

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 included in this annual report at Item 18, 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 to maintain product exclusivity. 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, a number of countries are increasingly easing the introduction of generic drugs or biosimilar products through accelerated approval procedures.

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.

Many Group products are already subject to aggressive generic competition, and additional products of the Group could become subject to generic competition in the future.

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

Product liability is a significant business risk for any pharmaceutical company, and the Group’s ongoing diversification may increase our product liability exposure (see “The diversification of the Group’s business exposes us to additional risks” below). Substantial damage awards have been made – notably in the United States and other common law jurisdictions – against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. Sometimes side effects of pharmaceutical drugs cannot be adequately 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, including restrictions of therapeutic indications, new contraindications, warnings or precautions, and occasionally even the suspension or withdrawal of a product marketing authorization. Several pharmaceutical companies have 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 each of these claims or will not face additional claims in the future.

Although we continue to insure a portion of our product liability with third-party carriers, 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 financial risk of our pharmaceutical and vaccines businesses (see “Item 4. Information on the Company – B. Business Overview – Insurance and Risk Coverage.”) Due to insurance conditions, even when the Group has insurance coverage, recoveries from insurers may not be totally successful. 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, may harm our reputation and can impact the 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 competition law, marketing practices and pricing 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.

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, or in similar matters to be faced in the future, 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 and biosimilar competition to existing products through new regulatory proposals intended to, or resulting in, changes to the scope of patent or data exclusivity rights and use of accelerated regulatory pathways for generic and biosimilar drug approvals.

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 "Item 4. Information on the Company – B. Business Overview – 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 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 acquisitions and 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 competition from new products that are perceived as being superior. In 2010, we spent €4,401 million on research and development, amounting to approximately 14.5% 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 "Item 4. Information on the Company – B. Business Overview – 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). Moreover, decisions concerning the studies to be carried out can have a significant impact on the marketing strategy for a given product. Multiple in-depth studies can demonstrate that a product has additional benefits, facilitating the product's marketing, but such studies are expensive and time consuming and may delay the product's submission to health authorities for approval. 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 which may negatively affect our operating results. Each regulatory authority may also 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. Following each product marketing approval, the medical need served by the product and the corresponding reimbursement rate are evaluated by other governmental agencies which may in some cases require additional studies, including comparative studies, which may both effectively delay marketing of the new product and add to its development costs.

As a complement to our portfolio of products, we pursue 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 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.

We generate a substantial share of our revenues from the sale of certain key products (see “Item 5. Operating and Financial Review and Prospects – Results of Operations – year ended December 31, 2010 compared with year ended December 31, 2009 – Net Sales by Product – Pharmaceuticals”), which represented 43.8% of the Group’s consolidated revenues in 2010. Among these products is Lantus®, which was the Group’s leading product with revenues of €3,510 million in 2010, representing 11.6% of the Group’s consolidated revenues for the year. Lantus® is a flagship product of the Diabetes division, one of the Group’s growth platforms. A reduction in sales or in the growth of sales of one or more of our flagship products (in particular sales of Lantus®) could affect our business, results of operations and financial condition.

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.
- the margins of consumer health and generic products are generally lower than those of the traditional branded prescription pharmaceutical business. Moreover, the periodic review of the effectiveness, safety and use of certain over-the-counter drug products by health authorities or lawmakers may result in modifications to the regulations that apply to certain components of such products, which may require them be withdrawn from the market and/or that their formulation be modified.
- specialty products (such as those developed by Genzyme) that treat rare, life-threatening diseases that are used by a small number of patients are often expensive to develop compared to the market opportunity, but third-party payers trying to limit health-care expenses may become less willing to support their per-unit cost.

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.

Successful completion of the Genzyme acquisition could temporarily lessen our strategic flexibility.

While the proposed acquisition of Genzyme would provide the Group with attractive new opportunities, the diversification into new business lines and the management of substantial additional research, manufacturing and commercial operations may occupy significant organizational attention. Moreover, to acquire Genzyme, the

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Group will be required to incur a substantial amount of debt. As a result, we would be required to make significant payments to lenders. Our post-acquisition level of indebtedness could also cause our credit rating to be downgraded, increase our financing costs, limit our capacity to secure additional financing and limit our ability to engage in additional transactions.

