D. Risk Factors

Risks Relating to Our Company

We may not be able to expand our presence profitably in the United States, a market that is a key to our growth strategy, and where we are investing substantial resources.

We may not achieve our growth strategy if we do not profitably expand our presence in the United States, the world's largest pharmaceuticals market. We have identified the United States, which accounted for 22.7% of our consolidated sales in 2002, as a potential major source of future growth and plan to expand significantly our direct presence in the United States in the coming years. For example, in April 2002, we purchased Pharmacia's interest in the joint venture that sold Stilnox® (under the name Ambien®) and Kerlone® in the United States. We face a number of potential obstacles to profitable growth in the United States, including:

- A need to structure effectively our U.S. organization in relation to the size of the market.
- The targeting of new markets.
- The fact that the United States market is dominated by major U.S. pharmaceutical companies.
- Potential changes in health care reimbursement policies and possible cost control regulations in the United States.

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

We commercialize some of our products outside Europe in collaboration with other pharmaceutical companies. We currently have major collaborative arrangements with Bristol-Myers Squibb for the marketing of Plavix® and Aprovel® and with Organon, a subsidiary of Akzo Nobel, for the marketing of Arixtra®. We also have alliances with several Japanese companies for the marketing of our products in Japan. See Item 4 "Information on the Company — Business Overview — Marketing and Distribution." When we commercialize our products through collaboration arrangements, we are subject to the risks 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 Bristol-Myers Squibb are subject to the operational management of Bristol-Myers Squibb in some countries, including the United States. In March 2002, Bristol-Myers Squibb began a program to reduce inventory levels of Plavix® and Aprovel® at wholesalers in the United States, which had a negative impact on U.S. sales of Plavix® and Aprovel®. For additional information regarding the impact of the inventory reduction program on our results of operations, see Item 5 "Operating and Financial Review and Prospects." In addition to these types of actions, we cannot be certain that our partners will perform their obligations as expected. Further, our partners might pursue their own existing or alternative technologies or product candidates in preference to those being developed or marketed in collaboration with us.

We depend on third parties for the manufacturing of the active ingredients for some of our products, including Stilnox®, Eloxatin® and Xatral®, three of our strategic products.

Although our general policy is to manufacture the active ingredients for our products ourselves, we subcontract the manufacture of some of our active ingredients to third parties, which exposes us to the risk of a supply interruption in the event that our suppliers experience financial difficulties or are unable to manufacture a sufficient supply of our products. The manufacture of the active ingredients for Stilnox®, Eloxatin® and Xatral®, which are three of our six strategic products, is currently done by third parties. See Item 4 "Information on the Company — Business Overview — Production and Raw Materials" for a description of these outsourcing arrangements. Although we have not experienced any problems in the past, if disruptions were to arise from problems with our manufacturers, this would impact our ability to sell our products in the quantities demanded by the market, and could damage our reputation and relationships with our customers. Even though we try to have backup sources of supply whenever possible, including by manufacturing backup supplies of our principle active ingredients at a second or third facility, we cannot be certain they will be sufficient if our principal sources become unavailable.

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

We occasionally provide information and materials to research collaborators in academic institutions or other public or private entities, or request them to conduct tests to investigate certain materials. In all cases we enter into appropriate confidentiality agreements with such entities. However, those entities might assert intellectual property rights with regard 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 protection will provide meaningful protection, or if they are breached, that we will have adequate remedies. You should read Item 4 “Information on the Company — Business Overview — Patents and Intellectual Property Rights” for more information about our patents and licenses.

We have two principal shareholders who continue to maintain a significant degree of influence.

Our two principal shareholders, L’Oréal and Total, owned 19.5% and 24.5% of our share capital, respectively, as of April 30, 2003. Our bylaws provide that our fully paid up shares that have been held in registered form for at least two years under the name of the same shareholder acquire double voting rights. As a result, as of April 30, 2003, L’Oréal and Total held shares representing 27.9% and 35.0%, respectively, of our voting rights, and are in a position to exert significant influence in the election of our directors and officers and other corporate actions that require shareholder approval. The ownership of a large percentage of our capital and voting rights by our two principal shareholders, who are also members of our board of directors, may have the effect of delaying, deferring or preventing a change in our control and may discourage bids for our shares.

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

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 and, to a lesser extent, the Japanese yen. In 2002, approximately 22.7% of our consolidated sales were realized in the United States, and 4.2% were realized in Japan (the United States also represented 45.2% of our 2002 operating profit excluding unallocated costs). While we incur expenses in those currencies, the impact of these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations. For more information concerning our exchange rate exposure, see Item 11 “Quantitative and Qualitative Disclosures About Market Risk.”

