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. 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 certificates 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. Moreover, some countries are becoming more likely to consider granting a compulsory license to patents protecting an innovator's product; India's decision of March 2012 granting a compulsory license to a generic company to a Bayer patent is illustrative of this risk. 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, manufacturers of generic products are also increasingly seeking to challenge patents before they expire, and our infringement claim may not result in a decision that our rights are valid, enforceable or infringed.

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 and patent laws.

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 increased risks." below). Substantial damage awards and/or settlements have been handed down — 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. Furthermore, we commercialize several devices using new technologies which, in case of malfunction, could cause unexpected damages and lead to 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, pricing, compliance issues, as well as other legal matters, could adversely affect our business, results of operations and financial condition.

The marketing of our products is heavily regulated. The Group's business covers an extremely wide range of activities worldwide and involves numerous partners. Despite our efforts any failure to comply directly or indirectly (including as a result of a business partners' breach) with law could lead to substantial liabilities. Governments and regulatory authorities around the world have been strengthening enforcement activities in recent years. 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. The Group also faces significant litigation and government investigations or audits, including allegations of securities law violations, corruption, claims related to employment matters, patent and intellectual property disputes, consumer law claims and tax audits. 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. Responding to such investigations is costly and distracts management's attention from our business.

Unfavorable outcomes in any of these matters, or in similar matters to be faced in the future, could preclude the commercialization of products, harm our reputation, negatively affect the profitability of existing products and subject us to substantial fines (including treble damages), punitive damages, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls or exclusion from government reimbursement programs and could have a material adverse effect on our business, results of operations or financial conditions. These risks may encourage the company to enter into settlement agreement with governmental authorities including with no admission of wrongdoing. Those settlements may involve large cash payments and penalties. Settlement of healthcare fraud cases may require companies to enter into a corporate integrity agreement, which is intended to regulate company behavior for a period of years. For instance in December 2012, Sanofi U.S. entered into a settlement agreement with the U.S. Attorney's Office, District of Massachusetts, the United States Department of Justice and multiple states to resolve all claims arising out of an investigation into sampling of Sanofi's former viscosupplement product, Hyalgan®. As part of the settlement, Sanofi U.S. paid U.S.$109 Million to the settling parties and will enter into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services.

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 — Regulatory framework".

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

Our strategic objectives may not be fully realized.

Our strategy is focused on four pillars in order to deliver sustainable long-term growth and maximize shareholder returns: grow a global healthcare leader with synergistic platforms, bring innovative products to market, seize value-enhancing growth opportunities, and adapt our structure for future opportunities and challenges. 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 pursuing a Group-wide cost savings program which we expect, together with the expected synergies from our acquisition of Genzyme, to generate additional incremental cost savings by 2015. This also includes an adaptation plan regarding the activities of the Group in France. There is no assurance that the Group will successfully realize this plan. Moreover, the publicity given to this adaptation plan, may prejudice the Group's image and its reputation (see "— The expansion of social media platforms and mobile technologies present new risks and challenges." below). We may fail to realize all the expected cost savings resulting from these initiatives, which could materially and adversely affect our financial results.

Our research and development efforts may not succeed in adequately renewing our product portfolio.

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 2012, we spent €4,922 million on research and development, amounting to approximately 14.1% of our net sales.

We may not be investing in the right technology platforms, 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 addressing the same unmet need reaches the market earlier.

Developing a product is a costly, lengthy and uncertain process. 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). There can be no assurance that our research and development strategy will deliver the expected result in the targeted timeframe or at all, which could affect our profitability in the future.

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.

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.

The success of a product also depends on our ability to educate patients and healthcare providers and provide them with innovative data about the product and its 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 to realize the full value of our investment in its development.

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 manufacturing approvals in sufficient time to meet product demand, which could lead to a significant loss of sales of that drug and could affect our business, results of operations or 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.

