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

We rely on our patents and proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected.

Through patent and other proprietary rights such as supplementary protection certificate in Europe for instance, we hold exclusivity rights for a number of our research-based products. However, the protection that we are able to obtain varies from product to product and country to country and may not be sufficient to maintain effective product exclusivity because of local variations in the patents, differences in national law or legal systems, development in law or jurisprudence, or inconsistent judgments. We are involved in litigation worldwide to enforce certain of these patent rights against generics and proposed generics (see "Item 8. Financial Information — A. Consolidated Financial Statements and Other Financial Information — Information on Legal or Arbitration Proceedings" 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 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 a generic product "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.

Further, 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. Also a successful result in one country may not predict success in another country because of local variations in the patents.

To the extent valid third-party patent rights cover our products, we or our partners may be required to obtain licenses from the holders of these patents in order to manufacture, use or sell these products, and payments under these licenses may reduce our profits from these products. We may not be able to obtain these licenses on favorable terms, or at all. If we fail to obtain a required license or are unable to alter the design of our technology to fall outside the scope of a third-party patent, we may be unable to market some of our products, which may limit our profitability.

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 could increase our product liability exposure (see notably "— The diversification of the Group's business exposes us to additional risks" below). Substantial damage awards and/or settlements have been made — notably in the United States and other common law jurisdictions — against pharmaceutical companies based on claims for injuries allegedly caused by the use of their products. Such claims can also be accompanied by consumer fraud claims by customers or third-party payers seeking reimbursement of the cost of the product. Often the side effect profile of pharmaceutical drugs cannot be fully established 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 newly detected or suspected adverse reactions to their products, and as a result of such withdrawal now 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. Also our risk exposure also increased due to the fact that we are now commercializing some devices using new technologies which, in case of malfunction, could cause unexpected damages and trigger our liability (see "— We are increasingly dependent on information technologies and networks." below).

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 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. Such regulatory proposals, if enacted, could make prosecution of patents for new products more difficult and time consuming or could adversely affect the exclusivity period for our products, thereby materially and adversely affecting our financial results.

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

Risks Relating to Our Business

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

Many of our products are subject to aggressive generic competition, and additional products of the Group could become subject to generic competition in the future as product patents and/or exclusivities for several of our products have recently expired, or are about to expire. For example pediatric exclusivity for Aprovel® and Plavix® which contribute significantly to our net income will expire in the United States in March 2012 and May 2012, respectively, and the compound patent of Aprovel® will expire in most of the European Union in August 2012. Also, the U.S. market exclusivity of Eloxatin® will expire in August 2012, pursuant to settlement agreements. We expect this generic competition to continue and to implicate drug products with even relatively modest revenues.

The introduction of a generic version of a branded medicine typically results in a significant and rapid reduction in net sales for the branded product because generic manufacturers typically offer their unbranded versions at sharply lower prices. Accordingly, approval and market entry of a generic product often reduces 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 and adversely affect our business, results of operations and financial condition. The extent of sales erosion also depends on the number of generic versions of our products that are actually marketed. For instance in 2011, there was only one generic product of enoxaparin sodium (Lovenox®) marketed in the United States. The introduction of a second generic on the U.S. market in early 2012 is likely to decrease our sales and revenues on this product.

Our long-term objectives may not be fully realized.

We have established a strategy focused on three pillars: increased innovation in R&D, adaptation of our structure for future opportunities and challenges and pursuit of external growth opportunities. We may not be able to fully realize our strategic objectives and, even if we are able to do so, these strategic objectives may not deliver the expected benefits.

For example, our strategy involves concentrating efforts around identified growth platforms and meeting significant growth objectives over 2012-2015. There is no guarantee that we will meet these objectives or that these platforms will grow in line with anticipated growth rates. A failure to continue to expand our business in targeted growth platforms could affect our business, results of operations or financial condition.

As a further example, we are implementing a cost savings program across the Group and expect this new initiative, together with expected synergies from our recent acquisition of Genzyme, to generate additional incremental cost savings by 2015. We may fail to realize all the expected cost savings, which could materially and adversely affect our financial results.

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 2011, we spent €4,811 million on research and development, amounting to approximately 14.4% of our net sales.

Developing a product is a costly, lengthy and uncertain process. Also we may not be investing in the right technology platforms, leading therapeutic area, and products classes in order to build a robust pipeline and fulfill unmet medical needs. Fields of discovery and especially biotechnology are highly competitive and characterized by significant and rapid technological changes. Numerous companies are working on the same targets and a product considered as promising at the very beginning may become less attractive if a competitor showing the same mechanism of action reaches earlier the market.

