 2,400,000, i.e., 200% of the fixed portion of his compensation. His variable compensation is to be paid in 2010.

For 2010, the fixed compensation and the terms and conditions of the variable compensation of Christopher Viehbacher have been maintained.

**Stock options awarded to Christopher Viehbacher in 2009**

Origin	Date of Board grant	Nature of the options	Value (in )	Number of options awarded in 2009	Exercise price (in )	Exercise period
Sanofi -aventis	03/02/09	Subscription options	1,237,500	250,000	45.09	03/04/2013 03/01/2019

On March 2, 2009, 250,000 options to subscribe for shares were granted to Christopher Viehbacher: 200,000 in accordance with what was contemplated on the announcement of his appointment in September 2008 and 50,000 more as part of the 2009 stock option plan. All of his stock options are subject to a performance condition. The performance condition must be fulfilled each financial year preceding the exercise period (2009, 2010, 2011 and 2012), and requires the ratio of adjusted net income excluding selected items (which was a non-GAAP financial measure used until the end of 2009) to net sales to be at least 18%. Using the Black & Scholes method, each option was valued at 4.95, valuing the total benefit at 1,237,500.

**Stock options exercised by Christopher Viehbacher in 2009**

Christopher Viehbacher did not exercise any stock option in 2009 as no stock option was yet exercisable.

**Stock options held by Christopher Viehbacher**

On March 1, 2010, 275,000 options to subscribe for shares were awarded to Christopher Viehbacher. All the stock options are subject to a performance condition. The performance condition, which must be fulfilled each financial year preceding the exercise period (2010, 2011, 2012 and 2013), requires the ratio of business net income to net sales to be at least 18% (see Item 5. Operating and Financial Review and Prospects

Sources of Revenues and Expenses (Business Net Income ).

As of the date of this annual report including the March 1, 2010 grant, the number of outstanding options held by Christopher Viehbacher represented 0.04% of the share capital.

**Performance shares awarded to Christopher Viehbacher in 2009**

<b>Origin</b>	<b>Date of Board award</b>	<b>Number of performance shares awarded in 2009</b>	<b>Value (in )</b>	<b>Acquisition date</b>	<b>Availability date</b>
Sanofi-aventis	03/02/09	65,000	2,221,700	03/03/2011	03/04/2013

On March 2, 2009, in accordance with what was contemplated on the announcement of his appointment in September 2008, 65,000 performance shares were awarded to Christopher Viehbacher. All of his performance shares are subject to a performance condition. The performance condition must be fulfilled each financial year

**Table of Contents**

preceding the vesting of the shares (2009 and 2010), and requires the ratio of adjusted net income excluding selected items (which was a non-GAAP financial measure used until the end of 2009) to net sales to be at least 18%. The value of each performance share amounts 34.18, valuing the total benefit at 2,221,700.

**Performance shares awarded to Christopher Viehbacher which became available in 2009**

No performance shares awarded to Christopher Viehbacher became available in 2009.

**Performance shares awarded to Christopher Viehbacher**

At year end 2009 and as of the date of this annual report, the number of performance shares awarded to Christopher Viehbacher represented 0.005% of the share capital.

**Pension arrangements for Christopher Viehbacher**

Christopher Viehbacher is covered by the sanofi-aventis top-up defined benefit pension plan, identical to the Sanofi-Synthélabo plan (see above) offered to executives, within the meaning of AGIRC, 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. Based on the assumptions used in the actuarial valuation of this plan, approximately 400 executives are potentially eligible for this plan, almost all of them active executives. Its features are identical to those of the Sanofi-Synthélabo plan described above for Jean-François Dehecq. The admission of Christopher Viehbacher to this plan was approved by the General Meeting of April 17, 2009.

**Commitments in favor of executive directors in post as of December 31, 2009**

<b>Executive director</b>	<b>Contract of employment</b>	<b>Top-up pension plan</b>	<b>Compensation or benefits payable or potentially payable on termination of office or change in control</b>	<b>Compensation payable under non-competition clause</b>
Jean-François Dehecq	No	Yes	Yes	No
Christopher Viehbacher	No	Yes	Yes	No

Jean-François Dehecq's termination benefit was approved at successive Shareholders' Annual General Meetings, and most recently that of 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.

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

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.

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 income excluding selected items (which was a non-GAAP financial measure used until the end of 2009) to net sales for each financial year must be at least 15%.

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%.

This commitment was approved in May 2008, before the adoption of the AFEP-MEDEF corporate governance code. Payment of the termination benefit is not limited to non-voluntary departure linked to a change in control or strategy, but also covers retirement. Jean-François Dehecq is in a position to retire and claim his pension rights at short notice. Nevertheless, taking into account the major role he has played in the creation and expansion of sanofi-aventis, it has been decided not to modify the terms and conditions of his termination benefit.

## **Table of Contents**

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 French Commercial Code, payment of the termination benefit would 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 income excluding selected items (which was a non-GAAP financial measure used until the end of 2009) to net sales for each financial year must be at least 15%;

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.

The terms for the termination benefit entitlement of Christopher Viehbacher were approved by the Shareholders' Annual General Meeting of April 17, 2009.

Any activation of this termination benefit will be carried out in compliance with the AFEP-MEDEF corporate governance code, i.e. only if the departure is non-voluntary and linked to a change in control or strategy.

### **Lock-up period for shares obtained on exercise of stock options by, or disposition of performance shares by, 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.

Under the Internal Rules of the sanofi-aventis Board of Directors, they may not contract any hedging instruments in respect of their own interests, and, as far as sanofi-aventis is aware, no such instruments have been contracted.

#### **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 2008 and 2009, including those whose term of office ended during the year.

Attendance fees in respect of 2008, the amount of which was set by the Board meeting of February 10, 2009, were paid in 2009.

Attendance fees in respect of 2009, the amount of which was set by the Board meeting of March 1, 2010, were paid in 2010.

**Table of Contents**

For 2009, 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.

The variable portion of the fee is linked to actual attendance by directors in accordance with the principles described below:

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.

However, a reduction coefficient of 0.56% was applied in order to keep the attendance fees within the total attendance fee entitlement.

(in euros)	2008		Pension paid in 2008	Total gross compensation	2009		Pension paid in 2009	Total theoretical compensation <sup>(5)</sup>	Total actual compensation <sup>(6)</sup>
	Attendance fees in respect of 2008 to be paid in 2009				Attendance fees in respect of 2009 to be paid in 2010				
	Fixed	Variable			Fixed	Variable			
René Barbier de La Serre <sup>(1)</sup>	6,250	47,500		53,750					
Uwe Bicker <sup>(2)</sup>	10,000	42,000		52,000	15,000	71,000		86,000	85,519
Jean-Marc Bruel	15,000	72,500	373,700	461,200	15,000	90,000	376,189	481,189	480,601
Robert Castaigne	15,000	42,500		57,500	15,000	107,500		122,500	121,814
Patrick de La Chevardière <sup>(2)</sup>	10,000	25,000		35,000	15,000	27,500		42,500	42,262
Thierry Desmarest	15,000	80,000		95,000	15,000	62,500		77,500	77,066
Jürgen Dormann <sup>(1)</sup>	6,250	29,000	1,593,750	1,629,000					
Lord Douro	15,000	56,000		71,000	15,000	79,000		94,000	93,474
Jean-René Fourtou	15,000	80,000	1,590,040	1,685,040	15,000	62,500	1,602,013	1,679,513	1,679,079
Claudie Haigneré <sup>(2)</sup>	10,000	30,000		40,000	15,000	60,000		75,000	74,580
Igor Landau	15,000	35,000	2,176,098	2,226,908	15,000	47,500	2,193,300	2,255,800	2,255,450
Hubert Markl <sup>(1)</sup>	6,250	14,000		20,250					
Christian Mulliez	15,000	40,000		55,000	15,000	47,500		62,500	62,150
Lindsay Owen-Jones	15,000	65,000		80,000	15,000	47,500		62,500	62,150
Klaus Pohle	15,000	126,000		141,000	15,000	141,000		156,000	155,127
Gunter Thielen <sup>(2) (3)</sup>	10,000	35,500		45,500	12,500	22,000		34,500	34,307
Gérard Van Kessel	15,000	125,000		140,000	15,000	127,500		142,500	141,702
Serge Weinberg <sup>(4)</sup>					1,250	5,000		6,250	6,215
Bruno Weymüller <sup>(1)</sup>	6,250	10,000		16,250					
<b>Total</b>	<b>215,000</b>	<b>955,000</b>	<b>5,734,398</b>	<b>6,904,398</b>	<b>208,750</b>	<b>998,000</b>	<b>4,171,502</b>	<b>5,378,252</b>	<b>5,371,496</b>
<b>Total attendance fees</b>						<b>1,206,750 <sup>(5)</sup></b>			
		<b>1,170,000</b>				<b>1,199,994 <sup>(6)</sup></b>			

- (1) Left office May 14, 2008.
- (2) Assumed office May 14, 2008.
- (3) Resigned from office November 24, 2009.
- (4) Assumed office December 16, 2009.
- (5) Before the 0.56% reduction.
- (6) After the 0.56% reduction.

## **Pensions**

The amount recognized in 2009 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 4 million.

## **Table of Contents**

As retirees, Jean-Marc Bruel, 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 2 active executives, 4 early retirees and 25 retired executives. At its meeting of February 11, 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.

## **Compensation of senior management**

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 ).

In 2009, total gross compensation before social charges paid to or accrued for the members of our Management Committee in post in 2009, including the Chief Executive Officer, amounted to 19 million, including 10 million for the members of the Executive Committee. Fixed compensation represented 12 million, including 7 million for the members of the Executive Committee.

In 2009, 1,205,400 stock options were granted to the 23 members of our Management Committee, including 650,000 stock options granted to the 9 members of our Executive Committee (including the 250,000 stock options granted to Christopher Viehbacher).

In 2009, no restricted shares or performance shares were awarded to the members of our Executive Committee or to the members of our Management Committee with the exception of Christopher Viehbacher, who was awarded 65,000 performance shares.

As of December 31, 2009, 4,319,959 options had been granted to the members of our Management Committee, including 1,876,168 options to the members of our Executive Committee. As of the same date, 4,066,217 options granted to the members of our Management Committee were outstanding, including 1,771,211 options granted to the members of our Executive Committee. These figures include the options granted to Christopher Viehbacher, who is a member of our Management Committee and 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, 2009 below.

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.

## **Table of Contents**

The total amount accrued and recognized in the income statement for the year ended December 31, 2009 in respect of corporate pension plans for (i) directors 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 14 million.

This total amount accrued for the year ended December 31, 2009 included 6.6 million for members of the Management Committee collectively (including 4 million for members of the Executive Committee collectively).

## **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 and Jean-François Dehecq, see also Item 6. Directors, Senior Management and Employees B. Compensation and pension arrangements for Jean-François Dehecq ; 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.

Members of these committees are chosen by the Board from among its members, based on their experience.

## **Audit Committee**

At December 31, 2009, the Audit Committee comprised:

**Klaus Pohle**, Chairman;

**Jean-Marc Bruel**;

**Robert Castaigne**; and

**Gérard Van Kemmel**.

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

Three of the four members of the Audit Committee are independent Directors. All its members, including Robert Castaigne, are 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 and French legislation. See Item 16A. Audit Committee Financial Expert.

The roles of the Audit Committee are to review:

the process for the preparation of financial information;

the effectiveness of the internal control and risk management systems;

the audit of the parent company financial statements and consolidated financial statements by the statutory auditors; and

the independence of the statutory auditors.

The role of the Committee is not so much to examine the financial statements in detail as to monitor the process of preparing them and to assess the validity of elective accounting treatments used for significant transactions.

In fulfilling its role, the Committee interviews the statutory auditors and the officers responsible for finance, accounting and treasury management. It is possible for such interviews to take place without the Chief Executive

## **Table of Contents**

Officer being present if the Committee sees fit. The Committee may also visit or interview managers of operational entities in furtherance of its role, having given prior notice to the Chairman of the Board and to the Chief Executive Officer.

The Committee interviews the person responsible for internal audit, and gives its opinion on the organization of the internal audit function.

The Committee is able to call upon external experts.

Sufficient time must be allowed for the financial statements to be examined (at least two days prior to the examination of the financial statements by the Board).

The examination of the financial statements by the Audit Committee is accompanied by a presentation by the statutory auditors highlighting key issues not only regarding the financial results but also the elective accounting treatments used, along with a presentation by the Chief Financial Officer describing the Group's risk exposure and significant off balance sheet commitments.

In addition, the Committee:

directs the selection process for the statutory auditors when their mandates are due for renewal, submits the results of this process to the Board of Directors, and issues a recommendation;

is informed of the fees paid to the statutory auditors, ensures that the signatory partners are rotated every five years, and oversees compliance with other rules relating to auditor independence;

in conjunction with statutory auditors, assesses any risk to their independence and any measures taken to mitigate such risk;

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 applied; and

ensures that independent Directors receive no compensation other than attendance fees.

During 2009, the Audit Committee met eight times.

## **Compensation Committee**



At December 31, 2009, this Committee was composed of:

**Gérard Van Kemmel**, Chairman;

**Thierry Desmarest**;

**Jean-René Fourtou**; and

**Lindsay Owen-Jones**.

The Compensation Committee is composed of four Board members, two of whom are independent. Gunter Thielen, an independent Director, was also a member of this Committee until November 24, 2009.

The roles of the Compensation Committee are:

to make recommendations and proposals to the Board about the compensation, pension and welfare plans, top-up pension plans, benefits in kind and other pecuniary benefits of the executive directors of sanofi-aventis, and about the granting of performance shares and stock options;

to define the methods used to set the variable portion of the compensation of the executive directors, and check that these methods are applied;

**Table of Contents**

to formulate general policy on the granting of performance shares and 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 the Chief Executive Officer on the compensation of key senior executives.

The Compensation Committee met twice in 2009.

**Appointments and Governance Committee**

At December 31, 2009, this Committee was composed of:

**Jean-François Dehecq**, Chairman;

**Thierry Desmarest**;

**Lord Douro**;

**Jean-René Fourtou**;

**Claudie Haigneré**;

**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 executive officers;

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

to establish corporate governance rules for the Company, and to oversee the application of those rules;

to ensure that there is adequate succession planning for the Company's executive bodies;

to oversee compliance with ethical standards within the Company and in its dealings with third parties;

to determine whether each Director qualifies as being independent, both on his or her initial appointment and annually prior to publication of the Reference Document, and report its conclusions to the Board of Directors;

to propose methods for evaluating the operating procedures of the Board, and oversee the application of these methods; and

to examine the Chairman's report on corporate governance.

The Appointments and Governance Committee met twice in 2009.

### **Strategy Committee**

At December 31, 2009, 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.

**Table of Contents**

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;

development priorities;

financial and stock market strategies, and compliance with key financial ratios;

potential diversification opportunities; and

more generally, any course of action judged essential to the Company's future.

The Strategy Committee met twice in 2009.

**D. Employees**

**Number of Employees**

As of December 31, 2009, sanofi-aventis employed 104,867 people worldwide. The tables below give a breakdown of employees by geographic area and function as of December 31, 2009. Central and Eastern European countries are included in Other Europe.

**Employees by geographic area**

	As of December 31,					
	2009	%	2008	%	2007	%
France	27,694	26.41%	28,223	28.74%	28,592	28.7%
Other Europe	30,202	28.80%	25,292	25.75%	26,785	27.0%
United States	14,517	13.84%	15,228	15.50%	15,921	16.0%
Japan	3,198	3.05%	3,121	3.18%	2,989	3.0%
Other countries	29,256	27.90%	26,349	26.83%	25,208	25.3%
<b>Total</b>	<b>104,867</b>	<b>100%</b>	<b>98,213</b>	<b>100%</b>	<b>99,495</b>	<b>100%</b>

**Employees by function**

	As of December 31,					
	2009	%	2008	%	2007	%
Sales	34,292	32.70%	33,507	34.12%	35,115	35.3%
Research and Development	19,132	18.24%	18,976	19.32%	19,310	19.4%
Production	36,849	35.14%	31,903	32.48%	31,292	31.5%
Marketing and Support Functions	14,594	13.92%	13,827	14.08%	13,778	13.8%
<b>Total</b>	<b>104,867</b>	<b>100%</b>	<b>98,213</b>	<b>100%</b>	<b>99,495</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, to negotiate, and to sign agreements.

During 2009, 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 and the transformation program launched by management at the start of the year.

At European level, the employee representatives on the sanofi-aventis European Works Council (40 members and 40 alternates, drawn from the 27 European Union member states) were re-elected in

## Table of Contents

September 2009 for an additional four-year term, as were the nine Committee officers. The Council met in April, June, July, October and November 2009 to give the employee representatives regular updates on initiatives associated with the transformation program (R&D, Commercial Operations, Vaccines, Industrial Affairs and Support Functions). The five employee representatives on the Board of Directors of the sanofi-aventis parent company were also re-elected, at the European Works Council meeting of that took place on October 1, 2009.

In Europe, negotiations were conducted during 2009 in association with the reorganization programs required in a number of countries in particular within our commercial operations largely in response to changes in government healthcare policies and to the genericization of some of our products.

In France, the employee representatives on the Group Works Council (25 members and 25 alternates) were re-elected for an additional two-year term in June 2009. The representatives designated by the trade unions were reappointed at the same time, also for a two-year term. The French Group Works Council met in June, July, November and December 2009. At these meetings, the Committee was updated on our activities and financial position, employment trends within the Group, and initiatives associated with the transformation program launched by management in January 2009.

A number of agreements applicable to all our French companies were signed or amended in 2009:

Health, Safety and Environment agreement;

Occupational Health agreement;

Amendment no. 3 to the agreement on the Group savings scheme ( PEG );

Amendments nos. 2 & 3 to the agreement on the collective retirement savings plan ( PERCO ).

In addition, management has prepared an action plan on the employment of seniors, which will be implemented in January 2010 and last three years. This plan covers areas such as:

career development planning;

enhancement of skills and qualifications, and access to training;

knowledge and skills transfer, and the development of mentoring.

Other specific agreements were signed within individual group companies (sanofi-aventis Recherche et Développement, Sanofi Winthrop Industrie, Sanofi Chimie, sanofi-aventis France, sanofi pasteur and sanofi-aventis Groupe).

***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 that 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 2009 in respect of voluntary profit-sharing for the year ended December 31, 2008 represented 3.9% of total payroll.

In June 2008, sanofi-aventis signed a three-year Group-wide agreement, effective from the 2008 financial year, and applicable to all French companies more than 50% owned by sanofi-aventis. Under the agreement, payments under the Group voluntary profit-sharing scheme are linked to growth in our adjusted net income excluding selected items (which was a non-GAAP financial measure used until the end of 2009).

**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.

## **Table of Contents**

The amount distributed by our French companies during 2009 in respect of the statutory scheme for the year ended December 31, 2008 represented 7.4% 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.

An amendment to this agreement was signed in April 2009, primarily to bring the agreement into line with a change in French legislation (Law 2008-1258 of December 3, 2008) designed to protect against erosion in the purchasing power of income from employment, under which each qualifying employee can elect to receive some or all of his or her profit-sharing bonus immediately.

## **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 2009, 75.8% of the employees who benefited from the profit-sharing schemes opted to invest in the collective retirement savings plan.

In 2009, 114.7 million and 54.1 million were invested in the Group savings scheme and the collective retirement savings plan respectively through the voluntary and statutory schemes for 2008, and through top-up contributions.

## **Employee Share Ownership**



At December 31, 2009, shares held by employees of sanofi-aventis and of related companies and by former employees under Group employee savings schemes amounted to 1.38% of the share capital.

## **E. Share Ownership**

### **Senior Management**

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, 2009, a total of 4,319,959 unexercised options to subscribe for or to purchase sanofi-aventis shares were held by the 23 members of the Management Committee of sanofi-aventis, including the 1,876,168 unexercised options to subscribe for or to purchase sanofi-aventis shares held by the 9 members of the Executive Committee (including 250,000 held by Christopher Viehbacher). The terms of these options are summarized in the tables below.

At December 31, 2009, Christopher Viehbacher was the only member of the Management Committee and the only member of the Executive Committee of sanofi-aventis who had been awarded shares. He had been awarded 65,000 performance shares. The terms of this award are summarized in the tables below.

On March 2, 2009, Christopher Viehbacher was (i) granted 250,000 options to subscribe for shares, exercisable at a price of 45.09 per share from March 4, 2013 until March 1, 2019 and subject to a performance condition; and (ii) awarded 65,000 performance shares to be transferred on March 3, 2011 and available on March 4, 2013, subject to a performance condition.

## **Table of Contents**

During 2009, the members of the Management Committee of sanofi-aventis exercised 476 options to purchase or to subscribe for shares.

On December 11, 2009, Jean-René Fourtou, a member of the Board of Directors, exercised 234,782 options to subscribe for 234,782 shares at a price of 50.04 per share.

### **Existing Option Plans as of December 31, 2009**

As of December 31, 2009, a total of 87,870,341 options were outstanding, including 7,380,442 options to purchase sanofi-aventis shares and 80,489,899 options to subscribe for sanofi-aventis shares. Out of this total, 57,717,316 were immediately exercisable, including 7,380,442 options to purchase shares and 50,336,874 options to subscribe for shares.

Stock options (which may be options to subscribe for shares or options to purchase shares) 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.

For each plan, the Compensation Committee and the Board of Directors assess whether it should take the form of options to subscribe for shares or options to purchase shares, 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 of Directors 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.

At its meeting of March 2, 2009, in addition to the 250,000 stock options granted to Christopher Viehbacher, the Board of Directors granted 5,591 beneficiaries a total of 7,486,480 options, each giving entitlement to subscribe for one sanofi-aventis share (representing 0.57% of our share capital before dilution).

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 (see Item 6. Directors, Senior Management and Employees Compensation Compensation and pension arrangements for corporate officers).

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.



**Table of Contents****Share Purchase Option Plans**

Origin	Date of shareholder authorization	Date of Board grant	Number of options initially granted	- to the 10 employees		Start date of exercise period	Expiration date	Purchase price (in )	Number exercised as of 12/31/2009	Number canceled as of 12/31/2009	Number outstanding
				- to corporate officers <sup>(1)</sup>	granted the most 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	313,600		16,600
Synthélabo	6/28/1990	1/12/1996	208,000	0	52,000	1/12/2001	1/12/2016	8.56	188,730		19,270
Synthélabo	6/28/1990	4/05/1996	228,800	0	67,600	4/05/2001	4/05/2016	10.85	191,830		36,970
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	284,530		11,870
Synthélabo	6/23/1998	3/30/1999	716,040	0	176,800	3/31/2004	3/30/2019	38.08	382,565	5,720	327,755
Sanofi-Synthélabo	5/18/1999	5/24/2000	4,292,000	310,000	325,000	5/25/2004	5/24/2010	43.25	2,697,186	118,800	1,476,014
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	109,700	2,551,739
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	149,600	2,901,250

(1) 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.

(2) Employed as of the date of grant.

**Hoechst GmbH Share Purchase Option Plans**

A total of 128,974 Hoechst GmbH options to purchase shares had not been exercised on December 31, 2009.

**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 as of 12/31/2009	Number canceled as of 12/31/2009	Number outstanding
				- to corporate officers <sup>(1)</sup>	granted the most options <sup>(2)</sup>						
Aventis	5/26/1999	12/15/1999	5,910,658	586,957	463,485	1/06/2003	12/15/2009	50.04	4,816,991	1,093,667	0
Aventis	5/26/1999	5/11/2000	877,766	0	86,430	5/11/2003	5/11/2010	49.65	558,935	95,459	223,372
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	2,354,953	10,339,911
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	2,843,019	9,650,791
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	4,637,561	1,806,871	5,330,982
Aventis	5/14/2002	12/02/2003	12,012,414	352,174	715,000	12/03/2006	12/02/2013	40.48	4,650,275	1,657,153	5,704,986
Sanofi-Synthélabo	5/18/1999	12/10/2003	4,217,700	240,000	393,000	12/11/2007	12/10/2013	55.74	188,780	193,850	3,835,070
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	1,690,905	13,531,100
Sanofi-aventis	5/31/2005	12/14/2006	11,772,050	450,000	585,000	12/15/2010	12/14/2016	66.91	0	740,430	11,031,620
Sanofi-aventis	5/31/2007	12/13/2007	11,988,975	325,000	625,000	12/14/2011	12/13/2017	62.33	0	512,990	11,475,985
Sanofi-aventis	5/31/2007	03/02/2009	7,736,480	250,000	655,000	03/04/2013	03/01/2019	45.09	0	91,060	7,645,420

(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.

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

At its meeting of March 1, 2010, in addition to the 275,000 stock options granted to Christopher Viehbacher, the Board of Directors granted 5,727 beneficiaries a total of 7,846,355 options to subscribe for one sanofi-aventis share each (representing 0.6% of our share capital before dilution). Half the stock options granted to the members of the Executive Committee and all the stock options granted to Christopher Viehbacher are subject to a performance condition. The performance condition must be fulfilled each financial year preceding the exercise period (2010, 2011, 2012 and 2013), and requires the ratio of business net income to net sales to be at least 18% (see Item 5. Operating and Financial Review and Prospects Sources of Revenues and Expenses Business Net Income ).

Options granted to the Chief Executive Officer in 2010 represented 0.8% of the maximum total grant approved at the Shareholders Annual General Meeting of April 17, 2009 (2.5% of our share capital) and 3% of the total grant made to all of the beneficiaries on March 1, 2010.

## **Table of Contents**

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 as of December 31, 2009**

For the first time in 2009, the Board of Directors 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.

Shares are awarded to employees on the basis of a list submitted to the Compensation Committee, which then submits the list to the Board of Directors, which awards the shares. The Board of Directors sets the vesting conditions for the award, and any lock-up conditions for the shares. No performance conditions are attached.

At its meeting of March 2, 2009, the Board of Directors set up two plans:

a French plan by which it awarded 2,293 beneficiaries a total of 590,060 restricted shares, subject to an acquisition period of two years followed by a lock-up period of two years; and

an international plan by which it awarded 2,945 beneficiaries a total of 604,004 restricted shares, subject to an acquisition period of four years.

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 favor of Christopher Viehbacher, who was awarded 65,000 performance shares on March 2, 2009, in line with the undertakings made to him on September 10, 2008, at the time of the announcement of his appointment as Chief Executive Officer 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. All of his performance shares are awarded subject to a performance condition. The performance condition, which must be fulfilled each financial year before the transfer of the shares (i.e., 2009 and 2010), requires the ratio of adjusted net income excluding selected items (which was a non-GAAP financial measure used until the end of 2009) to net sales to be at least 18%.

Performance shares awarded to the Chief Executive Officer in 2009 represented 0.49% of the maximum total grant approved at the Shareholders Annual General Meeting of May 31, 2007 (1% of our share capital) and 5.44% of the total grant made to all of the beneficiaries on March 2, 2009.

### **Share Plans**

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Origin	Date of shareholder authorization	Date of award	Number of shares initially awarded	- to corporate officers <sup>(1)</sup>	- to the 10 employees the most shares <sup>(2)</sup>	Date of award	Acquisition date	Availability date	Number transferred as of 12/31/2009	Number of rights canceled as of 12/31/2009	Number outstanding
Sanofi-aventis	5/31/2007	03/02/2009	590,060	65,000	13,900	03/02/2009	03/03/2011	03/04/2013	0	965	589,095
Sanofi-aventis	5/31/2007	03/02/2009	604,004	0	13,200	03/02/2009	03/04/2013	03/04/2013	0	12,050	591,954

(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.

As of December 31, 2009, a total of 1,181,049 shares were outstanding as the acquisition period of each plan had not yet expired.

At its meeting of March 1, 2010, the Board of Directors set up two plans:

a French plan by which it awarded 2,262 beneficiaries a total of 531,725 restricted shares, subject to an acquisition period of two years followed by a lock-up period of two years; and

an international plan by which it awarded 3,333 beneficiaries a total of 699,524 restricted shares, subject to an acquisition period of four years.

**Table of Contents**

No shares were awarded to executive Directors, members of the Executive Committee or members of the Management Committee as part of the March 2010 plan.

**Shares Owned by Members of the Board of Directors**

As of December 31, 2009, members of our Board of Directors held in the aggregate 452,936 shares, or under 1% of the share capital and of the voting rights, excluding the beneficial ownership of 96,692,473 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).

**Transactions in Shares by Members of the Board of Directors and comparable persons in 2009**

On February 19, 2009, Christopher Viehbacher, Chief Executive Officer, bought 10,000 shares at a price of 46.27 per share.

On May 12, 2009, Philippe Luscan, Senior Vice President Industrial Affairs, sold 121 units of FCPE sanofi-aventis (mutual fund) at a price of 43.88 per unit.

On September 14, 2009, Christian Mulliez, a member of the Board of Directors, bought 250 shares at a price of 47.91 per share.

On December 11, 2009, Jean-René Fourtou, a member of the Board of Directors, exercised 234,782 options to subscribe for 234,782 shares at a price of 50.04 per share and sold the resulting 234,782 shares at a price of 53 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, 2010, 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.

	Total number of issued shares		Number of real voting rights (excluding own shares) <sup>(2)</sup>		Theoretical number of voting rights (including own shares) <sup>(3)</sup>	
	Number	%	Number	%	Number	%
<b>L Oréal</b>	118,227,307	8.97	236,454,614	15.36	236,454,614	15.27
<b>Total</b>	91,760,293	6.96	180,967,806	11.76	180,967,806	11.69
<b>Treasury shares</b>	9,332,455	0.71			9,332,455	0.60
- of which held directly by sanofi-aventis	9,203,481	0.70				
<b>Employees <sup>(1)</sup></b>	18,146,041	1.37	32,291,732	2.10	32,291,732	2.09
<b>Public</b>	1,081,123,913	81.99	1,089,427,232	70.78	1,089,427,232	70.35
<b>Total</b>	<b>1,318,590,009</b>	<b>100</b>	<b>1,539,141,384</b>	<b>100</b>	<b>1,548,473,839</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, 2010.

(3) Based on the total number of voting rights as of January 31, 2010 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* (Articles of Association) provide for double voting rights for shares held in registered form for at least two years. All of our shareholders may benefit from double voting rights if these conditions are met, and no shareholder benefits from specific voting rights. For more information relating to our shares, see Item 10. Additional Information B. Memorandum and Articles of Association.

L Oréal and Total 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, 2008 and 2009 after no significant changes in 2006 and 2005. At year end 2006, their respective holdings were 10.52% and 13.13% of our share capital compared to 8.97% and 6.96% on January 31, 2010.

L Oréal disclosed that, following the modification of the total number of shares and voting rights, it had exceeded the 15% legal voting rights threshold and held an interest of 8.99% of our share capital and 15.10% of our voting rights (notification dated September 21, 2009).

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 ).

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

For the year ended December 31, 2009, we were informed that the following share ownership declaration thresholds had been passed:

Natixis Asset Management disclosed that it had exceeded the 3% ownership threshold stipulated in our *statuts* and held 3.08% of our share capital (notification dated March 5, 2009);

Crédit Agricole Asset Management disclosed that through its *Fonds Communs de Placement* (mutual funds) (i) it had exceeded and then gone below the 3% ownership threshold stipulated in our *statuts*, (ii) had gone below and then exceeded the 2% voting rights threshold stipulated in our *statuts* and held *in fine* an interest of 2.97% of our share capital (notification dated April 17, 2009) and 2.04% of our voting rights (notification dated September 4, 2009);

Crédit Suisse disclosed that the Credit Suisse Group had gone below and then had exceeded the 1% ownership threshold stipulated in our *statuts* and held *in fine* an interest of 1.07% of our share capital (notification dated April 21, 2009);

## **Table of Contents**

Caisse des Dépôts et Consignations disclosed that it gone below and then had exceeded the 2% ownership threshold stipulated in our *statuts* and held *in fine* an interest of 2% of our share capital and 1.68% of our voting rights (notification dated October 14, 2009);

Dodge & Cox disclosed that it gone below and then had exceeded the 2% ownership threshold stipulated in our *statuts* and held *in fine* an interest of 2.01% of our share capital and 1.69% of our voting rights on behalf of its clients (notification dated October 7, 2009);

Total disclosed that, following several sales of shares, it had gone below the 11%, 10%, 9%, 8% ownership thresholds and the 18%, 17%, 16%, 15%, 14%, 13% voting rights thresholds stipulated in our *statuts* and held *in fine* 7.99% of our share capital (notification dated November 17, 2009) and 12.98% of our voting rights (notification dated November 23, 2009).

Since January 1, 2010 we have been informed that the following share ownership declaration thresholds have been passed:

Amundi disclosed that, through its *Fonds Communs de Placement* (mutual funds) it had exceeded the 3% ownership threshold stipulated in our *statuts* and held 3.02% of our share capital and 2.55% of our voting rights (notification dated January 7, 2010);

Total disclosed that, following several sales of shares, it had gone below the 7% ownership threshold and the 12% voting rights threshold stipulated in our *statuts* and held *in fine* 6.99% of our share capital and 11.97% of our voting rights (notification dated January 25, 2010); and

BNP Paribas Asset Management disclosed that, through its *Fonds Communs de Placement* (mutual funds), its *Sociétés d'Investissement à Capital Variable* (mutual funds) and mandates it had exceeded the 1% ownership threshold stipulated in our *statuts* and held 1% of our share capital and 0.85% of our voting rights (notification dated February 2, 2010).