In 2012, our patented pharmaceutical business faced important patent expirations and generic competition. For example Avapro®, Plavix®, and Eloxatin® lost their market exclusivity in the U.S in March, May and August 2012, and Aprovel® lost its market exclusivity in the E.U in August 2012.

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. 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.

Additionally, in many countries such as the United States or France, applicable legislation encourages the use of generic products to reduce spending on prescription drugs. Therefore, 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.

Additional products of the Group could become subject to generic competition in the future as we expect this generic competition to continue and to implicate drug products even those with relatively modest revenues.

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, 2012 compared with year ended December 31, 2011 — Net Sales by Product — Pharmaceuticals segment"), which represented 42.2% of the Group's consolidated revenues in 2012. Among these products is Lantus®, which was the Group's leading product with revenues of €4,960 million in 2012, representing 14.2% 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.

In general, if the products referred to above were to encounter problems such as loss of patent protection, material product liability litigation, unexpected side effects, regulatory proceedings, publicity affecting doctor or patient confidence, pressure from existing competitive products, changes in labeling, or if a new, more effective treatment were introduced, or if there were a reduction in sales of one or more of our flagship products or in their growth, the impact on our business, results of operations and financial condition could be significant.

We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments.

As a complement to our portfolio of products, we pursue a strategy of selective acquisitions, in-licensing and partnerships in order to develop growth opportunities. The implementation of this strategy depends on our ability to identify business development opportunities and execute them at a reasonable cost and under acceptable conditions of financing. Moreover, entering into 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 (see Note D.21.1. to the consolidated financial statements included at Item 18 of this annual report).

Because of the active competition among pharmaceutical groups for such business development activities, there can be no assurance of our success in completing these transactions when such opportunities are identified.

Once identified, the inability to quickly or efficiently integrate newly acquired activities or businesses; a longer integration than expected; the loss of key employees; or higher than anticipated integration costs, could delay our growth objectives and prevent us from achieving expected synergies.

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, including with regards to the potential of research and development pipelines, manufacturing issues, compliance issues, or the outcome of ongoing legal and other proceedings. It may also take a considerable amount of time and be difficult to implement a risk analysis and risk mitigation plan 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.

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

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:

- 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 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. 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. 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 continue to 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)), and compliance issues including corruption and fraud, as we operate in many parts of the world where these problems exist. Our existing policies and procedures, which are designed to help ensure that we, our employees, agents, intermediaries, and other third parties 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 we or they may take 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.

Each regulatory authority may also impose its own requirements either at the time of the filing of the dossier or later during its review 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. For example in August 2012, Genzyme received a Refuse to File letter from the FDA in response to the supplemental Biologics License Application to the FDA seeking approval of Lemtrada™. The FDA did not request additional data or further studies but requested a modified presentation of the data sets to enable agency to better navigate the application. Finally, Genzyme resubmitted at the end of November 2012 the Lemtrada™ file and the FDA accepted on January 28, 2013 the application for review. In December 2012, the CHMP of the European Medicines Agency (EMA) has adopted a negative opinion for the marketing authorization application for Kynamro™, but this product was approved by the FDA in January 2013.

Health authorities are increasingly focusing on product safety and on the risk/benefit profile of pharmaceuticals products. In particular, the FDA and the 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 commercial harm, overly restrictive regulatory actions and erratic share price performance.

Government authorities and regulators in the U.S. and in E.U. are considering measures to reduce the risk of supply shortages of live-saving medicine in particular if there are no viable therapeutic alternatives. It cannot be ruled out that these ongoing initiatives may generate additional costs for the Group if they result in a requirement to set-up back up supply channels or to increase the level of the inventories to avoid shortages.

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. For example, in July 2012, Sanofi Pasteur received a Warning Letter from the FDA following regular inspections conducted at manufacturing facilities in Canada and France. 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. In 2010, Genzyme entered into a consent decree with the FDA relating to its Allston facility and paid U.S.$175.0 million to the U.S. Federal Government as disgorgement of past profits. The consent decree required 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 and the plan was accepted by FDA. Remediation of the Allston facility in accordance with that plan is underway and is currently expected to continue for three more years.

