SANOFI-AVENTIS
Form 20-F
March 07, 2008
**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**

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

**OR**

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

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

**For the transition period from to**

**Commission File Number: 001-31368**

# Sanofi-Aventis

(Exact name of registrant as specified in its charter)

**N/A**

(Translation of registrant s name into English)

**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, 2007 was:**

Ordinary shares: 1,365,916,644

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

YES 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.

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, 2007.

Unless the context requires otherwise, the terms sanofi-aventis, the Company, the Group, we, our or us refer to sanofi-aventis and our consolidated subsidiaries. References to Aventis refer to Aventis and its consolidated subsidiaries for periods prior to August 20, 2004.

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

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

- trademarks used or that may be or have been used under license by sanofi-aventis and /or its affiliates, such as Actonel®, Optinate® and Acrel®, trademarks of Procter & Gamble Pharmaceuticals, Alvesco®, a trademark of ALTANA Pharma AG, Campto®, a trademark of Kabushiki Kaisha Yakult Honsha, Copaxone®, a trademark of Teva Pharmaceutical Industries, Exubera®, a trademark of Pfizer Products Inc., Mutagrip®, a trademark of Institut Pasteur, PER.C6®, a trademark of Crucell Holland B.V., TroVax®, a trademark of Oxford BioMedica, Autopen®24, a trademark of Owen Mumford, Ltd., Gardasil® and Rotateq®, trademarks of Merck & Co., Inc., Herceptin®, a trademark of Genetech, NanoCrystal®, a trademark of Elan Pharmaceuticals, VelocImmune®, a trademark of Regeneron Pharmaceuticals, Inc., Xyzal®, a trademark of UCB;

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

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

The data relative to market shares and ranking information presented in Item 4. Information on the Company B. Business Overview Markets Competition is based on sales data from IMS Health MIDAS (IMS) and GERS (for France), retail and hospital, for calendar year 2007, in constant euros (unless otherwise indicated).

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

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

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

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

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

Table of Contents

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

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

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

statements of assumptions underlying such statements.

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

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

the success of our research and development programs;

our ability to protect our intellectual property rights;

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

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

trends in the exchange rate and interest rate environments.

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

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

Table of Contents

**TABLE OF CONTENTS**

Table of Contents

**PART I**

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

N/A

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

N/A

**Item 3. Key Information**

***A. Selected Financial Data***

**SUMMARY SELECTED FINANCIAL DATA**

The tables below set forth selected consolidated financial data for sanofi-aventis. These financial data are derived from the sanofi-aventis consolidated financial statements. Sanofi-aventis financial statements for the years ended December 31, 2007, 2006 and 2005 are included in Item 18 of this annual report.

The consolidated financial statements of sanofi-aventis for the years ended December 31, 2007, 2006 and 2005 have been prepared in compliance with IFRS issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union. The term IFRS refers collectively to international accounting standards (IAS and IFRS) and to interpretations of the interpretations committee (SIC and IFRIC). The opening balance sheet as of the IFRS transition date (January 1, 2004) and the comparative financial statements for the year ended December 31, 2004 have been prepared in accordance with the same principles. IFRS accounts have not been published for the year ended December 31, 2003.

Sanofi-aventis reports its financial results in euro.

Table of Contents

## SELECTED CONDENSED FINANCIAL INFORMATION

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

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

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

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

(d) Dividends for 2007 will be proposed for approval at the annual general meeting scheduled for May, 14, 2008.

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

Table of Contents

## EXCHANGE RATE INFORMATION

***Exchange Rate Information***

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2003 through February 2008 expressed in U.S. dollar per euro. The information concerning the U.S. dollar exchange rate is based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York (the Noon Buying Rate ). We provide the exchange rates below solely for your convenience. We do not represent that euros were, could have been, or could be, converted into U.S. dollars at these rates or at any other rate. For information regarding the effect of currency fluctuations on our results of operations, see Item 5. Operating and Financial Review and Prospects.

| | Period-end Rate | Average Rate [1] | High | Low |
|---|---|---|---|---|
| | (U.S. dollar per euro) | | | |
| 2003 | 1.26 | 1.14 | 1.26 | 1.04 |
| 2004 | 1.35 | 1.25 | 1.36 | 1.18 |
| 2005 | 1.18 | 1.24 | 1.35 | 1.17 |
| 2006 | 1.32 | 1.27 | 1.33 | 1.19 |
| 2007 | 1.46 | 1.38 | 1.49 | 1.29 |
| Last 6 months | | | | |
| 2007 | | | | |
| September | 1.42 | 1.39 | 1.42 | 1.36 |
| October | 1.45 | 1.42 | 1.45 | 1.41 |
| November | 1.47 | 1.47 | 1.49 | 1.44 |
| December | 1.46 | 1.46 | 1.48 | 1.43 |
| 2008 | | | | |
| January | 1.48 | 1.47 | 1.49 | 1.46 |
| February | 1.52 | 1.48 | 1.52 | 1.45 |

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

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

***B. Capitalization and Indebtedness***

N/A

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

N/A

***D. Risk Factors***

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

Table of Contents

**Risks Relating to Legal Matters**

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

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

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

- new, additional inventions will be patentable;
- patents for which applications are now pending will be issued or reissued to us;
- the scope of any patent protection will be sufficiently broad to exclude competing products; or
- the laws providing patent protection will not change in a way that would limit protection.

