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 and Regulatory 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 data exclusivity or supplementary protection certificates in Europe, we hold exclusivity rights for a number of our research-based products. However, the protection that we are able to obtain varies in its duration and scope from product to product and country to country. This protection may not be sufficient to maintain effective product exclusivity because of local differences in the patents, in national laws or applicable legal systems, or developments in law or jurisprudence, which may give rise to inconsistent judgments.

Moreover, patent and other proprietary rights do not always provide effective protection for our products. Manufacturers of generic products or biosimilars are increasingly seeking to challenge patent coverage before the patents expire, and manufacturers of biosimilars or interchangeable versions of the products are seeking to have their version of the product approved before the exclusivity period ends. Furthermore, in an infringement suit against a third party, we may not prevail and the decision rendered may not consider that our patent or other proprietary rights are valid, enforceable or infringed. Our competitors may also successfully avoid patents, for example, through design innovation, and we may not hold sufficient evidence of infringement to bring suit.

In certain cases, to terminate or avoid patent litigation, we or our partners may be required to obtain licenses from the holders of third-party intellectual property rights that cover aspects of our existing and future products in order to manufacture, use or sell them. Any payments under these licenses may reduce our profits from such products and we may not be able to obtain these licenses on favorable terms or at all. If we fail to obtain a required license for a country where the valid third-party intellectual property right exists or are unable to alter the design of our technology to fall outside the scope of third-party intellectual property rights, we may be unable to market some of our products in certain countries, which may limit our profitability.

Also, some countries may consider granting a compulsory license to use patents protecting an innovator's product, which limits the protection granted to such products.

We are involved in litigation worldwide to enforce certain of our patent rights against generics, proposed generics and biosimilars (see "Item 8. Financial Information — A. Consolidated Financial Statements and Other Financial Information — Information on Legal or Arbitration Proceedings" for additional information including on litigation related to Lantus® one of the Group's flagship products) of our small molecule and biological pharmaceutical products. Even in cases where we ultimately prevail in an 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 or a biosimilar 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. A successful result against a competing product for a given patent or in a specific country is not necessarily predictive of our future success against another competing product or in another country because of local variations in the patents and patent laws.

Further, we have increased the proportion of biological therapeutics in our pipeline relative to traditional small molecule pharmaceutical products. We expect to face increasing competition from biosimilars in the future. With the accelerated regulatory pathways provided in the U.S. and Europe for biosimilar drug approval, biosimilars can be a threat to the exclusivity of any biological therapeutics we sell or may market in the future and can pose the same issues as the small molecule generic threat described hereinabove. To the extent that governments could adopt more permissive approval frameworks (for instance regarding the duration of data exclusivity that could be shortened, or the scope of new products receiving data exclusivity that could be narrowed) and competitors could be able to obtain broader marketing approval for biosimilars including as a substitutable product, our products would become subject to increased competition (see also "Changes in the laws or regulations that apply to us could affect the Group's

business, results of operations and financial condition"). If a biosimilar version of one of our products were approved, it could reduce our sales of that product.

However, with our presence as a manufacturer of generics and anticipated entry into biosimilars, we will utilize patent challenge strategies against other innovators' patents, similar to those of long-established generic companies, but there is no assurance that these strategies will be successful.

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 diversification could increase our product liability exposure as liability claims relating to our 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. 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.

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 these claims or will not face additional claims in the future.

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. Following the implementation of European pharmacovigilance legislation in 2012, the Company and the European Regulatory Agencies (under the supervision of the PRAC (Pharmacovigilance Risk Assessment Committee)) have reinforced their systematic and intensive safety signal detection systems which may detect safety issues even with mature products that have been on the market for considerable time. As a result market authorization suspension or withdrawal may take place. Following a recall or a withdrawal, pharmaceutical companies can face significant product liability claims.

Furthermore, we commercialize several devices (notably those using new technologies) which, in case of malfunction, could cause unexpected damages and lead to product liability claims (see "– We are increasingly dependent on information technologies and networks.").

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. This is true particularly in the United States, and especially for genericized products where Sanofi is the innovator, as innovators have been held liable in some U.S. jurisdictions for damages caused by a product commercialized by generic manufacturers. 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 – B.9. Insurance and Risk Coverage"). In case of self-insurance, the legal costs that we would bear for handling such claims and potential indemnifications to be paid to claimants could affect our financial condition.