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) hold approximately 8% of our share capital. Institutional shareholders (excluding L. Oréal and Total) hold approximately 72% of our share capital. Such shareholders are primarily American (26.1%), French (19%) and British (10.7%). German institutions hold 3.4% of our share capital, Swiss institutions hold 1.3%, institutions from other European countries hold 7.1% and Canadian institutions hold 0.6% of our share capital. Other international institutional investors (excluding those from Europe and the United States) hold approximately 3.6% of our share capital.

(source: a survey conducted by Euroclear France as of December 31, 2009, and internal information).

### ***Shareholders Agreement***

We are unaware of any shareholders agreement currently in force.

### **B. Related Party Transactions**

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

In the ordinary course of business, we purchase or provide materials, supplies and services from or to 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 17, 2009 sanofi-aventis acquired the interest held by Merck & Co., Inc. (Merck) in Merial Limited (Merial) and Merial is now a wholly-owned subsidiary of sanofi-aventis. As per the terms of the agreement signed on July 29, 2009, sanofi-aventis also had an option, following the closing of the Merck/Schering-Plough merger, to combine the Intervet/Schering-Plough Animal Health business with Merial to form an animal health joint venture that would be equally owned by the new Merck and sanofi-aventis. On March 8, 2010, sanofi-aventis did in fact exercise its contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial. In addition to execution of final agreements, formation of the new animal health joint venture remains subject to

**Table of Contents**

approval by the relevant competition authorities and other closing conditions (for more information see Item 8 B. Significant Changes Meria and Notes D.1 and D.8.1 to our consolidated financial statements included at Item 18 of this annual report). Other than this agreement, during 2009 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, 2009, 2008, and 2007 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, 2007 and 2008 and our shareholders will be asked to approve the payment of an annual dividend of 2.40 per share for the 2009 fiscal year at our next annual shareholders meeting. If approved, this dividend will be paid on May 25, 2010.

We expect that we will continue to pay regular dividends based on our financial condition and results of operations. The proposed 2009 dividend equates to a distribution of 36.3% of our business earnings per share. For information on the non-GAAP financial measure, business earnings per share, see Item 5. Operating and Financial Review and Prospects Business Net Income.

The following table sets forth information with respect to the dividends paid by our Company in respect of the 2005, 2006, 2007, and 2008 fiscal years and the dividend that will be proposed for approval by our shareholders in respect of the 2009 fiscal year at our May 17, 2010 shareholders meeting.

	2009 <sup>(1)</sup>	2008	2007	2006	2005
Net Dividend per Share (in €)	2.40	2.20	2.07	1.75	1.52
Net Dividend per Share (in \$) <sup>(2)</sup>	3.46	3.06	3.02	2.31	1.80

<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 depository, 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 2009, the annual payment per PSSA in respect of 2008 was equal to 16.6390.

	2008	2007	2006	2005	2004
Annual payment per PSSA	16.6390	15.7234	13.4695	12.9929	0
Annual payment per PSSA-ADS	\$ 6.0204	\$ 5.8550	\$ 4.5877	\$ 4.1438	\$ 0

## **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.

#### *Rhodia Litigation*

*(Update to the caption "Rhodia" at Note D.22.e) to our consolidated financial statements included herein at Item 18.)*

On February 10, 2010, Rhodia submitted its pleadings brief (*conclusions récapitulatives*) in connection with the complaint it had filed with the Commercial Court of Paris against sanofi-aventis in July 2007. In its brief, Rhodia has asked the Court to hold that sanofi-aventis was at fault in failing to provide Rhodia with sufficient capital to meet its pension obligations and environmental liabilities, and has claimed indemnification in the amount of 1.3 billion for retirement commitments and approximately 311 million for environmental liabilities. Sanofi-aventis will submit its answer in the coming weeks. The case should be decided in 2010.

### **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 2009.

#### *Merial*

On March 8, 2010, sanofi-aventis exercised its option to combine Merial with Intervet/Schering-Plough, Merck's animal health business. This option was granted to sanofi-aventis in the Merial acquisition agreement signed July 29, 2009. See Note D.1 to our consolidated financial statements included at Item 18 of this annual report.

The new joint venture will be equally-owned by Merck and sanofi-aventis. Its formation is subject to execution of final agreements, antitrust review in the United States, Europe and other countries and other customary closing conditions. The completion of the transaction is expected to occur in approximately the next 12 months, and each of Merial and Intervet/Schering-Plough will continue to operate independently until the



closing of the transaction.

The enterprise value of Merial has been fixed at \$8 billion and the enterprise value of Intervet/Schering-Plough at \$8.5 billion, leading to a true-up payment of \$250 million to Merck to establish a 50/50 joint venture. An additional amount of \$750 million will be paid by sanofi-aventis, as per the terms of the agreement signed on July 29, 2009. All payments, including adjustments for debt and certain other liabilities will be made upon closing of the transaction.

*Other*

On January 11, 2010, sanofi-aventis launched its tender offer for all outstanding shares of Chattem, Inc (Chattem), subject to customary closing conditions. On February 9, 2010, sanofi-aventis acquired 89.8% of Chattem's shares on a fully-diluted basis (or approximately 97% of outstanding shares) by accepting all validly tendered shares. The remaining shares were acquired in a short form merger on March 10, 2010.

On January 29, 2010, sanofi-aventis signed agreements with Minsheng Pharmaceuticals Co., Ltd to establish a new Consumer Health Care joint venture. Subject to certain conditions precedent and to regulatory approvals, sanofi-aventis is to obtain a majority equity stake in the future venture.

On February 23, 2010, the petition by sanofi-aventis to squeeze-out the remaining minority holders of Zentiva N.V. was ratified by the Dutch courts.

**Table of Contents**

**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 The Bank of New York.

Our shares trade on the Eurolist market of NYSE 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 NYSE Euronext Paris and on the New York Stock Exchange (source: Bloomberg).

Calendar period	NYSE Euronext		NYSE	
	High (price per share in )	Low (price per share in )	High (price per ADS in \$)	Low (price per ADS in \$)
<b>Monthly</b>				
February 2010	54.88	51.68	37.93	34.90
January 2010	58.90	52.18	41.59	36.32
December 2009	56.78	50.47	40.80	38.25
November 2009	52.46	48.35	39.53	35.83
October 2009	53.90	49.25	40.17	36.00
September 2009	51.68	46.11	38.00	32.91
<b>2009</b>				
First quarter	49.93	38.43	32.80	24.59
Second quarter	48.67	39.32	33.83	25.57
Third quarter	51.68	40.91	38.00	28.60
Fourth quarter	56.78	48.35	40.80	35.83
Full Year	56.78	38.43	40.80	24.59
<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 of 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

## **Table of Contents**

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.

### **The Euronext Paris Market**

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 on Euronext Paris. 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 issuers with a market capitalization over 1 billion, B for issuers with a market capitalization between 1 billion and 150 million, and C for issuers with a market capitalization under 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 historical and expected trading volume. Our shares trade in the category known as *continu*, which includes the most actively traded securities. Securities belonging to the *continu* category 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 a range of plus or minus 1% of the closing auction price.

Euronext Paris may temporarily interrupt trading in a security admitted to trading on the Euronext Paris Market if matching a bid or ask offer recorded in the system would inevitably result in a price beyond a certain threshold, determined on the basis of a percentage fluctuation above or below a set reference price. With respect to equity securities included in the CAC 40 Index and trading in 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 fluctuates by more than 3% above or below the relevant reference price. Euronext Paris may also suspend trading of a security admitted to trading on the Euronext Paris Market in certain circumstances including at the request of the issuer or 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 trading day following the trade. For certain liquid securities, market intermediaries which are members of Euronext Paris are also permitted to offer investors the opportunity to place orders through a deferred settlement service (*Ordres Stipulés à Règlement-Livraison Différés* OSRD). 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 fourth trading day before the end of the month, either to settle by the last trading day of the month or to 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 S.A. 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 3,271 PSSAs outstanding as of December 31, 2009. 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

155



**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 on behalf of the Company 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*

Directors are required to hold at least one share during the term of their appointment.

### **Share Capital**

As of December 31, 2009, our share capital amounted to 2,636,958,104, divided into 1,318,479,052 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 9,422,716 shares (or 0.71 % of our outstanding share capital), as treasury shares as of such date. As of December 31, 2009, the book value of such shares was 526 million.

## **Table of Contents**

At an extraordinary general meeting held on April 17, 2009, 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 1.3 billion. See *Changes in Share Capital* *Increases in Share Capital*, below.

The maximum total amount of authorized but unissued shares as of December 31, 2009 was 581.7 million, reflecting the unused part of the April 17, 2009 shareholder authorization, outstanding options to subscribe for shares and awards of 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 combined general meeting of April 17, 2009 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 the Euronext Paris Market during the 20 consecutive trading days preceding the date on which the options are granted.

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

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.

### **Awards of Shares**

Our combined general meeting held on April 17, 2009 authorized our Board of Directors for 38 months to allot existing or new consideration free shares to some or all salaried employees and corporate officers of the Company or of companies of the Group in accordance with Articles L. 225-197-1 et *seq* of the French Commercial Code.

The existing or new shares allotted under this authorization may not represent more than 1% of the share capital as of the date of the decision by the Board of Directors.

## **Table of Contents**

The authorization provides that allotment of shares to the allottees will become irrevocable either (i) at the end of a minimum vesting period of two years, the allottees being required to retain their shares for a minimum period of two years from the irrevocable allotment thereof, or (ii) after a minimum vesting period of four years, in which case allottees may not be subject to any minimum retention period.

In case of newly issued shares, the authorization entails the express waiver by the shareholders, in favor of the allottees of restricted shares, of their preemptive rights in respect of shares that are to be issued as and when restricted shares are exercised.

The Board of Directors sets the terms on which restricted shares 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 restricted shares plans currently in force.

## **Changes in Share Capital in 2009**

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, 2009, there were 234,852,104 shares that were entitled to double voting rights, representing 17.81% of our total share capital, approximately 15.21% of our voting rights held by holders other than us and our subsidiaries, and 15.12% of our total voting rights.

Double voting rights are not taken into account in determining whether a quorum exists.

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 information regarding beneficial ownership directly from such person. See Memorandum and Articles of Association Form, Holding and Transfer of Shares , below.

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

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;



**Table of Contents**

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

approving 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 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:

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

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***

All prior notice periods provided for below are minimum periods required by French law and cannot be shortened, except in case of a public offer for our shares.

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 and on our website. 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.

## **Table of Contents**

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;

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.

## **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:

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

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

## **Table of Contents**

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**

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) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public offer for 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.

## **Votes Required for Shareholder Action**

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

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) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public offer for 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 attached 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 offer for our shares (article L. 233-32 of the French Commercial Code).

## **Table of Contents**

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 shareholders 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 reserves 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 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, 2009, our legal reserve amounted to 282,280,863, representing 10.7% 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.

***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 set by our Board of Directors during the 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, subject to 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.



**Table of Contents**

**Changes in Share Capital**

*Increases in Share Capital*

As provided for 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

exercising the 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 offer for 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*).

On April 17, 2009, our shareholders approved various 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 1.3 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 of capital increases that may be carried out with preemptive rights maintained was set at 1.3 billion;
- the maximum aggregate par value of capital increases that may be carried out without preemptive rights was set at 500 million;
- the maximum aggregate par value 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).

## **Table of Contents**

On April 17, 2009, 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:

- the 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;
- the 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 [Awards of Shares](#) above.

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 April 17, 2009, our shareholders delegated to our Board of Directors for 26 months the right to reduce our share capital by canceling our own shares.

### **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 Stock Exchange.

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.

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

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 Stock Exchange 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.

## **Table of Contents**

### ***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 provides the account holder with a securities account statement. 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 the Euronext Paris Market 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 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 do not need to be cancelled if the company redeeming the shares grants options on or awards those shares to its employees within one year following 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.

## **Table of Contents**

### **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 <sup>1</sup>/<sub>3</sub>%, 50%, 66 <sup>2</sup>/<sub>3</sub>%, 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, before the end of the fourth trading day following 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 before the end of the fourth trading day following the date it crosses the threshold. The AMF makes the notice public.

Subject to certain limited exceptions, French law and AMF regulations impose additional reporting requirements on persons who acquire more than 10%, 15%, 20% or 25% of the outstanding shares or voting rights of a listed company in France. These persons must file a report with the company and the AMF before the end of the fifth trading day following the date they cross the threshold.

In the report, the acquirer will have to specify its intentions for the following six month including:

- whether it acts alone or in concert with others;
- the means of financing of the acquisition (the notifier shall indicate in particular whether the acquisition is being financed with equity or debt, the main features of that debt, and, where applicable, the main guarantees given or received by the notifier. The notifier shall also indicate what portion of its holding, if any, it obtained through securities loans);
- whether or not it intends to continue its purchases;
- whether or not it intends to acquire control of the company in question;
- the strategy it contemplates *vis-à-vis* the issuer;
- the way it intends to implement it: (i) any plans for a merger, reorganization, liquidation, or partial transfer of a substantial part of the assets of the issuer or of any other entity it controls within the meaning of Article L. 233-3 of the French Commercial Code, (ii) any plans to modify the business of the issuer, (iii) any plans to modify the memorandum and articles of association of the issuer, (iv) any plans to delist a category of the issuer's financial instruments, and (v) any plans to issue the issuer's financial instruments;

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

- any agreement for the temporary transfer of shares or voting rights; and
- whether it seeks representation on the Board of Directors.

The AMF makes the report public. Upon any change of intention, it will have to file a new report for the following six-month period.

In order to enable 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 an applicable 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.



## **Table of Contents**

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 goes above or below one of the thresholds described in the preceding sentence. Any person or entity that fails to comply with such notification requirement, 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 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.

On April 17, 2009, 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 80.00 and the maximum amount that sanofi-aventis may pay for the repurchases is 10,524,203,680. A description of this share repurchase program as adopted by the Board of Directors on April 17, 2009 (*descriptif du programme de rachat d'actions*) was published on March 4, 2009.

***Purposes of Share Repurchase Programs***

European regulation 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.

## **Table of Contents**

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.

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.

**Table of Contents**

*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, 2009, we did not use the authority delegated by our shareholders to repurchase our shares on the stock market.

As of December 31, 2009, we directly owned 9,293,742 sanofi-aventis shares with an aggregate par value of 18,587,484 (representing around 0.70 % of our share capital and with a value estimated at the share price upon purchase of 524,629,506).

In 2009, of the 8,193,471 shares allocated to stock purchase option plans outstanding at December 31, 2008, 592,255 shares were transferred to grantees of options, comprising:

354,059 shares transferred directly by us; and

238,196 shares transferred indirectly (by Hoechst GmbH).

Following these transfers, the shares owned directly or indirectly by us were allocated as follows:

7,601,216 shares were allocated to outstanding stock purchase option plans comprising:

7,472,242 directly-owned shares, representing 0.57% of our share capital; and

128,974 indirectly-owned shares, representing 0.01% of our share capital.

1,821,500 shares were allocated to cancellation, representing 0.14% of our share capital.

There has been no reallocation and no cancellation of repurchased shares.

***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 on their web site 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.

## **Table of Contents**

### **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 (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, including the protocol of January 13, 2009), 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 made several changes to the Treaty, including changes to the Limitation on Benefits provision. The protocol entered into force on December 23, 2009; its provisions became effective in respect of withholding taxes for amounts paid or credited



---

## **Table of Contents**

on or after January 1, 2009 and in respect of other taxes for taxable years beginning on or after January 1, 2010. *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 5% 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.*

## **French Taxes**

### *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.

## **Table of Contents**

### **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.*

### **ADSs-Ordinary Shares**

### **French Taxes**

#### *Taxation of Dividends*

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

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). From March 1, 2010, dividends paid by a French corporation, such as sanofi-aventis, towards non-cooperative States or territories, as defined in Article 238-0 A of the French General Tax Code, will generally be subject to French withholding tax at a rate of 50%, irrespective of the tax residence of the beneficiary of the dividends if the dividends are received in such States or territories; however, eligible U.S. holders entitled to Treaty benefits under the Limitation on Benefits provision contained in the Treaty and receiving dividends in non-cooperative States or territories will not be subject to this 50% withholding tax.

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 certain technical changes were made to these requirements by the new protocol. U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits in light of their own particular circumstances.

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 depository with a treaty form (Form 5000). Dividends paid to a U.S. holder that has not filed the

## **Table of Contents**

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.

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 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 2009 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 2010 taxable year. *Holders of ordinary*

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

*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 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

**Table of Contents**

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.*

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 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 depository, 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 depository 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) owned by U.S. holders. 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 before March 1, 2010. 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

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

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*

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.



---

**Table of Contents**
**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.

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 2009 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 2010 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 depositary, 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 depositary 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.*

**Table of Contents**

***F. Dividends and Paying Agents***

N/A

***G. Statement by Experts***

N/A

***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.

As of December 31, 2009, cash and cash equivalents amounted to 4,692 million. The Group tends to diversify its short term investments with leading banks on monetary supports which maturity is lower than three months. As of December 31, 2009, these short term investments were mainly made of:

Mutual funds investments classified as Euro money-market funds by the *Autorité des Marchés Financiers*, within a limit of 10% of held assets.

Bank term deposits with a maturity lower than three months. These short-term investments are entered into with leading financial institutions.

As of December 31, 2009, the Group had 12.3 billion of undrawn confirmed credit facilities, of which 7.7 billion expire in 2012, 4.0 billion in 2011, 0.6 billion in 2010. Our credit facilities are not subject to financial covenant ratios.

<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**

Our policy is to diversify our sources of funding 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. Debt securities issued in 2009 (for more information, see Note D.17 to the consolidated financial statements) helped extend the average term of our total debt to 4.1 years as of December 31, 2009, compared to 2.3 years as of December 31, 2008. Short-term commercial paper programs (U.S. dollar-denominated commercial paper swapped into euros and euro-denominated commercial paper) are used to meet our short-term financing needs. Drawdowns under these programs are generally renewed for periods of two months. The commercial paper programs are backed by confirmed short term credit facilities (see description above), 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). None of these programs was drawn as of December 31, 2009.

In the event 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 in their terms. This situation could damage the capacity of the Group to refinance its debt or to issue new debt on reasonable terms.

**Interest Rate Risk**

Our cost of debt is influenced by trends in interest rates as regards the floating-rate portion of our total debt (credit facilities, commercial paper) linked to Eonia, US Libor and Euribor, in proportion to the amounts drawn under these programs. To optimize the cost of our short-term and medium-term debt or reduce its volatility, we use interest rate swaps, cross-currency swaps, and, if necessary interest rate options, to alter the fixed rate / floating rate mix of our debt.

As of December 31, 2009, 67% of our total debt (amounting to 8,796 million), was fixed-rate and 33% was floating-rate after taking account of interest rate derivatives. Our cash and cash equivalents (amounting to 4,692 million) are entirely floating-rate.

As of December 31, 2009, the sensitivity of our total debt, net of cash and cash equivalents to interest rate fluctuations over a full year is detailed in the table below:

Change in 3-month Euribor	Impact on pre-tax net income (in million)
+100 bp	18
+ 25 bp	4
-25 bp	(4)
-100 bp	Non applicable

**Foreign Exchange Risk***a. Operational Foreign Exchange Risk*

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

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 2009, for example, 32% 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).

**Table of Contents**

The table below shows operational currency hedging derivatives in place as of December 31, 2009, with the notional amount translated into euros at the relevant closing exchange rate. See also Note D.20 to the consolidated financial statements for the accounting classification of these instruments as of December 31, 2009.

**Operational foreign exchange derivatives as of December 31, 2009 <sup>(1)</sup>:**

(in million)	Notional amount	Fair value
<b>Forward currency sales</b>	<b>2 800</b>	<b>(51)</b>
<i>of which: U.S. dollar</i>	1,757	(41)
<i>Japanese yen</i>	269	1
<i>Russian rouble</i>	132	(4)
<i>Pound Sterling</i>	111	
<i>Hungarian forint</i>	104	(1)
<b>Forward currency purchases</b>	<b>377</b>	<b>6</b>
<i>of which: Hungarian forint</i>	114	3
<i>U.S. dollar</i>	69	
<i>Pound Sterling</i>	68	1
<i>Canadian dollar</i>	42	1
<i>Swiss franc</i>	20	
<b>Put options purchased</b>	<b>448</b>	<b>14</b>
<i>of which: U.S. dollar</i>	278	8
<b>Call options written</b>	<b>881</b>	<b>(17)</b>
<i>of which: U.S. dollar</i>	555	(10)
<b>Put options written</b>	<b>278</b>	<b>(8)</b>
<i>of which: U.S. dollar</i>	278	(8)
<b>Call options purchased</b>	<b>555</b>	<b>10</b>
<i>of which: U.S. dollar</i>	555	10
<b>Total</b>	<b>5,339</b>	<b>(46)</b>

<sup>(1)</sup> As of December 31, 2008, the notional amount of forward currency sales was 3,305 million with a fair value of 219 million (including forward sales of U.S. dollars of a notional amount of 2,461 million with a fair value of 182 million). As of December 31, 2008, the notional amount of forward currency purchases was 601 million with a fair value of - 11 million (including forward sales of U.S. dollars of a notional amount of 140 million with a fair value of 3 million). In addition, as of December 31, 2008, the Group portfolio included purchased put options of a notional amount of 24 million with an immaterial fair value, and written call options of a notional amount of 48 million with a fair value of - 7 million.

As of December 31, 2009, none of these instruments had an expiry date after December 31, 2010.

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, 2009 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.

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

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 2010; and



**Table of Contents**

forecast foreign-currency cash flows relating to commercial transactions to be carried out in 2010. These hedges (forward contracts and options) cover approximately 8% to 40% of the expected net cash flows for 2010 in currencies subject to budgetary hedging. The portfolio of derivatives relating to 2010 U.S. dollar denominated cash flows consists entirely of forward contracts and accounts for around 8% of the 2010 expected cash flows. Given that these forward contracts were designated as cash flow hedges as of December 31, 2009, the sensitivity of the foreign exchange gain or loss and the impact on equity related to these instruments over 2010 would be as follows:

Constant euro/U.S. dollar exchange rate over 2010	Foreign exchange gain/(loss) on U.S. dollar hedging in million	Impact on equity
Depreciation of 10% in the U.S. dollar ( 1 = \$1.5847)	28	33
Exchange rate maintained at the December 31, 2009 rate ( 1 = \$1.4406)	(5)	
Appreciation of 10% in the U.S. dollar ( 1 = \$1.2965)	(46)	(41)

**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, expose certain entities 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 mainly affects the sanofi-aventis parent company on the U.S. dollar and is hedged by firm financial instruments, usually forward contracts and currency swaps.

The table below shows financial currency hedging instruments in place as of December 31, 2009, calculated using exchange rates prevailing as of that date. See also Note D.20 to the consolidated financial statements for the accounting classification of these instruments as of December 31, 2009.

**Financial foreign exchange derivatives as of December 31, 2009 <sup>(1)</sup>:**

(in million)	Notional amount	Fair value	Expiry
<b>Forward currency purchases</b>	<b>6,760</b>	<b>185</b>	
<i>of which: U.S. dollar <sup>(*)</sup></i>	5,634	180	2010
<i>Pound sterling</i>	433	2	2010
<i>Swiss franc</i>	152	1	2010
<b>Forward currency sales</b>	<b>3,169</b>	<b>(7)</b>	
<i>of which: U.S. dollar</i>	1,634	(28)	2010
<i>Japanese yen</i>	837	18	2010
<i>Czech koruna</i>	394	7	2010
<b>Total</b>	<b>9,929</b>	<b>178</b>	

<sup>(\*)</sup> Corresponding to the hedging of intra-group U.S. dollar deposits placed with the sanofi-aventis parent company.

<sup>(1)</sup> As of December 31, 2008, the notional amount of forward currency purchases was 9,210 million with a fair value of - 80 million (including forward purchases of U.S. dollars of a notional amount of 8,256 million with a fair value of - 66 million). As of December 31, 2008, the notional amount of forward currency sales was 1,954 million with a fair value of - 22 million (including forward sales of U.S. dollars of a notional amount of 1,043 million with a fair value of - 23

million).

These swaps generate a net financial foreign exchange gain or loss arising from the differential between the interest rates of the hedged currency and the euro, given that the foreign exchange gain or loss on the foreign-currency assets and liabilities is offset by the change in the intrinsic value of the hedging instruments. As regards the U.S. dollar, the interest rate differential on forward currency purchases had a negative impact of 24 million on the foreign exchange gain/loss in 2009, compared to a negative impact of 51 million in 2008.

As of December 31, 2009, none of the instruments had an expiry date after December 31, 2010.

We may also hedge some future foreign-currency cash flows relating to investment or divestment transactions.

**Table of Contents****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 to our consolidated financial statements. As a result, any fluctuation in the U.S. dollar against the euro affects shareholders' equity as expressed in euros. As of December 31, 2009, 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. As regards investing operations and derivative instruments, a limit is set for each financial institution, depending on its rating. Compliance with these limits, which are computed by reference to the notional amount of the transaction and weighted to reflect the residual maturity and nature of the commitment, is monitored on a daily basis.

As of December 31, 2009, the distribution of our exposure by rating and the percentage committed to the dominant counterparty were as follows:

	Cash and cash equivalents (excluding mutual funds) <sup>(1)</sup>	Notional amounts of currency hedges <sup>(2)</sup>	Notional amounts of interest rate hedges <sup>(2)</sup>	Credit facilities
AA	304	2,538	981	2,560
AA-	104	2,551		3,465
A+	427	8,812	1,124	4,899
A				881
A-				485
BBB ratings and not rated				
Unallocated	40			
Total	875	13,901	2,105	12,290
% / rating of the dominant counterparty	28% / AA	15% / A+	21% / AA	11% / A+

<sup>(1)</sup> The cash equivalents include mutual funds investments for 3,128 million.

<sup>(2)</sup> The notional amounts are computed on the basis of the forward rates negotiated at the inception date of the derivative instruments.

Mutual funds investments are mainly made by the sanofi-aventis parent company. These mutual funds investments, classified as Euro Money-Market Funds by the *Autorité des Marchés Financiers*, show low volatility, low sensitivity to interest rate risk and a very low probability of loss of principal. Depository banks of the mutual funds as well as depositaries of sanofi-aventis are at least A+ rated.

Crystallization 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. Description of Securities other than Equity Securities**

N/A

**Table of Contents**

**12.D American Depositary Shares**

**Fees Payable By ADS Holders**

A copy of our Form of Amended and Restated Deposit Agreement with JPMorgan Chase Bank N.A. ( JPMorgan ) (including the Form of American Depositary Receipt or ADR ) was filed with the SEC as an exhibit to our Form F-6 filed on August 7, 2007 (the Deposit Agreement ). Pursuant to the Deposit Agreement, holders of our ADSs may have to pay to JPMorgan, either directly or indirectly, fees or charges up to the amounts set forth in the table below.

<b>Associated Fee</b>	<b>Depository Action</b>
\$5.00 or less per 100 ADSs (or portion thereof)	Execution and delivery of ADRs for distributions and dividends in shares and rights to subscribe for additional shares or rights of any other nature and surrender of ADRs for the purposes of withdrawal, including the termination of the Deposit Agreement
\$0.02 or less per ADS (or portion thereof)	Any cash distribution made pursuant to the Deposit Agreement, including, among other things: <ul style="list-style-type: none"> <li>cash distributions or dividends,</li> <li>distributions other than cash, shares or rights,</li> <li>distributions in shares, and</li> <li>rights of any other nature, including rights to subscribe for additional shares.</li> </ul>
Taxes and other governmental charges	As applicable
Registration fees in effect for the registration of transfers of shares generally on the share register of the company or foreign registrar and applicable to transfers of shares to or from the name of JPMorgan or its nominee to the custodian or its nominee on the making of deposits and withdrawals	As applicable
A fee equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities	Distributions of securities other than cash, shares or rights
Any other charges payable by JPMorgan, its agents (and their agents), including BNP Paribas, as custodian (by deductions from cash dividends or other cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them)	Servicing of shares or other deposited securities
Expenses incurred by JPMorgan	Cable, telex and facsimile transmission (where expressly provided for in the Deposit Agreement)

Foreign currency conversion into U.S. dollars

**Fees Paid to sanofi-aventis by the Depositary**

JPMorgan, as depositary, has agreed to reimburse sanofi-aventis up to \$4,000,000 per year for expenses sanofi-aventis incurs relating to legal fees, investor relations servicing, investor-related presentations, ADR-related advertising and public relations in those jurisdictions in which the ADRs may be listed or otherwise quoted, investor relations channel, perception studies, accountants fees in relation to our annual report on

**Table of Contents**

Form 20-F or any other expenses directly or indirectly relating to managing the program or servicing the shareholders. From January 1, 2009 to March 1, 2010, sanofi-aventis has obtained reimbursements corresponding to the ceiling of \$4,000,000 for 2009. Furthermore, JPMorgan has agreed to waive up to \$425,000 each year in servicing fees for routine corporate actions, such as annual general meetings and divided distributions, as well as for other assistance such as tax and regulatory compliance fees, investor relations advisory services, etc.

**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, 2009 based on the framework in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Business combinations that have been consummated during the year 2009 have been excluded from the scope of management's assessment of and conclusion on internal control over financial reporting as of December 31, 2009. The acquired businesses comprise essentially Zentiva, Medley, and Merial, whose respective contributions to the Company's consolidated financial statements as of and for the year ended December 31, 2009 are presented in the following table (the other acquired businesses are not significant):

	As a % of total sales	As a % of total assets	As a % of consolidated net income
Zentiva	1.6%	3.3%	(1.3%)
Medley	0.6%	1.1%	0.3%
Merial	N/A <sup>(1)</sup>	7.9%	3.1%



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

(1) Not applicable, as Merial is accounted for on a separate line item. Net income from the held-for-exchange Merial business in accordance with IFRS 5, and its revenues and expenses, including its sales, are presented as a single amount on this line item.

Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2009 to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles.

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.

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, 2009, 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.

**Table of Contents**

(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]

**Item 16A. 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 Gérard Van Kemmel qualifies as an independent financial expert based on his experience as a partner at an international accounting firm. The Board of Directors also deemed Klaus Pohle to be an independent financial expert taking into account his education and professional experience in financial matters, accountancy and internal control.

**Item 16B. 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.

**Item 16C. Principal Accountants Fees and Services**

See Note E to our consolidated financial statements included at Item 18 of this annual report.

**Item 16D. Exemptions from the Listing Standards for Audit Committees**

N/A

**Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

In 2009, neither sanofi-aventis nor affiliated purchasers made purchases of equity securities of sanofi-aventis registered pursuant to Section 12 of the Exchange Act. For more information see Item 10. Additional Information Trading in Our Own Shares Use of Share Repurchase Programs .

**Item 16F. Change in Registrant s Certifying Accountant**

N/A

**Item 16G. Corporate Governance**

Sanofi-aventis is incorporated under the laws of France, with securities listed on regulated public markets in the United States (New York Stock Exchange) and France (Euronext Paris). Consequently, as described further in 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.

## **Table of Contents**

In line with New York Stock Exchange rules applicable to domestic issuers, sanofi-aventis aims to maintain a board of directors at least half of the members of which 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 under French 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 the Board of Directors 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-121 incorporated herein by reference.

**Item 19. Exhibits**

- 1.1 Articles of association (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 Jérôme Contamine, 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 Jérôme Contamine, Principal Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
- 23.1 Consent of Ernst & Young Audit dated March 12, 2010
- 23.2 Consent of PricewaterhouseCoopers Audit dated March 12, 2010
- 99.1 Report of the Chairman of the Board of Directors for 2009 as required by Art. L. 225-37 paragraph 6 of the French Commercial Code

**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 12, 2010

---

**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-4</b>
<b><u>CONSOLIDATED BALANCE SHEETS</u></b>	<b>F-6 - F-7</b>
<b><u>CONSOLIDATED INCOME STATEMENTS</u></b>	<b>F-8</b>
<b><u>CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME</u></b>	<b>F-9</b>
<b><u>CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY</u></b>	<b>F-10</b>
<b><u>CONSOLIDATED STATEMENTS OF CASH FLOWS</u></b>	<b>F-11</b>
<b><u>NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS</u></b>	<b>F-12</b>
<b><u>- A. Basis of preparation</u></b>	<b>F-12 - F-14</b>
<b><u>- B. Summary of significant accounting policies</u></b>	<b>F-14 - F-37</b>
<b><u>- C. Alliances</u></b>	<b>F-38 - F-39</b>
<b><u>- D. Detailed notes to the financial statements</u></b>	<b>F-40 - F-117</b>
<b><u>- E. Principal Accountants Fees and Services</u></b>	<b>F-117</b>
<b><u>- F. List of principal companies included in the consolidation for the year ended December 31, 2009</u></b>	<b>F-118 - F-121</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, 2009, 2008 and 2007, and the related consolidated statements of income, comprehensive income, changes in equity and cash-flows for each of the three years in the period ended December 31, 2009. 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, 2009, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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, 2009, 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 9, 2010 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, March 9, 2010

PricewaterhouseCoopers Audit

ERNST & YOUNG Audit

Catherine Pariset

Philippe Vogt

Christian Chiarasini

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, 2009, 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.

