SANOFI-AVENTIS
Form 20-F
March 04, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

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

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

OR

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

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

For the transition period from to

Commission File Number: 001-31368

Sanofi-Aventis

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant s name into English)

France

(Jurisdiction of incorporation or organization)

174, avenue de France, 75013 Paris, France

(Address of principal executive offices)

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

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

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

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

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

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

The number of outstanding shares of each of the issuer s classes of capital or common stock as of December 31, 2008 was:

Ordinary shares: 1,315,525,463

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

YES x NO ¨.

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

YES ¨ NO x.

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

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

Yes x No ¨

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

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

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

U.S. GAAP ¨ International Financial Reporting Standards as issued by the International Accounting Standards Board x Other ¨

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

Item 17 ¨ Item 18 ¨

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

YES ¨ NO x.

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PRESENTATION OF FINANCIAL AND OTHER INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

- projections of operating revenues, net income, adjusted net income, earnings per share, adjusted earnings per share, capital expenditures, positive or negative synergies, dividends, capital structure or other financial items or ratios;
- statements of our plans, objectives or goals, including those relating to products, clinical trials, regulatory approvals and competition;
- statements about our future economic performance or that of France, the United States or any other countries in which we operate; and
- statements of assumptions underlying such statements.

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

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

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

our ability to renew our product portfolio;

the increasingly challenging regulatory environment for the pharmaceutical industry;

uncertainties over the pricing and reimbursement of pharmaceutical products;

fluctuations in currency exchange rates; and

slowdown of global economic growth.

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

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

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PART I

Item 1. Identity of Directors, Senior Management and Advisers

N/A

Item 2. Offer Statistics and Expected Timetable

N/A

Item 3. Key Information

A. Selected Financial Data

SUMMARY SELECTED FINANCIAL DATA

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

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

Sanofi-aventis reports its financial results in euros.

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SELECTED CONDENSED FINANCIAL INFORMATION

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

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

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

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

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

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

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EXCHANGE RATE INFORMATION

Exchange rate information

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

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

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

B. Capitalization and Indebtedness

N/A

C. Reasons for Offer and Use of Proceeds

N/A

D. Risk Factors

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

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Risks Relating to Legal Matters

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Relating to Our Business

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

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products to take the place of product