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 including during the course of a development trial and that we will have to abandon a product in which we have invested substantial amounts and human resources, including in late stage development (Phase III). 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.

Also our success depends on our ability to educate patients and healthcare providers and provide them with innovative data about our products and their uses. If these education efforts are not effective, then we may not be able to increase the sales of our new products to the market.

On the same topic, for the research and development of drugs in rare diseases, we produce relatively small amounts of material at early stages. Even if a product candidate receives all necessary approvals for commercialization, we may not be able to successfully scale-up production of the product material at a reasonable cost or at all and we may not receive additional approvals in sufficient time to meet product demand.

As a complement to our portfolio of products, we pursue a strategy of selective 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 the Group continues to depend 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, 2011 compared with year ended December 31, 2010 — Net Sales by Product — Pharmaceuticals"), which represented 37.6% of the Group's consolidated revenues in 2011. Among these products is Lantus®, which was the Group's leading product with revenues of €3,916 million in 2011, representing 11.7% 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.

Sales of Cerezyme®, our enzyme-replacement product for patients with Gaucher disease which is also amongst our flagship products, totaled €441 million for the year ended December 31, 2011, below the usual level of sales due to important production disruptions since 2009 (see "— The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition and delay the launch of new products." below). In addition the patient population with Gaucher disease is limited. Furthermore, changes in the methods for treating patients with such disease could limit growth, or result in a decline, in Cerezyme® sales.

In general, a reduction in sales of one or more of our flagship products or in their growth could affect our business, results of operations and financial condition.

We may lose market share to competing remedies or generic brands if they are perceived to be equivalent or 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.

For example, Cerezyme® and Fabrazyme® shortages due to manufacturing issues at our facility in Allston, Massachusetts (United-States) (see "— The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition and delay the launch of new products." below) created, and continue to create, opportunities for our competitors and have resulted in a decrease in the number of patients using these products and a loss of our overall market share of Gaucher and Fabry patients, respectively. Even if we are able again to provide a full, sustainable product supply, there is no guarantee these patients will return to using our products.

Additionally, the market for our products could also be affected if a competitor's innovative drug in the same market were to become available as generic because a certain number of patients can be expected to switch to a lower-cost alternative therapy.

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

We are 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, such as Genzyme, the loss of key employees or integration costs that are higher than anticipated, could delay our growth objectives and prevent us from achieving expected synergies. For instance, challenges that we may face in our efforts to integrate Genzyme include, among others:

- addressing manufacturing problems and supply constraints that have negatively affected Genzyme's business in recent years;

- ensuring continued compliance with a consent decree that Genzyme entered into with the FDA in May 2010 relating to a manufacturing facility in Allston, Massachusetts (United-States) (see “Item 4. Information on the Company — B. Business Overview — Production and Raw Materials.”);
- the outcome of ongoing legal and other proceedings to which Genzyme is a party, including shareholder litigation and patent litigation;
- preserving and developing Genzyme’s goodwill in the genetic disease community; and
- realizing the potential of the research and development pipeline.

If we fail to effectively integrate Genzyme or the integration takes longer than expected, we may not achieve the expected benefits of the transaction.

Moreover, we may miscalculate the risks associated with newly acquired activities or businesses 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.

While 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 not present at all. 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 (see “— The ongoing slowdown of global economic growth and the global financial crisis could have negative consequences for our business” below).
- 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, and third-party payers trying to limit health-care expenses may become less willing to support their per-unit cost.

Moreover, losses that may be sustained or caused by these new businesses may differ, with regards to their nature, scope and level, from the types of product liability claims that we have handled in the past (see “— Product liability claims could adversely affect our business, results of operations and financial condition” above), and thus our current risk management and insurance coverage may not be adapted to such losses. These risks could affect our business, results of operations or financial condition.

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

Emerging markets have been identified as one of our growth platforms and are among the pillars of our overall strategy. Any difficulties in adapting to emerging 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.

There is no guarantee that our efforts to expand sales in emerging markets will succeed. 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 harm our business," below)), corruption and fraud, as we operate in many parts of the world where corruption exists to some degree.

Our existing policies and procedures, which are designed to help ensure that we, our employees and our agents comply with the U.S. Foreign Corrupt Practices Act (FCPA), the UK Bribery Act, and other anti-bribery laws, may not adequately protect us against liability under these laws for actions taken by our employees, agents and intermediaries with respect to our business. Failure to comply with domestic or international laws could result in various adverse consequences, including possible delay in the approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, or the imposition of criminal or civil sanctions, including substantial monetary penalties.

Our products and manufacturing facilities are subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we fail to comply with the regulations or maintain the approvals.