As described in the accompanying Report of Management on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting excluded the internal controls of business combinations that have been consummated during 2009. The acquired businesses comprise essentially Zentiva, Medley and Merial. We have also excluded the 2009 business combinations from our audit of internal control over financial reporting of the Group. Zentiva, Medley and Merial's respective contributions to the Group's consolidated financial statements as of and for the year ended December 31, 2009 are presented in the following table:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

	As a % of total sales	As a % of total assets	As a % of consolidated net income
Zentiva	1.6%	3.3%	(1.3)%
Medley	0.6%	1.1%	0.3 %
Meril	N/A	7.9%	3.1 %

In our opinion, the Group maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

F-3

**Table of Contents**

We also have audited, in accordance with the standards of the PCAOB, the consolidated balance sheets of the Group as of December 31, 2009, 2008 and 2007, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2009 and our report dated March 9, 2010 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, March 9, 2010

PricewaterhouseCoopers Audit

ERNST & YOUNG Audit

Catherine Pariset

Philippe Vogt

Christian Chiarasini

Jacques Pierres

F-4

**Table of Contents**

[THIS PAGE INTENTIONALLY LEFT BLANK]

F-5

**Table of Contents****CONSOLIDATED BALANCE SHEETS**

<i>( million)</i>	<i>Note</i>	December 31, 2009	December 31, 2008	December 31, 2007
<b>ASSETS</b>				
Property, plant and equipment	D.3.	7,830	6,961	6,538
Goodwill	D.4.	29,733	28,163	27,199
Intangible assets	D.4.	13,747	15,260	19,182
Investments in associates	D.6.	955	2,459	2,493
Financial assets non-current	D.7.	998	821	1,037
Deferred tax assets	D.14.	2,912	2,920	2,912
<b>Non-current assets</b>		<b>56,175</b>	<b>56,584</b>	<b>59,361</b>
Inventories	D.9.	4,444	3,590	3,729
Accounts receivable	D.10.	6,015	5,303	4,904
Other current assets	D.11.	2,104	1,881	2,126
Financial assets current	D.12.	277	403	83
Cash and cash equivalents	D.13. - D.17.	4,692	4,226	1,711
<b>Current assets</b>		<b>17,532</b>	<b>15,403</b>	<b>12,553</b>
Assets held for sale or exchange	D.8.	6,342		
<b>TOTAL ASSETS</b>		<b>80,049</b>	<b>71,987</b>	<b>71,914</b>

The accompanying notes on pages F-12 to F-121 are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED BALANCE SHEETS**

<i>( million)</i>	<i>Note</i>	December 31, 2009	December 31, 2008	December 31, 2007
<b>LIABILITIES &amp; EQUITY</b>				
Equity attributable to equity holders of the Company	<b>D.15.</b>	48,188	44,866	44,542
Minority interests	<b>D.16.</b>	258	205	177
<b>Total equity</b>		<b>48,446</b>	<b>45,071</b>	<b>44,719</b>
Long-term debt	<b>D.17.</b>	5,961	4,173	3,734
Provisions and other non-current liabilities	<b>D.18.</b>	8,311	7,730	6,857
Deferred tax liabilities	<b>D.14.</b>	4,933	5,668	6,935
<b>Non-current liabilities</b>		<b>19,205</b>	<b>17,571</b>	<b>17,526</b>
Accounts payable		2,654	2,791	2,749
Other current liabilities	<b>D.19.</b>	5,445	4,721	4,713
Short-term debt and current portion of long-term debt	<b>D.17.</b>	2,866	1,833	2,207
<b>Current liabilities</b>		<b>10,965</b>	<b>9,345</b>	<b>9,669</b>
Liabilities related to assets held for sale or exchange	<b>D.8.</b>	1,433		
<b>TOTAL LIABILITIES &amp; EQUITY</b>		<b>80,049</b>	<b>71,987</b>	<b>71,914</b>

The accompanying notes on pages F-12 to F-121 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, 2009	Year ended December 31, 2008	Year ended December 31, 2007
<b>Net sales</b>	<b>D.34. - D.35.</b>	<b>29,306</b>	<b>27,568</b>	<b>28,052</b>
Other revenues		1,443	1,249	1,155
Cost of sales		(7,880)	(7,337)	(7,571)
<b>Gross profit</b>		<b>22,869</b>	<b>21,480</b>	<b>21,636</b>
Research and development expenses		(4,583)	(4,575)	(4,537)
Selling and general expenses		(7,325)	(7,168)	(7,554)
Other operating income	<b>D.25.</b>	866	556	522
Other operating expenses	<b>D.26.</b>	(481)	(353)	(307)
Amortization of intangibles		(3,528)	(3,483)	(3,654)
<b>Operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals, and litigation</b>		<b>7,818</b>	<b>6,457</b>	<b>6,106</b>
Restructuring costs	<b>D.27.</b>	(1,080)	(585)	(137)
Impairment of property, plant and equipment and intangibles	<b>D.5.</b>	(372)	(1,554)	(58)
Gains and losses on disposals, and litigation	<b>D.28.</b>		76	
<b>Operating income</b>		<b>6,366</b>	<b>4,394</b>	<b>5,911</b>
Financial expenses	<b>D.29.</b>	(324)	(335)	(329)
Financial income	<b>D.29.</b>	24	103	190
<b>Income before tax and associates</b>		<b>6,066</b>	<b>4,162</b>	<b>5,772</b>
Income tax expense	<b>D.30.</b>	(1,364)	(682)	(687)
Share of profit/loss of associates	<b>D.31.</b>	814	692	446
<b>Net income excluding the held-for-exchange Merial business <sup>(1)</sup></b>		<b>5,516</b>	<b>4,172</b>	<b>5,531</b>
Net income from the held-for-exchange Merial business <sup>(1)</sup>	<b>D.8.</b>	175	120	151
<b>Net income</b>		<b>5,691</b>	<b>4,292</b>	<b>5,682</b>
Net income attributable to minority interests	<b>D.32.</b>	426	441	419
<b>Net income attributable to equity holders of the Company</b>		<b>5,265</b>	<b>3,851</b>	<b>5,263</b>
Average number of shares outstanding (million)	<b>D.15.9.</b>	1,305.9	1,309.3	1,346.9
Average number of shares outstanding after dilution (million)	<b>D.15.9.</b>	1,307.4	1,310.9	1,353.9
- Basic earnings per share (in euros)		4.03	2.94	3.91
- Diluted earnings per share (in euros)		4.03	2.94	3.89

<sup>(1)</sup> Reported separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations). For the other disclosures required under IFRS 5, refer to Note D.8. to our consolidated financial statements.

The accompanying notes on pages F-12 to F-121 are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

<i>( million)</i>	Year ended December 31, 2009	Year ended December 31, 2008	Year ended December 31, 2007
<b>Net income</b>	<b>5,691</b>	<b>4,292</b>	<b>5,682</b>
<b>Income (expense) recognized directly in equity:</b>			
Available-for-sale financial assets	110	(132)	(5)
Cash flow hedges	(175)	104	8
Remeasurement of previously-held equity interests:			
Merial	1,215		
Zentiva	108		
Actuarial gains/(losses)	(169)	(829)	282
Change in cumulative translation difference	(301)	948	(2,764)
Tax effect of income and expenses recognized directly in equity <sup>(1)</sup>	(241)	132	(119)
<b>Total income/(expense) recognized directly in equity</b>	<b>547</b>	<b>223</b>	<b>(2,598)</b>
<b>Total recognized income/(expense) for the period</b>	<b>6,238</b>	<b>4,515</b>	<b>3,084</b>
<i>Attributable to equity holders of the Company</i>	<i>5,811</i>	<i>4,090</i>	<i>2,666</i>
<i>Attributable to minority interests</i>	<i>427</i>	<i>425</i>	<i>418</i>

<sup>(1)</sup> See analysis in Note D.15.7.

The accompanying notes on pages F-12 to F-121 are an integral part of the consolidated financial statements.



Table of Contents

## CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

( million)	Share capital	Additional paid-in capital and retained earnings	Treasury shares	Stock options and other share-based payment	Other items recognized directly in equity	Attributable to equity holders of the Company	Attributable to minority interests	Total equity
<b>Balance at January 1, 2007</b>	<b>2,719</b>	<b>43,776</b>	<b>(492)</b>	<b>1,369</b>	<b>(1,772)</b>	<b>45,600</b>	<b>220</b>	<b>45,820</b>
Income/(expense) recognized directly in equity <sup>(1)</sup>		176			(2,773)	(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>5,439</b>			<b>(2,773)</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
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>(2)</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>47,162</b>	<b>(2,275)</b>	<b>1,468</b>	<b>(4,545)</b>	<b>44,542</b>	<b>177</b>	<b>44,719</b>
Income/(expense) recognized directly in equity <sup>(1)</sup>		(693)			932	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>3,158</b>			<b>932</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>(3)</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>44,819</b>	<b>(552)</b>	<b>1,581</b>	<b>(3,613)</b>	<b>44,866</b>	<b>205</b>	<b>45,071</b>
Income/(expense) recognized directly in equity <sup>(1)</sup>		869			(323)	546	1	547
Net income for the period		5,265				5,265	426	5,691
		<b>6,134</b>			<b>(323)</b>	<b>5,811</b>	<b>427</b>	<b>6,238</b>

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<b>Total recognized income/(expense) for the period</b>								
Dividend paid out of 2008 earnings ( 2.20 per share)			(2,872)			(2,872)		(2,872)
Payment of dividends and equivalents to minority shareholders							(418)	(418)
Share-based payment:								
Exercise of stock options	6	134				140		140
Proceeds from sale of treasury shares on exercise of stock options			26			26		26
Value of services obtained from employees				114		114		114
Tax effect of exercise of stock options				1		1		1
Step acquisition <sup>(4)</sup>		102				102	31	133
Other movements							13	13
<b>Balance at December 31, 2009</b>	<b>2,637</b>	<b>48,317</b>	<b>(526)</b>	<b>1,696</b>	<b>(3,936)</b>	<b>48,188</b>	<b>258</b>	<b>48,446</b>

(1) See Note D.15.7.

(2) Includes discount of 21 million in 2007 (see Note D.15.3.).

(3) See Note D.15.5.

(4) Adjustment to retained earnings prior to acquisition of Zentiva, in particular the impairment loss recognized against the carrying amount of the equity interest in 2007 (see Note D.6.).

The accompanying notes on pages F-12 to F-121 are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED STATEMENTS OF CASH FLOWS**

( million)	Note	Year ended December 31, 2009	Year ended December 31, 2008	Year ended December 31, 2007
<b>Net income attributable to equity holders of the Company</b>		<b>5,265</b>	<b>3,851</b>	<b>5,263</b>
Net income from the held-for-exchange Merial business		(175)	(120)	(151)
Dividends received from Merial		179	116	145
Minority interests, excluding BMS <sup>(1)</sup>		21	19	16
Share of undistributed earnings of associates		34	23	139
Depreciation, amortization and impairment of property, plant and equipment and intangible assets		5,011	5,985	4,664
Gains and losses on disposals of non-current assets, net of tax <sup>(2)</sup>		(25)	(45)	(64)
Net change in deferred taxes		(1,169)	(1,473)	(1,476)
Net change in provisions		161	56	(247)
Cost of employee benefits (stock options and other share-based payments)		114	125	134
Impact of the workdown of acquired inventories remeasured at fair value		27		
Unrealized (gains)/losses recognized in income		(81)	(13)	(506) <sup>(5)</sup>
<b>Operating cash flow before changes in working capital</b>		<b>9,362</b>	<b>8,524</b>	<b>7,917</b>
(Increase)/decrease in inventories		(489)	(84)	(89)
(Increase)/decrease in accounts receivable		(429)	(309)	(60)
Increase/(decrease) in accounts payable		(336)	(28)	(156)
Net change in other current assets, financial assets (current) and other current liabilities		407	420	(506)
<b>Net cash provided by/(used in) operating activities <sup>(3)</sup></b>		<b>8,515</b>	<b>8,523</b>	<b>7,106</b>
Acquisitions of property, plant and equipment and intangible assets	<b>D.3. - D.4.</b>	(1,785)	(1,606)	(1,610)
Acquisitions of investments in consolidated undertakings, net of cash acquired	<b>D.1.</b>	(5,563)	(661)	(214)
Acquisitions of available-for-sale financial assets	<b>D.1.</b>	(5)	(6)	(221)
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>	85	123	329
Net change in loans and other non-current financial assets		(19)	(4)	
<b>Net cash provided by/(used in) investing activities</b>		<b>(7,287)</b>	<b>(2,154)</b>	<b>(1,716)</b>
Issuance of sanofi-aventis shares	<b>D.15.</b>	142	51	271
Dividends paid:				
to sanofi-aventis shareholders		(2,872)	(2,702)	(2,364)
to minority shareholders, excluding BMS <sup>(1)</sup>		(6)	(6)	(9)
Additional long-term borrowings	<b>D.17.</b>	4,697	765	1,639
Repayments of long-term borrowings	<b>D.17.</b>	(1,989)	(1,253)	(2,065)
Net change in short-term borrowings	<b>D.17.</b>	(785)	557	(509)
Acquisition of treasury shares	<b>D.15.4.</b>		(1,227)	(1,806)
Disposals of treasury shares, net of tax	<b>D.15.</b>	26	6	23
<b>Net cash provided by/(used in) financing activities</b>		<b>(787)</b>	<b>(3,809)</b>	<b>(4,820)</b>

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<b>Impact of exchange rates on cash and cash equivalents</b>	<b>25</b>	<b>(45)</b>	<b>(12)</b>
<b>Net change in cash and cash equivalents</b>	<b>466</b>	<b>2,515</b>	<b>558</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>4,226</b>	<b>1,711</b>	<b>1,153</b>
<b>Cash and cash equivalents, end of period</b>	<b>D.13. 4,692</b>	<b>4,226</b>	<b>1,711</b>

- (1) See Note C.1. (i)  
(2) Including available-for-sale financial assets.  
(3) Including:

Income tax paid	(2,981)	(2,317)	(3,030)
Interest paid	(269)	(317)	(315)
Interest received	88	132	88
Dividends received from non-consolidated entities	5	5	3

- (4) Property, plant and equipment, intangible assets, investments in consolidated subsidiaries and participating interests.  
(5) Arising primarily on the translation of U.S. dollar surplus cash from American subsidiaries transferred to the sanofi-aventis parent company.

The accompanying notes on pages F-12 to F-121 are an integral part of the consolidated financial statements.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**Year ended December 31, 2009**

***INTRODUCTION***

Sanofi-aventis is a global healthcare group engaged in the research, development, manufacture and marketing of healthcare products, drugs and vaccines. The sanofi-aventis pharmaceutical portfolio includes flagship products, together with a broad range of prescription and generic drugs and consumer health products.

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, 2009, and the notes thereto, were adopted by the sanofi-aventis Board of Directors on February 9, 2010.

***A. BASIS OF PREPARATION***

**A.1. International Financial Reporting Standards (IFRS)**

The consolidated financial statements cover the twelve-month periods ended December 31, 2009, 2008 and 2007.

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, 2009.

The consolidated financial statements of sanofi-aventis as of December 31, 2009 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, 2009.

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

IFRS adopted by the European Union as of December 31, 2009 are available under the heading IASs/IFRSs, Standards and Interpretations 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, 2009 are described in Note A.2. Standards, amendments and interpretations issued by the IASB but not mandatorily applicable in 2009 are described in Note B.28.

### **A.2. New standards, amendments and interpretations applicable in 2009**

In 2009, the IASB issued an amendment to IFRS 7 (Financial Instruments: Disclosures). This amendment, which defines a three-level hierarchy for fair value measurement methods, is applicable from 2009 onwards and has been adopted by the European Union. The disclosures required under this amendment are supplied in Note B.8.6. Fair value of financial instruments .

During the period, the IASB issued amendments to IFRIC 9 (Reassessment of Embedded Derivatives) and to IAS 39 (Financial Instruments: Recognition and Measurement) relating to embedded derivatives. These amendments, which have been adopted by the European Union, are applicable to financial periods ending on or after June 30, 2009. They specify the treatment to be applied to embedded derivatives where non-derivative financial assets are reclassified out of the held-for-trading category. Because sanofi-aventis does not make such reclassifications, these amendments do not apply to its consolidated financial statements.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

In 2009, sanofi-aventis applied for the first time the following standards and standards amendments, all of which were issued by the IASB in 2008 and earlier and have been adopted by the European Union:

IFRS 8, (Operating Segments), which replaces IAS 14. Under IFRS 8, published segment information must be prepared on the basis of data used internally to measure the performance of segments and to allocate resources between segments. Sanofi-aventis reviewed its operating segments during 2009, and now reports information for two operating segments, Pharmaceuticals and Human Vaccines (Vaccines). All other activities are combined in a separate segment, Other. Previously, sanofi-aventis reported two segments, Pharmaceuticals and Vaccines, under IAS 14. Operating segment information is disclosed in Note D.34. Split of net sales and Note D.35. Segment information .

The revised version of IAS 1 (Presentation of Financial Statements). Sanofi-aventis applies the recommendations of the revised IAS 1 in presenting its financial statements, including (i) presentation of income and expense recognized directly in equity separately from the consolidated income statement, in a consolidated statement of comprehensive income; (ii) separate presentation of income tax for each component of other comprehensive income recognized directly in equity; and (iii) separate presentation of reclassifications from equity to profit or loss. IAS 1 also requires an opening balance sheet to be presented in the event of retrospective restatement of an entity's balance sheet; sanofi-aventis did not make any such retrospective restatements in 2009.

Amendment to IAS 23 (Borrowing Costs). Under this amendment, entities are now required to capitalize borrowing costs directly attributable to the acquisition or in-house construction of items of property, plant and equipment. The optional treatment of recognizing such costs as an expense is no longer permitted. Because sanofi-aventis elected to capitalize such costs on first-time adoption of IFRS, application of this amendment in 2009 had no impact on the consolidated financial statements.

Amendment to IFRS 2 (Share-Based Payment). This amendment relates to the definition of vesting conditions, and to the accounting treatment of cancellations. Application of this amendment in 2009 had no impact on the consolidated financial statements.

The first Annual Improvements to IFRSs standard, issued in 2008. The most relevant amendments to sanofi-aventis are described below. They are not inconsistent with the standards they amend, because they merely provide clarification to the existing text; and they have no impact on the consolidated financial statements of sanofi-aventis, because the accounting treatment applied by sanofi-aventis already complied with the treatment proposed in the amendments.

Amendments to IAS 28 (Investments in Associates), IAS 32 (Financial Instruments: Presentation) and IFRS 7 (Financial Instruments: Disclosures), relating to impairment of an investment in an associate. These amendments specify that if an investment in an associate is impaired, the impairment loss cannot be allocated to any asset (in particular, goodwill) that forms part of the carrying amount of the investment. Consequently, the impairment loss may be reversed in the event of a subsequent improvement in the recoverable amount of the investment.

Amendment to IAS 38 (Intangible Assets), relating to advertising and promotional activities. Under this amendment, promotional expenses involving the supply of goods are recognized when the Group has a right to access those goods, and promotional expenses involving the supply of services are recognized when the Group receives that service. Prepayments are recognized as an asset until the Group obtains access to the goods or receives the service.

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

The following interpretations have been adopted by the European Union, and are mandatorily applicable, according to the IASB, with effect from 2009:

IFRIC 13 (Customer Loyalty Programmes), which sets out the accounting treatment for awards granted by entities to their customers in connection with the sale of goods or services. Because sanofi-aventis does not grant awards of this nature at present, this interpretation has no impact on the consolidated financial statements.

F-13



---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

IFRIC 15 (Agreements for the Construction of Real Estate), which clarifies whether revenue arising from sales of real estate assets (in particular off-plan sales) should be recognized using the percentage of completion method or on completion. This interpretation does not apply to the activities carried on by sanofi-aventis.

IFRIC 16 (Hedges of a Net Investment in a Foreign Operation), which clarifies the nature of the hedged risk and the accounting treatment of this type of hedge. The only risk to which hedge accounting may be applied is the risk relating to differences arising between the functional currency of the foreign operation and the functional currency of the intermediate or ultimate parent entity. In the event of disposal of the hedged foreign operation, the effective portion of the hedge initially recognized in other comprehensive income is reclassified to profit or loss, as is the portion of the foreign currency translation reserve that relates to the divested operation. The first-time application of IFRIC 16 did not generate a material impact on the consolidated financial statements of sanofi-aventis.

IFRIC 18 (Transfer of Assets from Customers). This interpretation, which has been adopted by the European Union, specifies the treatment of transfers of items of property, plant and equipment from a customer to a public service operator; it has no impact on the consolidated financial statements of sanofi-aventis, since the Group is not involved in this type of activity.

**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.);

provisions relating to product liability 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.);

the amount of provisions for restructuring, tax risks, environmental risks and litigation (see Note B.12.).

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).

Companies over which sanofi-aventis exercises significant influence are accounted for by the equity method.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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 recorded 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, 2009**

Where the contractual arrangements for a business combination include an adjustment to the cost of the combination contingent upon future events, this adjustment is included in the cost of the combination at the acquisition date if the adjustment is probable and can be measured reliably.

If the adjustment is not probable or cannot be measured reliably, it is not included in the cost of the combination on initial recognition of the combination. If the adjustment subsequently becomes probable and reliably measurable, the additional consideration is treated as an adjustment to the cost of the combination (i.e. as an adjustment to goodwill).

Where control is acquired in stages, goodwill is determined at each stage as the excess of the cost of the transaction over the fair value of the share of assets acquired at each successive transaction date. The remeasurement of the fair value of the previously-held equity interest is recognized in equity on the line *Remeasurement of previously-held equity interests*.

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.

New accounting rules for business combinations will apply from 2010. The principal changes arising from these rules are described in Note B.28.

Purchase price allocations are performed under the responsibility of management, with assistance from an independent valuer in the case of major acquisitions.

**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*.

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

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.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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.

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

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

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, upfront and milestone payments to third parties related to pharmaceutical products for which regulatory marketing approval has not yet been obtained are recognized as intangible assets, and 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.



**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

**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.

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 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.

Rights to products sold by the Group are amortized on a straight line basis over their useful lives, which are in a range from 5 to 20 years. Useful lives are determined on the basis of cash flow forecasts that take account of (among other factors) the period of legal protection of the related patents.

**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.

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

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

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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.

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.

**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.

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

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.

Under IAS 36, each CGU to which goodwill is allocated must (i) represent the lowest level within the entity at which the goodwill is monitored for internal management purposes, and (ii) not be larger than an operating

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

segment determined in accordance with IFRS 8 (Operating Segments), before application of the IFRS 8 aggregation criteria. Consequently, the CGUs used by sanofi-aventis to test goodwill for impairment correspond to the geographical sub-segments of each operating segment.

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 seven 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 are allocated between CGUs on a basis that is reasonable, and consistent with the allocation of the corresponding goodwill.

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*.

**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 or exchange**

In accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations), non-current assets and groups of assets must be classified as held for sale in the balance sheet if their carrying amount will be recovered principally through a sale transaction rather than through continuing use. Within the meaning of IFRS 5, the term *sale* also includes exchanges for other assets.

Non-current assets or asset groups held for sale must be available for immediate sale in their present condition, subject only to terms that are usual and customary for sales of such assets, and a sale must be highly probable. Criteria used to determine whether a sale is highly probable include:

the appropriate level of management must be committed to a plan to sell;

an active program to locate a buyer and complete the plan must have been initiated;

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

the asset must be actively marketed for sale at a price that is reasonable in relation to its current fair value;

the sale should be completed within 12 months from the date of classification as held for sale or exchange;

actions required to complete the plan should indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn.

Before the initial classification of the non-current asset (or asset group) as held for sale or exchange, the carrying amounts of the asset (or of all the assets and liabilities in the asset group) must be measured in accordance with the applicable standards.

Subsequent to classification as held for sale or exchange, the non-current asset (or asset group) is measured at the lower of carrying amount or fair value less costs to sell, with any write-down recognized by means of an impairment loss. Once a non-current asset has been classified as held for sale or exchange, it is no longer depreciated or amortized.

In the absence of any specific indication in the current IFRS 5 as to how to account for a partial disposal of an equity interest leading to loss of control, sanofi-aventis has adopted the following treatment: all the assets and liabilities included in a partial disposal of an equity interest leading to loss of control are classified in the balance sheet line items *Assets held for sale or exchange* or *Liabilities related to assets held for sale or exchange*, provided that the partial disposal satisfies the IFRS 5 classification criteria. This presentation is consistent with that adopted by the IASB in the amendment to IFRS 5 (IFRS 5, paragraph 8A), issued in May 2008 as part of the Annual Improvements to IFRSs standard, relating to a disposal resulting in loss of exclusive control. This amendment will be mandatorily applicable effective January 1, 2010 (see Note B.28.).

The profit or loss generated by a held-for-sale asset group is reported on a separate line in the income statement for the current period and for the comparative periods presented, provided that the asset group:

represents a separate major line of business or geographical area of operations; or,

is part of a single co-ordinated plan to dispose of a separate major line of business or geographical area of operations; or,

is a subsidiary acquired exclusively with a view to resale.

**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.

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*.



---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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*.

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 comprehensive income 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 measured reliably.

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, 2009, 2008 or 2007.

#### 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***.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

**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.

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.

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 trade receivables are recognized under *Selling and general expenses* 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.

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.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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.

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 comprehensive income. 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 comprehensive income. 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.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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.

**B.8.6. Fair value of financial instruments**

Under IFRS 7, fair value measurements must be classified using a fair value hierarchy with the following levels:

Level 1: quoted prices in active markets for identical assets or liabilities (without modification or repackaging);

Level 2: quoted prices in active markets for similar assets and liabilities, and valuation techniques in which all important inputs are derived from observable market data;

Level 3: valuation techniques in which not all important inputs are derived from observable market data.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

The table below sets forth the principles used to measure the fair value of the principal financial assets and liabilities recognized by sanofi-aventis in its consolidated balance sheet:

Note	Type of financial instrument	Measurement principle applied in the consolidated balance sheet	Level in the IFRS 7 hierarchy of fair value as disclosed in the notes to the consolidated financial statements	Method used to determine fair value as disclosed in the notes to the consolidated financial statements			
				Valuation model	Exchange rate	Interest rate	Volatility
D.7.	Available-for-sale financial assets (quoted securities)	Fair value	1	Quoted market price		N/A	
D.7.	Long-term loans and advances	Amortized cost	N/A	The amortized cost of long-term loans and advances at the balance sheet date is not materially different from their fair value.			
D.7.	Assets recognized under the fair value option <sup>(1)</sup>	Fair value	1	Market value (net asset value)		N/A	
D.20.	Forward currency contracts	Fair value	2	Present value of future cash flows	ECB Fixing	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon	N/A
D.20.	Currency options	Fair value	2	Options with no knock-out feature:  Garman & Kohlhagen  Knock-out options: Merton, Reiner & Rubinstein	ECB Fixing	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon	Mid in-the-money
D.20.	Interest rate swaps	Fair value	2	Present value of future cash flows	N/A	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon	N/A
D.20.	Cross-currency swaps	Fair value	2	Present value of future cash flows	ECB Fixing	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon	N/A
D.13.		Fair value	1	Market value		N/A	



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

	Investments in collective investment schemes		(net asset value)	
<b>D.13.</b>	Negotiable debt instruments, sight deposits and term deposits	Amortized cost	N/A	Because these instruments have a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as disclosed in the notes to the consolidated financial statements
<b>D.17.</b>	Financial liabilities	Amortized cost <sup>(2)</sup>	N/A	For financial liabilities with a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as disclosed in the notes to the consolidated financial statements

For financial liabilities with a maturity of more than 3 months, fair value as disclosed in the notes to the consolidated financial statements is determined either by reference to quoted market prices at the balance sheet date (quoted instruments) or by discounting the future cash flows based on observable market data at the balance sheet date (unquoted instruments).

<sup>(1)</sup> These assets are held to fund a deferred compensation plan offered to certain employees, included in the obligations described in Note D.18.1.

<sup>(2)</sup> In the case of financial liabilities designated as hedged items in a fair value hedging relationship, the carrying amount in the consolidated balance sheet includes changes in fair value relating to the hedged risk(s).

The other financial assets and liabilities included in the Group balance sheet are the following:

Non-derivative current financial assets and liabilities: due to their short-term maturity, the fair value of these instruments approximates their carrying amount, i.e., historical cost less any credit risk allowance.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

Investments in equity instruments not quoted in an active market: in accordance with IFRS 7 the fair value of these instruments is not disclosed because their fair value cannot be measured reliably.

Contingent considerations as part of business combinations: in accordance with IFRS 3, a financial liability is recognized if payment is more likely than not and a reliable estimate is determinable. The fair value of these financial liabilities is determined by discounting this estimate at the balance sheet date.

**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 expired.

**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.

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

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.

### **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

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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*.

Provisions relating to the insurance programs in which the Group's captive insurance company participates are based on risk exposure estimates calculated by management, with assistance from independent actuaries, using IBNR (Incurred But Not Reported) techniques. These techniques use past claims experience, within the Group and in the market, to estimate future trends in the cost of claims.

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; 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

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

(Revenue). In particular, the contracts between sanofi pasteur and government agencies specify terms for the supply and acceptance of batches of vaccine; revenue is recognized when these conditions are met.

The Group 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 countries where product returns are possible, sanofi-aventis has implemented a returns policy that allows the customer to return products within a certain period either side of the expiry date (usually 6 months before and 12 months after the expiry date). The provision is estimated on the basis of past experience of product returns.

The Group also takes account of factors such as levels of inventory in its various distribution channels, product expiry dates, information about potential discontinuation of products, the entry of competing generics into the market, and the launch of over-the-counter medicines.

In each case, the provisions are subject to continuous review and adjustment as appropriate based on the most recent information available to management.

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

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.

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, 2009**

**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. The industrial cost of goods sold includes the cost of materials, depreciation of property, plant and equipment and software, personnel costs, and other expenses attributable to production.

**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 in respect of product marketing agreements. 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 line items 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 85 of the revised IAS 1 (Presentation of Financial Statements), because it is relevant to an understanding of the Group's financial performance. This line item allows the Group to present

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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 carry-forwards. 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, 2009**

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 carry-forwards existing at the date of the combination, a corresponding reduction is made to the amount of goodwill.

*Income tax expense* includes the effect of tax disputes, and any penalties and late payment interest arising from such disputes.

**B.23. Employee benefit obligations**

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

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. The amount of the liability is recognized net of the 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, 2009**

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 comprehensive income, 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 as an expense.

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 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. The expense recognized in this evaluation takes into account 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.24.3. Restricted share plans**

Sanofi-aventis may award restricted share plans to certain of its employees. The terms of these plans may make the award contingent on performance criteria for some grantees.

In accordance with IFRS 2, an expense equivalent to the fair value of such plans is recognized on a straight line basis over the vesting period of the plan. Performance conditions are vesting conditions, and are built into the fair value of the plan. Depending on the country, the vesting period of such plans is either two or four years. Plans with a two-year vesting period are subject to a two-year 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.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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 restricted share issue, earnings per share for prior periods is adjusted accordingly.

**B.26. Segment information**

In accordance with IFRS 8 (Operating Segments), the segment information reported by sanofi-aventis is prepared on the basis of internal management data provided to the Chief Executive Officer, who is the Group's chief operating decision maker. The performance of these segments is monitored individually using internal reports and common indicators.

Sanofi-aventis reports information for two operating segments: Pharmaceuticals and human Vaccines (Vaccines). All other activities are combined in a separate segment, Other. These segments reflect the Group's internal organizational structure, and are used internally for performance measurement and resource allocation.

Information on operating segments is provided in Note D.34. Split of net sales and Note D.35. Segment information .

**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 award of restricted 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, 2009**

Total equity includes *Equity attributable to equity holders of the Company* and *Minority interests*, as shown on the consolidated balance sheet. 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 2010 onwards**

New standards and interpretations applied in the consolidated financial statements for the first time in 2009 are described in Note A.2. New standards, amendments and interpretations applicable in 2009 .

The note below describes standards, amendments and interpretations issued by the IASB that will be mandatorily applicable in 2010 or subsequent years, and the Group's position regarding future application.

***Standards and amendments applicable to the sanofi-aventis consolidated financial statements***

At the start of 2008, the IASB issued revised versions of IFRS 3 (Business Combinations) and IAS 27 (Consolidated and Separate Financial Statements). These revised standards have been adopted by the European Union, and will be applied by sanofi-aventis to business combinations and transactions resulting in loss of control completed from 2010 onwards. The main changes introduced by these revised standards are described below.