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's attention, may harm our reputation and can impact the demand for our products. Substantial product liability claims could adversely affect our business, results of operations and financial condition.

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 anticipate the regulations, comply with them and/or maintain the approvals.

Obtaining marketing authorization is a long and regulated process requiring extensive documentation and data to be provided to the regulatory authorities. Regulatory processes differ from one authority to another. Either at the

time of the filing of the application for a marketing authorization or later during its review, each regulatory authority may impose its own requirements, including requiring local clinical studies, and may delay or refuse to grant approval, even though a product has already been approved in another country.

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 increased their requirements particularly in terms of the volume of data needed to demonstrate a product's efficacy and safety. Even after regulatory approval, marketed products are subject to continual review, risk evaluations or comparative effectiveness studies. These requirements have increased the costs associated with maintaining regulatory approvals and achieving reimbursement for our products. Post-regulatory approval reviews and data analyses can lead to the issuance of recommendations by government agencies, health professional and patient or other specialized organizations regarding the use of products; for example, a recommendation to limit the patient scope of a drug's indication, impose marketing restrictions, or suspend or withdraw the product can result in a reduction in sales volume, as well as an increased risk of litigation.

Moreover, to monitor our compliance with applicable regulations, the FDA, the EMA and comparable agencies in other jurisdictions routinely conduct inspections of our facilities and may identify potential deficiencies. For example, further to the Warning Letter received from the FDA in July 2012 and following inspections conducted at manufacturing facilities in Canada and France, Sanofi Pasteur has submitted a remediation plan to the FDA. In 2014 the issues raised in the 2012 Warning Letter were waived by the FDA. If we were to receive another Warning Letter following the inspection of one of our facilities and if we fail to adequately respond to that or any other warning letter identifying a deficiency further to a control, or otherwise fail to comply with applicable regulatory requirements, under the applicable pharmaceutical regulation, we could be subject to enforcement, remedial and/or punitive actions by the FDA, the EMA or other regulatory authorities.

In addition, to the extent that new regulations raise the costs of obtaining and maintaining product authorizations, or limit the economic value of a new product to its originator, the growth prospects of our industry and of the Group are diminished. Approximately 70% of our current development portfolio consists of biological products that may in the future bring new therapeutic responses to current unmet medical needs, but that may also lead to more technical constraints and costly investments from an industrial standpoint as biological products are complex to produce. These constraints and costs could adversely affect our business, results of operations and financial condition.

Claims and investigations relating to compliance, competition law, marketing practices, pricing, 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. We have adopted a Code of Ethics that calls for employees to comply with applicable legislation and regulations, as well as with the specific values and rules of conduct set forth in that Code. We have also set up policies and procedures which are designed to help ensure that we, our employees, officers, agents, intermediaries and other third parties comply with applicable laws and regulations (including the U.S. Foreign Corrupt Practices Act (FCPA), the UK Bribery Act, the OECD Anti-Bribery Convention and other anti-bribery laws and regulations).

Notwithstanding these efforts, deviations may occur and there can be no assurance that we and/or our officers will not face liability under laws and regulations for actions taken with respect to our business.

Any failure to comply directly or indirectly (including as a result of a business partners' breach) with the laws and regulations applicable to us could lead to substantial liabilities and harm the Group's reputation. Governments and regulatory authorities around the world have been strengthening enforcement activities in recent years. Sanofi and certain of its subsidiaries are under investigation or could become the subject of additional investigations 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 whistleblower 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 or market and could have a material adverse effect on our business, results of operations or financial conditions.

These risks may encourage us to enter into settlement agreements and those settlements may involve significant monetary payments and/or criminal penalties and may include admissions of wrongdoing. Settlement of healthcare fraud cases in the United States may require companies to enter into a Corporate Integrity Agreement, which is intended to regulate company behavior for a specified period of years. We have entered into such agreements in the past and for example we expect to enter into such an agreement and be subject to the terms and conditions of the agreement for a period of five years as part of a settlement relating to our Seprafilm® and Hyalgan® products.

Changes in the laws or regulations that apply to us could affect the Group's business, results of operations and financial condition.

All aspects of our business, including research and development, manufacturing, marketing, pricing or sales are subject to extensive legislation and regulation. Changes in applicable laws could have a material adverse effect on our business.

For example, 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 could make prosecution of patents for new products more difficult and time consuming or could adversely affect the exclusivity period for our products (see "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" above).

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 — B.6. Markets — B.6.2. Competition" and "— B.6.3. Regulatory framework".