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, are increasingly focusing on product safety and on the risk/benefit profile of pharmaceuticals products. In particular, the 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. For the same reasons, the marketed products are subject to continual review, risk evaluations or comparative effectiveness studies even after regulatory approval. These requirements have resulted in increasing the costs associated with maintaining regulatory approvals and achieving reimbursement for our products.

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 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 volume, such as, for example, a recommendation to limit the patient scope of a drug's indication. For instance in September 2011, the EMA defined a more restrictive indication for Multaq®, one of our cardiovascular products. 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 the Group are diminished. Also about 50% of our current research and development portfolio is constituted by biological products, that may bring in the future new therapeutic responses to current unmet medical needs but which may also lead to more technical constraints and costly investments from an industrial standpoint.

Moreover, we and certain of our third-party suppliers are also required to comply with applicable regulations, known as good manufacturing practices, which govern the manufacture of pharmaceutical products. To monitor our compliance with those applicable regulations, the FDA, the EMA and comparable agencies in other jurisdictions routinely conduct inspections of our facilities and may identify potential deficiencies which might be expensive and time consuming to address. If we fail to adequately respond to a warning letter

identifying a deficiency, or otherwise fail to comply with applicable regulatory requirements, we could be subject to enforcement, remedial and/or punitive actions by the FDA, the EMA or other regulatory authorities.

For example, in May 2010, Genzyme entered into a consent decree with the FDA relating to its Allston facility (see "Item 4. Information on the Company — B. Business Overview — Production and Raw Materials."). Pursuant to the consent decree, in November 2010, Genzyme paid $175.0 million to the U.S. Federal Governement disgorgement of past profits. The consent decree also requires Genzyme to implement a plan to bring the Allston facility into compliance with applicable laws and regulations. Genzyme submitted a comprehensive remediation plan to FDA in April 2011. Remediation of the Allston facility in accordance with that plan is underway and is currently expected to continue for four more years, however, there is no guarantee that this timeframe will be respected.

We incurred substantial debt in connection with the acquisition of Genzyme which may limit our business flexibility compared to some of our peers

Our consolidated debt increased substantially in connection with our acquisition of Genzyme because we incurred debt to finance the acquisition price, and because our consolidated debt includes the debt incurred by Genzyme prior to the acquisition. Although we already achieved a partial deleverage by the end of 2011 (as of December 31, 2011, our debt, net of cash and cash equivalents amounted to €10.9 billion), we make significant debt service payments to our lenders and this could limit our ability to engage in new transactions which could have been part of our strategy.

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

The commercial success of our existing products and our products candidates 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 (for instance products determined to be less cost-effective than alternatives);
- increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates; and
- the tendency of governments and private health care providers to favor generic pharmaceuticals.

In addition to the pricing pressures they exert, governmental 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, health care reform law is increasing the government's role with respect to price, reimbursement and the coverage levels for healthcare-related expenses for the large government health care sector, imposed cost containment measures and imposed drug companies' rebates to the government. Implementation of health care reform has affected and could still 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"). Some states are also considering legislation that would control the prices of and access to drugs and we believe that federal and state legislatures and health agencies will continue to focus on healthcare reform implementation in the future.

We encounter similar cost containment issues in countries outside the United States. In certain countries, including countries in the EU and Canada, the coverage of prescription drugs, pricing and levels of reimbursement are subject to governmental control. For example, in Spain, recent direct price-related measures include price discount to all products launched more than 10 years ago, all genericized products needing to be at a minor (lower) price, and no more gradualism in price reductions of originator post generics introduction. Additionally, measures such as INN prescriptions, have been implemented. Another example, in Turkey Government has accelerated enforcement of drugs costs containment measures which include increased institutional discount applied on reimbursement prices and lower reference prices for reimbursement of Generics and originals with Generics as well as 20-year old drugs without Generics.

Due to the ongoing cost containment policies being pursued in many jurisdiction in which we operate, we are unable to predict the availability or amount of reimbursement for our product candidates.

In addition, 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.

The ongoing slowdown of global economic growth and the financial crisis 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, as well as ongoing sovereign debt crisis affecting several European countries, 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”. Moreover, to the extent that the economic and financial crisis is directly affecting business, it may also lead to a disruption or delay in the performance of third parties on which we rely for parts of our business, including collaboration partners and suppliers (for more information see “Item 5. Operating and Financial Review and Prospects — Liquidity.”). Such disruptions or delays could have a material and adverse effect on our business and results of operations. See “— We rely on third parties for the manufacture and supply of a substantial portion of our raw materials, active ingredients and medical devices; supply disruptions and/or quality concerns could adversely affect our operating results and financial condition”, “We rely on third parties for the marketing of some of our products” and “ Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition” below.