The revised IFRS 3 (Business Combinations), which is applicable to financial periods beginning on or after July 1, 2009, changes the way in which the acquisition method is applied. Firstly, the revised standard introduces an option to calculate goodwill on the basis of either (i) the entire fair value of the acquiree, or (ii) a share of the fair value of the acquiree proportionate to the interest acquired. This option may be elected for each acquisition individually. Secondly, in the case of a step acquisition, the previously-held equity interest in the acquiree must be remeasured at its acquisition-date fair value, with the difference between this fair value and the carrying amount taken to profit or loss, along with any gains or losses relating to the previously-held interest that were initially recognized directly in equity (other comprehensive income) and are reclassifiable to profit or loss. Thirdly, contingent purchase consideration must be recognized at fair value at the acquisition date irrespective of the probability of payment, with the obligation to pay recognized either as a liability or as equity; if this obligation is initially recognized as a liability, subsequent adjustments must be recognized in profit or loss. Finally, acquisition-related costs must now be recognized as an expense at the acquisition date, and deferred tax assets not recognized at the acquisition date (or during the twelve-month remeasurement period) that are subsequently recognized must be recognized directly as a gain.

The amendments to IAS 27 (Consolidated and Separate Financial Statements) apply to financial periods beginning on or after July 1, 2009, and change the way in which entities account for transactions with non-controlling interests: under the revised standard, the impact of such transactions must be recognized in equity provided there is no change of control. In addition, in the

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

event of a partial disposal resulting in loss of control, the retained equity interest must be remeasured at fair value; the gain or loss recognized on the disposal will include the effect of this remeasurement and the gain or loss on the sale of the shares, including items initially recognized in equity and reclassified to profit or loss.

In 2008, the IASB issued an amendment to IAS 39 (Financial Instruments: Recognition and Measurement), applicable to financial periods beginning on or after July 1, 2009, relating to eligibility for hedge accounting. In particular, the amendment specifies (i) the conditions under which the inflation risk on a debt instrument is eligible for hedge accounting, and (ii) the treatment to be applied to the ineffectiveness of the time value element of options designated as hedges. This amendment has no impact on the consolidated financial statements of sanofi-aventis because (i) the Group has not issued any inflation-linked debt instruments and (ii) the accounting treatment applied by the Group to the time value element of options designated as hedges already complies with the treatment specified by the amendment. This amendment has been adopted by the European Union.

F-35

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The first Annual Improvements to IFRSs standard, issued in 2008, includes an amendment to IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations), mandatorily applicable simultaneously with application of the revised IAS 27. This amendment clarifies the treatment under IFRS 5 of partial disposals resulting in loss of control, and specifies that in such cases all assets and liabilities of the subsidiary must be classified as held for sale. This standard has been adopted by the European Union and is applicable to financial periods beginning on or after July 1, 2009. The practice applied by sanofi-aventis already complies with this amendment (see Note B.7.).

In April 2009, the IASB issued the second Annual Improvements to IFRSs standard. The most relevant amendments to sanofi-aventis are described below. They are not inconsistent with the standards they amend, because they merely provide clarification to the existing text, and sanofi-aventis does not expect their application to have a material impact. This standard has not yet been adopted by the European Union.

IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations). This amendment, applicable to financial periods beginning on or after January 1, 2010, clarifies that the disclosures required in respect of non-current assets classified as held for sale or discontinued operations are limited to (i) the disclosures specified in IFRS 5 and (ii) specific disclosures required under other IFRSs in respect of non-current assets classified as held for sale or discontinued operations.

IFRS 8 (Operating Segments). This amendment is applicable to financial periods beginning on or after January 1, 2010, and clarifies that segment information about total assets is only required if this information is regularly provided to the entity's chief operating decision maker.

IAS 18 (Revenue). The appendix to IAS 18 has been supplemented by examples to help determine whether an entity is acting as principal or agent in a transaction.

Amendment to IAS 36 (Impairment of Assets). This amendment is applicable to financial periods beginning on or after January 1, 2010, and specifies that the segments used in allocating goodwill must correspond to segments as defined in IFRS 8 before aggregation.

Amendment to IAS 38 (Intangible Assets), on measuring the fair value of intangible assets acquired in a business combination. The amendment, applicable to financial periods beginning on or after July 1, 2009, clarifies the criteria for the identification of intangible assets acquired in a business combination and accounted for separately from goodwill. A further change clarifies the scope of fair value measurement techniques for intangible assets for which there is no active market.

Amendment to IAS 39 (Financial Instruments: Recognition and Measurement) on cash flow hedge accounting. These changes, which apply to financial periods beginning on or after January 1, 2010, confirm that gains or losses on a hedged item must be reclassified from equity to profit or loss in the same period as that in which the hedged forecast cash flows affect profit or loss.

In late 2009, the IASB issued the following standards and amendments, of which only the amendment to IAS 32 had been adopted by the European Union at the balance sheet date:

Amendment to IAS 24 (Related Party Disclosures). This amendment, applicable to financial periods beginning on or after January 1, 2011, sets out the disclosure requirements in respect of future commitments related to a particular event involving

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

related parties. Sanofi-aventis already discloses such information. The amendment also aims to simplify the disclosure requirements for entities that are related to a government department or agency; this part of the amendment does not apply to sanofi-aventis.

IFRS 9 (Financial Instruments). This standard is intended to replace IAS 39 (Financial Instruments: Recognition and Measurement); it completes the first of the three phases of the IASB financial instruments project, and deals solely with the classification and measurement of financial assets. This standard will be applicable to financial periods beginning on or after January 1, 2013.

Amendment to IAS 32 (Financial Instruments: Disclosure), on the classification of rights issues. This amendment is applicable to financial periods beginning on or after February 1, 2010, and deals

---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

with issues of subscription rights in a currency other than the issuer's functional currency. To date, such issues have been accounted for as derivatives (i.e. as a liability). Under the amendment, subscription rights must be recognized as equity when certain conditions are met, irrespective of the currency in which the exercise price is expressed. Because sanofi-aventis has not issued any instruments of this type, this amendment does not apply to the consolidated financial statements.

***Standards and amendments not applicable to the sanofi-aventis consolidated financial statements***

The IASB issued the following amendments (not yet adopted by the European Union) in 2009 and early 2010:

Amendment to IFRS 2 (Share-Based Payment), relating to group cash-settled share-based payment transactions. This amendment, applicable from January 1, 2010, clarifies how the subsidiary of a group (within the meaning of IAS 27, Consolidated and Separate Financial Statements) should account for some group and treasury share-based payment transactions in its individual financial statements. These amendments relate solely to individual financial statements or to the financial statements of sub-groups reporting under IFRS, and hence have no impact on the consolidated financial statements of sanofi-aventis. The amendments to IFRS 2 also incorporate guidance previously included in IFRIC 8 (Scope of IFRS 2) and IFRIC 11 (IFRS 2 – Group and Treasury Share Transactions).

Amendments to IFRS 1 (First-Time Adoption of IFRS), one allowing additional exemptions for first-time adopters, the other relating to IFRS 7. These amendments are applicable from 2010, but relate solely to first-time adopters of IFRS and hence have no impact on the consolidated financial statements of sanofi-aventis.

***New interpretations***

The IASB has also issued the following interpretations, which are mandatorily applicable from 2010 onwards:

IFRIC 17 (Distributions of Non-cash Assets to Owners). This interpretation, which has been adopted by the European Union and is applicable to financial periods beginning on or after July 1, 2009, specifies that a distribution of non-cash assets as dividend must be recognized when it has been duly authorized by the competent body, and measured at the fair value of the assets distributed. At the end of each reporting period and at the date of settlement, the fair value of these assets is reviewed, and the amount of dividend payable is adjusted via equity. When the dividend is settled, any difference between the carrying amount of the assets distributed and the carrying amount of the dividend payable is recognized in profit or loss. Because sanofi-aventis does not distribute non-cash assets as dividend, this interpretation is not applicable to its consolidated financial statements.

IFRIC 19 (Extinguishing Financial Liabilities with Equity Instruments). This interpretation, which applies to financial periods beginning on or after July 1, 2010 and has not yet been adopted by the European Union, addresses the classification and measurement methods to be used by an entity when the terms of a financial liability are renegotiated and result in the entity issuing equity instruments to a creditor to extinguish all or part of the financial liability. Given the absence of any transaction falling within the scope of this interpretation, IFRIC 19 does not apply to the consolidated financial statements of sanofi-aventis.

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

Amendment to IFRIC 14 (IAS19 – The Limit on a Defined Benefit Asset, Minimum Funding Requirements and their Interaction). This amendment, applicable to financial periods beginning on or after January 1, 2011 and not yet adopted by the European Union, is intended to clarify the scope and terms of IFRIC 14. It specifies the conditions for the application of IFRIC 14 to contributions intended to meet minimum funding requirements, and will be applicable from 2011 onwards. Sanofi-aventis does not expect this interpretation to have a material effect on its consolidated financial statements.

F-37

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

***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. 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.

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.

In the territory managed by sanofi-aventis, operations are recognized by the Group as follows:



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

- (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.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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 Warner Chilcott (previously with Procter & Gamble Pharmaceuticals) (the Alliance Partner )**

Actonel® (risedronate sodium) is a new-generation biphosphonate indicated for the treatment and prevention of osteoporosis. Historically, Actonel® was developed and marketed in collaboration with Procter & Gamble Pharmaceuticals. Procter & Gamble sold its pharmaceutical interests to Warner Chilcott on October 30, 2009. Consequently, Actonel® has since that date been marketed in collaboration with Warner Chilcott.

This alliance agreement 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 parties to the alliance agreement (sanofi-aventis or the Alliance Partner) invoices product sales. Co-promotion is carried out under contractual agreements and is not based on any specific legal entity. The Alliance Partner sells the product and incurs all 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 until December 31, 2008, 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. The share due to the Alliance Partner is recognized in *Cost of sales*.

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

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

The product has been marketed by the Alliance Partner independently in Germany, Belgium and Luxembourg since January 2008; in the Netherlands since April 1, 2008; and in the United Kingdom since January 1, 2009. Sanofi-aventis recognizes its share of revenues under the alliance agreement in *Other operating income*.

In all other territories, sanofi-aventis has exclusive rights to sell the product and recognizes all revenue and expenses from its own operations in its income statement, but in return for these exclusive rights pays the Alliance Partner a royalty based on actual sales. This royalty is recognized in *Cost of sales*.

F-39

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

***D. DETAILED NOTES TO THE FINANCIAL STATEMENTS***

**D.1. Significant acquisitions**

Acquisitions are accounted for using the accounting policies described in Note B.3. Business combinations .

**The principal acquisitions during 2009 were as follows:**

**- Merial**

Further to the agreement signed July 29, 2009, sanofi-aventis completed on September 17, 2009 the acquisition of the interest held by Merck & Co., Inc. (Merck) in Merial Limited (Merial) for a consideration of \$4 billion in cash. Founded in 1997, Merial was previously held jointly (50/50) by Merck and sanofi-aventis, and is now 100% held by sanofi-aventis. Merial is one of the world's leading animal health companies, with sales of \$2.6 billion in 2009. With effect from September 17, 2009, sanofi-aventis has held 100% of the shares of Merial and has exercised exclusive control over the company. In accordance with IAS 27, Merial is accounted for by the full consolidation method in the consolidated financial statements of sanofi-aventis.

In connection with the agreement signed on July 29, 2009, sanofi-aventis also signed a call option agreement giving it the possibility, once the Merck/Schering-Plough merger is completed, of combining Intervet/Schering-Plough Animal Health and Merial in a joint venture held 50/50 by Merck and sanofi-aventis. The terms of the option contract set a value of \$8 billion for Merial. The minimum total value received by Merck and its subsidiaries in consideration for the transfer of Intervet/Schering-Plough to the combined entity would be \$9.25 billion, comprising a minimum value of \$8.5 billion for Intervet/Schering-Plough (subject to potential upward revision after valuations performed by the two parties) and an additional consideration of \$750 million. On completion of the valuation of Intervet/Schering-Plough and after taking account of certain adjustments customary in this type of transaction, a balancing payment would be made to establish 50/50 parity between Merck and sanofi-aventis in the combined entity.

Detailed information about the impact of Merial on the consolidated financial statements of sanofi-aventis at December 31, 2009 is provided in Note D.8. Assets held for sale or exchange .

The provisional purchase price allocation of Merial is shown below:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<i>(\$ million)</i>		<b>Historical cost</b>	<b>Fair value remeasurement</b>	<b>Fair value</b>
Intangible assets		147	4,670	4,817
Property, plant and equipment		740	130	870
Deferred taxes		53	(1,343)	(1,290)
Inventories		492	241	733
Other assets and liabilities		264	(46)	218
<b>Net assets of Merial as of September 17, 2009</b>	<b>a</b>	<b>1,696</b>	<b>3,652</b>	<b>5,348</b>
<b>Share of net assets acquired as of September 17, 2009 (50%)</b>	<b>b</b>			<b>2,674</b>
<b>Goodwill (September 17, 2009 transaction)</b>	<b>c</b>			<b>1,362</b>
<b>Purchase price</b>	<b>d = b+c</b>			<b>4,036<sup>(1)(2)</sup></b>

(1) Includes acquisition-related costs of \$36 million

(2) Equivalent to a net cash outflow of 2,829 million

F-40

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The value of Merial in the consolidated financial statements of sanofi-aventis breaks down as follows:

(\$ million)

<b>Purchase price</b>	<b>d</b>	<b>4,036</b>
<b>+ Carrying amount of the previously-held equity interest in Merial (equity method)</b>		<b>1,765</b>
<b>+ Remeasurement of the previously-held equity interest (50%), excluding goodwill</b>	<b>See D.15.7.</b>	<b>1,358</b>
<b>Total value of Merial in the sanofi-aventis consolidated financial statements as of September 17, 2009</b>		<b>7,159</b>
<b>Comprising:</b>		
- Net assets of Merial as of September 17, 2009	a	5,348
- Goodwill (September 17, 2009)	c	1,362
- Goodwill (August 20, 2004)		449

**- Shantha Biotechnics**

On August 31, 2009, sanofi-aventis acquired ShanH, a company that controls the vaccines company Shantha Biotechnics (Shantha), based in Hyderabad in India. As of December 31, 2009, the Group held approximately 95% of Shantha. Shantha generated net sales of approximately 50 million in 2009.

Shantha has generated net sales of 17 million since the acquisition date.

The provisional purchase price allocation is shown below:

( million)	Historical cost	Fair value remeasurement	Fair value
Intangible assets		374	374
Property, plant and equipment	26	96	122
Deferred taxes	(3)	(160)	(163)
Other assets and liabilities	1	(1)	
<b>Net assets of Shantha as of August 31, 2009</b>	<b>24</b>	<b>309</b>	<b>333</b>
<b>Assets and liabilities attributable to minority interests</b>			<b>12</b>
<b>Share attributable to equity holders of the Company</b>			<b>321</b>
<b>Goodwill</b>			<b>250</b>
<b>Purchase price</b>			<b>571</b>

**- BiPar**

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

On April 27, 2009, sanofi-aventis acquired 100% of BiPar Sciences (BiPar), an American biopharmaceutical company developing novel tumorselective approaches for the treatment of different types of cancers. BiPar is the leading company in the emerging field of DNA (DeoxyriboNucleic Acid) repair using Poly ADP-Ribose Polymerase (PARP) inhibitors. The pivotal Phase III trial for BSI-201, BiPar's lead product candidate in metastatic triple negative breast cancer, started in July 2009.

The purchase price is contingent on the achievement (regarded as probable) of milestones related to the development of BSI-201, and could reach \$500 million. Details of commitments related to business combinations are provided in Note D.21.

F-41

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The provisional purchase price allocation of BiPar is shown below:

<i>(\$ million)</i>	<b>Historical cost</b>	<b>Fair value remeasurement</b>	<b>Fair value</b>
Intangible assets <sup>(1)</sup>		715	715
Deferred taxes	26	(257)	(231)
Other assets and liabilities	2		2
<b>Net assets of BiPar as of April 27, 2009</b>	<b>28</b>	<b>458</b>	<b>486</b>
<b>Goodwill</b>			
<b>Purchase price</b>			<b>486</b>

(1) Relates to BSI-201, a product currently in the development phase (see Note D.4.).

**- Medley**

On April 27, 2009, sanofi-aventis acquired 100% of the shares of Medley, Brazil's third largest pharmaceutical company and a leading generics company, with net sales of approximately 160 million in 2008. The purchase price, based on a 500 million enterprise value, was 348 million inclusive of acquisition-related costs.

Since the acquisition date, Medley has generated net sales of 163 million and business operating income (as defined in Note D.35. below) of 58 million. Medley's contribution to net income attributable to equity holders of the Company was 17 million; this figure takes account of expenses charged during the period in relation to the fair value remeasurement of assets at the acquisition date.

The provisional purchase price allocation of Medley is shown below:

<i>( million)</i>	<b>Historical cost</b>	<b>Fair value remeasurement</b>	<b>Fair value</b>
Intangible assets	2	168	170
Property, plant and equipment	35	10	45
Deferred taxes	26	(71)	(45)
Long-term and short-term debt	(118)		(118)
Other assets and liabilities	(89)	2	(87)
<b>Net assets of Medley as of April 27, 2009</b>	<b>(144)</b>	<b>109</b>	<b>(35)</b>
<b>Goodwill</b>			<b>383</b>
<b>Purchase price</b>			<b>348</b>



**- Zentiva**

On March 11, 2009, sanofi-aventis successfully closed its offer for Zentiva N.V. (Zentiva). As of December 31, 2009, sanofi-aventis held about 99.1% of Zentiva's share capital. The purchase price was 1,200 million, including acquisition-related costs. Prior to this acquisition, sanofi-aventis had owned 24.9% of Zentiva, which was accounted for as an associate using the equity method (see Note D.6.). The Zentiva group reported sales of CZK 18,378 million ( 735 million) in 2008.

Since the acquisition date, Zentiva has generated net sales of 457 million and business operating income (as defined in Note D.35. below) of 60 million. The contribution made by Zentiva entities to net income attributable to equity holders of the Company was a loss of 52 million; this figure takes account of expenses charged during the period in relation to the fair value remeasurement of assets at the acquisition date.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The provisional purchase price allocation of Zentiva is shown below:

( million)		Historical cost	Fair value remeasurement	Fair value
Intangible assets		123	853	976
Property, plant and equipment		303	59	362
Deferred taxes		(1)	(176)	(177)
Inventories		100	17	117
Cash and cash equivalents		81		81
Long-term and short-term debt		(633)		(633)
Other assets and liabilities		74	25	99
<b>Net assets of Zentiva as of March 31, 2009</b>	<b>a</b>	<b>47</b>	<b>778</b>	<b>825</b>
<b>Share attributable to minority interests in the Zentiva sub-group</b>	<b>b</b>			<b>35</b>
<b>Equity interest acquired March 31, 2009 (74.2%)</b>	<b>c</b>			<b>586</b>
<b>Goodwill (transaction of March 31, 2009)</b>	<b>d</b>			<b>614</b>
<b>Purchase price</b>	<b>e=c+d</b>			<b>1,200<sup>(1)</sup></b>

(1) Including acquisition-related costs of 10 million

The value of Zentiva in the consolidated financial statements of sanofi-aventis breaks down as follows:

<b>Purchase price</b>	<b>e</b>	<b>1,200</b>
<b>+ Carrying amount of the previously-held equity interest in Zentiva (equity method)</b>		<b>392</b>
<b>+ Remeasurement of the previously-held equity interest (24.9%), excluding goodwill</b>	<i>See D.15.7.</i>	<b>80</b>
<b>Total value of Zentiva in the sanofi-aventis consolidated financial statements as of March 31, 2009</b>		<b>1,672</b>
<b>Comprising:</b>		
- Net assets of Zentiva as of March 31, 2009 (a excluding direct and indirect minority interests)		783
- Goodwill (March 31, 2009)	<b>d</b>	614
- Goodwill (March 31, 2006)		275

The other principal business combinations in the year ended December 31, 2009 were as follows:

Oenobiol (November 2009), one of France's leading players in health and beauty dietary supplements, which generated approximately 57 million of net sales in 2008/2009;

Laboratorios Kendrick (March 2009), one of Mexico's leading manufacturers of generics (2008 net sales: approximately 26 million);

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

Helvepharm (July 2009), a Swiss generics company (2008 net sales: approximately 16 million);

Fovea Pharmaceuticals (October 2009), an ophthalmology company, described in Note D.21.

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.).

F-43

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

**- 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:**

**- Regeneron**

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.).

**D.2. Divestments**

No material divestments occurred during 2009, 2008 or 2007.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009****D.3. Property, plant and equipment**

Property, plant and equipment (including assets held under finance leases) comprise:

( million)	Land	Buildings	Plant & equipment	Fixtures, fittings & other	Property, plant and equipment in process	Total
Gross value at January 1, 2007	233	2,811	4,072	1,212	1,011	9,339
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>
Changes in scope of consolidation	61	245	199	26	13	544
Acquisitions and other increases	1	32	87	63	1,170	1,353
Disposals and other decreases	(3)	(22)	(23)	(157)	(17)	(222)
Translation differences	6	26	24	5	4	65
Transfers	(5)	463	581	122	(1,348)	(187)
<b>Gross value at December 31, 2009</b>	<b>275</b>	<b>4,044</b>	<b>5,847</b>	<b>1,604</b>	<b>1,334</b>	<b>13,104</b>
Accumulated depreciation & impairment at January 1, 2007	(15)	(724)	(1,581)	(779)	(21)	(3,120)
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
Accumulated depreciation & impairment at Dec. 31, 2007	(3)	(888)	(1,976)	(940)	(33)	(3,840)
Depreciation expense		(205)	(476)	(161)		(842)

Edgar Filing: SANOFI-AVENTIS - Form 20-F

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>
Depreciation expense		(238)	(530)	(161)		(929)
Impairment losses	(4)	(73)	(22)	(4)	(5)	(108)
Disposals	2	12	24	148	2	188
Translation differences		(4)	(16)	(3)		(23)
Transfers	3	87	103	(5)		188
<b>Accumulated depreciation &amp; impairment at Dec. 31, 2009</b>	<b>(3)</b>	<b>(1,309)</b>	<b>(2,841)</b>	<b>(1,081)</b>	<b>(40)</b>	<b>(5,274)</b>
Carrying amount: January 1, 2007	218	2,087	2,491	433	990	6,219
Carrying amount: December 31, 2007	210	2,106	2,522	442	1,258	6,538
Carrying amount: December 31, 2008	211	2,207	2,579	489	1,475	6,961
<b>Carrying amount: December 31, 2009</b>	<b>272</b>	<b>2,735</b>	<b>3,006</b>	<b>523</b>	<b>1,294</b>	<b>7,830</b>

F-45

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The Transfers line for the year ended December 31, 2009 mainly comprises reclassifications of assets to *Assets held for sale or exchange*.

Property, plant and equipment pledged as security for liabilities amounted to 15 million as of December 31, 2009 ( 10 million as of December 31, 2008 and 13 million as of December 31, 2007).

Following impairment tests conducted on property, plant and equipment using the method described in Note B.6., an impairment loss of 107 million was recognized in the year ended December 31, 2009 in respect of sites designated as held for sale (principally, Alnwick in the United Kingdom and Porcheville in France), see Note D.8.2. In the year ended December 31, 2008, an impairment loss of 41 million was recognized, primarily on industrial sites in France and the United States. In the year ended December 31, 2007, an impairment loss of 22 million was recognized, principally on industrial sites in Europe.

Acquisitions made in the Pharmaceuticals segment related primarily to investments in industrial facilities ( 496 million in 2009, versus 501 million in 2008 and 536 million in 2007) and in facilities and equipment of research sites ( 325 million in 2009, versus 376 million in 2008 and 374 million in 2007). Acquisitions made in the Vaccines segment totaled 446 million in 2009 (versus 382 million in 2008 and 335 million in 2007). Capitalized borrowing costs amounting to 30 million were included in acquisitions of property, plant and equipment in 2009, versus 24 million in 2008 and 21 million in 2007. Firm orders for property, plant and equipment amounted to 351 million at December 31, 2009, compared with 450 million at December 31, 2008 and 379 million at December 31, 2007.

The table below shows amounts for items of property, plant and equipment held under finance leases:

( million)	December 31, 2009	December 31, 2008	December 31, 2007
Land	7	7	7
Buildings	99	99	97
Other property, plant and equipment	6	7	6
<b>Total gross value</b>	<b>112</b>	<b>113</b>	<b>110</b>
Accumulated depreciation and impairment	(81)	(83)	(77)
<b>Carrying amount</b>	<b>31</b>	<b>30</b>	<b>33</b>

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009****D.4. Intangible assets and goodwill**

Intangible assets and goodwill break down as follows:

( million)	Acquired Aventis R&D	Other Acquired R&D	Rights to marketed Aventis products	Trademarks, patents, licenses and other rights	Software	Total intangible assets
Gross value at January 1, 2007	3,054	187	30,371	1,491	587	35,690
Changes in scope of consolidation				25		25
Acquisitions and other increases		176		136	42	354
Disposals and other decreases		(9)		(2)	(16)	(27)
Translation differences	(175)	(17)	(1,595)	(97)	(20)	(1,904)
Transfers	(235)	(1)	235	1	(6)	(6)
<b>Gross value at December 31, 2007</b>	<b>2,644</b>	<b>336</b>	<b>29,011</b>	<b>1,554</b>	<b>587</b>	<b>34,132</b>
Changes in scope of consolidation		198		139	2	339
Acquisitions and other increases		85		18	47	150
Disposals and other decreases		(74)		(2)	(53)	(129)
Translation differences	109	15	1,008	66	1	1,199
Transfers	(300)	(2)	300	(15)	1	(16)
<b>Gross value at December 31, 2008</b>	<b>2,453</b>	<b>558</b>	<b>30,319</b>	<b>1,760</b>	<b>585</b>	<b>35,675</b>
Changes in scope of consolidation		789		1,405	12	2,206
Acquisitions and other increases		275		62	56	393
Disposals and other decreases		(70)		(1)	(2)	(73)
Translation differences	(45)	(51)	(451)	47	2	(498)
Transfers	(87)	(9)	87	11	2	4
<b>Gross value at December 31, 2009</b>	<b>2,321</b>	<b>1,492</b>	<b>29,955</b>	<b>3,284</b>	<b>655</b>	<b>37,707</b>
Accumulated amortization & impairment at January 1, 2007	(299)	(14)	(10,490)	(710)	(439)	(11,952)
Amortization expense		(7)	(3,486)	(152)	(80)	(3,725)
Impairment losses, net of reversals	11		(69)			(58)
Disposals		1			15	16
Translation differences	21	1	679	51	15	767
Transfers			1		1	2
Accumulated amortization & impairment at Dec. 31, 2007	(267)	(19)	(13,365)	(811)	(488)	(14,950)



Edgar Filing: SANOFI-AVENTIS - Form 20-F

Amortization expense		(29)	(3,277)	(176)	(52)	(3,534)
Impairment losses, net of reversals	(1,233)	(69)	(253)	1		(1,554)
Disposals		71		2	53	126
Translation differences	(2)	(1)	(486)	(37)	1	(525)
Transfers	18		(18)	24	(2)	22
<b>Accumulated amortization &amp; impairment at Dec. 31, 2008</b>	<b>(1,484)</b>	<b>(47)</b>	<b>(17,399)</b>	<b>(997)</b>	<b>(488)</b>	<b>(20,415)</b>
Amortization expense		(70)	(3,155)	(303)	(50)	(3,578)
Impairment losses, net of reversals		(28)	(344)			(372)
Disposals		69		2		71
Translation differences	28	2	288	19	(1)	336
Transfers		2		(4)		(2)
<b>Accumulated amortization &amp; impairment at Dec. 31, 2009</b>	<b>(1,456)</b>	<b>(72)</b>	<b>(20,610)</b>	<b>(1,283)</b>	<b>(539)</b>	<b>(23,960)</b>
Carrying amount: January 1, 2007	2,755	173	19,881	781	148	23,738
Carrying amount: December 31, 2007	2,377	317	15,646	743	99	19,182
Carrying amount: December 31, 2008	969	511	12,920	763	97	15,260
<b>Carrying amount: December 31, 2009</b>	<b>865</b>	<b>1,420</b>	<b>9,345</b>	<b>2,001</b>	<b>116</b>	<b>13,747</b>

F-47

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

Movements in goodwill for the last three financial periods are shown below:

<i>( million)</i>	<b>Gross value</b>	<b>Impairment</b>	<b>Carrying amount</b>
Balance at January 1, 2007	28,499	(27)	28,472
Changes in scope of consolidation	7		7
Disposals and other decreases <sup>(1)</sup>	(63)		(63)
Translation differences	(1,217)		(1,217)
<b>Balance at December 31, 2007</b>	<b>27,226</b>	<b>(27)</b>	<b>27,199</b>
Changes in scope of consolidation	403		403
Disposals and other decreases <sup>(1)</sup>	(6)		(6)
Translation differences	565	2	567
<b>Balance at December 31, 2008</b>	<b>28,188</b>	<b>(25)</b>	<b>28,163</b>
Changes in scope of consolidation	1,882		1,882
Disposals and other decreases <sup>(1)</sup>	(84)		(84)
Translation differences	(228)		(228)
<b>Balance at December 31, 2009</b>	<b>29,758</b>	<b>(25)</b>	<b>29,733</b>

<sup>(1)</sup> Including the effects of deferred taxes recognized subsequent to the acquisition date (see Note D.14.).

**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.

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

Goodwill arising from the acquisition of Aventis amounted to 27,221 million at December 31, 2009, versus 27,632 million at December 31, 2008 and 27,034 million at December 31, 2007.

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, 2009, 83.7% of the carrying amount of these rights related to the Pharmaceuticals segment, and 16.3% to the Vaccines segment. The five principal pharmaceutical products in this portfolio by carrying amount (Lantus<sup>®</sup>/Apidra<sup>®</sup>: 2,166 million, Lovenox<sup>®</sup>: 1,019 million; Taxotere<sup>®</sup>: 756 million; Actonel<sup>®</sup>: 564 million; Allegra<sup>®</sup>: 359 million) accounted for approximately 62.2% of the total carrying amount of product rights for the Pharmaceuticals business as of December 31, 2009.

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<sup>®</sup>-Apidra<sup>®</sup> pens, and new indications for Taxotere<sup>®</sup>.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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.

During 2009, some of the acquired Aventis research and development ( 87 million) came into commercial use; it is being amortized from the date of marketing approval. The main product involved is Sculptra<sup>®</sup> in the United States.

**Other acquisitions**

Increases in intangible assets and goodwill during the year ended December 31, 2009 were mainly due to business combinations completed during the year. Details of the purchase price allocations for the principal acquisitions made during 2009 are provided in Note D.1. Significant acquisitions . The main effects on intangible assets at the acquisition dates are summarized below:

The Shantha purchase price allocation led to the recognition of intangible assets of 374 million and goodwill of 250 million.

The Medley purchase price allocation led to the recognition of intangible assets of 170 million and goodwill of 383 million.

The Zentiva purchase price allocation led to the recognition of intangible assets of 976 million, mainly comprising the value of marketed products and the Zentiva trademark. Goodwill of 894 million was recognized, including the effect of buyouts of minority interests during the period.

In the BiPar purchase price allocation, the principal product under development (BSI-201) was valued at 539 million.

Acquisitions of intangible assets during the year ended December 31, 2009 (other than software and assets recognized in business combinations) totaled 337 million and related primarily to license agreements, including the collaboration agreements signed with Exelixis and Merrimack (see Note D.21.).

The provisional purchase allocations for the principal acquisitions made in 2008 (see Note D.1.) were as follows:

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

The Symbion Consumer purchase price allocation led to the recognition of intangible assets of 116 million. Goodwill arising on this acquisition amounted to 206 million.

The Acambis purchase price allocation led to the recognition of intangible assets of 223 million (of which 198 million related to research projects). Goodwill arising on this acquisition amounted to 197 million.

There were no material adjustments to these purchase price allocations during the year ended December 31, 2009.

Acquisitions of intangible assets (other than software and assets recognized in business combinations) 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.).

Acquisitions of intangible assets (other than software and assets recognized in business combinations ) in 2007 were 312 million. This amount includes payments made under collaboration agreements, including those signed during the year with Oxford BioMedica (Trovax<sup>®</sup>) and Regeneron (see Note D.21.). It also includes the buyout of the Japanese rights for Panaldine<sup>®</sup> (Daiichi) and Myslee<sup>®</sup> (Astellas).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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, 2009	Year ended December 31, 2008	Year ended December 31, 2007
Cost of sales	11	10	18
Research and development expenses	14	14	16
Selling and general expenses	24	28	45
Other operating expenses	1		1
<b>Total</b>	<b>50</b>	<b>52</b>	<b>80</b>

**D.5. Impairment of property, plant and equipment, goodwill and intangibles**

The allocation of goodwill is shown below:

( million)	December 31, 2009			December 31, 2008			December 31, 2007		
	Pharma- ceuticals	Vaccines	Total	Pharma- ceuticals	Vaccines	Total	Pharma- ceuticals	Vaccines	Total
Europe	13,528		13,528	12,414		12,414	12,428		12,428
North America	10,739	680	11,419	11,057	693	11,750	10,577	464	11,041
Other countries	4,368	418	4,786	3,830	169	3,999	3,561	169	3,730
<b>Total carrying amount</b>	<b>28,635</b>	<b>1,098</b>	<b>29,733</b>	<b>27,301</b>	<b>862</b>	<b>28,163</b>	<b>26,566</b>	<b>633</b>	<b>27,199</b>

In 2009, 2008 and 2007, the recoverable amount of the segmental CGUs was determined by reference to the value in use of each CGU, based on discounted estimates of the future cash flows from the CGU in accordance with the policies described in Note B.6.1.