In addition, changes in the various tax laws of the jurisdictions where affiliates of the Group operate, or changes 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 instance, both the OECD's initiative on Base Erosion and Profits Shifting (BEPS) and the European Union's initiative on the Code of Conduct for Business Taxation could lead to significant changes to tax laws and regulations in the future. Additionally, due to the complexity of the fiscal environment, the ultimate resolution of any tax matters may result in payments greater or lesser than amounts accrued.

For information regarding risks related to changes in environmental rules and regulations, see "— Environmental liabilities and costs related to compliance with applicable regulations may have a significant adverse effect on our results of operations" below.

Risks Relating to Our Business

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

Discovering and developing a new product is a costly, lengthy and uncertain process. 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 compensate for the decreasing sales of our products facing expiry of patents and regulatory data exclusivity or competition from new products of competitors that are perceived as being superior. In 2014, we spent €4,824 million on research and development, amounting to 14.3% of our net sales.

Our industry is driven by the imperative need for constant innovation, but we may not be investing in the right technology platforms, therapeutic areas, 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.

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 — B.5. Global Research & Development — B.5.2. Pharmaceuticals". Accordingly, there is a substantial risk at each stage of development — including clinical studies — that we will not achieve our goals of safety and/or effectiveness and that we will have to abandon a product in which we have invested substantial amounts and human resources, even 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 would negatively affect our operating results.

In November 2014, we announced our intent to launch up to 18 new medicines and vaccines between 2014-2020, but 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.

Following each product marketing approval, the medical need served by the product and the corresponding reimbursement rate are evaluated by other governmental agencies, requiring in some cases additional studies, including comparative studies, which may both effectively delay marketing of the new product and add to its development costs.

After marketing approval of our products, other companies, investigators whether independently or with our authorization, may conduct studies or analysis beyond our control that may ultimately report results negatively affecting our sales either permanently or temporarily. It may take time for Sanofi to address the reported findings. For instance following a third party analysis of data alleging a link between insulin glargine and cancer, Sanofi initiated a large scale epidemiological program in 2009 to generate more information on whether there was any association between cancer and insulin use and to assess whether there was any difference in risk between insulin glargine and other insulins. Results of Sanofi's studies were available only three years later and concluded there was no increased risk of cancer in people with diabetes treated with Lantus®.

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, 2014 compared with year ended December 31, 2013 — Net Sales by Product — Pharmaceuticals segment"). Lantus® is particularly important; it was the Group's leading product with revenues of €6,344 million in 2014, representing 18.8% of the Group's consolidated revenues for the year. Lantus® is a flagship product of the Diabetes division, one of the Group's main divisions. However, in November 2014, we announced that we expect our global Diabetes sales to be flat to slightly growing at constant exchange rates between 2015 and 2018 (assuming no entry of a substitutable insulin glargine biosimilar on the U.S. market before 2019). Nevertheless our actual sales may differ from these expectations given the numerous underlying assumptions such as the dynamics of the basal insulin market in the U.S., the conversion of patients from Lantus® to Toujeo®, the continued growth of our diabetes products in Emerging Markets, or the U.S. launches of Afrezza®, Lyxumia® and LixiLan. Furthermore, the launch of new medicines and vaccines in other therapeutic areas and the sustained performance of our other growth platforms may not allow us to reduce the relative contribution of Lantus® to our overall performance.

Our flagship products benefit from certain intellectual property protections such as patents and exclusivity periods but patent and proprietary rights, even if they are not challenged, are subject to expiration dates. Expiration of effective intellectual property protections for our products typically results in the entry of one or more generic competitors, often leading to a rapid and severe decline in revenues on those products. For example, Plavix® lost its market exclusivity in the United States in May 2012 and as a result, its U.S. sales dropped by 90% within the two months following the loss of market exclusivity (for information on the expected impact of biosimilar entry see "— We may lose market share to competing remedies, biosimilar or generic brands.")

Furthermore, in general, if our flagship products were to encounter problems such as 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 adverse impact on our business, results of operations and financial condition could be significant.

We may lose market share to competing remedies, biosimilar or generic brands.

We are faced with intense competition from generic products, biosimilars and brand-name drugs including from retail chains and distributors. For example in 2015 in Japan, we expect generic competition on Plavix® starting from mid year.

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 adversely affect our results of operations.

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, we may not be able to increase the sales of our new products or realize the full value of our investment in their development.