Further, we believe our net sales may be negatively impacted by the continuing challenging global economic environment, as high unemployment levels and increases in co-pays may lead some patients to switch to generic products, delay treatments, skip doses or use less effective treatments to reduce their costs. Moreover, current economic conditions in the United States have resulted in an increase in the number of patients in the Medicaid program, under which sales of pharmaceuticals are subject to substantial rebates and, in many U.S. states, to formulary restrictions limiting access to brand-name drugs, including ours.

Our animal health business may also be negatively affected by the current slowdown in global economic growth (for instance tight credit conditions may limit the borrowing power of livestock producers, causing some to switch to lower-priced products).

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

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. We must also be able to produce sufficient quantities of the products to satisfy demand. Our biologic products (including vaccines) in particular are subject to the risk of manufacturing stoppages or the risk of loss of inventory because of the difficulties inherent to the 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 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

[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.

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 "— 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.

Like many of our competitors, we have faced, and to a certain extent continue to face, significant manufacturing issues, most notably in our Genzyme subsidiary for the production of Cerezyme® and Fabrazyme®. In June 2009, Genzyme announced it had detected a virus that impairs cell growth in one of the bioreactors used in the Allston, Massachusetts facility to produce Cerezyme®. This contamination has had a material adverse effect on Cerezyme® and Fabrazyme® revenues. We will continue to work with minimal levels of inventory for Cerezyme® and Fabrazyme® until we are able to build inventory. However, there can be no guarantee that we will be able to return to pre-contamination supply levels of such products, nor can there be any guarantee that we will not face similar issues in the future or that we will successfully manage such issues when they arise.

We rely on third parties for the manufacture and supply of a substantial portion of our raw materials, active ingredients and medical devices; supply disruptions and/or quality concerns could adversely affect our operating results and financial condition.

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.

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, adversely affect our operating results and financial condition and delay the launch of new products" above. We may not have redundant manufacturing capacity for certain products particularly biologic products. For instance in summer 2011 a technical incident occurred in the filling line used for Apidra 3mL cartridges at our manufacturing site in Frankfurt and this has caused temporary shortages for Apidra 3mL cartridges. Also all of our bulk Cerezyme® products are produced solely at our Allston, Massachusetts facility. 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.

Further, 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.

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®, 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" and "Item 4. Information on the Company — B. Business Overview — Vaccine 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 during the course of these agreements or at the time of their renewal or renegotiation may affect the marketing of certain of our products and may cause a decline in our revenues and affect our results of operations.

Counterfeit versions of our products 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 harm the business of companies such as Sanofi. Additionally, it is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. If a Group product was the subject of counterfeits, the Group could incur substantial reputational and financial harm. See “Item 4. Information on the Company — B. Business Overview — Competition.”

We are subject to the risk of non-payment by our customers.[1]

We run the risk of delayed payments or even 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 poses particular client credit risk issues, because of the concentrated distribution system in which approximately 62% of our consolidated U.S. pharmaceutical sales are accounted for by just three wholesalers. In addition, the Group’s three main customers represent 17.4% of our gross 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).

Since the beginning of 2010, financial difficulties in some countries of southern Europe have increased especially in Greece and Portugal. Part of our customers in these countries are public or subsidized health systems. The deteriorating economic and credit conditions in these countries has led to longer payment terms. This trend may continue and we may need to reassess the recoverable amount of our debts in these countries during the coming financial years (for more information see “Item 5. Operating and Financial Review and Prospects — Liquidity.”).

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).

Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on the Group’s results of operations and financial results.

New or revised accounting standards, rules and interpretations issued from time to time by the IASB (International Accounting Standards Board) could result in changes to the recognition of income and expense that may materially and adversely affect the Group’s financial 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.

In addition, substantial value is allocated to intangible assets and goodwill resulting from business combinations, as disclosed at Note D.4. to our consolidated financial statements included in this annual report at Item 18, which could be substantially impaired upon indications of impairment (primarily relating to pharmacovigilance, patent litigation and the launch of competing products), with adverse effects on our financial condition and the value of our assets.

Also if any of our strategic equity investments decline in value and remain below cost for an extended duration, we may be required to write down our investment.

In addition the global financial crisis and in particular the ongoing sovereign debt crisis affecting certain European countries could also negatively affect the value of our assets (see "— Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition" below and "— The ongoing slowdown of global economic growth and the financial crisis could have negative consequences for our business" above). For example, given the current level of investor confidence in the ability of the Greek State to avoid default, as a result of mark to market accounting standards, we recognized an impairment of €49 million on certain Greek bonds held by us in 2011.