The assumptions used in testing goodwill for impairment in 2009 were:

	Pharmaceuticals	Vaccines
Operating margin (as a percentage of net sales)	29% - 34%	30% - 36%
Perpetual growth rate	1%	1% - 3%

After-tax discount rate	9.5%	9.5%
-------------------------	------	------

These assumptions are reviewed annually.

The operating margin used is the range of values per the strategic plan for each operating segment.

The perpetual growth rate is an average rate by operating segment and geographical area.

The discount rate is the average for all geographical areas within a single operating segment.

Sanofi-aventis also applies assumptions on the probability of success of its current research and development projects, and more generally on its ability to refresh its product portfolio in the longer term.

No impairment losses have been recognized against goodwill in 2009, 2008 and 2007.

Goodwill for the Pharmaceuticals segment relates primarily to Europe and North America. The assumptions used to calculate the value in use of these two CGUs comprise an after-tax discount rate of 9.5% and a perpetual growth rate of 1%. No impairment would need to be recognized unless the discount rate used to calculate value in use were to exceed the 9.5% rate actually used by more than 2.6 percentage points. Similarly, a zero perpetual growth rate would not result in any impairment of the goodwill of these CGUs.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The after-tax discount rates used in 2009 for other intangible assets are shown below:

	<b>Pharmaceuticals</b>	<b>Vaccines</b>
After-tax discount rate		
Acquired in-process R&D	11%	11%
Rights to marketed products	10%	10%

Certain intangible assets for which indications of potential impairment were identified in the years ended December 31, 2009, 2008 and 2007 were tested for impairment.

In 2009, impairment losses of 372 million were recognized based on the results of impairment tests. These losses related mainly to the marketed products Actonel® ( 177 million), Benzaclic® ( 89 million) and Nasacort® ( 70 million), and take account of changes in the competitive environment and the approval dates of generics.

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.

Impairment losses taken against property, plant and equipment are disclosed in Note D.3.

**D.6. Investments in associates**



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

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).

Investments in associates break down as follows:

( million)	% interest	Dec. 31, 2009	Dec. 31, 2008	Dec. 31, 2007
Sanofi Pasteur MSD	50.0	407	427	467
Merial (until September 17, 2009)	50.0	(3)	1,203	1,151
InfraServ Höchst	31.2	95	96	97
Entities and companies managed by Bristol-Myers Squibb (1)	49.9	234	196	178
Zentiva (until March 30, 2009)	24.9	(4)	332(2)	346(2)
Financière des Laboratoires de Cosmétologie Yves Rocher	39.1	123	119	103
Other investments		96	86	151
<b>Total</b>		<b>955</b>	<b>2,459</b>	<b>2,493</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 carrying amount is net of an impairment loss of 102 million recognized in 2007.

(3) Merial has been accounted for by the full consolidation method since September 18, 2009; see Note D.8.

(4) Zentiva has been accounted for by the full consolidation method since March 31, 2009; see Note D.1.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The financial statements include commercial transactions between the Group and certain of its associates:

<i>( million)</i>	<b>2009</b>	<b>2008</b>	<b>2007</b>
Sales	517	432	404
Royalties <sup>(1)</sup>	1,179	1,014	945
Accounts receivable <sup>(1)</sup>	419	370	355
Purchases	247	254	236
Accounts payable	32	30	29
Other liabilities <sup>(1)</sup>	297	242	365

(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:

<i>( million)</i>	<b>Principal associates <sup>(1)</sup></b>			<b>Principal joint ventures <sup>(2)</sup></b>		
	<b>100% impact</b>			<b>Share held by sanofi-aventis</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>
Non-current assets	526	1,919	1,950	27	354	323
Current assets	1,278	2,717	2,788	224	688	687
Non-current liabilities	336	913	1,190	32	99	104
Current liabilities	792	1,798	1,552	178	404	418
Equity attributable to equity holders of the Company	391	1,622	1,712	41	536	486
Minority interests	285	303	284	2	2	2
Net sales	9,325	9,770	9,165	1,203	1,537	1,431
Cost of sales	2,397	2,555	2,371	359	433	394
Operating income	3,144	2,838	2,338	312	372	313
Net income	2,880	2,384	2,054	222	225	206

(1) The figures reported above are full-year figures, before allocation of partnership profits. The following associates are included in this table for 2008 and 2007: BMS/Sanofi Pharmaceuticals Holding Partnership, BMS/Sanofi Pharmaceuticals Partnership, BMS/Sanofi-Synthelabo Partnership, Yves Rocher, Merial, Sanofi Pasteur MSD, and Zentiva. For 2009, figures for Merial are not included in this table with effect from September 18, 2009 (the date since when Merial has been accounted for by the full consolidation method), and figures for Zentiva are not included in this table with effect from March 31, 2009 (the date since when Zentiva has been accounted for by the full consolidation method).

(2) The principal joint ventures are:

Merial (until September 17, 2009)  
Sanofi Pasteur MSD

<b>Partner</b>	<b>Business</b>
Merck & Co., Inc.	Animal Health
Merck & Co., Inc.	Vaccines

**D.7. Financial assets non-current**

The main items included in *Financial assets non-current* are:

<i>( million)</i>	December 31, 2009	December 31, 2008	December 31, 2007
Available-for-sale financial assets	588	491	676
Pre-funded pension obligations (see Note D.18.1.)	3	1	7
Long-term loans and advances	256	186	219
Assets recognized under the fair value option	100	72	85
Derivative financial instruments (see Note D.20.)	51	71	50
<b>Total</b>	<b>998</b>	<b>821</b>	<b>1,037</b>

F-52

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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 248 million at December 31, 2009 ( 195 million at December 31, 2008 and 243 million at December 31, 2007). In November 2007, sanofi-aventis raised 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 did not give sanofi-aventis significant influence over Regeneron.

A 13% interest in ProStrakan, carried at an amount of 25 million as of December 31, 2009 ( 24 million at December 31, 2008 and 23 million at December 31, 2007).

Interests in research and development companies such as Proteome Science ( 2 million at December 31, 2009, 3 million at December 31, 2008 and 9 million at December 31, 2007) and Genfit ( 5 million at December 31, 2009, 4 million at December 31, 2008).

Financial assets held to match commitments ( 269 million at December 31, 2009, 223 million at December 31, 2008 and 306 million at December 31, 2007).

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.).

The cumulative unrealized net after-tax gain recognized directly in equity on available-for-sale financial assets at December 31, 2009 was 38 million. This compares with a cumulative unrealized net after-tax loss of 49 million at December 31, 2008, mainly on the investment in Regeneron ( 49 million), and a cumulative unrealized net after-tax gain of 48 million at December 31, 2007 (see Note D.15.7.).

The impact of a 10% fall in stock prices on quoted shares included in available-for-sale assets at December 31, 2009 would have been as follows:

<i>( million)</i>	<b>Sensitivity</b>
Income/(expense) recognized directly in equity, before tax	(40)
Income before tax	(2)
<b>Total</b>	<b>(42)</b>

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

A 10% fall in stock prices of other available-for-sale financial assets combined with a simultaneous 0.5% rise in the yield curve would have had the following impact at December 31, 2009:

<i>( million)</i>	<b>Sensitivity</b>
Income/(expense) recognized directly in equity, before tax	(16)
Income before tax	
<b>Total</b> <sup>(1)</sup>	<b>(16)</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 31 million at December 31, 2009, against 34 million at December 31, 2008 and 36 million at December 31, 2007.

Long-term loans and advances are measured at amortized cost, which at the balance sheet date was not materially different from their fair value. The increase in long-term loans and advances between December 31, 2008 and December 31, 2009 was mainly due to the indemnification asset in respect of the vendor's guarantee of liabilities recognized on the acquisition of Medley (see Note D.1.).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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 or exchange**

A breakdown as of December 31, 2009 of assets held for sale or exchange, and of liabilities related to assets held for sale or exchange, is shown below:

( million)		December 31, 2009
Merial	D.8.1.	6,338
Other	D.8.2.	4
<b>Total assets held for sale or exchange</b>		<b>6,342</b>
Merial	D.8.1.	1,433
<b>Total liabilities related to assets held for sale or exchange</b>		<b>1,433</b>

**D.8.1. Merial**

On September 17, 2009, sanofi-aventis acquired, in addition to its initial 50% interest in Merial, the remaining 50% interest held by Merck. Simultaneously, a contract was signed whereby once the merger between Merck and Schering-Plough has been completed sanofi-aventis will be able to exercise an option to create a single group combining Merial and Intervet/Schering-Plough, to be held 50% by sanofi-aventis and 50% by Merck/Schering-Plough (see Note D.1.)

With effect from September 17, 2009, sanofi-aventis has had exclusive control over Merial by virtue of its 100% interest in the company, and has accounted for Merial by the full consolidation method. Due to the high probability that the option will be exercised, thereby diluting the interest held by sanofi-aventis in Merial and leading to the loss of exclusive control, the entire interest in Merial has to be accounted for in accordance with IFRS 5, the main principles of which are described in Note B.7.

Consequently, as of December 31, 2009 (in accordance with IFRS 5), the entire assets of Merial are reported on the line *Assets held for sale or exchange*, and the entire liabilities of Merial are reported on the line *Liabilities related to assets held for sale or exchange*. The net income of Merial is reported on the line *Net income from the held-for-exchange Merial business*.



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The table below shows the assets and liabilities of Merial classified in **Assets held for sale or exchange** and **Liabilities related to assets held for sale or exchange** as of December 31, 2009, after elimination of intercompany balances between Merial and other Group companies.

<i>( million)</i>	<b>December 31, 2009</b>
<b>Assets</b>	
Property, plant and equipment and financial assets	684
Goodwill	1,258
Intangible assets	3,347
Deferred tax assets	60
Inventories	425
Accounts receivable	373
Other current assets	64
Cash and cash equivalents	127
<b>Total assets held for sale or exchange</b>	<b>6,338</b>
<b>Liabilities</b>	
Long-term debt	6
Long-term provisions	85
Deferred tax liabilities	966
Short-term debt	22
Accounts payable	124
Other current liabilities	230
<b>Total liabilities related to assets held for sale or exchange</b>	<b>1,433</b>

The components of *Net income from the held-for-exchange Merial business* are shown below:

<i>( million)</i>	<b>Year ended December 31, 2009</b>	<b>Year ended December 31, 2008</b>	<b>Year ended December 31, 2007</b>
<b>Net sales</b> <sup>(2)</sup>	<b>479</b>		
Operating income <sup>(2)</sup>	69		
Net financial income/(expense) <sup>(2)</sup>	2		
Income tax expense <sup>(2)</sup>	(35)		
Share of profit/(loss) of associates <sup>(1)</sup>	139	120	151
<b>Net income from the held-for-exchange Merial business</b>	<b>175</b>	<b>120</b>	<b>151</b>

(1) until September 17, 2009.

(2) from September 18, 2009.





**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The table below sets forth, as required by IFRS 5, disclosures of how net income attributable to equity holders of the Company, net income attributable to minority interests, basic earnings per share and diluted earnings per share are split between activities other than Merial and the held-for-exchange Merial business:

<i>( million)</i>	<b>Year ended December 31, 2009</b>	<b>Year ended December 31, 2008</b>	<b>Year ended December 31, 2007</b>
Net income excluding the held-for-exchange Merial business	5,516	4,172	5,531
Net income from the held-for-exchange Merial business	175	120	151
<b>Net income</b>	<b>5,691</b>	<b>4,292</b>	<b>5,682</b>
<b>- Net income attributable to minority interests:</b>			
Net income excluding the held-for-exchange Merial business	426	441	419
Net income from the held-for-exchange Merial business			
<b>Net income attributable to minority interests</b>	<b>426</b>	<b>441</b>	<b>419</b>
<b>- Net income attributable to equity holders of the Company:</b>			
Net income excluding the held-for-exchange Merial business	5,090	3,731	5,112
Net income from the held-for-exchange Merial business	175	120	151
<b>Net income attributable to equity holders of the Company</b>	<b>5,265</b>	<b>3,851</b>	<b>5,263</b>
<b>- Basic earnings per share:</b>			
Excluding the held-for-exchange Merial business (in euros)	3.90	2.85	3.80
Held-for-exchange Merial business (in euros)	0.13	0.09	0.11
<b>Basic earnings per share (in euros)</b>	<b>4.03</b>	<b>2.94</b>	<b>3.91</b>
<b>- Diluted earnings per share:</b>			
Excluding the held-for-exchange Merial business (in euros)	3.90	2.85	3.78
Held-for-exchange Merial business (in euros)	0.13	0.09	0.11
<b>Diluted earnings per share (in euros)</b>	<b>4.03</b>	<b>2.94</b>	<b>3.89</b>

The table below sets forth the net sales of Merial's principal products, expressed in millions of U.S. dollars:

<i>(\$ million)</i>	<b>Year ended December 31, 2009</b>	<b>Year ended December 31, 2008</b>	<b>Year ended December 31, 2007</b>
Frontline® and other fipronil products	996	1,053	1,033
Vaccines	794	790	675

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Avermectin	475	512	478
Other	289	288	263
<b>Total</b>	<b>2,554</b>	<b>2,643</b>	<b>2,449</b>

The contractual obligations and other commitments of Merial as of December 31, 2009 are as follows:

( million)	Total	Under 1 year	From 1 to 3 years	From 3 to 5 years	Over 5 years
Contractual obligations and other commercial commitments:					
outflows	148	94	29	16	9
inflows	(37)	(33)	(3)		(1)
Total contractual obligations and other commercial commitments	111	61	26	16	8

F-56

Table of Contents

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Year ended December 31, 2009

**D.8.2. Other assets held for sale**

As of December 31, 2009, other assets held for sale relate to the ongoing divestment of the R&D facilities at Alnwick and Porcheville and of an industrial site. An impairment loss of 107 million was charged against these assets (and recognized under **Restructuring costs** in the income statement) prior to their reclassification as 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. These assets were fully written down as of that date.

There were no assets held for sale as of December 31, 2007.

**D.9. Inventories**

Inventories break down as follows:

( million)	December 31, 2009			December 31, 2008			December 31, 2007		
	Gross	Impairment	Net	Gross	Impairment	Net	Gross	Impairment	Net
Raw materials	752	(96)	656	615	(91)	524	607	(83)	524
Work in process	2,456	(241)	2,215	2,028	(226)	1,802	2,073	(230)	1,843
Finished goods	1,709	(136)	1,573	1,449	(185)	1,264	1,534	(172)	1,362
<b>Total</b>	<b>4,917</b>	<b>(473)</b>	<b>4,444</b>	<b>4,092</b>	<b>(502)</b>	<b>3,590</b>	<b>4,214</b>	<b>(485)</b>	<b>3,729</b>

The impact of changes in provisions for impairment of inventories in 2009 was a net expense of 26 million, compared with a net expense of 30 million in 2008 and a net expense of 39 million in 2007.

Impairment taken against inventory at December 31, 2009 relates primarily to the product Ketek®.

Inventories pledged as security for liabilities amount to 10 million at December 31, 2009 (versus 10 million at December 31, 2008).

**D.10. Accounts receivable**

Accounts receivable break down as follows:

<i>( million)</i>	December 31, 2009	December 31, 2008	December 31, 2007
Gross value	6,111	5,391	5,034
Impairment	(96)	(88)	(130)
<b>Net value</b>	<b>6,015</b>	<b>5,303</b>	<b>4,904</b>

The impact of changes in provisions for impairment of accounts receivable in 2009 is a net expense of 5 million (against a net reversal of 7 million in 2008 and a net expense of 17 million in 2007).

The gross value of overdue receivables at December 31, 2009 is 884 million (versus 794 million at December 31, 2008 and 801 million at December 31, 2007).

<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, 2009	<b>884</b>	288	172	132	110	182
December 31, 2008	<b>794</b>	267	146	121	95	165
December 31, 2007	<b>801</b>	218	166	130	115	172

F-57

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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:

<i>( million)</i>	December 31, 2009	December 31, 2008	December 31, 2007
Taxes recoverable	1,019	927	1,185
Other receivables <sup>(1)</sup>	914	781	754
Prepaid expenses	171	173	187
<b>Total</b>	<b>2,104</b>	<b>1,881</b>	<b>2,126</b>

<sup>(1)</sup> 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, 2009	December 31, 2008	December 31, 2007
Interest rate derivatives measured at fair value (see Note D.20.)	18	33	
Currency derivatives measured at fair value (see Note D.20.)	251	348	67
Other current financial assets	8	22	16
<b>Total</b>	<b>277</b>	<b>403</b>	<b>83</b>

**D.13. Cash and cash equivalents**

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<i>( million)</i>	<b>December 31, 2009</b>	<b>December 31, 2008</b>	<b>December 31, 2007</b>
Cash	689	502	831
Cash equivalents <sup>(1)</sup>	4,003	3,724	880
<b>Cash and cash equivalents <sup>(2) (3)</sup></b>	<b>4,692</b>	<b>4,226</b>	<b>1,711</b>

- (1) Cash equivalents at December 31, 2009 comprised 3,128 million invested in collective investment schemes classified as Euro Money-Market Funds by the *Autorité des Marchés Financiers* and 875 million of term deposits.
- (2) Includes cash held by captive insurance and reinsurance companies in accordance with insurance regulations amounting to 430 million at December 31, 2009, 429 million at December 31, 2008, and 420 million at December 31, 2007.
- (3) Includes 81 million held by the Venezuelan subsidiary, which is subject to foreign exchange controls.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009****D.14. Net deferred tax position**

The net deferred tax position breaks down as follows:

<i>( million)</i>	December 31, 2009	December 31, 2008	December 31, 2007
Deferred tax on:			
Consolidation adjustments (intragroup margin in inventory)	858	845	808
Provision for pensions and other employee benefits	1,097	1,070	915
Remeasurement of acquired intangible assets <sup>(1)</sup>	(4,144)	(4,805)	(6,123)
Recognition of Aventis property, plant and equipment at fair value	(99)	(65)	(77)
Tax cost of distributions made from reserves <sup>(2)</sup>	(643)	(769)	(693)
Stock options	21	6	48
Tax losses available for carry-forward (see below)	70	171	266
Other non-deductible provisions and other items	819	799	833
<b>Net deferred tax liability</b>	<b>(2,021)</b>	<b>(2,748)</b>	<b>(4,023)</b>

<sup>(1)</sup> Includes a deferred tax liability of 3,467 million as of December 31, 2009 relating to the remeasurement of Aventis intangible assets.

<sup>(2)</sup> In some 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 7 billion) which the Group regards as likely to be distributed in the foreseeable future (see Note D.30.).

The table below shows when the tax losses available for carry-forward are due to expire:

<i>( million)</i>	Tax loss carry- forwards at December 31, 2009 <sup>(*)</sup>	Tax loss carry- forwards at December 31, 2008 <sup>(*)</sup>	Tax loss carry- forwards at December 31, 2007 <sup>(*)</sup>
2008			63
2009		30	32
2010	8	50	33
2011	19	20	23
2012	21	74	31
2013 and later	594	671	888
<b>Total</b>	<b>642</b>	<b>845</b>	<b>1,070</b>

<sup>(\*)</sup> Excluding tax loss carry-forwards on asset disposals. Tax loss carry-forwards on asset disposals amounted to 597 million at December 31, 2009; 776 million at December 31, 2008; and 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 in place, tax losses can usually be netted against taxable income generated by the entities in the consolidated tax group.

Deferred tax assets not recognized because given the expected results of the entities in question, their future recovery was not considered probable, amount to 486 million at December 31, 2009 (including 99 million on asset disposals), compared with 374 million at December 31, 2008 (including 162 million on asset disposals) and 274 million at December 31, 2007 (including 131 million on asset disposals).

The recognition of deferred tax assets previously unrecognized when accounting for business combination, therefore requiring a corresponding adjustment to goodwill, amount to 88 million at December 31, 2009, 6 million at December 31, 2008, and 43 million at December 31, 2007.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009****D.15. Consolidated shareholders' equity****D.15.1. Share capital**

The share capital of 2,636,958,104 comprises 1,318,479,052 shares with a par value of 2.

Treasury shares held by the Group are as follows:

Closing	Number of shares	%
December 31, 2009	9,422,716	0.71%
December 31, 2008	10,014,971	0.76%
December 31, 2007	37,725,706	2.76%
January 1, 2007	8,940,598	0.66%

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
<b>January 1, 2007</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 on merger of Rhône Cooper into sanofi-aventis	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>
During 2009	Capital increase by exercise of stock subscription options	2,953,589	6	134
<b>December 31, 2009</b>		<b>1,318,479,052</b>	<b>2,637</b>	<b>6,738</b>

For disclosures about the management of capital as required under IFRS 7, refer to Note B.27.

**D.15.2. Restricted share plan**

The meeting of the sanofi-aventis Board of Directors on March 2, 2009 decided to award a restricted share plan. A total of 1,194,064 shares were awarded, 604,004 of which will vest after a four-year service period and 590,060 of which will vest after a two-year service period but will be subject to a further two-year lock-up period (including 65,000 shares which are also contingent upon performance conditions).

In accordance with IFRS 2 (Share-Based Payment), sanofi-aventis has estimated the fair value of this plan on the basis of the fair value of the equity instruments awarded, as representing the fair value of the employee services received during the period.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

Fair value was measured at the date of grant. The fair value of each share awarded corresponds to the quoted market price per share as of that date ( 41.10), adjusted for expected dividends during the vesting period.

The fair value of the restricted share plan was measured at 37 million. This amount is being recognized as an expense over the vesting period, with a corresponding increase in equity. The total expense recognized for this plan during 2009 was 11 million.

As of December 31, 2009, the total number of restricted shares outstanding was 1,181,049.

**D.15.3. Capital increase for employee share ownership plan**

There were no share issues reserved for employees in either 2009 or 2008.

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.

**D.15.4. Repurchase of sanofi-aventis shares**

Sanofi-aventis did not repurchase any of its own shares during 2009.

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).

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).

**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.).

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>	<b>December 31, 2009</b>	<b>December 31, 2008</b>	<b>December 31, 2007</b>
Attributable to equity holders of the Company	(3,965)	(3,669)	(4,631)
Attributable to minority interests	(15)	(16)	(2)
<b>Total</b>	<b>(3,980)</b>	<b>(3,685)</b>	<b>(4,633)</b>

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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 inventories.

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 86 million at December 31, 2009; compared with 98 million as of both December 31, 2008 and December 31, 2007.

**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, 2009	Year ended December 31, 2008	Year ended December 31, 2007
<b>Balance, beginning of period</b>	<b>(4,436)</b>	<b>(4,659)</b>	<b>(2,061)</b>
Available-for-sale financial assets:			
Change in fair value	110 <sup>(1)</sup>	(132)	(5)
Tax effects	(23)	33	(10)
Cash flow hedges:			
Change in fair value	(175) <sup>(2)</sup>	104	8
Tax effects	61	(37)	(3)
Zentiva fair value remeasurement <sup>(3)</sup>			
Change in fair value	108		
Tax effects	(28)		
Merial fair value remeasurement <sup>(3)</sup>			
Change in fair value	1,215		
Tax effects	(293)		
Actuarial gains and losses and impact of asset ceiling:			
Asset ceiling	2	2	(1)
Actuarial gains/(losses) excluding associates and joint ventures (see Note D.18.1.)	(169)	(824)	277
Actuarial gains/(losses) in associates and joint ventures	(2)	(7)	6
Tax effects	36	136	(106)
Change in cumulative translation differences			
Translation differences on foreign subsidiaries	(283) <sup>(4)</sup>	948	(2,764)
Hedges of net investments in foreign operations	(18)		
Tax effects	6		

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<b>Balance, end of period</b>	<b>(3,889)</b>	<b>(4,436)</b>	<b>(4,659)</b>
<i>Attributable to equity holders of the Company</i>	<i>(3,873)</i>	<i>(4,419)</i>	<i>(4,658)</i>
<i>Attributable to minority interests</i>	<i>(16)</i>	<i>(17)</i>	<i>(1)</i>

- (1) Includes reclassifications to profit or loss: ( 1) million in 2009, ( 11) million in 2008, and 11 million in 2007.
- (2) Includes reclassifications to profit or loss: ( 123) million in 2009 and ( 9) million in 2008 in operating income; ( 35) million in 2009 and ( 17) million in 2008 in net financial expense.
- (3) Fair value remeasurement of the previously-held equity interest (Zentiva 24.9%, Merial 50%) as of the date when control was acquired (see Note D.1.).
- (4) Includes translation differences of 7 million arising on Merial since the acquisition date.

F-62

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

**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.

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.

**b) Description of stock option plans**



*2009 stock subscription option plan granted by sanofi-aventis*

On March 2, 2009, the Board of Directors granted 7,736,480 stock subscription options at an exercise price of 45.09 per share.

The vesting period is four years, and the plan expires on March 2, 2019.

*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.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The table shows all sanofi-aventis stock purchase option plans still outstanding or under which options were exercised in the year ended December 31, 2009.

<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, 2009</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	16,600
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	36,970
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	11,870
Synthélabo	03/30/1999	716,040	03/31/2004	03/30/2019	38.08	327,755
Aventis (Hoechst AG)	09/07/1999	2,930,799	09/08/2002	09/07/2009	41.25	
Sanofi-Synthélabo	05/24/2000	4,292,000	05/25/2004	05/24/2010	43.25	1,476,014
Sanofi-Synthélabo	05/10/2001	2,936,500	05/11/2005	05/10/2011	64.50	2,551,739
Sanofi-Synthélabo	05/22/2002	3,111,850	05/23/2006	05/22/2012	69.94	2,901,250
<b>Total</b>						<b>7,380,442</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 440 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.

The table shows all sanofi-aventis stock subscription option plans still outstanding or under which options were exercised in the year ended December 31, 2009.

<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, 2009</b>
Aventis	12/15/1999	5,910,658	01/06/2003	12/15/2009	50.04	
Aventis	05/11/2000	877,766	05/11/2003	05/11/2010	49.65	223,372

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

Aventis	11/14/2000	13,966,871	11/15/2003	11/14/2010	67.93	10,339,911
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	9,650,791
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	5,330,982
Aventis	12/02/2003	12,012,414	12/03/2006	12/02/2013	40.48	5,704,986
Sanofi-Synthélabo	12/10/2003	4,217,700	12/11/2007	12/10/2013	55.74	3,835,070
Sanofi-aventis	05/31/2005	15,228,505	06/01/2009	05/31/2015	70.38	13,531,100
Sanofi-aventis	12/14/2006	11,772,050	12/15/2010	12/14/2016	66.91	11,031,620
Sanofi-aventis	12/13/2007	11,988,975	12/14/2011	12/13/2017	62.33	11,475,985
Sanofi-aventis	03/02/2009	7,736,480	03/03/2013	03/02/2019	45.09	7,645,420

**Total** **80,489,899**

The exercise of all outstanding stock subscription options would increase shareholders' equity by approximately 4,991 million. The exercise of each option results in the issuance of one share.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009***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:

	Number of options	Exercise price Weighted average per share ( )	Total ( million)
Options outstanding at January 1, 2007	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>
Options granted	7,736,480	45.09	349
Options exercised	(3,545,344)	46.69	(165)
Options cancelled <sup>(1)</sup>	(1,000,535)	61.72	(62)
Options forfeited	(625,210)	48.89	(31)
Options outstanding at December 31, 2009	87,870,341	61.87	5,436
<i>Of which exercisable</i>	<i>57,717,316</i>	<i>63.04</i>	<i>3,638</i>

<sup>(1)</sup> Cancellations mainly due to the departure of the grantees.

The table below provides summary information about options outstanding and exercisable as of December 31, 2009:

**Outstanding****Exercisable**

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Range of exercise prices per share	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	43,870	5.19	7.19	43,870	7.19
From 10.00 to 20.00 per share	67,944	6.96	14.90	67,944	14.90
From 20.00 to 30.00 per share	11,870	8.49	28.38	11,870	28.38
From 30.00 to 40.00 per share	327,755	9.25	38.08	327,755	38.08
From 40.00 to 50.00 per share	15,049,792	6.19	43.23	7,404,372	41.31
From 50.00 to 60.00 per share	9,166,052	3.32	53.18	9,166,052	53.18
From 60.00 to 70.00 per share	40,021,167	4.77	66.04	17,513,562	67.92
From 70.00 to 80.00 per share	23,181,891	3.93	70.80	23,181,891	70.80
<b>Total</b>	<b>87,870,341</b>			<b>57,717,316</b>	

*Measurement of stock option plans*

The fair value of the plan awarded in 2009 is 34 million, and the fair value of the plan awarded in 2007 is 143 million.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The following assumptions were used in determining the fair value of these plans:

Dividend yield: 5.72% (2009 plan) and 3.08% (2007 plan).

Volatility of sanofi-aventis shares, computed on a historical basis: 27.06% (2009 plan) and 19.36% (2007 plan).

Risk-free interest rate: 2.84% (2009 plan), 4.21% (2007 plan).

Plan maturity: 6 years (2009 and 2007 plans). The plan maturity is the average expected remaining life of the options, based on observations of past employee behavior.

The fair value of the options granted in 2009 and 2007 is 4.95 and 11.92 per option, respectively.

The expense recognized for stock option plans, and the matching entry taken to shareholders' equity, amounted to 102 million in the year ended December 31, 2009 (including 12 million for the Vaccines segment); 125 million in the year ended December 31, 2008 (including 13 million for the Vaccines segment); and 115 million in the year ended December 31, 2007 (including 10 million for the Vaccines segment).

As of December 31, 2009, the total cost related to non-vested share-based compensation arrangements was 127 million, to be recognized over a weighted average period of 1.93 years. The current tax benefit related to share-based compensation arrangements in 2009 amounted to 2 million (2008: 2 million; 2007: 19 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 millions)</i>	<b>December 31, 2009</b>	<b>December 31, 2008</b>	<b>December 31, 2007</b>
Average number of shares outstanding	1,305.9	1,309.3	1,346.9
Adjustment for options with potentially dilutive effect	1.1	1.6	7.0
Adjustment for restricted shares with potentially dilutive effect	0.4		
<b>Average number of shares used to compute diluted earnings per share</b>	<b>1,307.4</b>	<b>1,310.9</b>	<b>1,353.9</b>

In 2009, a total of 80.3 million stock options were not taken into account in the calculation because they did not have a potentially dilutive effect, compared with 76.2 million in 2008 and 65.4 million in 2007.

**D.16. Minority interests**

Minority interests in consolidated companies break down as follows:

<i>( million)</i>	December 31, 2009	December 31, 2008	December 31, 2007
<b>Minority interests of ordinary shareholders:</b>			
BMS <sup>(1)</sup>	104	111	80
Zentiva	32		
Aventis Pharma Ltd India	73	60	64
Maphar	7	6	6
Sanofi-aventis Pakistan	5	5	6
Shantha Biotechnics	12		
Other	25	23	21
<b>Total</b>	<b>258</b>	<b>205</b>	<b>177</b>

<sup>(1)</sup> 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).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009****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, 2009	December 31, 2008	December 31, 2007
Long-term debt, at amortized cost	5,961	4,173	3,734
Short-term debt and current portion of long-term debt	2,866	1,833	2,207
<b>Total debt</b>	<b>8,827</b>	<b>6,006</b>	<b>5,941</b>
Cash and cash equivalents	(4,692)	(4,226)	(1,711)
<b>Debt, net of cash and cash equivalents</b>	<b>4,135</b>	<b>1,780</b>	<b>4,230</b>

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:

<i>( million)</i>	December 31, 2009	December 31, 2008	December 31, 2007
Debt, net of cash and cash equivalents	4,135	1,780	4,230
Total equity	48,446	45,071	44,719
<b>Gearing ratio</b>	<b>8.5%</b>	<b>3.9%</b>	<b>9.5%</b>

A reconciliation of carrying amount to value on redemption is shown below:

<i>( million)</i>	Carrying amount: Dec. 31, 2009	Amortized cost	Adjustment to debt measured at fair value	Dec. 31, 2009	Value on redemption Dec. 31, 2008	Dec. 31, 2007
Long-term debt	5,961	17	(35)	5,943	4,123	3,686
Short-term debt and current portion of long-term debt	2,866	2	(15)	2,853	1,815	2,187



Edgar Filing: SANOFI-AVENTIS - Form 20-F

<b>Total debt</b>	<b>8,827</b>	<b>19</b>	<b>(50)</b>	<b>8,796</b>	<b>5,938</b>	<b>5,873</b>
Cash and cash equivalents	(4,692)			(4,692)	(4,226)	(1,711)
<b>Debt, net of cash and cash equivalents</b>	<b>4,135</b>	<b>19</b>	<b>(50)</b>	<b>4,104</b>	<b>1,712</b>	<b>4,162</b>

a) Principal financing transactions during the year

The following financing transactions took place during 2009:

CHF250 million fixed-rate bond issue bearing annual interest of 3.25%, fungible with the CHF275 million bond issue maturing December 2012, which is thereby raised to CHF525 million ( 354 million);

1.5 billion fixed-rate bond issue bearing annual interest of 3.5%, maturing May 17, 2013, issued under the EMTN<sup>1</sup> program;

1.5 billion fixed-rate bond issue bearing annual interest of 4.5%, maturing May 18, 2016, issued under the EMTN<sup>1</sup> program;

700 million fixed-rate bond issue bearing annual interest of 3.125%, maturing October 10, 2014, issued under the EMTN<sup>1</sup> program;

800 million fixed-rate bond issue bearing annual interest of 4.125%, maturing October 11, 2019, issued under the EMTN<sup>1</sup> program.