Our indebtedness may limit our business flexibility compared to some of our peers.

Our consolidated debt increased substantially in connection with our acquisition of Genzyme in 2011. Although we continued to reduce our debt in 2012 (as of December 31, 2012, our debt, net of cash and cash equivalents amounted to €7.7 billion), we still 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 increasing pricing and reimbursement pressure on our pharmaceutical products that could negatively affect our revenues and/or margins.

The commercial success of our existing products and our products candidates depends in part on the conditions under which our products are reimbursed. Our products continue to be subject to increasing price and reimbursement pressure due to, amongst others:

- 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, the new federal health care reform law is increasing the government's role with respect to price, reimbursement and the coverage levels for healthcare services and products within the large government health care sector. This law also imposed cost containment measures and rebates and fees on pharmaceutical companies. 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 U.S. states are also considering legislation that would influence the marketing of prices of and access to drugs, and U.S. federal and state officials will likely 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 instance early 2013, in China the National Development and Reform Commission set new national retail ceiling prices for 700 formulations of 400 drugs; among them was Lantus® whose price was cut by 12.9% (effective February 1, 2013).

Due to the ongoing cost containment policies being pursued in many jurisdictions 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. Such a slowdown has reduced 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.

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, lack of developed third party payer system, 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.

The growth of our OTC and CHC business may also be negatively affected by the current slowdown in global economic growth as consumer spending is closely tied to the global economy. Also our animal health business could be impacted. For example, tight credit conditions may limit the borrowing power of livestock producers, causing some to switch to lower-priced products.

Although macroeconomic and financial measures have been taken in 2012 by governments and monetary authorities, notably in Europe reducing thus the risk of failure of a State, the slowing economic environment, the default or failure of major players including wholesalers or public sector buyers financed by insolvent States may affect the financial situation of the Group but can also cause the Group to 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 discovery, manufacture and marketing of some of our products" below.

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. We may not have redundant manufacturing capacity for certain products particularly biologic products. For instance 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.

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(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.

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 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). Group products are increasingly reliant on the use of product-specific devices for administration; a technical problem in these devices could jeopardize the approval or the commercialization of the products or require a recall.

Supply shortages are subject to public scrutiny and are subject to even greater public criticism when they occur with respect to life saving medicines with limited therapeutic alternatives. Such shortages can have a negative impact on the image of the Group independent of the level of revenues lost as a result of the shortage of a particular product. The investigation and remediation of any identified manufacturing problems can cause production delays, substantial expense, lost sales and delay the launch of new products, which could adversely affect our operating results and financial condition.

Like many of our competitors, we have faced and may face in the future manufacturing issues. For example, Genzyme experienced in the past significant difficulties in manufacturing Cerezyme® and Fabrazyme® for several years. In summer 2011 a technical incident occurred in the filling line used for Apidra 3mL cartridges at our manufacturing site in Frankfurt which caused temporary shortages for Apidra 3mL cartridges. In April 2012 Sanofi Pasteur temporarily imposed supply limitations for Pentacel® and Daptacel® vaccines in the U.S. due to a manufacturing delay that temporarily reduced the effective capacity to below the level needed to fully satisfy market demand in the U.S. In June 2012 Sanofi Pasteur voluntarily recalled the Bacille Calmette-Guérin (BCG) vaccine produced in its Canadian facility due to manufacturing issues. This withdrawal is expected to last several months while the renovation of the building is completed. There can be no 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 discovery, manufacture and marketing of some of our products.

Our industry is highly collaborative, whether in the discovery and development of new products, in-licensing, the marketing and distribution of approved products, or manufacturing activities. We expect that the reliance on third parties for key aspects of our business will continue to characterize our activities.

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.

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.