We are increasingly dependent on information technologies and networks.

Our business depends on the use of information technologies, which means that certain key areas such as research and development, production and sales are to a large extent dependent on our information technology capabilities. We are commercializing some devices using new technologies which, in case of malfunctions could lead to a misuse causing a risk of damages to patients (see "— Product liability claims could adversely affect our business, results of operations and financial condition" above). Our inability or the inability of our third-party service providers (for instance the accounting of some of our subsidiaries has been externalized) to implement adequate security and quality measures for data processing could lead to data 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.

Natural disasters prevalent in certain regions in which we do business could affect our operations

Some of our production sites are located in areas exposed to natural disasters, such as earthquakes (in North Africa, Middle East, Asia, Pacific, Europe, Central and Latin Americas), floods (in Africa, Asia Pacific and Europe) and hurricanes. In the event of a major disaster we could experience severe destruction or interruption of our operations and production capacity. As a result, our operations could suffer serious harm which could have a material adverse effect on our business, financial condition and results of operations.

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.

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 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's 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 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, CLP/GHS, 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 2011, 29.8% of our net sales were realized in the United States. While we incur expenses in those currencies, the impact of currency exchange rates on these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate and when technically feasible, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of

[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.

adverse currency exchange rate fluctuations on our results of operations or financial condition. In addition, in the specific context of the sovereign debt crisis affecting certain European countries, the alleged or actual disruption in the use of the euro as currency in one or more European Monetary Union countries and the associated fluctuations in currency exchange rates could have a material effect on our financial condition and earnings, the magnitude and consequences of which are unpredictable. 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, 2011, the Group's net debt amounted approximately to €10.9 billion, an amount which increased substantially with the acquisition of Genzyme in 2011. 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 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 (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 depositary 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 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 holders 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.

Our largest shareholders own a significant percentage of the share capital and voting rights of Sanofi.

As of December 31, 2011, L'Oréal and Total held approximately 8.82% and 3.22% of our issued share capital, respectively, accounting for approximately 15.69% and approximately 5.52%, respectively, of the voting rights (excluding treasury shares) of Sanofi. 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 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 that they do not consider their stakes in our Company as strategic to them, and Total makes regular sales of its holdings on the financial market. 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.

Risks Relating to our Contingent Value Rights (CVRs)

In addition to the risks relating to our shares, CVR holders are subject to additional risks.

In connection with our acquisition of Genzyme, we issued CVRs under a CVR agreement entered into by and between us and American Stock Transfer & Trust Company, the trustee. A copy of the form of the CVR agreement is attached as exhibit 4.1 to our Registration Statement on Form F-4 (Registration No. 333-172638), as amended. Pursuant to the CVR agreement, each holder of a CVR is entitled to receive cash payments upon the achievement of certain milestones, based on U.S. regulatory approval of Lemtrada™ (alemtuzumab for treatment of multiple sclerosis), and on achievement of certain aggregate net sales thresholds. See "Item 10. Additional Information — C. Material Contracts — The Contingent Value Rights Agreement."

CVR holders are subject to additional risks, including:

- an active public market for the CVRs may not develop or the CVRs may trade at low volumes, both of which could have an adverse effect on the resale price, if any, of the CVRs;
- because a public market for the CVRs has a limited history, the market price and trading volume of the CVRs may be volatile;
- if the milestones specified in the CVR agreement are not achieved for any reason within the time periods specified therein, and if net sales do not exceed the thresholds set forth in the CVR agreement for any reason within the time periods specified therein, no payment will be made under the CVRs and the CVRs will expire without value;
- since the U.S. federal income tax treatment of the CVRs is unclear, any part of any CVR payment could be treated as ordinary income and required to be included in income prior to the receipt of the CVR payment;
- any payments in respect of the CVRs are subordinated to the right of payment of certain of our indebtedness;
- we are not prohibited from acquiring the CVRs, whether in open market transactions, private transactions or otherwise, and on November 17, 2011, Sanofi publicly disclosed that it has obtained the necessary coporate authorizations to acquire any or all of the outstanding CVRs (for more information see "Item 5. Operating and Financial Review and Prospectus — Liquidity.");
- we may under certain circumstances purchase and cancel all outstanding CVRs; and
- while we have agreed to use diligent efforts, until the CVR agreement is terminated, to achieve each of the Lemtrada™-related CVR milestones set forth in the CVR agreement, we are not required to take all possible actions to achieve these goals, and the failure to achieve such goals would have an adverse effect on the value, if any, of the CVRs.