<sup>1</sup> Euro Medium Term Notes

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

Three bond issues were repaid on maturity:

July 2007 bond issue with a nominal value of ¥19.15 billion ( 144 million), which matured July 10, 2009;

July 2007 bond issue with a nominal value of 200 million, which matured July 13, 2009;

December 2006 bond issue with a nominal value of 100 million, which matured December 21, 2009.

A 1 billion syndicated bank loan was repaid in July 2009.

In addition, a 461 million syndicated bank loan, fully drawn down by Zentiva N.V., a company acquired in March 2009 (see Note D.1.), was repaid on July 10, 2009.

**b) Debt, net of cash and cash equivalents by type, at value on redemption**

( million)	December 31, 2009			December 31, 2008			December 31, 2007		
	Non-current	Current	Total	Non-current	Current	Total	Non-current	Current	Total
Bond issues	5,236	1,982	<b>7,218</b>	2,418	488	<b>2,906</b>	2,390	1,390	<b>3,780</b>
Credit facility drawdowns				1,000	34	<b>1,034</b>	1,000	1	<b>1,001</b>
Other bank borrowings	678	529	<b>1,207</b>	670	262	<b>932</b>	257	266	<b>523</b>
Commercial paper					717	<b>717</b>		102	<b>102</b>
Finance lease obligations	15	9	<b>24</b>	21	4	<b>25</b>	25	4	<b>29</b>
Other borrowings	14	16	<b>30</b>	14	11	<b>25</b>	14	1	<b>15</b>
Bank credit balances		317	<b>317</b>		299	<b>299</b>		423	<b>423</b>
<b>Total debt</b>	<b>5,943</b>	<b>2,853</b>	<b>8,796</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>
Cash and cash equivalents		(4,692)	<b>(4,692)</b>		(4,226)	<b>(4,226)</b>		(1,711)	<b>(1,711)</b>
<b>Debt, net of cash and cash equivalents</b>	<b>5,943</b>	<b>(1,839)</b>	<b>4,104</b>	<b>4,123</b>	<b>(2,411)</b>	<b>1,712</b>	<b>3,686</b>	<b>476</b>	<b>4,162</b>

Bond issues made under the EMTN (Euro Medium Term Notes) program comprise:

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

September 2003 issue [ISIN: XS0176128675] with a nominal value of 1,500 million, maturing September 2010, bearing annual interest at 4.25%;

January 2007 issue [ISIN: XS0282647634] amounting to £200 million ( 225 million), maturing January 2010, bearing annual interest at 5.50% and swapped into euros at a floating rate indexed to 3-month Euribor;

June 2008 issue amounting to ¥15 billion ( 113 million), maturing June 2013, bearing interest at a floating rate indexed to 3-month JPY Libor, and swapped into euros at a floating rate indexed to 3-month Euribor;

May 2009 issue [ISIN: XS0428037666] amounting to 1,500 million, maturing May 2013, bearing annual interest at 3.5%;

May 2009 issue [ISIN: XS0428037740] amounting to 1,500 million, maturing May 2016, bearing annual interest at 4.5%;

October 2009 issue [ISIN: XS0456451938] amounting to 700 million, maturing October 2014, bearing annual interest at 3.125%;

October 2009 issue [ISIN: XS0456451771] amounting to 800 million, maturing October 2019, bearing annual interest at 4.125%.

### **Bond issues made outside the EMTN (Euro Medium Term Notes) program comprise:**

December 2007 issue [ISIN: CH0035703021] amounting to CHF200 million ( 135 million), 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, 2009**

December 2007 and February 2008 issues [ISIN: CH0035703070] amounting to CHF400 million ( 270 million), maturing December 2015, bearing annual interest of 3.375%, and swapped into euros at a fixed rate of 4.867%;

December 2008 and January 2009 issues [ISIN: CH0048787532] amounting to CHF525 million ( 354 million), maturing December 2012, bearing annual interest of 3.25%, and swapped into euros as follows: CHF275 million at a fixed rate of 4.894%, and CHF250 million at a floating rate indexed to 3-month Euribor.

Sanofi-aventis has put in place the following arrangements to manage its liquidity needs:

A syndicated bank facility of 8 billion, of which 0.3 billion expires in March 2011 and 7.7 billion in March 2012. There were no drawdowns under this facility as of December 31, 2009;

A syndicated 364-day bank facility, contracted in 2005 for an initial amount of 5 billion, initially with four 364-day extension options. The final extension option was exercised in early 2009, extending the expiry of the facility from January 2009 to January 2010. During 2009, the facility was renewed early, extending the expiry date from January 2010 to January 2011. With effect from January 2010, the amount of this facility will be 4.0 billion, versus 3.7 billion in 2009. There were no drawdowns under this facility as of December 31, 2009;

A bilateral 364-day bank facility of \$0.6 billion ( 0.4 billion) expiring January 2010. This facility was renewed in January 2010, and now expires in January 2011;

A bilateral 364-day bank facility of \$0.25 billion ( 0.2 billion) expiring February 2010.

These short-term bank facilities, which are confirmed but have not been drawn down, are used in particular to back two commercial paper programs, of 6 billion in France and \$6 billion in the United States. In 2009, the average drawdown under these programs was 0.4 billion (maximum 0.8 billion). These programs were not mobilized as of December 31, 2009.

The financing in place at December 31, 2009 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;

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Series A participating shares issued in 1989, of which 3,271 remain outstanding, valued at 0.2 million.

c) Debt by maturity, at value on redemption

( million)	Total	December 31, 2009					2015 and later
		Current 2010	Non-current				
		2011	2012	2013	2014		
Bond issues	7,218	1,982	354	1,613	700	2,569	
Other bank borrowings	1,207	529	11	225	433	7	
Finance lease obligations	24	9	3	3	3	3	
Other borrowings	30	16				14	
Bank credit balances	317	317					
<b>Total debt</b>	<b>8,796</b>	<b>2,853</b>	<b>14</b>	<b>582</b>	<b>2,049</b>	<b>710</b>	
Cash and cash equivalents	(4,692)	(4,692)					
<b>Debt, net of cash and cash equivalents</b>	<b>4,104</b>	<b>(1,839)</b>	<b>14</b>	<b>582</b>	<b>2,049</b>	<b>710</b>	

F-69

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

( million)	Total	Current 2009	December 31, 2008				2014 and later
			2010	2011	Non-current		
			2012	2013			
Bond issues	<b>2,906</b>	488	1,845	185	119		269
Credit facility drawdowns <sup>(1)</sup>	<b>1,034</b>	34		1,000			
Other bank borrowings	<b>932</b>	262	13	7	208	439	3
Commercial paper <sup>(2)</sup>	<b>717</b>	717					
Finance lease obligations	<b>25</b>	4	3	6	2	3	7
Other borrowings	<b>25</b>	11					14
Bank credit balances	<b>299</b>	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	<b>(4,226)</b>	(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>

<sup>(1)</sup> Maturities used for credit facility drawdowns are those of the facility, not the drawdown.

<sup>(2)</sup> Commercial paper had a maturity of no more than three months as of December 31, 2008.

( million)	Total	Current 2008	December 31, 2007				2013 and later
			2009	2010	Non-current		
			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>

<sup>(1)</sup> The maturity used for the 100 million bond issue is the date of the bondholders' first early redemption option (June 2008).

<sup>(2)</sup> 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, 2009 break down as follows:

<b>Year of expiry</b>	<b>Undrawn confirmed credit facilities available ( million)</b>
2010	590
2011	4,027 <sup>(1)</sup>
2012	7,673
<b>Total</b>	<b>12,290</b>

<sup>(1)</sup> An additional 300 million became available effective January 13, 2010.

Confirmed credit facilities mainly comprise:

a syndicated credit facility of 8 billion expiring in 2011 ( 0.3 billion) and in 2012 ( 7.7 billion).

F-70

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

confirmed short-term bank facilities available for backing commercial paper programs, amounting to 3.7 billion at December 31, 2009 and not being used to back commercial paper programs as of that date (raised to 4.0 billion effective January 13, 2010).

As of December 31, 2009, 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, 2009. The figures shown are the value on redemption, before the effects of derivative instruments:

( million)	December 31, 2009						2015 and later
	Total	2010	2011	2012	2013	2014	
Fixed-rate	7,441	1,860		554	1,758	700	2,569
<i>% fixed-rate</i>	<i>85%</i>						
Floating-rate (maturity based on contractual repricing date)	1,355	1,355					
<i>% floating-rate</i>	<i>15%</i>						
<b>Debt</b>	<b>8,796</b>	<b>3,215</b>		<b>554</b>	<b>1,758</b>	<b>700</b>	<b>2,569</b>
Cash and cash equivalents	(4,692)	(4,692)					
<i>% floating-rate</i>	<i>100%</i>						
<b>Debt, net of cash and cash equivalents</b>	<b>4,104</b>	<b>(1,477)</b>		<b>554</b>	<b>1,758</b>	<b>700</b>	<b>2,569</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, 2009						2015 and later
	Total	2010	2011	2012	2013	2014	
Fixed-rate	5,912	1,500		385	1,758		2,269
<i>% fixed-rate</i>	<i>67%</i>						



Edgar Filing: SANOFI-AVENTIS - Form 20-F

Floating-rate <sup>(1)</sup>	2,884	2,884			
<i>% floating-rate</i>	<i>33%</i>				
<b>Debt</b>	<b>8,796</b>	<b>4,384</b>	<b>385</b>	<b>1,758</b>	<b>2,269</b>
Cash and cash equivalents	(4,692)	(4,692)			
<i>% floating-rate</i>	<i>100%</i>				
<b>Debt, net of cash and cash equivalents</b>	<b>4,104</b>	<b>(308)</b>	<b>385</b>	<b>1,758</b>	<b>2,269</b>

(1) Floating-rate debt includes 1 billion of debt transformed into floating-rate for 2010 but reverting to fixed rate thereafter, comprising 0.7 billion maturing 2014 and 0.3 billion maturing 2019.

F-71

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The table below shows the fixed/floating rate split at redemption value after taking account of derivative instruments on December 31, 2008 and 2007:

( million)	<b>2008</b>	<b>%</b>	<b>2007</b>	<b>%</b>
Fixed-rate	3,412	57%	2,892	49%
Floating-rate	2,526	43%	2,981	51%
<b>Debt</b>	<b>5,938</b>	<b>100%</b>	<b>5,873</b>	<b>100%</b>
Cash and cash equivalents	(4,226)		(1,711)	
<b>Debt, net of cash and cash equivalents</b>	<b>1,712</b>		<b>4,162</b>	

The weighted average interest rate on debt at December 31, 2009 was 4.09% before derivative instruments and 3.93% after derivative instruments. All cash and cash equivalents were invested at an average rate of 0.87% at December 31, 2009.

Based on the Group's level of debt, and taking account of derivative instruments in place at December 31, 2009, sensitivity to movements in market interest rates over a full year in 2010 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	18	18
+ 25 bp	4	5
- 25 bp	(4)	(5)
- 100 bp	<i>Not applicable</i>	<i>Not applicable</i>

**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, 2009, 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, 2009	
	Before derivative instruments	After derivative instruments
EUR	3,208	4,304
CHF	750	(8)
GBP	167	(58)

Edgar Filing: SANOFI-AVENTIS - Form 20-F

JPY	116	3
USD	(22)	(22)
Other currencies	(115)	(115)
<b>Debt, net of cash and cash equivalents</b>	<b>4,104</b>	<b>4,104</b>

The table below shows debt, net of cash and cash equivalents by currency at December 31, 2008 and 2007, after taking account of derivative instruments contracted to convert third-party debt into the functional currency of the borrower entity:

<i>( million)</i>	<b>2008</b>	<b>2007</b>
EUR	1,603	4,192
USD	(19)	78
GBP	(64)	(81)
Other currencies	192	(27)
<b>Debt, net of cash and cash equivalents</b>	<b>1,712</b>	<b>4,162</b>

F-72

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009****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, 2009 was 4,341 million (December 31, 2008: 1,779 million; December 31, 2007: 4,162 million), versus a value on redemption of 4,104 million (December 31, 2008: 1,712 million; December 31, 2007: 4,162 million).

Derivative instruments contracted for debt management purposes had a positive fair value of 7 million at December 31, 2009, compared with a positive fair value of 18 million at December 31, 2008 and 29 million at December 31, 2007 (see Note D.20.).

**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, 2009:

	December 31, 2009						
	Contractual cash flows by maturity						
( million)	Total	2010	2011	2012	2013	2014	2015 and later
<b>Debt</b>	<b>10,118</b>	<b>3,049</b>	<b>231</b>	<b>797</b>	<b>2,254</b>	<b>844</b>	<b>2,943</b>
principal	8,681	2,737	6	570	2,052	709	2,607
interest <sup>(1)</sup>	1,437	312	225	227	202	135	336
<b>Net cash flows related to derivative instruments</b>	<b>(14)</b>	<b>51</b>	<b>8</b>	<b>(9)</b>	<b>(24)</b>	<b>2</b>	<b>(42)</b>
<b>Total</b>	<b>10,104</b>	<b>3,100</b>	<b>239</b>	<b>788</b>	<b>2,230</b>	<b>846</b>	<b>2,901</b>

<sup>(1)</sup> Interest cash flows are estimated on the basis of forward interest rates applicable as of December 31, 2009.

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.

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

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 and 2007:

( million)	December 31, 2008						2014 and later
	Contractual cash flows by maturity						
	Total	2009	2010	2011	2012	2013	
<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.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

	December 31, 2007						2013 and later
	Contractual cash flows by maturity						
( million)	Total	2008	2009	2010	2011	2012	
<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 <sup>(1)</sup>	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>

(1) Interest cash flows are estimated on the basis of forward interest rates applicable as of December 31, 2007.

**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, 2007</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	(14)	(12)	(614) <sup>(3)</sup>		(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 <sup>(6)</sup>	(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 provision	(65)		(531) <sup>(3)</sup>		(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 <sup>(6)</sup>	824				824
<b>December 31, 2008</b>	<b>4,068</b>	<b>366</b>	<b>3,084</b>	<b>212</b>	<b>7,730</b>

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Changes in scope of consolidation	13		228	9	250
Charged during the period	683	183	1,256 <sup>(2)</sup>	66	2,188
Provisions utilized	(603)	(61)	(251)		(915)
Reversals of unutilized provisions	(130)	(1)	(753) <sup>(3)</sup>	(24)	(908)
Transfers <sup>(1)</sup>	133	(232)	(104)	(70)	(273)
Unwinding of discount		3	36	2	41
Unrealized gains and losses				(12) <sup>(5)</sup>	(12)
Translation differences	9	(1)	37	(4)	41
Actuarial gains/losses on defined-benefit plans <sup>(6)</sup>	169				169
<b>December 31, 2009</b>	<b>4,342</b>	<b>257</b>	<b>3,533</b>	<b>179</b>	<b>8,311</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 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.

(6) Amounts recognized directly in equity (see Note D.15.7.).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009****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 employees as well as some members of the Board of Directors.

Actuarial valuations of the Group's benefit obligations were computed by management with assistance from external appraisers as of December 31, 2009, 2008 and 2007. 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, 2009, from 3% to 5% at December 31, 2008, and from 2.75% to 5% at December 31, 2007.

An annuity inflation rate for the principal countries ranging from 2% to 5% at December 31, 2009, from 2% to 3% at December 31, 2008, and from 2% to 4% at December 31, 2007.

A weighted average long-term healthcare cost inflation rate of 4.34% at December 31, 2009, 4.53% at December 31, 2008, and 4.49% at December 31, 2007, applied to post-employment benefits.

Inflation rate assumptions, as shown in the table below:

<b>Inflation rate</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>
- Euro zone	2%	2%	2%
- United States	3%	3%	3%
- United Kingdom	3.1%	3.1%	2.75%

Discount rates used to determine the present value of defined benefit obligations at the balance sheet date, as shown in the table below:



Edgar Filing: SANOFI-AVENTIS - Form 20-F

Discount rate	Pensions and other long-term benefits			Other post-employment benefits		
	Year ended December 31,			Year ended December 31,		
	2009	2008	2007	2009	2008	2007
Weighted average for all regions:	5.34%	5.98%	5.42%	5.76%	6.01%	5.93%
- Euro zone	4.5% or 5.25% <sup>(1)</sup>	5.75% or 6%	5% or 5.25%	5.25%	6%	5.25%
- United States	5.75%	6%	6%	5.75%	6%	6%
- United Kingdom	5.75%	6.5%	5.75%	5.75%	6.5%	5.75%

<sup>(1)</sup> Depends on the term of the plan: 4.5% medium-term, 5.25% 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.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

Sensitivity analysis of pension plans and other post-employment benefits in the principal countries shows that a 0.5% reduction in discount rates would increase the Group's obligation by approximately 500 million, of which approximately 150 million would relate to the United Kingdom, 150 million to Germany, 110 million to France and 90 million to the United States.

Assumptions about the expected long-term rates of return for plan assets. The majority of fund assets are invested in Germany, the United States and the United Kingdom. The expected long-term rates of return used are as follows:

Expected long-term rate of return on plan assets	Pensions and other long-term benefits Year ended December 31,			Other post-employment benefits Year ended December 31,		
	2009	2008	2007	2009	2008	2007
<b>Range of rates of return on plan assets:</b>	2% - 13.5%	2.5% - 13.5%	2.5% - 12%	8%	8%	8%
Weighted average for all regions	6.86%	6.97%	7.01%	8%	8%	8%
- Germany	6.75%	6.75%	7%			
- United States	8%	8%	8%	8%	8%	8%
- United Kingdom	6.5%	7%	6.75%			

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.

An analysis of the sensitivity of the benefit cost to changes in the expected long-term rate of return on plan assets shows that a 0.5% reduction in the rate of return would increase the benefit cost by approximately 25 million.

The weighted average allocation of funds invested in Group pension plans is shown below:

Asset category (percentage)	Funds invested		
	2009	2008	2007
Equities	51%	46%	51%
Bonds	46%	49%	47%
Real estate	1%	2%	}
Cash	2%	3%	
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

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

The target allocation of funds invested as of December 31, 2009 is not materially different from the actual allocation as of December 31, 2008 and December 31, 2007.

F-76

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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)		
	2009	2008	2007	2009	2008	2007
<b>Valuation of obligation:</b>						
Beginning of period	7,742	8,481	9,187	368	339	321
Service cost	218	228	236	16	12	13
Contributions from plan members	4	4	6			
Interest cost	446	435	414	21	19	18
Actuarial (gain)/loss	759	(579)	(437)	1	5	(12)
Plan amendments	219 <sup>(2)</sup>	71	(24)			45
Translation differences	64	(336)	(326)	(6)	8	(29)
Plan curtailments/settlements	(131)	(68)	(51)	(4)		
Changes in scope of consolidation, transfers	145 <sup>(3)</sup>	34	(5)		2	
Benefits paid	(542)	(528)	(519)	(20)	(17)	(17)
<b>Obligation at end of period</b>	<b>8,924</b>	<b>7,742</b>	<b>8,481</b>	<b>376</b>	<b>368</b>	<b>339</b>
<b>Fair value of plan assets:</b>						
Beginning of period	3,957	5,362	5,575	41	51	56
Expected return on plan assets	278	362	366	3	4	4
Difference between actual and expected return on plan assets	547	(1,348)	(161)	6	(12)	1
Translation differences	49	(270)	(257)	(2)	2	(6)
Contributions from plan members	4	4	6			
Employer's contributions	405	175	146	1		
Plan settlements	(5)	(2)	(39)			
Changes in scope of consolidation, transfers		25				
Benefits paid	(359)	(351)	(274)	(5)	(4)	(4)
<b>Fair value of plan assets at end of period</b>	<b>4,876</b>	<b>3,957</b>	<b>5,362</b>	<b>44</b>	<b>41</b>	<b>51</b>
<b>Net amount shown in the balance sheet:</b>						
Net obligation	4,048	3,785	3,119	332	327	288
Unrecognized past service cost	(49)	(55)	(28)	6	6	6
Effect of asset ceiling	2	4	6			
<b>Net amount shown in the balance sheet</b>	<b>4,001</b>	<b>3,734</b>	<b>3,097</b>	<b>338</b>	<b>333</b>	<b>294</b>
<b>Amounts recognized in the balance sheet:</b>						
Pre-funded obligations (see Note D.7.)	(3)	(1)	(7)			
Obligations provided for <sup>(1)</sup>	4,004	3,735	3,104	338	333	294
<b>Net amount recognized</b>	<b>4,001</b>	<b>3,734</b>	<b>3,097</b>	<b>338</b>	<b>333</b>	<b>294</b>
<b>Benefit cost for the period:</b>						

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Service cost	218	228	236	16	12	13
Interest cost	446	435	414	21	19	18
Expected return on plan assets	(278)	(362)	(366)	(3)	(4)	(4)
Amortization of past service cost	224 <sup>(2)</sup>	42	9			34
Recognition of actuarial (gains)/losses	38	(38)	(8)			
Effect of plan settlements	(122) <sup>(4)</sup>	(38)	(9)	(4)		
Effect of plan curtailments	(3)	(27)	(3)			
<b>Benefit cost for the period</b>	<b>523</b>	<b>240</b>	<b>273</b>	<b>30</b>	<b>27</b>	<b>61</b>

(1) Long-term benefits awarded to employees prior to retirement (mainly discretionary bonuses, long service awards and deferred compensation plans) accounted for 371 million of these obligations at December 31, 2009, 346 million at December 31, 2008, and 367 million at December 31, 2007. The expense associated with these obligations totaled 84 million in 2009, 31 million in 2008, and 44 million in 2007.

(2) Includes 199 million of social security charges and Fillon levies due on early retirement plans in France (see Note D.18.2.).

(3) Includes 123 million relating to plan transfers in France (early retirement plans, previously recognized as restructuring provisions, see Note D.18.2.) and 13 million relating to the acquisition of Zentiva.

(4) Includes 106 million for France and 12 million for the United States.

F-77

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

Actuarial gains and losses on pensions and other post-employment benefits break down as follows:

( million)	2009	2008	2007	2006
Actuarial gain/(loss) arising during the period <sup>(1)</sup>	(207)	(786)	289	359
Comprising:				
gain/(loss) on experience adjustments	531	(1,326)	(135)	126
gain/(loss) on changes in assumptions <sup>(2)</sup>	(738)	540	424	233
Breakdown of experience adjustments:				
gain/(loss) on plan assets <sup>(3)</sup>	553	(1,360)	(160)	191
gain/(loss) on obligations	(22)	34	25	(65)
Amount of obligations at the balance sheet date	9,300	8,110	8,820	9,508
Fair value of plan assets at the balance sheet date	4,920	3,998	5,413	5,631

<sup>(1)</sup> For 2009, comprises a loss of 169 million recognized in equity (see Note D.15.7.) and a loss of 38 million taken directly to the income statement; for 2008, 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.

<sup>(2)</sup> Changes in assumptions relate mainly to changes in discount rates.

<sup>(3)</sup> Experience adjustments are due to trends in the financial markets.

The net pre-tax actuarial loss recognized directly in equity (excluding associates and Merial) was 1,143 million as of December 31, 2009, versus 974 million as of December 31, 2008 and 150 million as of December 31, 2007.

As of December 31, 2009, the present value of obligations in respect of pensions and similar benefits under wholly or partially funded plans was 6,897 million, and the present value of unfunded obligations was 2,027 million (compared with, respectively, 5,924 million and 1,817 million at December 31, 2008, and 6,557 million and 1,924 million at December 31, 2007).

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 449 million at December 31, 2009, 393 million at December 31, 2008 and 428 million at December 31, 2007.

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 other post-employment benefits.

( million)	Sensitivity of assumptions 2009
------------	---------------------------------------

Edgar Filing: SANOFI-AVENTIS - Form 20-F

1% increase in healthcare costs	
Impact on benefit cost for the period	3
Impact on obligation in the balance sheet	33
1% reduction in healthcare costs	
Impact on benefit cost for the period	(2)
Impact on obligation in the balance sheet	(17)

F-78

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The total cost of pensions and other benefits for 2009, amounting to 553 million, is split as follows:

Cost of sales	111 million
Research and development expenses	98 million
Selling and general expenses	195 million
Other operating expenses	59 million
Restructuring costs	77 million

The remaining 13 million relates to actuarial losses on deferred compensation plans funded by assets accounted for under the fair value option (see Note D.7.), and is offset by changes in the fair value of those assets.

The total cost of pensions and other benefits (excluding the effect of plan curtailments and settlements) for 2008 was 332 million, compared with 346 million in 2007, split as follows:

*Cost of sales:* 91 million in 2008, 87 million in 2007;

*Research and development expenses:* 61 million in 2008, 59 million in 2007;

*Selling and general expenses:* 180 million in 2008, 200 million in 2007.

The table below shows the expected cash outflows on pensions and other post-employment benefits over the next ten years:

<i>( million)</i>	<b>Pensions and similar benefits</b>
<b>Estimated employer's contribution in 2010</b>	<b>410</b>
<b>Estimated benefit payments:</b>	
2010	643
2011	631
2012	637
2013	648
2014	636
2015 through 2019	3,272

**D.18.2. Restructuring provisions**



Edgar Filing: SANOFI-AVENTIS - Form 20-F

The table below shows movements in restructuring provisions classified in *Other non-current liabilities* and *Other current liabilities*:

( million)	Year ended December 31, 2009	Year ended December 31, 2008	Year ended December 31, 2007
<b>Balance, beginning 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
Change in provisions recognized in profit or loss for the period	837	510	180
Provisions utilized	(388)	(228)	(273)
Transfers	(110) <sup>(1)</sup>	(3)	
Unwinding of discount	3	5	
Translation differences	(2)	(1)	(8)
<b>Balance, end of period</b>	<b>1,018</b>	<b>678</b>	<b>395</b>
of which:			
Classified in Other non-current liabilities	257	366	188
Classified in Other current liabilities	761	312	207

<sup>(1)</sup> Includes 123 million transferred to *Provisions for pensions and other benefits* (see Note D.18.1.).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

An analysis of restructuring costs by type is provided in Note D.27.

The current portion of these provisions mainly relates to gross payments to be incurred in the short term under early retirement plans in France. As of December 31, 2009, the balance reported for these provisions represents payments in lieu of notice and termination benefits payable under these and other plans in France and Europe. The related social security charges and Fillon levies are recognized under *Provisions for pensions and other long-term employee benefits* (see Note D.18.1.).

**D.18.3. Other provisions**

Other provisions include provisions for environmental, tax, commercial and product liability risks, and for litigation.

( million)	December 31, 2009	December 31, 2008	December 31, 2007
Tax exposures	2,009	1,770	1,645
Environmental risks and remediation	695	589	494
Product liability risks, litigation and other	829	725	987
<b>Total</b>	<b>3,533</b>	<b>3,084</b>	<b>3,126</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 137 million of these provisions will be utilized in 2010 and 365 million over the period from 2011 through 2014.

Product liability risks, litigation and other mainly comprises provisions for risks relating to product liability (including IBNR provisions as described in Note B.12.), government investigations, regulatory or competition law claims or contingencies arising from business divestments (other than environmental risks).

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

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>	December 31, 2009	December 31, 2008	December 31, 2007
Taxes payable	631	664	797
Employee-related liabilities	1,458	1,366	1,337
Restructuring provisions (see Note D.18.2.)	761	312	207
Interest rate derivatives (see Note D.20.)	62		
Currency derivatives (see Note D.20.)	119	249	187
Amounts payable for acquisitions of non-current assets	251	292	429
Liabilities relating to contingent consideration on buyouts of minority interests	76		
Other liabilities	2,087	1,838	1,756
<b>Total</b>	<b>5,445</b>	<b>4,721</b>	<b>4,713</b>

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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.).

**D.20. Derivative financial instruments and market risks**

The table below shows the fair value of derivative instruments as of December 31, 2009:

( million)	Non-current assets	Current assets	Total assets	Non-current liabilities	Current liabilities	Total liabilities	Fair value at Dec. 31, 2009 (net)	Fair value at Dec. 31, 2008 (net)	Fair value at Dec. 31, 2007 (net)
<b>Currency derivatives</b>		251	251		(119)	(119)	132	99	(120)
operational		34	34		(80)	(80)	(46)	201	33
financial		217	217		(39)	(39)	178	(102)	(153)
net investment hedges									
<b>Interest rate derivatives</b>	51	18	69		(62)	(62)	7	18	29
<b>Total</b>	<b>51</b>	<b>269</b>	<b>320</b>		<b>(181)</b>	<b>(181)</b>	<b>139</b>	<b>117</b>	<b>(91)</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 the debt is not contracted in the functional currency of the borrower or lender entity). Less frequently, sanofi-aventis uses equity derivatives in connection with the management of its portfolio of equity investments.

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, 2009, sanofi-aventis had no material embedded derivatives.

**Counterparty risk**

As of December 31, 2009, all currency and interest rate hedges were contracted with leading banks, and no single counterparty accounted for more than 15% of the Group's overall currency or interest rate positions.

**D.20.1. Currency and interest rate derivatives**

**a) 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).

F-81

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The table below shows operational currency hedging instruments in place as of December 31, 2009, with the notional amount translated into euros at the relevant closing exchange rate.

<i>December 31, 2009</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
<i>( million)</i>							
<b>Forward currency sales</b>	<b>2,800</b>	<b>(51)</b>	<b>583</b>	<b>(7)</b>	<b>(7)</b>	<b>2,217</b>	<b>(44)</b>
<i>of which U.S. dollar</i>	1,757	(41)	367	(5)	(5)	1,390	(36)
<i>of which Japanese yen</i>	269	1	150	(1)	(1)	119	2
<i>of which Russian rouble</i>	132	(4)				132	(4)
<i>of which Pound sterling</i>	111					111	
<i>of which Hungarian forint</i>	104	(1)				104	(1)
<b>Forward currency purchases</b>	<b>377</b>	<b>6</b>				<b>377</b>	<b>6</b>
<i>of which Hungarian forint</i>	114	3				114	3
<i>of which U.S. dollar</i>	69					69	
<i>of which Pound sterling</i>	68	1				68	1
<i>of which Canadian dollar</i>	42	1				42	1
<i>of which Swiss franc</i>	20					20	
<b>Put options purchased</b>	<b>448</b>	<b>14</b>	<b>20</b>	<b>1</b>		<b>428</b>	<b>13</b>
<i>of which U.S. dollar</i>	278	8				278	8
<b>Call options written</b>	<b>881</b>	<b>(17)</b>	<b>20</b>	<b>(1)</b>		<b>861</b>	<b>(16)</b>
<i>of which U.S. dollar</i>	555	(10)				555	(10)
<b>Put options written</b>	<b>278</b>	<b>(8)</b>				<b>278</b>	<b>(8)</b>
<i>of which U.S. dollar</i>	278	(8)				278	(8)
<b>Call options purchased</b>	<b>555</b>	<b>10</b>				<b>555</b>	<b>10</b>
<i>of which U.S. dollar</i>	555	10				555	10
<b>Total</b>	<b>5,339</b>	<b>(46)</b>	<b>623</b>	<b>(7)</b>	<b>(7)</b>	<b>4,716</b>	<b>(39)</b>

As of December 31, 2009, none of these instruments has an expiry date after December 31, 2010.

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, 2009 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

Edgar Filing: SANOFI-AVENTIS - Form 20-F

hedged items. Consequently, the commercial foreign exchange gain or loss to be recognized on these items (hedges and hedged instruments) in 2010 is not expected to be material.

F-82

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

Forecast foreign-currency cash flows relating to commercial transactions to be carried out in 2010. These hedges (forward contracts and options) cover from 8% to 40% of the expected net cash flows for 2010 in currencies subject to budgetary hedging. The portfolio of derivatives contracted to cover 2010 U.S. dollar cash flows consists solely of forward contracts, and represents 8% of the forecast net cash flows for 2010. 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 2010 is as follows:

<b>Assumes a constant /\$ exchange rate over the year ending December 31, 2010</b>	<b>Foreign exchange gain/(loss) on U.S. dollar hedges ( million)</b>	<b>Impact on equity at December 31, 2009 ( million)</b>
Depreciation of 10% in the U.S. dollar ( 1 = \$1.5847)	28	33
Exchange rate maintained at the December 31, 2009 rate ( 1 = \$1.4406)	(5)	
Appreciation of 10% in the U.S. dollar ( 1 = \$1.2965)	(46)	(41)

The table below shows operational currency hedging instruments in place as of December 31, 2008, with the notional amount translated into euros at the relevant closing exchange rate.