We may not be able to anticipate precisely the date of market entry of generics or biosimilars or the potential impact on our sales both of which depend on numerous parameters. 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 significantly lower prices, resulting in both an adverse price and volume effects for our genericized products. For example, Plavix® lost its market exclusivity in the United States in May 2012 and as a result, its U.S. sales dropped by 90% within the two months following the loss of market exclusivity. Substitution is often permitted for generics that are considered to be interchangeable or clinically identical. With respect to biosimilars, in the United States only biosimilars that refer to an innovator drug that was approved under a Biologics License Application may be designated as interchangeable with the original biologic and only in circumstances where specific criteria are met. In Europe, in many countries, automatic substitution of biologics is officially prohibited or not recommended. Nevertheless competition from even non-substitutable biosimilars would likely result in a decrease in prices, additional rebates, promotion effort and lower margins.

Approval of a generic or biosimilar that is substitutable for one of our products would increase the risk of accelerated market penetration by that generic or biosimilar to a greater extent than would be the case for a non-substitutable product.

These trends are exacerbated by applicable legislation which encourages the use of generic products to reduce spending on prescription drugs in many countries such as the United States and France. 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. We expect this generic competition to continue and to implicate more of our products, including those with relatively modest sales.

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, delay the launch of new products and negatively impact our image.

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. 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 shortage or interruption in the event that these suppliers are unable to manufacture our products meeting Group quality standards or experience financial difficulties. 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®. Any of these factors could adversely affect our business, operating results or financial condition. See "Item 4. Information on the Company — B. Business Overview — B.8. Production and Raw Materials" for a description of these outsourcing arrangements.

Our products are also increasingly reliant on the use of product-specific devices for administration which may result in technical issues. For example, Praluent®, currently under development, will be administered with an auto-injector manufactured by a third party. The success of this product, once launched, will depend partially on the performance of this device.

We must also be able to produce sufficient quantities of the products to satisfy demand. We may have difficulties scaling-up production of our products which are under development once they are approved. In 2014 we entered into an agreement with Boehringer Ingelheim for the manufacture of therapeutic monoclonal antibodies to reinforce our manufacturing capacity to support upcoming product launches, however, there is no certainty that this agreement will deliver the expected benefits in terms of manufacturing capabilities.

Our biological products in particular, are subject to the risk of manufacturing stoppages or the risk of loss of inventory because of the difficulties inherent in the processing of biological materials and the potential unavailability of adequate amounts of raw materials meeting our standards (for the impact on our financial statements see "– 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.")

For example, starting from 2012 Sanofi Pasteur encountered production issues which caused delays in the supply of Pentacel® vaccine in the U.S. While these problems have either been remediated or are in the process of being remediated, Sanofi Pasteur continues to face a strong demand for its vaccines that requires it in certain cases to manage the supply allocation. Sanofi Pasteur is working to increase its capacities but cannot reasonably estimate how long it will take to address these constraints. 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.

Additionally, specific conditions must be respected both by the Group and our customers for the storage and distribution of many of our biological products, for example, cold storage for certain vaccines and insulin-based products.

The complexity of these processes, as well as strict internal and health authorities standards for the manufacture of our products, subject us to risks as the investigation and remediation of any identified or suspected problems can cause production delays, substantial expense, product recalls, lost sales and inventories, and delay the launch of new products, which could adversely affect our operating results and financial condition, cause reputational damage and the risk of product liability (see "– Product liability claims could adversely affect our business, results of operations and financial condition").

When manufacturing disruptions occur, we may not have alternate manufacturing capacity, particularly for certain biological products. In the event of manufacturing disruptions, it is also difficult to use back-up facilities or set up new facilities because biological products are more complex to manufacture. 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 require significant time.

Supply shortages are subject to even greater criticism when they occur with respect to life saving medicines with limited or no viable therapeutic alternatives. Independently of the level of revenues lost as a result of the shortage of a particular product, such shortages can have a negative impact on the patients, customers and professional healthcare providers' confidence and the image of the Group. Government authorities and regulators in the United States and in the European Union are also considering measures to reduce these risks. It cannot be ruled out that these ongoing initiatives may generate additional costs for the Group if they result in a requirement to establish back up supply channels or to increase inventory levels to avoid shortages.