Risks Relating to Our Industry

We invest substantial sums in research and development in order to remain competitive, and we may not recover these sums if our products are unsuccessful in clinical trials or fail to receive regulatory approval.

We need to invest heavily in research and development to remain competitive.

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. Even if our research and development efforts are fruitful, our competitors may develop more effective products or a greater number of successful new products. In 2002, we spent €1,218 million on research and development, amounting to approximately 16.4% of our consolidated net sales. Our ongoing investments in new product launches and research and development for future products could produce higher costs without a proportionate increase in revenues.

The research and development process is lengthy and carries a substantial risk of product failure.

The research and development process typically takes from 10 to 15 years from discovery to commercial product launch. This process is conducted in various stages, and during each stage there is a substantial risk that we will not achieve our goals and will have to abandon a product in which we have invested substantial amounts. For example, in order to develop a commercially viable product, we must demonstrate, through extensive pre-clinical and human clinical trials, that the compounds are safe and effective for use in humans. There is also no assurance that favorable results obtained in pre-clinical trials will be confirmed by later clinical trials, or that the clinical trials will establish sufficient safety and efficacy data necessary for regulatory approval. As of January 31, 2003, we had 52 compounds in pre-clinical and clinical development in our four targeted therapeutic areas, of which 23 were in phase II or phase III clinical trials. For additional information regarding clinical trials and the definition of the phases of clinical trials, see Item 4 “Information on the Company — Business Overview — Research and Development.” There can be no guarantee that any of these compounds will be proven safe or effective, or that they will produce commercially successful products.

After completing the research and development process, we must invest substantial additional resources seeking to obtain government approval in multiple jurisdictions, with no guarantee that approval will be obtained.

We must obtain and maintain regulatory approval for our pharmaceutical products from the European Union, United States and other regulatory authorities before the product may be sold in its markets. The submission of an application to a regulatory authority in a particular country or the European Union does not guarantee that it will grant a license to market the product. Each authority may impose its own requirements, including requiring local clinical studies, and may delay or refuse to grant approval, even though a product has already been approved in another country.

In our principal markets, the approval process for one or more indications of a new product is complex and lengthy, and typically takes from six months to two years from the date of application depending on the country. Moreover, if regulatory approval of a product is granted, the approval entails limitations on the indicated uses for which it may be marketed. A marketed product is also subject to continual review even after regulatory approval. Later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in marketing restrictions or withdrawal of the product, as well as possible legal sanctions. In addition, we are subject to strict government controls on the manufacture, labeling, distribution and marketing of our products. All of these factors can increase our costs of developing new products and the risk that we will not succeed in selling them successfully.

If we are unable to protect our proprietary rights, we may not compete effectively or operate profitably.

It is important for our success that we be able effectively to obtain, maintain and enforce our patents and other proprietary rights. Patent law relating to the scope of claims in the pharmaceutical field in which we

operate is a continually evolving field of law and can be subject to some uncertainty. Accordingly, we cannot be sure that:

- new additional inventions will be patentable,
- patents for which applications are now pending will be issued to us, or
- the scope of any patent protection will be sufficiently broad to exclude competitors.

Additionally, third parties may challenge the validity of the patents issued or licensed to us, which may result in the invalidation of these rights. We currently have over 9,000 patents and patent applications worldwide, and we license-in more than 30 additional patents. We cannot be sure how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings.

In the first half of 2002, two pharmaceutical companies, Apotex and Dr. Reddy's Laboratories, each filed an Abbreviated New Drug Application, or ANDA, with the U.S. Food and Drug Administration, or FDA, seeking to market a generic form of Plavix® in the United States and challenging certain U.S. patents relating to Plavix®. In March 2003, Apotex instituted a similar challenge in Canada. For additional information regarding ANDAs, see Item 4 "Information on the Company — Business Overview — Regulation." We have filed suit against Apotex and against Dr. Reddy's Laboratories for infringement of our patent rights. See Item 8 "Financial Information — Legal Proceedings." The Plavix® patent rights are material to our company's business, and if we were unsuccessful in asserting them or they were deemed invalid, any resulting introduction of a generic prescription version of Plavix® in the U.S. would reduce the price that we receive for this product and the volume of the product that we would be able to sell.

In recent years, governments faced with national crises have used pressure to obtain substantial concessions from pharmaceutical companies, including threatening compulsory licensing of products that they consider essential. While we support the efforts of national governments to combat major health care crises, if those efforts come at the expense of effective patent protection, the ability of our company and other pharmaceutical manufacturers to recover amounts spent on research and development will be adversely affected. In such event, we and other manufacturers might curtail our research and development expenditures, and as a result might not develop as many new products.

Our patents may be infringed, or we may infringe the patents of others.