<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
<i>( million)</i>							
<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>
<i>of which U.S. dollar</i>	2,461	182	1,358	108	111	1,103	74
<i>of which Japanese yen</i>	191	(5)	95	3	2	96	(8)
<i>of which Russian rouble</i>	134	15				134	15
<i>of which Pound sterling</i>	104	6				104	6
<i>of which Saudi Arabian riyal</i>	58	5	4			54	5
<i>of which Polish zloty</i>	53	6	33	5	6	20	1
<b>Forward currency purchases</b>	<b>601</b>	<b>(11)</b>				<b>601</b>	<b>(11)</b>
<i>of which Hungarian forint</i>	175	(1)				175	(1)
<i>of which U.S. dollar</i>	140	3				140	3
<i>of which Pound sterling</i>	75	(6)				75	(6)
<i>of which Russian rouble</i>	72	(6)				72	(6)
<i>of which Canadian dollar</i>	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>



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The table below shows operational currency hedging instruments in place as of December 31, 2007:

<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>

<sup>(1)</sup> Knock-out options expire worthless once a specified level of gain is reached.**b) 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, expose certain entities to financial foreign exchange risk. This is the risk of changes in the value of borrowings and loans denominated in a currency other than the functional currency of the borrower or lender. This risk mainly affects the sanofi-aventis parent company in respect of the U.S. dollar, and is hedged by firm financial instruments (currency swaps or forward contracts).

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

The table below shows instruments used to manage financial risk exposures as of December 31, 2009, with the notional amount translated into euros at the relevant closing exchange rate.

( million)	Notional amount	2009 Fair value	Expiry	Notional amount	2008 Fair value	Expiry	Notional amount	2007 Fair value	Expiry
<b>Forward currency purchases</b>	<b>6,760</b>	<b>185</b>		<b>9,210</b>	<b>(80)</b>		<b>8,261</b>	<b>(179)</b>	
<i>of which U.S. dollar</i> <sup>(1)</sup>	5,634	180	2010	8,256	(66)	2009	7,348	(167)	2008
<i>of which Pound sterling</i>	433	2	2010	235	(4)	2009	442	(11)	2008
<i>of which Swiss franc</i>	152	1	2010	140	5	2009	173	1	2008
<b>Forward currency sales</b>	<b>3,169</b>	<b>(7)</b>		<b>1,954</b>	<b>(22)</b>		<b>1,563</b>	<b>26</b>	
<i>of which U.S. dollar</i>	1,634	(28)	2010	1,043	(23)	2009	936	20	2008
<i>of which Japanese yen</i>	837	18	2010	665	(7)	2009	206	3	2008
<i>of which Czech koruna</i>	394	7	2010	22	1	2009	28		2008
<b>Total</b>	<b>9,929</b>	<b>178</b>		<b>11,164</b>	<b>(102)</b>		<b>9,824</b>	<b>(153)</b>	

<sup>(1)</sup> Corresponds to the hedging of U.S. dollar intra-group deposits placed with the sanofi-aventis parent company.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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, given that the foreign exchange gain or loss on the foreign-currency liabilities and receivables is 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 had a negative effect of 24 million on the net financial foreign exchange result in 2009, compared with a negative effect of 51 million in 2008. In addition, the Group may hedge some future foreign-currency cash flows relating to investment or divestment transactions.

The Group's interest rate exposure arises from (i) fixed-rate debt (primarily bond issues), the fair value of which moves in line with fluctuations in market interest rates; and (ii) floating-rate or adjustable-rate debt and cash investments (credit facilities, commercial paper, floating rate notes, funds placed in collective investment schemes), on which interest outflows and inflows are exposed to fluctuations in benchmark rates (principally Eonia, U.S. Libor and Euribor). To reduce the cost and/or volatility of its short-term and medium-term debt, sanofi-aventis uses interest rate swaps, cross-currency swaps, and in some cases interest rate options (purchases of caps, or combined purchases of caps and sales of floors) that alter the fixed/floating structure of its debt.

The table below shows instruments of this type in place at December 31, 2009:

( million)	Notional amounts by expiry date as of December 31, 2009					Fair value	Of which derivatives designated as fair value hedges		Of which derivatives designated as cash flow hedges		
	2010	2012	2013	2015	Total		Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
Interest rate swap, pay 1.27% / receive floating (1)	1,000				1,000	2	1,000	2			
<b>Cross currency swaps</b>											
- pay floating <sup>(2)</sup> / receive £ 5.50%	299				299	(62)	299	(62)			
- pay floating <sup>(2)</sup> / receive ¥ floating <sup>(3)</sup>			92		92	21					
- pay floating <sup>(4)</sup> / receive CHF 2.75%	122				122	16	122	16			
- pay 4.89% / receive CHF 3.26%		180			180	3			180	3	(2)
- pay 4.87% / receive CHF 3.38%				244	244	23			244	23	(2)
- pay floating <sup>(2)</sup> / receive CHF 3.26%		167			167	4	167	4			
<b>Total</b>	<b>1,421</b>	<b>347</b>	<b>92</b>	<b>244</b>	<b>2,104</b>	<b>7</b>	<b>1,588</b>	<b>(40)</b>	<b>424</b>	<b>26</b>	<b>(4)</b>

(1) Floating: benchmark rate 1-month Euribor

(2) Floating: benchmark rate 3-month Euribor

(3) Floating: benchmark rate 3-month Libor JPY

(4) Floating: benchmark rate 6-month Euribor

The table below shows instruments of this type in place at December 31, 2008:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

	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		
	2009	2010	2012	2013	2015	Total		Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
( million)												
Interest rate swap, pay 3.69% / receive floating (1)		1,000				1,000	(12)			1,000	(12)	(14)
<b>Cross currency swaps</b>												
- pay floating (1) / receive £ 5.50%		299				299	(74)	299	(74)			
- pay floating (1) / receive ¥ 0.22%		116				116	33	116	33			
- pay floating (1) / receive ¥ floating (2)				92		92	27					
- pay floating (3) / 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

F-85

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

The table below shows the portfolio of interest rate derivative instruments at December 31, 2007:

( million)	Notional amounts by expiry date as of December 31, 2007						Fair value	Of which derivatives designated as fair value hedges		Of which derivatives designated as cash flow hedges		Of which recognized in equity
	2008	2009	2010	2012	2015	Total		Notional amount	Fair value	Notional amount	Fair value	
Interest rate swap, pay 3.11% / receive floating <sup>(1)</sup>				1,000		1,000	50			1,000	50	50
Interest rate swap, pay floating ( ) Eonia + 0.59%	250					250						
<b>Cross currency swaps</b>												
- 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

The change in the structure of the Group's debt arising from these financial instruments is described in Note D.17., which also includes an analysis of the Group's sensitivity to interest rates.

**D.20.2. Equity derivatives**

The Group did not hold any equity derivatives as of December 31, 2009, December 31, 2008 or December 31, 2007.

**D.21. Contractual obligations and other commercial commitments**

The Group's contractual obligations and other commercial commitments (excluding Merial, see Note D.8.1.) comprise:

December 31, 2009  
( million)

Total

Payments due by period

Edgar Filing: SANOFI-AVENTIS - Form 20-F

		Under 1 year	From 1 to 3 years	From 3 to 5 years	Over 5 years
Debt <sup>(1)</sup> :					
- principal	8,681	2,737	576	2,761	2,607
- interest	1,437	312	452	337	336
- net cash flows related to derivative instruments	(14)	51	(1)	(22)	(42)
Operating lease obligations	1,197	278	350	201	368
Irrevocable purchase commitments <sup>(2)</sup> :					
- given	2,628	1,484	550	197	397
- received	(297)	(203)	(33)	(13)	(48)
Commercial commitments	5,781	235	546	542	4,458
Commitments relating to business combinations	439	76	268	95	
Commitment related to the tender offer for Chattem	1,319	1,319			
Commitment related to the combination of Intervet/Schering-Plough Animal Health and Merial <sup>(3)</sup>	694	694			
<b>Total contractual obligations and other commitments</b>	<b>21,865</b>	<b>6,983</b>	<b>2,708</b>	<b>4,098</b>	<b>8,076</b>
<b>Undrawn credit facilities<sup>(4)</sup></b>	<b>12,290</b>	<b>590</b>	<b>11,700</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) Estimated cash outflow related to the call option agreement described in Note D.1.

(4) 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, 2009****Leases****Finance leases**

Future minimum lease payments due under finance leases at December 31, 2009 are 27 million ( 31 million at December 31, 2008 and 35 million at December 31, 2007), including interest of 3 million ( 5 million at December 31, 2008 and 6 million at December 31, 2007). The payment schedule is as follows:

December 31, 2009 ( 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	24	9	6	6	3
- interest	3	1	1	1	
<b>Total</b>	<b>27</b>	<b>10</b>	<b>7</b>	<b>7</b>	<b>3</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, 2009 amounted to 1,197 million ( 1,192 million at December 31, 2008, 1,283 million at December 31, 2007).

Total rental expense recognized in the year ended December 31, 2009 was 273 million ( 282 million in the year ended December 31, 2008, 292 million in the year ended December 31, 2007).

**Guarantees**

Guarantees given and received (mainly surety bonds) are as follows:

( million)	2009	2008	2007
------------	------	------	------

Guarantees given	2,358	1,524	1,895
Guarantees received	(171)	(218)	(195)

*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 2009, sanofi-aventis and the American biotechnology company Alopexx Pharmaceuticals LLC (Alopexx) signed a collaboration agreement and option for a license on a first-in-class human monoclonal antibody for the prevention and treatment of infections originating in the bacterium that causes plague and other serious infections. This new antibody is currently in preclinical development. Sanofi-aventis will finance part of the Phase I clinical trials, and has made an upfront payment to Alopexx. In addition, sanofi-aventis will make milestone payments which could reach \$210 million, plus royalties on sales of commercialized products and additional milestone payments linked to sales performance.

In October 2009, sanofi-aventis and Micromet signed a global collaboration and license agreement to develop a BiTE<sup>®</sup> antibody against an antigen present at the surface of carcinoma cells. BiTE<sup>®</sup>



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

antibodies are novel therapeutic antibodies that activate patients' T-cells to seek out and destroy cancer cells. Micromet will receive milestone payments of up to \$162 million, and royalties on worldwide product sales. Micromet will also receive additional milestone payments linked to sales performance.

In October 2009, sanofi-aventis and Wellstat Therapeutics Corporation (Wellstat) signed a worldwide license agreement for PN2034, a novel first-in-class oral insulin sensitizer for the treatment of Type II diabetes. As a sensitizer, PN2034 is expected to normalize and therefore enhance insulin action in the livers of diabetic patients. The compound is currently in Phase II clinical testing. Total milestone payments could reach \$310 million. Wellstat will also receive royalties on worldwide product sales, and additional milestone payments linked to sales performance.

At end September 2009, sanofi-aventis and Merrimack Pharmaceuticals Inc. (Merrimack) signed an exclusive worldwide collaboration and licensing agreement for the MM-121 molecule for the management of solid malignancies. MM-121 is a first-in-class fully human monoclonal antibody designed to block signaling of the ErbB3 (also known as HER3) receptor. MM-121 is presently in Phase I of clinical development. Merrimack will receive milestone payments that could reach \$410 million, plus royalties on the worldwide product sales and additional milestone payments linked to worldwide product sales. Merrimack will participate in the clinical development of MM-121.

In May 2009, sanofi-aventis signed a global license agreement with Exelixis, Inc. (Exelixis) for the XL147 and XL765 molecules, and an exclusive collaboration agreement for the discovery of inhibitors of phosphoinositide-3 kinase (PI3K) for the management of malignant tumors. Sanofi-aventis made an upfront cash payment to Exelixis, and could make milestone payments that could reach over \$1 billion in aggregate. In addition, Exelixis will be entitled to receive royalties on sales of commercialized products, and milestone payments linked to the sales performance of those products.

In May 2009, sanofi-aventis and Kyowa Hakko Kirin Co., Ltd (Kyowa Hakko Kirin) signed a collaboration and licensing agreement under which sanofi-aventis obtained the worldwide rights to the anti-LIGHT fully human monoclonal antibody. This anti-LIGHT antibody is presently at preclinical development stage. It is expected to be first-in-class in the treatment of ulcerative colitis and Crohn's disease. Kyowa Hakko Kirin will receive milestone payments, the total amount of which could reach \$305 million. Kyowa Hakko Kirin will also be entitled to receive royalties and milestone payments linked to sales performance.

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 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. Dyax will also receive royalties on sales of antibody candidates.

In September 2003, sanofi-aventis signed a collaboration agreement with Regeneron in oncology to develop the Vascular Endothelial Growth Factor (VEGF) Trap program. Under the terms of the agreement, development milestone payments and royalties on VEGF Trap sales are payable to Regeneron. Total milestone payments could reach \$350 million. 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.

In November 2007, sanofi-aventis signed a further collaboration agreement with Regeneron to discover, develop and commercialize fully-human therapeutic antibodies. This agreement was broadened, and its term extended, on November 10, 2009. From 2010 through 2017, sanofi-aventis will increase its annual financial commitment to Regeneron's antibody research program to \$160 million. Under

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

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.

F-88

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

Sanofi-aventis has signed other collaboration agreements with laboratories and universities, under which total contingent payments over the next five years could reach around 129 million.

The main collaboration agreements in the Vaccines segment are described below:

Sanofi Pasteur has entered into a number of collaboration agreements with partners including Crucell, Intercell, Vactech, Maxigen, SSI and Syntiron, under which sanofi pasteur may be required to make total contingent payments of around 99 million over the next five years.

In June 2009, sanofi-aventis announced its intention to donate to the World Health Organization (WHO) 10% of its output of A(H1N1) influenza vaccine up to a maximum of 100 million doses to help developing countries deal with the influenza pandemic. This donation was a response to the 2009 influenza pandemic caused by the emergence of the new A(H1N1) influenza strain, and replaced a previous commitment made in 2008 in the context of the H5N1 pandemic threat. However, the 100 million dose donation will be based on A(H1N1) or H5N1 strains, or any other strain that could potentially create an influenza epidemic.

***Commitments relating to business combinations***

Commitments relating to business combinations relate mainly to contingent consideration in the form of milestone payments linked to the development of projects conducted by the acquired entity. Contingent consideration is recognized as a financial liability if payment is regarded as possible and the amount involved can be measured reliably; refer to Note B.3.1. for a description of the accounting policy applied.

These commitments relate to:

BiPar Sciences

For a description of BiPar s activities and the purchase price allocation, see Note D.1.

The additional purchase consideration is contingent on future milestone payments, which could reach \$157 million.

Fovea

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

On October 30, 2009, sanofi-aventis acquired Fovea Pharmaceuticals SA (Fovea), a privately-owned French biopharmaceutical company specializing in ophthalmology. Fovea has three products in clinical development: FOV 1101, currently in Phase II for persistent allergic conjunctivitis; FOV 2302, currently in Phase I, an intravitreal injection for the treatment of retinal vein occlusion induced macular edema; and FOV 2304, which entered Phase I at the end of 2009, for the treatment of diabetic macular edema. Milestone payments could reach 280 million.

### *Financial commitment relating to the tender offer for Chattem Inc*

On December 21, 2009, sanofi-aventis announced that it had entered into a definitive agreement to acquire 100% of the outstanding shares of Chattem Inc (Chattem) in a cash tender offer for approximately \$1.9 billion. Sanofi-aventis also announced its intention to convert its antihistamine brand Allegra® (fexofenadine) from a prescription medicine to an over-the-counter product in the United States. After the conversion, Chattem will assume responsibility for managing the Allegra® brand, and become the platform for sanofi-aventis over-the-counter and consumer health products in the United States. Under the terms of the agreement, sanofi-aventis launched on January 11, 2010 a tender offer for all the outstanding shares of Chattem for a cash price of \$93.50 per share, representing a premium of 44% to the average closing price of Chattem shares during the six months preceding the announcement of the transaction. The offer was contingent on a majority of the outstanding ordinary shares of Chattem being tendered into the offer, clearance from the relevant regulatory authorities, and the other customary closing conditions. On February 9, 2010, sanofi-aventis acquired 89.8% of Chattem's shares on a fully diluted basis, by accepting all validly tendered shares.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

***Financial commitment relating to Merial***

This commitment relates to the option contract described in Note D.1.

**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), competition law 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 the issues raised by these claims are highly complex and subject to substantial uncertainties; 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 829 million in 2009. These provisions are mainly related to product liabilities, government investigations, competition law, regulatory claims, warranties in connection with certain contingent liabilities arising from business divestitures other than environmental matters and other claims.

Provisions for environmental risks and remediation amount to 695 million in 2009, 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

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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.

The principal ongoing legal and arbitral proceedings are described below:

**a) Products**

*Sanofi Pasteur Hepatitis B Vaccine Litigation*

Since 1996, more than 180 lawsuits have been filed in various French civil courts against Sanofi Pasteur SA 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 syndrome or Guillain-Barré syndrome as a result of receiving the hepatitis B vaccine. Numerous judgments have rejected claims alleging such causal link. Nevertheless, it is difficult to provide an opinion on the evolution and final outcome of these cases. In its most recent decisions concerning sanofi-aventis, the Cour de Cassation (the French Supreme Court), on July 9, 2009, upheld a decision of the Court of Appeal of Lyon ordering Sanofi Pasteur MSD SNC to pay damages of 120,000 to a claimant whose multiple sclerosis syndrome appeared shortly after her vaccination against hepatitis B virus (HBV), but in September 2009, it upheld a decision of the Court of Appeal of Metz rejecting claims against Sanofi Pasteur MSD.

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.

Currently, there are 282 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

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

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 and 2008 and the petitioners decided that there was no need to proceed with the last theory.

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 VICP. The claimants asked for review of the decisions by the Claims Court which ultimately upheld the prior rulings. The petitioners may now seek appellate review in the U.S. Court of Appeals for the Federal Circuit. Decisions in the second set of test cases are expected in 2010.

Currently, all of the 282 cases are either in the preliminary response stage, in the discovery process, have been stayed pending adjudication by the Claims Court, or have pending plaintiffs' requests for reconsideration of preliminary determinations to stay proceedings pending such adjudication by the Claims Court.



---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009***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. A settlement is under negotiation and sanofi-aventis hopes the settlement may be concluded in 2010. Even if the settlement is concluded, some opt out litigation could still persist. The amount to be paid to the plaintiffs by the Group under the conditional settlement is fully covered by the existing reserves.

*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 and 2008, 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 sanofi-aventis, 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 and February 20, 2008 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 these decisions before the Supreme Court. The first administrative Court decisions (approximately 40 resolutions) issued between October 2009 and January 2010 have dismissed all these administrative claims. All the criminal actions submitted have been dismissed to date. Any amounts awarded to date have not been material to the Group on a consolidated basis. A substantial number of claims remain to be adjudicated and 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. In France approximately 60 claimants have filed a motion (*référé*) in order to appoint one or more expert(s) to conduct certain studies, in particular, concerning the alleged injury and causal link with the ingestion of the medication concerned.

*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 had administratively stayed the proceedings pending a U.S. Supreme Court decision in the Levine case (which presented issues of federal preemption relevant to state law claims). Following the March 2009 decision rendered by the U.S. Supreme Court in this case, 23 of these cases were reactivated, while a tolling agreement (agreement which tolls or suspends the running of the statute of limitations) remains in effect for additional potential plaintiffs.

**b) Patents***Plavix<sup>®</sup> Patent Litigation*

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

*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) 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<sup>®</sup> 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<sup>®</sup>. Apotex asserted antitrust counterclaims.

On January 24, 2006, sanofi-aventis learned that the FDA had granted final approval to the Apotex ANDA.

On March 21, 2006, sanofi-aventis and BMS announced that they had reached an agreement subject to certain conditions with Apotex to settle the patent infringement lawsuit pending among the parties. That agreement was withdrawn and subsequently a new agreement was reached in May 2006.

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

Ultimately the agreement failed to receive the 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, following a trial, 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. In November 2009, the U.S. Supreme Court declined to hear the petition by Apotex in the Plavix patent litigation.

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. The proceeding is ongoing in this matter before the Federal District Court.

In August 2009, the USPTO granted Apotex's request for a reexamination of the Plavix enantiomer patent ( 265). In December 2009, in a non-final office action, which is an intermediary stage of the proceeding, the USPTO examiner rejected several claims covering Plavix that were previously upheld by the Federal District Court and Federal Circuit Court of Appeals after extensive litigation. Sanofi-aventis intends to respond to the office action in February 2010. In January 2010, Apotex filed a motion seeking a stay of the damages action pending the outcome of the reexamination of the Plavix patent. That motion, which sanofi-aventis and BMS oppose, remains pending.

The same plaintiffs filed suit against other ANDA filers, namely Dr. Reddy's Laboratories, Teva and Cobalt, in the U.S. District Court for the Southern District of New York for infringement of these same patent rights.

Dr Reddy's, Teva and Cobalt agreed to be bound by the injunction against Apotex, ending these litigations.

Certain more significant Plavix®-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 had asserted the Korean patent for Plavix® (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. This Intellectual Property Tribunal decision was upheld on appeal in 2008 and before the Supreme Court in October 2009. The case is now ended.

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

*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. The 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 and its pharmaceutical salts was found to be invalid. All parties appealed. In September 2009, the Full Federal Court of Australia held the Australian patent covering clopidogrel to be invalid. Sanofi-aventis filed an appeal with the Supreme Court in November 2009.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009***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 relating to sanofi-aventis U.S. Allegra® patent and against Barr relating 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, 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 and Sun), Allegra-D® 12 Hour (Impax, Mylan, Dr. Reddy's, Sandoz and Sun) as well as Allegra-D® 24 Hour (Dr. Reddy's). These other suits were not settled by the agreements described above.

*Actonel® Patent Litigation*

Actonel® was originally 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). On October 30, 2009, P&G sold its pharmaceutical business to Warner Chilcott, succeeding to P&G's rights and obligations in the alliance. P&G had filed a patent infringement suit 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 U.S. District Court for the District of Delaware held P&G's U.S. Patent No. 5,538,122 (the 122 patent) 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 appealed all three final judgments. The three appeals were consolidated by the Federal Circuit and a hearing was held December 2, 2008. In May 2009, the U.S. Court of Appeals ruled in favor of P&G and confirmed the validity of the 122 patent.

In September 2008, and in January and March 2009, P&G and Roche brought suit in the U.S. District Court of Delaware in response to respectively Teva's, Sun Pharma Global's, and Apotex's applications to market a generic version of the 150mg Actonel® tablets.

*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 for the 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 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, 2009**

unenforceable. 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. On April 27, 2009, the U.S. Supreme Court denied sanofi-aventis' petition for a writ of certiorari. In the first semester 2009, the U.S. District Court for the Central District of California dismissed Amphastar's antitrust counterclaims in the Lovenox® patent litigation.

Further to the Federal Circuit Amphastar decision of May 14, 2008, the U.S. District Court for the Central District of California 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 No. 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 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 No. 5,389,618. On April 2, 2009, the German Federal Patent Court revoked the German Patent (DE 41 21 115) on the active ingredient covering Clexane®. Sanofi-aventis is not aware of any enoxaparin biosimilars having been submitted for the German market.

*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. In the patent infringement actions against Apotex and Novopharm, the Federal Court of Canada ruled on June 29, 2009 that the asserted patent was invalid. Each of Novopharm and Riva have 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. Sanofi-aventis has filed appeals of the Federal Court of Canada decisions on the patent invalidity before the Federal Court of Appeal. Neither appeal suspends the advancement of the existing damages claims.

*Taxotere® Patent Litigation*

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

*United States.* Sanofi-aventis received notifications from Hospira, Apotex and Sun in 2007 and 2008 who have filed 505 (b) (2) applications, and from Sandoz in 2009 who filed an ANDA with the U.S. Food and Drug Administration ( FDA ) seeking to market generic versions of Taxot®. In response to these notifications, sanofi-aventis has filed patent infringement lawsuits against Hospira and Apotex (2007), Sun (2008), and Sandoz (2009). The lawsuits are pending in the U.S. District Court for the District of Delaware. None of the applications contested U.S. Patent No. 4,814,470 claiming the active ingredient, which expires in May 2010. The cases against Hospira and Apotex were consolidated for a trial held between October 26, 2009 and November 2, 2009 but the court has not issued a decision yet. Presently, no trial dates have been scheduled for the Sun and Sandoz actions.

*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

F-95



---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

active ingredient of Taxotere<sup>®</sup>, alleging that Aventis Pharma SA'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 SA commenced an application for judicial review in the Federal Court of Canada. In Canada, the compound patent relating to this product has expired.

*Europe.* In several European countries, in particular Germany and France, the generic manufacturers have requested the revocation of some formulation and combination patents either before the patent office or courts. The proceedings are ongoing. In Hungary, a preliminary injunction against Pharmacenter, based on a formulation patent, has been granted to Aventis Pharma SA. Pharmacenter appealed the decision. In Germany, a decision on one of the formulation patents is expected in June 2010.

*Eloxatin<sup>®</sup> (oxaliplatin) Patent Litigation,*

*United States.* Starting in February 2007, over a dozen ANDA certifications relating to Eloxatine<sup>®</sup> (oxaliplatin) solution and/or lyophilized products were filed 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.

In June 2009, the U.S. District Court for the District of New Jersey granted a summary judgment motion in favor of certain generic manufacturers. The District Court held that the generic oxaliplatin products that would be introduced by these generic challengers would not infringe the '874 patent. While sanofi-aventis obtained appellate reversal of the District Court's judgment, a number of generic oxaliplatin products were launched at risk in the United States over the second half of 2009. Presently, sanofi-aventis has been unsuccessful in obtaining injunctive relief. On December 2, 2009, the court asked all the parties to consider settlement.

*Ambien<sup>®</sup> CR Patent Litigation*

Starting in 2007, sanofi-aventis filed suits for infringement of U.S. Patent No. 6,514,531 (the '531 patent) 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 Watson, Barr, Mutual and Sandoz. Watson subsequently converted to a Paragraph III certification, and Barr and Mutual have withdrawn their ANDAs, leaving suit in New Jersey ongoing only against Sandoz.

In 2007, sanofi-aventis also filed suit for infringement of the '531 patent in the U.S. District Court for the Middle District of North Carolina based on an ANDA for a generic version of Ambien<sup>®</sup> CR filed by Synthon. That case was transferred to the Eastern District of North Carolina, and subsequently was stayed pending a USPTO reexamination of the '531 patent. On December 22, 2009, Synthon provided sanofi-aventis with 120 days notice of its intention to launch its generic version of Ambien<sup>®</sup> CR.

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

Sanofi-aventis did not bring suit against Anchen, which was the first to notify sanofi-aventis of its Paragraph IV ANDA on the 12.5mg strength, or against Abrika (now Actavis), which was the first to notify sanofi-aventis on its Paragraph IV ANDA on the 6.25mg strength. Sanofi-aventis also did not bring suit against three other subsequent Paragraph IV filers: Lupin, Andrx and PTS Consulting. Marketing exclusivities in the United States for Ambien® CR expired in March 2009.

### *Nasacort® 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® 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® AQ patents (U.S. Patents 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® (triamcinolone acetonide) AQ. This settlement took effect on January 2, 2009.

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 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 U.S. 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.

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. 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.

On December 22, 2009, Sanofi-Aventis and Novo Nordisk concluded a settlement agreement ending all intellectual property disputes regarding SoloSTAR®, NovoPen® 4 and NovoFine® Autocover® in the USA, Germany and Denmark.

*Xatral® Patent Litigation*

Starting in August 2007, sanofi-aventis has received several ANDA certifications relating to Xatral® 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 for the District of Delaware. Trial against Mylan (who is the only remaining defendant) has been scheduled for March 2010.

*Xyzal® Tablets ANDA*

Sanofi-aventis has a co-commercialization agreement with UCB Inc. with respect to Xyzal® 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*

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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.

**c) Government Investigations, Competition Law and Regulatory Claims**

*Government Investigations Pricing and Marketing Practices*

*Private Labels.* In May 2009, sanofi-aventis U.S. entered into a civil settlement with the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts to resolve a Medicaid best price investigation involving one of its predecessor companies, Aventis Pharmaceuticals Inc. (API). The settlement ended an investigation into whether sales by API of certain products to a managed care organization for resale under that organization's private label should have been included in the best price calculations used to compute Medicaid rebates for API products. The settlement called for payment of \$95.5 million (plus interest) which includes payment of approximately \$55.5 million to resolve all federal claims and the establishment of an opt-in fund of approximately \$40 million for states desiring to resolve Medicaid rebate claims relating to the same conduct. The total amount of the settlement was fully covered by existing reserves.

*Lovenox® Marketing.* The U.S. Attorney's Office in Chicago, Illinois 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.

*Ambien® and Ambien® CR Marketing.* On August 11, 2008, sanofi-aventis U.S. received a subpoena issued by the U.S. Department of Health & Human Services Office of Inspector General and the U.S. Attorney's Office in San Francisco, California. The subpoena requested information regarding Ambien® and Ambien® CR in connection with an investigation of possible false or otherwise improper claims for payment under Medicare and Medicaid. Sanofi-aventis U.S. has provided documents in response to this subpoena.

*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.

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

A group of eleven defendants, including sanofi-aventis defendants, 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 which is expected in 2010, all the class actions suits against API before the U.S District Court in Boston will be ended consistent with the settlement. Sanofi-aventis share of the global settlement is fully covered by existing reserves. One additional purported class action remains in New Jersey and is in discovery phase.

*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 notably 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 pending 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.

In May 2009, sanofi-aventis U.S. entered into a group settlement (with six other pharmaceutical companies) to resolve claims brought by the State of Alabama, against Aventis Pharmaceuticals Inc. and Sanofi-Synthelabo Inc., sanofi-aventis predecessor companies. The settlement covers all AWP-based claims against sanofi-aventis and all of its predecessors, subsidiaries and other corporate affiliates involving the State's Medicaid program. The settlement involves confidential contributions by the companies, including sanofi-aventis, to a group settlement totaling \$89 million. Sanofi-aventis share of the settlement was fully covered by existing reserves.

*§ 340B Suit.* 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 in breach of pharmaceutical pricing agreements between the defendants and the Secretary of Health and Human Services. In May 2009, the Court denied the plaintiffs' motion for class certification without prejudice. Discovery is ongoing.

*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.

*European Commission Fines*

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

Following the appeal filed by Hoechst GmbH regarding the MCAA market fine of 74 million assessed against it by the European Commission, the fine was reduced in September 2009 to 66.6 million (not including interests). As neither Hoechst nor the Commission has appealed, the fine is subject to payment early 2010.

### *European Commission 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 final report was released on July 8, 2009. The Commission announced that the pharmaceutical industry remained under scrutiny and that it intends to intensify its investigations regarding anti-competitive conduct.



---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009***European Commission generics investigation*

On October 6, 2009, the European Commission conducted surprise inspections in the offices of several pharmaceutical companies, including sanofi-aventis, under suspicion of infringing antitrust rules of the European Union with respect to their activities concerning so-called generic products .

*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 laws and various state laws by settling a patent dispute regarding the brand-name prescription drug Cipro® 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 U.S. 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 was heard by the U.S. Court of Appeals for the Second Circuit in April 2009. No opinion has yet been issued.

*DDAVP® 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® 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® 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. Oral argument on plaintiffs' appeal of the decision to dismiss was heard by the U.S. Court of Appeals for the Second circuit in 2008. By order dated October 16, 2009, the appellate court reversed and remanded the case back to the District Court. Petitions for rehearing and rehearing en banc were denied.

*Plavix® 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® patent litigation (see *Plavix® 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® on the same or similar grounds. Plaintiffs seek relief including injunctive relief and monetary damages. Defendants have moved to dismiss the consolidated direct and indirect purchasers' complaints. Oral argument on this motion was heard in September 2008; no decision has yet been issued.

*Arava® 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®. 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 requested the judge to reconsider the jury's verdict. The plaintiff's motion requesting the Court to reconsider the jury's verdict and grant a new trial was denied on August 28, 2009. Following this decision the parties agreed that plaintiff would forego its appeal in return for sanofi-aventis withdrawing its motion for costs. The matter is now concluded.

F-100

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009***Lovenox® Antitrust Litigation*

In August 2008, Eisai Inc. ( Eisai ) brought suit against sanofi-aventis U.S. LLC and sanofi-aventis U.S. Inc. in the U.S. District Court for the District of New Jersey alleging that certain contracting practices for Lovenox® violate federal and state antitrust laws. In October 2008, the defendants filed a motion to dismiss Eisai's complaint, which was denied in June 2009. In November 2009, the defendants filed a second motion to dismiss, which remains pending.

**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 its 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.

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*

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 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 ). The proceedings are ongoing.

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

### *Zimulti® /Acompli® (rimonabant) Class Action*

In November 2007, a purported class action was filed in the U.S. District Court for the Southern District of New York on behalf of purchasers of sanofi-aventis shares. The complaint charged sanofi-aventis and certain of its current and former officers and directors with violations of the Securities Exchange Act of 1934. The complaint alleged that defendants' statements regarding rimonabant were materially false and misleading when made because defendants allegedly concealed data concerning rimonabant's propensity to cause depression. In September 2009, the motion was dismissed with prejudice. The plaintiffs have filed a motion for reconsideration.

### *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 U.S. District Court for the Southern District of New York alleging gender discrimination. The parties have entered into a settlement in December 2009 which is fully covered by the existing reserves.