Furthermore, we are sometimes required to use animals to test our products in the development phase and our vaccines before distributing them. Testing on animals is vital for the development of a product and many times, it is the only way to study the effects of a product under development in a living body before tests are made on humans. Studies performed on animals also provide significant information on the causes and progress of diseases. Some countries require additional tests to be made on animals, even if the product is already approved. If applicable regulations were to ban this practice, or if, due to pressure from animal welfare groups, we were no longer able to source animals to perform such tests, it would be difficult and in some cases impossible to develop or distribute our products in certain jurisdictions under the applicable marketing authorizations.

The pricing and reimbursement of our products is increasingly affected by government and other third parties decisions and cost reduction initiatives.

The commercial success of our existing products and our product 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;
- increase in cost containment policies related to health expenses in a context of economic slowdown; 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; policies requiring the automatic substitution of generics or biosimilars could also be put in place. For example, in the United States, the 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 healthcare sector. This law also imposed cost containment measures and rebates and fees on pharmaceutical companies. Implementation of health care reform has affected and will continue to affect our revenues and/or margins. For instance, in 2014, we had to increase the level of rebates for Lantus® required to maintain favorable formulary positions with key payers in the U.S. Some U.S. states are also considering legislation that would influence the marketing and 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 European Union, China and Canada, the coverage of prescription drugs, pricing and levels of reimbursement are subject to governmental control.

Governmental and private third-party payers and purchasers of pharmaceutical products may also claim damages related to a preliminary injunction alleging they have over-reimbursed a drug if we do not ultimately prevail in the patent litigation. For example in Australia our patent on clopidogrel was ultimately held invalidated. Since 2013, the Australian Government has been seeking damages for its alleged over-reimbursement of clopidogrel drugs due to the preliminary injunction we had obtained against GenRX (a subsidiary of Apotex) during the course of the litigation.

Furthermore there is a growing number of mergers of retail chains and distributors, this consolidation of distribution channels increases their capacity to negotiate price and other terms.

Due to these cost containment policies and pressure on our prices, our revenues and margins are, and could continue to be, negatively affected.

We are also unable to predict the availability or amount of reimbursement for our product candidates. The negotiation on the price in a country may also be incompatible with the global positioning of our product, which may lead us to not launch the product in that country.

Finally, 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 products on low cost markets for resale on higher cost markets.

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.

We 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 a global strategic collaboration with Regeneron for the discovery, development, commercialization and manufacturing of therapies based on monoclonal antibodies. We also have collaborative arrangements with Merck & Co., Inc. for the

distribution of vaccines in Europe (See "Item 4. Information on the Company — B. Business Overview — B.2. Main pharmaceutical products" and "Item 4. Information on the Company — B. Business Overview — B.3. Vaccine Products" for information on our alliances). We may also rely on partners to design and manufacture medical devices, notably for the administration of our products.

If disruptions or quality concerns were to arise in the third-party supply of raw materials, active ingredients or medical devices or if our partner were unable to manufacture a product, this could also 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, delay the launch of new products and negatively impact our image".

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, 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.

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 slowdown. The United States poses particular client credit risk issues, because of the concentrated distribution system in which approximately 65% of our consolidated U.S. pharmaceutical sales are accounted for by just three wholesalers. We are also exposed to large wholesalers in other markets, particularly in Europe. Worldwide, the Group's three main customers represent 23.0% of our gross total revenues. 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).

In some countries, some customers are public or subsidized health systems. The economic and credit conditions in these countries may lead to longer payment terms. Because of this context, we may need to reassess the recoverable amount of our debts in these countries during the coming financial years (see also "Item 5. Operating and Financial Review and Prospects — Liquidity and Capital Resources — Liquidity.").

The global economic conditions and the unfavorable financial environment could have negative consequences for our business [(2)].

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, major national economies or emerging markets could negatively affect growth in the global pharmaceutical market and, as a result, adversely affect our business. Unfavorable economic conditions have 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, increases in co-pays, and lack of developed third party payer system in certain regions, 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. Also, as a result of the insurance coverage mandate that goes into effect in the U.S. in 2015 and 2016, some

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(1) Information in this section is in addition 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.

(2) Information in this section is in addition 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.

employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees.

Our CHC and animal health business could also be adversely impacted as difficult economic conditions may limit the financial resources of people and livestock producers.

If economic conditions worsen or in case of default or failure of major players including wholesalers or public sector buyers financed by insolvent States, the financial situation of the Group, its results of operations and the distribution channels of its products may be affected. See also "We are subject to the risk of non-payment by our customers".