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 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 "– Counterfeit versions of our products could harm our business" below)), corruption and fraud. Any difficulties in adapting to these markets and/or a significant decline in the anticipated growth rate in these regions 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. 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. These post-regulatory approval routine reviews and data analyses can lead to the issuance of recommendations by government agencies, health professional and patient organizations or other specialized organizations regarding the use of products, which may result in a reduction in sales, such as, for example, a recommendation to limit the patient scope of a drug's indication. In addition, such reviews may result in the discovery of significant problems with respect to a competing product that is similar to one sold by the Group, which may in turn cast suspicion on the entire class to which these products belong and ultimately diminish the sales of the relevant product of the Group. When such issues arise, the contemplative nature of evidence-based health care and restrictions on what pharmaceutical manufacturers may say about their products are not always well suited to rapidly defending the Group or the public's legitimate interests in the face of the political and market pressures generated by social media and rapid news cycles, and this may result in unnecessary commercial harm, overly restrictive regulatory actions and erratic share price performance.

In addition, 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.

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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 new health care reform law increased the government's role with respect to price, reimbursement and the coverage levels for healthcare-related expenses for the large government health care sector. Implementation of the new law could affect our revenues and/or margins (for further details concerning this law and a description of certain regulatory pricing systems that affect our Group see "Item 4. Information on the Company – B. Business Overview – Pricing & Reimbursement").

Our operating results may also be affected by parallel imports, particularly within the European Union, whereby distributors engage in arbitrage based on national price differences to buy product on low cost markets for resale on higher cost markets.

A slowdown of global economic growth could have negative consequences for our business⁽¹⁾.

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® and Aprovel® in the United States and several other countries, with Warner Chilcott for the osteoporosis treatment Actonel®, with Teva for Copaxone®, and with Merck & Co., Inc. for the distribution of vaccines in Europe. See "Item 4. Information on the Company – B. Business Overview – Pharmaceutical Products – Main pharmaceutical products" for more information on our major alliances. When we market our products through collaboration arrangements, we are subject to the risk that certain decisions, such as the establishment of budgets and promotion strategies, are subject to the control of our collaboration partners, and that deadlocks may adversely affect the activities conducted through the collaboration arrangements. For example, our alliances with BMS are subject to the operational management of BMS in some countries, including the United States. 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 our customers for the storage and distribution of many of our products, e.g., cold storage for certain vaccines and insulin-based

⁽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 respect to information required by IFRS 7, and is covered by our independent registered public accounting firms' report on the consolidated financial statements.

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.

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® 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 “– 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®. 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 our 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 the Group 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

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incur potentially substantial costs as a result of, among other things, litigation of claims, product recalls, adoption of additional safety measures, manufacturing delays, investment in patient education, and development of synthetic substitutes for ingredients of biological origin. Such claims could also generate patient resistance, with a corresponding adverse effect on sales and results of operations.

We are subject to the risk of non-payment by our customers.⁽¹⁾

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 73% of our consolidated U.S. pharmaceutical sales are accounted for by just three wholesalers. In addition, the Group's three main customers represent 20.6% 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.19.1 to our consolidated financial statements included at Item 18 of this annual report).

We are increasingly dependent on our technological infrastructure and computer networks.

Our business depends on the use of computerized data, which means that certain key divisions such as research and development, production and sales are to a large extent dependent on our information technology network. Our inability to implement adequate security and memory storage systems for saved data could lead to their deterioration or loss in the event of a system malfunction, or allow data to be stolen or corrupted in the event of a security breach, which could have a material adverse effect on our business, operating results and financial condition.

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;
- 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.

⁽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 respect 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.

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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.

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⁽¹⁾

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 2010, approximately 30% 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

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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, 2010, the Group's net debt amounted to €1.6 billion, an amount which will increase substantially upon acquisition of Genzyme. In addition to debt outstanding, the Group has contracted a number of credit lines and put into place commercial paper and medium term note programs with the aim of providing liquidity. See "Item 11. Quantitative and Qualitative Disclosures about Market Risk." In the event of a market-wide liquidity crisis, the Group might be faced with reduced access to sources of financing, including under programs currently in place, or less favorable conditions.

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, 2010, L'Oréal and Total, our two largest shareholders, held approximately 9.02% and 5.51% of our issued share capital, respectively, accounting for approximately 15.61% and approximately 9.19%, 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, L'Oréal and Total will remain in a position to exert heightened influence in the election of the directors and officers of sanofi-aventis and in other corporate actions that require shareholders' approval.

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

Neither L'Oréal nor Total 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.