F-101

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

*Merial*

On August 31, 2009, a purported class action lawsuit was filed against Merial, alleging that Merial engaged in false and misleading advertising of Heartgard® and Heartgard® Plus by claiming 100% efficacy in the prevention of heartworm disease, as well as the prevention of zoonotic diseases. Plaintiffs also request punitive damages and a permanent injunction with respect to the alleged advertising. The case is at an early stage and the class has not been certified yet.

**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.

*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*

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

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®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 initiated in August 2003 for an alleged breach of a financial statement-related

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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 and product 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 actions and individual complaints that have 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 in connection with the detection of trace amounts of the genetically modified rice called Liberty Link Rice 601 (also known as LLRICE601 ) or Liberty Link 604 (also known as LLRICE604 ) in samples of commercial long-grain rice. LLRICE601 and LLRICE604, each a variety of long grain rice 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. In the first bellwether trial concluded on December 4, 2009, the jury rendered a verdict awarding compensatory damages, in the amount of \$1,955,387 in favour of one plaintiff, and \$53,336 in favour of another plaintiff.

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 SA 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.

*Celanese AG*

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

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:

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 splits 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

F-103



---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

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, 2009, was significantly below the first threshold of 250 million.

*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 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 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 Commercial Court of Paris (*Tribunal de Commerce de Paris*) seeking indemnification on the same grounds as described above. The relief sought in the Commercial Court of Paris 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

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

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.

F-104

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

*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 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 lands, 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.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009****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:

<i>( million)</i>	<b>Government and State programs <sup>(1)</sup></b>	<b>Managed Care and GPO programs <sup>(2)</sup></b>	<b>Charge- back incentives</b>	<b>Rebates and discounts</b>	<b>Sales returns</b>	<b>Other deductions</b>	<b>Total</b>
<b>January 1, 2007</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>
Current provision related to current period sales	566	433	904	2,036	204	128	4,271
Net change in provision related to prior period sales	19	7	12	(7)	31	31	31
Payments made	(477)	(431)	(903)	(1,893)	(175)	(136)	(4,015)
Translation differences	(8)	(7)	(3)	9	(3)	2	(10)
<b>December 31, 2009</b>	<b>386</b>	<b>187</b>	<b>80</b>	<b>425</b>	<b>202</b>	<b>46</b>	<b>1,326</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, 2009	Year ended December 31, 2008	Year ended December 31, 2007
Salaries	(5,019)	(4,774)	(4,891)
Social security charges (including defined-contribution pension plans)	(1,510)	(1,451)	(1,462)
Share-based payment	(114)	(125)	(115)
Employee share ownership plan			(21)
Defined-benefit pension plans	(404)	(305)	(346)
Other employee benefits	(233)	(259)	(197)
<b>Total</b>	<b>(7,280)</b>	<b>(6,914)</b>	<b>(7,032)</b>

The total number of employees at December 31, 2009 was 104,867, compared with 98,213 at December 31, 2008 and 99,495 at December 31, 2007 (these employee numbers are unaudited).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

Employee numbers by function (excluding Merial) as of December 31 are shown below (unaudited):

	<b>December 31, 2009</b>	<b>December 31, 2008</b>	<b>December 31, 2007</b>
Production	36,849	31,903	31,292
Research and development	19,132	18,976	19,310
Sales force	34,292	33,507	35,115
Marketing and support functions	14,594	13,827	13,778
<b>Total</b>	<b>104,867</b>	<b>98,213</b>	<b>99,495</b>

Merial had a total of 5,601 employees (unaudited) as of December 31, 2009.

**D.25. Other operating income**

Other operating income amounted to 866 million in 2009, compared with 556 million in 2008 and 522 million in 2007.

This line includes income arising under alliance agreements in the Pharmaceuticals segment ( 646 million in 2009, compared with 472 million in 2008 and 323 million in 2007), in particular the agreement on the worldwide development and marketing of Actonel<sup>®</sup> (see Note C.2.) and the Group's share of profits on Copaxone<sup>®</sup> from April 1, 2008, the date on which commercialization of this product in the United States and Canada reverted to Teva Pharmaceutical Industries.

It also includes operating foreign exchange gains and losses, representing a net gain of 40 million in 2009 versus a net loss of 94 million in 2008 and a net loss of 33 million in 2007, and proceeds from disposals related to ongoing operations, which amounted to 56 million in 2009, 24 million in 2008, and 60 million in 2007.

**D.26. Other operating expenses**

Other operating expenses amounted to 481 million in 2009, against 353 million in 2008 and 307 million in 2007. This item includes shares of profits due to alliance partners (other than BMS and the Alliance Partner under the Actonel<sup>®</sup> agreement) under product marketing agreements, primarily in Europe, Japan, the United States and Canada ( 186 million in 2009, versus 178 million in 2008 and 136 million in 2007).

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

In 2009, this item includes an expense of 69 million (versus 113 million in 2008) 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.).

This item also includes, for 2009, an expense of 59 million relating to pensions and other benefits for retirees.

In 2007, this item included an expense of 61 million, recognized following the signature of agreements on welfare and healthcare obligations in France for retirees and their beneficiaries.

F-107

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009****D.27. Restructuring costs**

Restructuring costs recognized in 2009 amount to 1,080 million ( 585 million in 2008 and 137 million in 2007), and break down as follows:

<i>( million)</i>	Year ended December 31, 2009	Year ended December 31, 2008	Year ended December 31, 2007
Employee-related expenses	869	498	137
Expenses related to property, plant and equipment	146		
Compensation for early termination of contracts (other than contracts of employment)	19		
Decontamination costs	30	50	
Other restructuring costs	16	37	
<b>Total</b>	<b>1,080</b>	<b>585</b>	<b>137</b>

In 2009, restructuring costs related primarily to measures announced by sanofi-aventis in June 2009 aimed at transforming its Research and Development operations in France in order to stimulate innovation and at adapting central support functions in order to streamline the organizational structure. These costs mainly comprise employee-related expenses, in the form of early retirement benefits and of termination benefits under voluntary redundancy plans. In France, these plans affected approximately 1,000 jobs in Research and Development and 450 jobs in central support functions.

Restructuring costs for the period also included amounts relating to transformation plans announced in other countries. The Research and Development transformation plan is a global project, which also affects the United States, the United Kingdom and Japan.

To a lesser extent, restructuring costs for the period reflect ongoing measures taken by sanofi-aventis to adapt its industrial facilities in Europe and adjust its sales forces.

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.

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.



**D.28. Gains and losses on disposals, and litigation**

Sanofi-aventis made no major divestments during the years ended December 31, 2009, 2008 or 2007.

In 2008, this item included 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 ).

F-108

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009****D.29. Financial income and expenses**

Financial income and expenses break down as follows:

<i>( million)</i>	<b>Year ended December 31, 2009</b>	<b>Year ended December 31, 2008</b>	<b>Year ended December 31, 2007</b>
Cost of debt <sup>(1)</sup>	(310)	(315)	(297)
Interest income	88	132	88
<b>Cost of debt, net of cash and cash equivalents</b>	<b>(222)</b>	<b>(183)</b>	<b>(209)</b>
Foreign exchange gains (non-operating)	(67)	(74)	87
Fair value gains/(losses) on other derivatives			4
Unwinding of discounting of provisions <sup>(2)</sup>	(42)	(37)	(38)
Net gains/(losses) on disposals of financial assets <sup>(3)</sup>	1	41	7
Impairment losses on financial assets, net of reversals <sup>(4)</sup>	(2)	(8)	(14)
Other items	32	29	24
<b>Net financial income/(expenses)</b>	<b>(300)</b>	<b>(232)</b>	<b>(139)</b>
<i>comprising: Financial expenses</i>	<i>(324)</i>	<i>(335)</i>	<i>(329)</i>
<i>Financial income</i>	<i>24</i>	<i>103</i>	<i>190</i>

<sup>(1)</sup> Includes gains/losses on interest rate derivatives used to hedge debt: 25 million gain in 2009, 2 million loss in 2008, 13 million gain in 2007.<sup>(2)</sup> Excluding provisions for pensions and similar obligations.<sup>(3)</sup> Includes 38 million from the sale of the investment in Millennium in 2008 (see Note D.7.).<sup>(4)</sup> Primarily available-for-sale financial assets.

The impact of the ineffective portion of hedging relationships was not material in 2009, 2008 or 2007.

**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:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<i>( million)</i>	Year ended December 31, 2009	Year ended December 31, 2008	Year ended December 31, 2007
Current taxes	(2,531)	(2,140)	(2,162)
Deferred taxes	1,167	1,458	1,475
<b>Total</b>	<b>(1,364)</b>	<b>(682)</b>	<b>(687)</b>

F-109

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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>	<b>Year ended December 31, 2009</b>	<b>Year ended December 31, 2008</b>	<b>Year ended December 31, 2007</b>
Standard tax rate applicable in France	34	34	34
Impact of reduced-rate income tax on royalties in France	(9)	(12)	(8)
Impact of change in net deferred tax liabilities as a result of changes in tax rates <sup>(1)</sup>	1		(9)
Impact of the ratification of the Franco-American treaty on net deferred tax liabilities relating to tax cost of distributions made from reserves	(2)		
Impact of tax borne by BMS for the territory managed by sanofi-aventis (see Note D.32.)	(3)	(4)	(3)
Other	1	(2)	(2)
<b>Effective tax rate</b>	<b>22</b>	<b>16</b>	<b>12</b>

<sup>(1)</sup> In 2009, mainly the reform of local business taxes in France; in 2007, primarily the reduction from 40% to 31.3% in Germany

Because the tax impact of royalties has remained relatively stable since 2007, the changes in the line *Impact of reduced-rate income tax on royalties in France* are mainly due to significant year-on-year fluctuations in pre-tax profits in 2009, 2008 and 2007.

A new protocol to the 1994 U.S.-France income tax treaty took effect on December 23, 2009. The new protocol eliminates source-country taxation of certain direct dividends (subject to conditions) and source-country taxation of cross-border royalty payments. The protocol applies retroactively to January 1, 2009 with respect to taxes that have been withheld at the former rate of 5% for both dividends and royalties. Consequently, the withholding taxes deducted at source in 2009 will be reimbursed and the deferred tax liability on tax cost of distributions made from reserves is reduced by 106 M .

The French Business Tax reform was enacted on December 31, 2009 and is applicable as from January 1, 2010. The Finance Bill repealed the Local Business Tax (*taxe professionnelle*). The new tax CET (*Contribution Economique Territoriale*) has two components, the CFE (*Cotisation Fonciere des Entreprises*), and the CVAE (*Cotisation sur la Valeur Ajoutee des Entreprises*). The second component is determined by applying a rate to the amount of value added generated by the business during the year.

Given that part of the CVAE component is calculated as the amount by which certain revenues exceed certain expenses, and given that this tax will be borne primarily by companies that own intellectual property rights, on income derived from those rights (royalties, and margin on sales to third parties and to other Group companies), sanofi-aventis regards the CVAE component as meeting the definition of income taxes specified in IAS 12, paragraph 2 ( taxes which are based on taxable profits ). Consequently, a deferred tax liability has been recognized, generating an expense of 59 million, relating primarily to depreciable assets in the balance sheet as of December 31, 2009 (the exemption allowed under IAS

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

12, paragraph 22c does not apply in this case). This deferred tax expense is reported on the *Income taxes* line in the income statement. With effect from the year ending December 31, 2010, the total current and deferred tax expense relating to the CVAE component will also be reported on this line in the income statement.

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 2009 was 1,229 million, before deducting the tax effect of 444 million (2008: 984 million, tax effect 361 million; 2007: 816 million, tax effect 290 million).

F-110

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

It also includes the share of profits or losses from other associates ( 29 million profit in 2009, 69 million profit in 2008 and 80 million loss in 2007). These figures include the effect of the Aventis acquisition (workdown of acquired inventories, amortization and impairment of intangible assets). The 2007 figure included an impairment loss of 102 million on the equity-accounted investment in Zentiva (see Note D.6.).

In accordance with IFRS 5 the share of profits from Meriel for 2008 and 2007 has been retrospectively reclassified to the line *Net income from the held-for-exchange Meriel business* (see Note D.8.).

**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 405 million in 2009, 422 million in 2008 and 403 million in 2007. 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 ( 21 million in 2009, 19 million in 2008 and 16 million in 2007).

**D.33. Related party transactions**

The principal related parties of sanofi-aventis are companies over which the Group has significant influence, 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, 2009, December 31, 2008 and December 31, 2007.

Details of transactions with related companies are disclosed in Note D.6.

Key management personnel include corporate officers (including three directors during 2009 and four directors during 2008 and 2007 covered by supplementary pension plans, see Item 6.B.) and the members of the Management Committee (23 members during 2009, 22 during 2008 and 21 during 2007).

The table below shows, by type, the compensation paid to key management personnel:

<i>( million)</i>	Year ended December 31, 2009	Year ended December 31, 2008	Year ended December 31, 2007
Short-term benefits <sup>(1)</sup>	34	37	30
Post-employment benefits <sup>(2)</sup>	14	16	14
Share-based payment <sup>(3)</sup>	9	11	12
<b>Total recognized in the income statement</b>	<b>57</b>	<b>64</b>	<b>56</b>

<sup>(1)</sup> Compensation, employer's social security contributions, directors' attendance fees, and any termination benefits.

<sup>(2)</sup> Estimated pension cost, calculated in accordance with IAS 19.

<sup>(3)</sup> Stock option expense computed using the Black-Scholes model, plus expense relating to the discount arising under the 2007 employee share ownership plan

The aggregate amount of supplementary pension obligations to corporate officers and key management personnel was 191 million at December 31, 2009, versus 183 million at December 31, 2008 and 163 million at December 31, 2007. The aggregate amount of lump-sum retirement benefits payable to corporate officers and key management personnel was 14 million at December 31, 2009, versus 10 million at December 31, 2008 and 12 million at December 31, 2007.

#### 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

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

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.

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 8.1%, 7.5% and 6.8% of gross sales in 2009.

**Net sales**

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 flagship products and of the other major products of the Pharmaceuticals segment:

( million)	Year ended December 31,		
	2009	2008	2007
Lantus®	3,080	2,450	2,031
Lovenox®	3,043	2,738	2,612
Plavix®	2,623	2,609	2,424
Taxotere®	2,177	2,033	1,874
Aprovel®/CoAprovel®	1,236	1,202	1,080
Eloxatine®	957	1,345	1,521
Apidra®	137	98	
Multaq®	25		
<b>Flagship products</b>	<b>13,278</b>	<b>12,475</b>	<b>11,542</b>
Stilnox®/Ambien®/Myslee®	873	822	1,250
Allegra®	731	666	706
Copaxone®	467	622	1,177
Tritace®	429	491	741
Amaryl®	416	379	392
Depakine®	329	322	316
Xatral®	296	319	333
Actonel®	264	330	320
Nasacort®	220	240	294
<b>Other Products</b>	<b>6,078</b>	<b>6,484</b>	<b>8,203</b>
<b>Consumer Health Care</b>	<b>1,430</b>	<b>1,203</b>	
<b>Generics</b>	<b>1,012</b>	<b>354</b>	
<b>Total Pharmaceuticals</b>	<b>25,823</b>	<b>24,707</b>	<b>25,274</b>

Net sales of the principal product ranges of the Vaccines segment are shown below:



Edgar Filing: SANOFI-AVENTIS - Form 20-F

<i>( million)</i>	Year ended December 31,		
	2009	2008	2007
Influenza Vaccines <sup>(1)</sup>	1,062	736	766
Pediatric Combination and Poliomyelitis Vaccines	968	768	660
Meningitis/Pneumonia Vaccines	538	472	482
Adult and Adolescent Booster Vaccines	406	399	402
Travel and Endemic Vaccines	313	309	327
Other Vaccines	196	177	141
<b>Total Vaccines</b>	<b>3,483</b>	<b>2,861</b>	<b>2,778</b>

(1) Seasonal and pandemic influenza vaccines.

F-112

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2009**

**D.35. Segment information**

As indicated in Note B.26., sanofi-aventis has two operating segments: the Pharmaceuticals segment and the Human Vaccines (Vaccines) segment. All other activities are combined in a separate segment, Other.

The Pharmaceuticals segment covers research, development, production and marketing of medicines. The sanofi-aventis pharmaceuticals portfolio consists of flagship products, plus a broad range of prescription medicines, generic medicines, and consumer health care products. This segment also includes all associates whose activities are related to pharmaceuticals, in particular the entities majority owned by BMS.

The Human Vaccines segment is wholly dedicated to vaccines, including research, development, production and marketing. This segment includes the Sanofi Pasteur MSD joint venture.

The Other segment includes all segments that are not reportable segments within the meaning of IFRS 8. This segment includes the Group's interest in the Yves Rocher group, the Animal Health business (Meriel), and the impact of retained commitments in respect of divested activities. Inter-segment transactions are not material.

**Segment results**

Sanofi-aventis reports segment results on the basis of Business operating income. This indicator, adopted in order to comply with IFRS 8, is used internally to measure operational performance and allocate resources.

Business operating income equates to Operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals, and litigation, as defined in Note B.20. to the consolidated financial statements, adjusted as follows:

amortization charged against intangible assets is eliminated;

the share of profits/losses of associates is added, and the share of net income attributable to minority interests is deducted;

other acquisition-related effects (primarily the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of acquisitions on investments in associates) are eliminated.

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Segment results are shown in the tables below:

<i>( million)</i>	<b>2009</b>			
	<b>Pharmaceuticals</b>	<b>Vaccines</b>	<b>Other</b>	<b>Total</b>
<b>Net sales</b>	<b>25,823</b>	<b>3,483</b>		<b>29,306</b>
Other revenues	1,412	31		1,443
Cost of sales	(6,527)	(1,326)		(7,853)
Research and development expenses	(4,091)	(491)	(1)	(4,583)
Selling and general expenses	(6,762)	(561)	(2)	(7,325)
Other operating income and expenses	387	(3)	1	385
Share of profit/(loss) of associates excluding Merial <sup>(1)</sup>	792	41	8	841
Share of profit/loss of Merial <sup>(1)</sup>			241	241
Net income attributable to minority interests	(426)	(1)		(427)
<b>Business operating income</b>	<b>10,608</b>	<b>1,173</b>	<b>247</b>	<b>12,028</b>
Financial income and expenses				(300)
Income tax expense				(3,099)
<b>Business net income</b>				<b>8,629</b>

<sup>(1)</sup> Net of taxes

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

<i>( million)</i>	<b>2008</b>			
	<b>Pharmaceuticals</b>	<b>Vaccines</b>	<b>Other</b>	<b>Total</b>
<b>Net sales</b>	<b>24,707</b>	<b>2,861</b>		<b>27,568</b>
Other revenues	1,208	41		1,249
Cost of sales	(6,231)	(1,104)		(7,335)
Research and development expenses	(4,150)	(425)		(4,575)
Selling and general expenses	(6,662)	(520)	14	(7,168)
Other operating income and expenses	297	1	(95)	203
Share of profit/(loss) of associates excluding Merial <sup>(1)</sup>	671	28	21	720
Share of profit/loss of Merial <sup>(1)</sup>			170	170
Net income attributable to minority interests	(441)			(441)
<b>Business operating income</b>	<b>9,399</b>	<b>882</b>	<b>110</b>	<b>10,391</b>
Financial income and expenses				(270)
Income tax expense				(2,807)
<b>Business net income</b>				<b>7,314</b>

<sup>(1)</sup> Net of taxes

<i>( million)</i>	<b>2007</b>			
	<b>Pharmaceuticals</b>	<b>Vaccines</b>	<b>Other</b>	<b>Total</b>
<b>Net sales</b>	<b>25,274</b>	<b>2,778</b>		<b>28,052</b>
Other revenues	1,085	70		1,155
Cost of sales	(6,549)	(1,022)		(7,571)
Research and development expenses	(4,103)	(429)	(5)	(4,537)
Selling and general expenses	(7,059)	(522)	27	(7,554)
Other operating income and expenses	292	(7)	(9)	276
Share of profit/(loss) of associates excluding Merial <sup>(1)</sup>	563	1	15	579
Share of profit/loss of Merial <sup>(1)</sup>			181	181
Net income attributable to minority interests	(419)			(419)
<b>Business operating income</b>	<b>9,084</b>	<b>869</b>	<b>209</b>	<b>10,162</b>
Financial income and expenses				(139)
Income tax expense				(2,963)
<b>Business net income</b>				<b>7,060</b>

<sup>(1)</sup> Net of taxes

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

Business net income is determined by taking business operating income and adding financial income and deducting financial expenses, including the related income tax effects.

Business net income is defined as *Net income attributable to equity holders of the Company*, determined under IFRS, excluding (i) amortization of intangible assets; (ii) impairment of intangible assets, (iii) other impacts associated with acquisitions (including impacts of acquisitions on associates); (iv) restructuring costs; gains and losses on disposals of non-current assets; costs or provisions associated with litigation; (v) the tax effect related to the items listed in (i) through (iv) as well as (vi) effects of major tax disputes, and (vii) the share of minority interests on (i) through (vi). Items listed in (iv) correspond to those reported in the line items *Restructuring costs* and *Gains and losses on disposals, and litigation*, which are defined in Note B.20. to our consolidated financial statements.

F-114

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

A reconciliation of Business net income to *Net income attributable to equity holders of the Company* is set forth below:

( million)	Year ended December 31, 2009	Year ended December 31, 2008	Year ended December 31, 2007
<b>Business net income</b>	<b>8,629</b>	<b>7,314</b>	<b>7,060</b>
(i) amortization of intangible assets	(3,528)	(3,483)	(3,654)
(ii) impairment of intangible assets	(372)	(1,554)	(58)
(iii) expenses arising on the workdown of acquired inventories <sup>(1)</sup>	(27)	(2)	
(iv) restructuring costs	(1,080)	(585)	(137)
(iii)/(iv) other items <sup>(2)</sup>		114	(61)
(v) tax effect on the items listed above	1,629	1,904	1,939
(iii)/(vi) other tax items <sup>(3)</sup>	106	221	337
(vii) share of minority interests on the items listed above	1		
(iii) expenses arising from the impact of the Merial acquisition <sup>(4)</sup>	(66)	(50)	(30)
(iii) expenses arising from the impact of acquisitions on associates <sup>(5)</sup>	(27)	(28)	(133)
<b>Net income attributable to equity holders of the Company</b>	<b>5,265</b>	<b>3,851</b>	<b>5,263</b>

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

(2) Other items comprise:

Harmonization of welfare and healthcare plans for retirees			(61)
Gain on sale of investment in Millennium		38	
Reversal of provisions for major litigation		76	

(3) Other tax items comprise:

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

(4) This line comprises: until September 17, 2009, amortization and impairment charged against the intangible assets of Merial; and from September 18, 2009, (i) the impact of the discontinuation of depreciation of the property, plant and equipment of Merial in accordance with IFRS 5 (see Note B.7.) and (ii) the expense arising from the workdown of inventories remeasured at fair value at the acquisition date.

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

**Other segment information**

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

The tables below show the split by operating segment of (i) the carrying amount of investments in associates and joint ventures accounted for by the equity method, (ii) acquisitions of property, plant and equipment, and (iii) acquisitions of intangible assets.

The principal associates and joint ventures accounted for by the equity method are: for the Pharmaceuticals segment, the entities managed by BMS (see Note C.1. to the consolidated financial statements for the year ended December 31, 2009), Handok, Infracerv, and (for the year ended December 31, 2008) Zentiva; for the Vaccines segment, Sanofi Pasteur MSD; and for the Other segment, Merial and Yves Rocher in 2007 and 2008, and Yves Rocher in 2009.

F-115

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

Acquisitions of intangible assets and property, plant and equipment correspond to acquisitions paid for during the period.

( million)	2009			Total
	Pharmaceuticals	Vaccines	Other	
Investments in associates and joint ventures accounted for by the equity method	420	412	123	955
Acquisitions of property, plant and equipment	940	465		1,405
Acquisitions of intangible assets	364	16		380

( million)	2008			Total
	Pharmaceuticals	Vaccines	Other	
Investments in associates and joint ventures accounted for by the equity method	706	431	1,322	2,459
Acquisitions of property, plant and equipment	967	375		1,342
Acquisitions of intangible assets	225	39		264

( million)	2007			Total
	Pharmaceuticals	Vaccines	Other	
Investments in associates and joint ventures accounted for by the equity method	768	471	1,254	2,493
Acquisitions of property, plant and equipment	977	359		1,336
Acquisitions of intangible assets	237	37		274

**Information by geographical region:**

The geographical information on net sales provided below is based on the geographical location of the customer.

In accordance with IFRS 8, the non-current assets reported below exclude financial instruments, deferred tax assets, and pre-funded pension obligations.

( million)	2009					
	Total	Europe	Of which France	North America	Of which United States	Other countries
Net sales	29,306	12,059	3,206	9,870	9,426	7,377
Non-current assets:						
property, plant and equipment	7,830	5,734	3,436	1,375	1,018	721
intangible assets	13,747	4,636		5,930		3,181
goodwill	29,733	13,528		11,419		4,786



Edgar Filing: SANOFI-AVENTIS - Form 20-F

( million)	2008					
	Total	Europe	Of which France	North America	Of which United States	Other countries
Net sales	<b>27,568</b>	12,096	3,447	9,042	8,609	6,430
Non-current assets:						
property, plant and equipment	<b>6,961</b>	5,174	3,181	1,320	1,042	467
intangible assets	<b>15,260</b>	4,573		7,429		3,258
goodwill	<b>28,163</b>	12,414		11,750		3,999

F-116

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Year ended December 31, 2009

( million)	Total	Europe	Of which France	2007		Other countries
				North America	Of which United States	
Net sales	<b>28,052</b>	12,184	3,610	9,989	9,474	5,879
Non-current assets:						
property, plant and equipment	<b>6,538</b>	4,958	2,884	1,157	843	423
intangible assets	<b>19,182</b>	6,327		9,081		3,774
goodwill	<b>27,199</b>	12,428		11,041		3,730

As described in Note D.5. to the consolidated financial statements, France is not a cash-generating unit. Consequently, information about goodwill is provided for Europe.

**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, 2009 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, 2009 and 2008:

( million)	Ernst & Young		PricewaterhouseCoopers	
	2009 Amount	2008 Amount	2009 Amount	2008 Amount
<b>Audit</b>				
<b>Audit opinion, review of statutory and consolidated financial statements</b> <sup>(1)</sup>	<b>13.1</b>	<b>11.7</b>	<b>14.1</b>	<b>12.2</b>
- of which sanofi-aventis SA	4.1	4.1	4.0	4.1
- of which consolidated subsidiaries	9.0	7.6	10.1 <sup>(3)</sup>	8.1
<b>Other audit-related services</b> <sup>(2)</sup>	<b>1.0</b>	<b>0.7</b>	<b>0.8</b>	<b>0.1</b>
- of which sanofi-aventis SA	0.1		0.1	
- of which consolidated subsidiaries	0.9	0.7	0.7	0.1
<b>Sub-total</b>	<b>14.1</b>	<b>12.4</b>	<b>14.9</b>	<b>12.3</b>
<b>Non-audit services</b>				
Tax				
Other				
<b>Sub-total</b>				
<b>TOTAL</b>	<b>14.1</b>	<b>12.4</b>	<b>14.9</b>	<b>12.3</b>

<sup>(1)</sup> 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

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

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.
- (3) Of which Merial audit fees for an amount of 1,7 million (Audit review as of December 31, 2009, and agreed upon procedures at acquisition date).

### **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 2009, the Audit Committee established a budget breaking down permitted audit-related services and non-audit services, and the related fees to be paid.

F-117

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009****F. LIST OF PRINCIPAL COMPANIES INCLUDED IN THE CONSOLIDATION FOR THE YEAR ENDED DECEMBER 31, 2009****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 GmbH / Bristol-Myers Squibb GesmbH OHG <sup>(1)</sup>	Austria	50.1
Sanofi-Aventis GmbH	Austria	100
Sanofi-Aventis Belgium	Belgium	100
Sanofi-Aventis s.r.o.	Czech Republic	100
Zentiva (from March 31, 2009)	Czech Republic	99.1
Sanofi-Aventis Denmark A/S	Denmark	100
Sanofi Winthrop BMS partnership (JV DK) <sup>(1)</sup>	Denmark	50.1
Sanofi-Aventis SA (Spain)	Spain	100
Sanofi Winthrop BMS AY <sup>(1)</sup>	Finland	50.1
Sanofi-Aventis 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
Fovea Pharmaceuticals	France	100
Francopia S.A.R.L.	France	100
Laboratoire Oenobiol SAS	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	50.1
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 A.E.B.E.	Greece	100
Chinoi Private Co. Ltd	Hungary	99.6
Sanofi-Aventis Private Co. Ltd	Hungary	99.6
Cahir Insurance Ltd	Ireland	100

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Carraig Insurance Ltd	Ireland	100
Sanofi-Aventis Ireland Ltd	Ireland	100
Sanofi-Aventis Spa	Italy	100
Sanofi-Aventis Norge AS	Norway	100
Sanofi Winthrop BMS partnership ANS <sup>(1)</sup>	Norway	50.1
Sanofi-Aventis Netherland BV	Netherlands	100
Sanofi Winthrop BMS VOF <sup>(1)</sup>	Netherlands	50.1
Sanofi-Aventis Sp Zoo	Poland	100
Winthrop Farmaceutica Portugal Lda	Portugal	100
Sanofi-Aventis Produtos Farmaceuticos Lda	Portugal	100

<sup>(1)</sup> Partnership with Bristol-Myers Squibb (see Note C.1.).

F-118

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

		<b>Financial interest %</b>
<i>Europe</i>		
Sanofi Winthrop BMS AEIE <sup>(1)</sup>	Portugal	51
Sanofi-Aventis Romania SRL	Romania	100
Aventis Pharma ZAO	Russia	100
Aventis Pharma Ltd	United Kingdom	100
Merial (from September 18, 2009)	United Kingdom	100
Sanofi Pasteur Holding Limited	United Kingdom	100
Sanofi-Synthelabo Ltd	United Kingdom	100
Sanofi-Synthelabo UK Ltd	United Kingdom	100
Winthrop Pharmaceuticals UK Ltd	United Kingdom	100
Fisons Limited	United Kingdom	100
May and Baker Limited	United Kingdom	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-Synthelabo CIS & Eastern countries SA	Switzerland	100
Sanofi-Aventis Ilaclari Ltd Sirketi	Turkey	100
Winthrop Ilac Anonim Sirketi	Turkey	100
Sanofi-Synthelabo Ilac AS	Turkey	100
Sanofi-Synthelabo BMS ADI Ortakligi partnership <sup>(1)</sup>	Turkey	50.1
Sanofi-aventis Ukraine LLC	Ukraine	100

<sup>(1)</sup> 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
Bipar Sciences 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-Synthelabo 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

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

Winthrop Pharma Saïdal S.P.A.	Algeria	70
Sanofi-Aventis Algérie	Algeria	100
Sanofi-Aventis Argentina S.A.	Argentina	100
Quimica Medical S.A.	Argentina	100
Sanofi-Aventis Australia Pty Limited	Australia	100
Sanofi-aventis Healthcare Holdings Pty Ltd	Australia	100

F-119

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

		<b>Financial interest %</b>
<i>Other Countries</i>		
Sanofi-aventis Healthcare 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
Carlson Health Pty Ltd	Australia	100
Sanofi-Aventis Comercial e Logistica Ltda	Brazil	100
Sanofi-Aventis Farmaceutica Ltda	Brazil	100
Medley Comercial e Logistica Ltda	Brazil	100
Medley S.A. Industria Farmaceutica	Brazil	100
Sanofi Pasteur Ltd	Canada	100
Sanofi-Aventis Canada Inc.	Canada	100
Sanofi-Aventis Pharma Inc.	Canada	100
Sanofi-Aventis de Chili SA	Chile	100
Sanofi-aventis Pharma Beijing Co. Ltd	China	100
Sanofi-aventis (Hangzhou) Pharmaceuticals Co Ltd	China	100
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 S.A.	Guatemala	100
Sanofi-Aventis Hong Kong Limited	Hong Kong	100
Sanofi-Synthelabo (India) Ltd	India	100
Aventis Pharma Limited (India)	India	50.1
Shantha Biotechnics Ltd	India	95
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 (Malaysia) SDN-BHD	Malaysia	100
Sanofi-Aventis (Malaysia) 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
Laboratorios Kendrick S.A.	Mexico	100
Sanofi-Aventis Consumer Healthcare New Zealand Ltd	New Zealand	100
Sanofi-Aventis Pakistan-Ltd	Pakistan	53
Sanofi-Aventis de Panama S.A.	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



F-120

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2009**

		<b>Financial interest %</b>
<i>Other Countries</i>		
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

**F.2. Principal associates**

		<b>Financial interest %</b>
InfraServ Höchst	Germany	31.2
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-Synthélabo Partnership	United States	49.9
Bristol-Myers Squibb / Sanofi-Synthélabo Puerto Rico Partnership	United States	49.9
Sanofi Pasteur MSD SNC	France	50
Société Financière des Laboratoires de Cosmétologie Yves Rocher	France	39.1
Zentiva (Until March 30, 2009)	Czech Republic	24.9
Merial (Until September 17, 2009)	United Kingdom	50

F-121