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

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

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

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

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

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

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

Table of Contents

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

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

Additionally, our successful assertion of a given patent against one competing product is not necessarily predictive of the future success or failure in the assertion of the same patent or *a fortiori* the corresponding foreign patent against a second competing product because of such factors as possible differences in the formulations of the competing products, intervening developments in law or jurisprudence, local variations in the patents and differences in national patent law and legal systems. For example, while we have been successful to date, subject to the opposing parties right of appeal, in asserting our Plavix® patent rights in the United States and Canada, a court in Korea has held the claims of the corresponding Korean patent to be invalid under Korean law.

Our patent rights are material to our business, and if we were unsuccessful in asserting them or they were deemed invalid, any resulting introduction of generic versions of our products in the United States, in Europe or in other markets would reduce the price that we receive for these products and/or the volume of the product that we would be able to sell, and could materially adversely affect our business, results of operations and financial condition. Additionally, a number of our products acquired through business combinations have substantial balance sheet carrying values, as disclosed at Note D.4 to our consolidated financial statements, which could be substantially impaired by the introduction of a generic competitor, with adverse effects on our financial results and assets.

Significant challenges to our proprietary rights concern such leading Group products as Plavix®, Lovenox®, Eloxatine®, Taxotere®, Xatral®, Ambien CR® and Allegra® as well as our SoloSTAR® devices. We are also involved in litigation challenging the validity or enforceability of patents related to a number of other products in the United States, the European Union and elsewhere, and challenges to other products may be expected in the future. We can give no assurance that as a result of these challenges we will not face generic competition for additional group products. See Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings and Note D.22.b) to our consolidated financial statements included in this annual report at Item 18 for additional information.

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

Product liability is a significant business risk for us, and has become a more significant risk as we expand in the United States (where product liability claims can be particularly costly). Substantial damage awards have been made in certain jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. Not all possible side effects of a drug can be anticipated based on preapproval clinical studies involving only several hundred to several thousand patients. Routine review and analysis of the continually growing body of post-marketing safety surveillance and clinical trials provide additional information for example potential evidence of rare, population-specific or long-term adverse reactions or of drug interactions that were not observed in preapproval clinical studies and may cause product labeling to evolve. Several pharmaceutical companies have recalled or withdrawn products from the market based on actual or suspected adverse reactions to their products, and currently face significant product liability claims. We are currently defending a number of product liability claims (see Note D.22 to the consolidated financial statements included at Item 18 of this annual report and Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings ), and there

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

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

Table of Contents

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

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

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

The marketing of our products is heavily regulated, and alleged failures to comply fully with applicable regulations could subject us to substantial fines, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls or exclusion from government reimbursement programs. Sanofi-aventis and certain of its subsidiaries are under investigation by various government entities in the United States. For example, in Europe in January 2008 the European Commission opened sector inquiry into competition in the pharmaceuticals sector; and in the United States the Group is defending a number of lawsuits, relating to antitrust and/or pricing and marketing practices, including, for example, class action lawsuits and whistle blower litigation. In 2007, we settled claims in the United States related to a predecessor company s marketing of Anzemet in a transaction involving a Corporate Integrity Agreement monitored by the U.S. Department of Health and Human Services. See Note D.22.c) to our consolidated financial statements included at Item 18 of this annual report.

Following judgments holding the U.S. patent protection of Lovenox® and of DDAVP® tablets to be unenforceable, a number of civil antitrust and fair trade claims have been filed against sanofi-aventis as putative class actions alleging that we have prevented competition and generated excess profits. Similar claims have followed an attempt to settle our U.S. Plavix® patent litigation. The proposed settlement of the U.S. Plavix® patent litigation against Apotex by the parties thereto is also the subject of a criminal investigation by the Antitrust Division of the U.S. Department of Justice and civil investigative demands by various federal and state government entities in the United States, of which the outcome and impact on sanofi-aventis cannot reasonably be assessed at this time. See Item 8. Financial Information A. Consolidated Financial Statements and other Financial Information Information on Legal or Arbitration Proceedings and Note D.22.c) to our consolidated financial statements included at Item 18 of this annual report.

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

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

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

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

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 in all of its principal markets, including litigation concerning product pricing, allegations of securities law violations, product liability claims, employment matters, patent and intellectual property disputes, consumer law claims and antitrust matters. In a similar vein, in the United States committees of the Senate and House of Representatives are conducting a series of hearings concerning the FDA and the conditions under which a number of products, including Ketek®, were approved.

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