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. Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights. This risk is increased by the growth in the number of patent applications filed and patents granted in the pharmaceutical industry.

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

Product liability is a significant commercial risk for us, and could 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. In addition, some pharmaceutical companies have recently withdrawn products from the market in the wake of significant product liability claims. Although we are not currently involved in any significant product liability cases claiming damages as a result of the use of our products, it is possible that such cases will be brought in the future. Further, there is a general trend in the insurance industry to exclude certain products from coverage. Although we maintain insurance to cover this risk, we cannot be certain that our insurance will be sufficient to cover all potential liabilities.

We face uncertainties over pricing of pharmaceutical products.

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

- a tendency of governments and private health care providers to favor generic pharmaceuticals;
- price controls imposed by governments in many countries; and
- parallel imports, in particular in the European Economic Area, a practice by which traders exploit price differentials among markets by purchasing in lower-priced markets for resale in higher-priced markets.

Price pressure is considerable in our two largest markets, Europe and the United States, which represented 57.7% and 22.7%, respectively, of our consolidated sales in 2002 (the United States also accounted for 45.2% of our 2002 operating profit excluding unallocated costs). Changes in the pricing environments in the United States or Europe (on an individual country basis) could have a significant impact on our revenues and operating profits. See Item 4 “Information on the Company — Business Overview — Pricing” for a description of certain regulatory pricing systems that impact our company.

Risks from the handling of hazardous materials could harm our operating results.

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

- fires 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 harm 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 incident to our business. For more detailed information on environmental issues, see Item 4 “Information on the Company — Business Overview — Health, Safety and Environment.”

Environmental liabilities and compliance costs may have a significant negative effect on our operating results.

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

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

These environmental remediation obligations could significantly reduce our operating results. In particular, our accruals for these obligations may be insufficient if the assumptions underlying these accruals prove incorrect or if we are held responsible for additional, currently undiscovered contamination. Any shortfalls could have a material impact on our operating profits. See Item 4 “Information on the Company — Business Overview — Health, Safety and Environment” and “— Regulation” for additional information regarding our environmental policies.

Furthermore, we are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. An adverse outcome in any of these might have a significant negative impact on our operating results. Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to our company and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures as well as other costs and liabilities, thereby harming our business and operating results.

Risks Relating to an Investment in our Shares or ADSs

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

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

If you hold ADSs rather than shares it may be difficult for you to exercise some of your rights as a shareholder.

As a holder of ADSs, it may be more difficult for you to exercise your rights as a shareholder than it would be if you directly held shares. For example, if we offer new shares and you have the right to subscribe for a portion of them, the depositary is allowed, in its own discretion, to sell for your benefit that right to subscribe for new shares instead of making it available to you. Also, to exercise your voting rights, ADS holders must instruct the depositary how to vote their shares. Because of this extra procedural step involving the depositary, the process for exercising voting rights will take longer for you, as a holder of ADSs, than for holders of shares. ADSs for which the depositary does not receive timely voting instructions will not be voted at any meeting. For a detailed description of your rights as a holder of ADSs, you should read Item 12 “Description of Securities other than Equity Securities — Description of American Depositary Shares.”

Sales of our shares that will be eligible for sale in the near future may cause the market price of our shares or ADSs to decline.

At April 30, 2003, we had 732,450,981shares outstanding, approximately 44.05% of which are held by our two largest shareholders, Total and L’Oréal. Of the shares held by these shareholders on April 30, 2003, 38,157,539 shares are available for sale in the public market, and the remainder will become available for sale in the public market on December 1, 2004 when the shareholders’ agreement between those shareholders expires. Since the merger, and including in 2002, Total has gradually been reducing its shareholding in our company.

Sales of a substantial number of our shares, or a perception that such sales may occur, could adversely affect the market price for our shares and ADSs. See Item 10 “Additional Information — Share Capital — Shares Eligible for Future Sale” for a more detailed description of the eligibility of our shares for future sale.

Because all of our directors and officers reside outside of the United States and a substantial portion of our assets are located in France, you may have difficulty enforcing certain rights.

All of our directors and officers reside outside the United States and a substantial portion of our assets is located in France. As a result, it may be difficult for you to effect service of process within the United States on such persons and 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. Additionally, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France. For additional information see Item 10 “Additional Information — Memorandum and Articles of Association — Enforceability of Civil Liabilities.”

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, net earnings per share, capital expenditures, 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 similar expressions are 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 — Risk Factors” beginning on page 10, include but are not limited to:

- our ability to continue to expand our presence profitably in the United States;
- the success of our research and development programs;
- our ability to protect our intellectual property rights; and
- the risks associated with reimbursement of healthcare costs and pricing reforms, particularly in the United States and Europe.

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. We do not undertake any obligation to update them in light of new information or future developments.