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 also conduct a number of significant research and development programs and market some of our products in collaboration with other biotechnology and pharmaceutical companies. For example, we currently have collaborative arrangements with Regeneron for the discovery, development and commercialization of therapies based on monoclonal antibodies, 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 alliances). We may also rely on partners to design and manufacture medical devices, notably for the administration of our products. When we research and market our products through collaboration arrangements, we are subject to the risk that certain decisions, such as the establishment of budgets, development and promotion strategies and specific tasks, are under the control of our collaboration partners, and that deadlocks, failures in the development or differing priorities may adversely affect the activities conducted through the collaboration arrangements. 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 58% of our consolidated U.S. pharmaceutical sales are accounted for by just three wholesalers. In addition, the Group's three main customers represent 17.0% 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 2010, some countries of southern Europe have faced important financial difficulties. Some customers in these countries are public or subsidized health systems. The deteriorating economic and credit conditions in these countries may lead to longer payment terms. Because of this trend 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).

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(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.

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.

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 "— The ongoing slowdown of global economic growth and the financial crisis could have negative consequences for our business" above and "— Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition" below).

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 a number of devices using new technologies which, in case of malfunctions could lead to a risk of harm to patients (see "— Product liability claims could adversely affect our business, results of operations and financial condition" above) or the unavailability of our products. While we have invested heavily in the protection of data and information technology, there can be no assurance that our efforts or those 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 would be sufficient to protect against data deterioration or loss in the event of a system malfunction, or prevent data from being 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.

The expansion of social media platforms and mobile technologies presents new risks and challenges.

New technologies are increasingly used to communicate about our products or the diseases they are intended to treat. The use of these media requires specific attention, monitoring programs and moderation of comments. For instance, patients may use these channels to comment on the effectiveness of a product and to report an alleged adverse event. Negative posts or comments about the Company, its business, its directors or officers on any social networking web site could seriously damage our reputation. In addition, our associates may use the social media tools and mobile technologies inappropriately which may give rise to liability, or which could lead to the exposure of sensitive information. In either case, such uses of social media and mobile technologies could have a material adverse effect on our business, financial condition and results of operations.

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 pathogen 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 and "Item 8. Financial Information — A. Consolidated Financial Statements and Other Financial Information — Information on Legal or Arbitration Proceedings".

Environmental regulations are evolving (*i.e.*, in Europe, REACH, CLP/GHS, SEVESO, IPPC/IED, 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 2012, 31% 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 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 threatened or actual withdrawal 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, 2012, the Group's net debt amounted approximately to €7.7 billion. 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.

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(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.

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 issue new shares and existing shareholders 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, holders of ADSs 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.

Recent French tax legislation applicable to the ADSs may affect their attractiveness.

The implementation of new tax legislation such as the French financial transaction tax of 0.2% (*Taxe sur les Transactions Financières* — TTF) enacted in 2012 (see "Item 10. — E. Taxation"), which applies by its terms to trading in our shares and ADSs without regard to territoriality could increase the costs linked to the issuance, transfer and cancellation of ADSs. Moreover, uncertainties regarding how such a tax would be assessed and collected from beneficial owners or financial intermediaries outside of France could discourage holding of such instruments.

We cannot foresee the extent to which this tax and uncertainty over its technical and practical aspects may reduce the liquidity and economic value of our ADSs.

Our largest shareholder owns a significant percentage of the share capital and voting rights of Sanofi.

As of December 31, 2012, L'Oréal held approximately 8.91% of our issued share capital, accounting for approximately 16.13% of the voting rights (excluding treasury shares) of Sanofi. See "Item 7. Major Shareholders and Related Party Transactions — A. Major Shareholders." Affiliates of L'Oréal currently serve on our Board of Directors. To the extent L'Oréal continues to hold a large percentage of our share capital and voting rights, it will remain in a position to exert heightened influence in the appointment 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.

To our knowledge, L'Oréal is not subject to any contractual restrictions on the sale of the shares it holds in our Company. L'Oréal announced that it does not consider its stake in our Company as strategic to it. 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 (see also Note D.18. to the consolidated financial statements included at Item 18 of this annual report). 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;

- the market price and trading volume of the CVRs may be volatile;