Moreover, economic and financial difficulties may have an adverse impact on third parties who are important to our business, including collaboration partners and suppliers, which could cause such third parties to delay or disrupt performance of their obligations to us, resulting in a material and adverse effect on our business or results of operations. See "— We rely on third parties for the discovery, manufacture and marketing of some of our products" above. For more information see "Item 5. Operating and Financial Review and Prospects — Liquidity and Capital Resources — Liquidity."

Counterfeit versions of our products harm our business.

Counterfeiting activities and the presence of counterfeit products in a number of markets and over the Internet continue to be a challenge for maintaining a safe drug supply. Counterfeit products are frequently unsafe or ineffective, and can be life-threatening. To distributors and users, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs along with increased levels of counterfeiting could be mistakenly attributed to the authentic product, affect patient confidence in the authentic product and harm the business of companies such as Sanofi. If a Group product were to be the subject of counterfeits, the Group could incur substantial reputational and financial harm. See "Item 4. Information on the Company — B. Business Overview — B.6. Markets — B.6.2. Competition."

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.

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, discontinued research and development project, patent litigation and the launch of competing products), with adverse effects on our financial condition and the value of our assets.

Furthermore, 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. We also own a significant stake in Regeneron Pharmaceuticals Inc. (22.3% of share capital as of December 31, 2014), which is listed on the NASDAQ and has been accounted for using the equity method since 2014. Any material deterioration in Regeneron's share price or financial performance would be an indicator that the value of our investment might have become impaired. This would require us to perform an impairment test, which could have a negative impact on our financial statements.

The inherent variability of biologics manufacturing increases the risk of write-offs of these products. Due to the value of the materials used, the carrying amount of biological products is much higher than that of small-molecule products.

The financial environment and in particular the economic difficulties affecting certain European countries, Russia and Venezuela could also negatively affect the value of our assets (see "— The global economic conditions and the unfavorable financial environment could have negative consequences for our business" and "— Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition").

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

Our pension liabilities are affected by factors such as the performance of plan assets, interest rates, actuarial data and experience and changes in laws and regulations.

Our future funding obligations for our main defined-benefit pension plans depend on changes in the future performance of assets held in trust for these plans, the interest rates used to determine funding levels (or company liabilities), actuarial data and experience, inflation trends, the level of benefits provided for by the plans, as well as changes in laws and regulations. Adverse changes in those factors could increase our unfunded obligations under such plans, which would require more funds to be contributed and hence negatively affect our cash flow and results (see Note D.19.1 to our consolidated financial statements included at Item 18 of this annual report).

We are increasingly dependent on information technologies and networks.

Our business increasingly 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 systems or those of third party providers, notably for storing and transferring confidential or sensitive information. Moreover, we commercialize 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") or the unavailability of our products. While we and our third-party service providers have secure information technology systems for the protection of data, there can be no assurance that our efforts or those of our third-party service providers to implement adequate security and control measures would be sufficient to protect against service disruption, 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 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 and diseases or to provide health services. 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. When such issues arise, the 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. Negative posts or comments about Sanofi, our business, directors or officers on any social networking web site could seriously damage our reputation. In addition, our employees and partners may use the social media tools and mobile technologies inappropriately which may give rise to liability for the Company, 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.

Risks Relating to the Group Structure and Strategy

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 collaborations 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 and also "— We rely on third parties for the discovery, manufacture and marketing of some of our products").

Our growth objectives could be delayed or ultimately not realized, and expected synergies could be adversely impacted if:

- we are unable to quickly or efficiently integrate newly acquired activities or businesses;
- integration takes longer than expected;
- the loss of key employees occurs; or
- we have higher than anticipated integration costs.

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.

Moreover, we may miscalculate the risks associated with newly acquired activities or businesses at the time they are acquired or not have the means or access to all the relevant information 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 globalization of the Group's business exposes us to increased risks in specific areas.

Emerging Markets are among the pillars of our overall strategy. Difficulties in adapting to Emerging Markets, a significant decline in the anticipated growth rate in these regions or an unfavorable movement of the exchange rates of these countries' currencies against the euro could impair our ability to take advantage of these growth opportunities and could affect our business, results of operations or financial condition.

The significant expansion of our activities in Emerging Markets further exposes us to more volatile economic conditions, political instability, competition from multinational or locally based companies that are already well established in these markets, the inability to adequately respond to the unique characteristics of Emerging Markets, particularly with respect to their regulatory frameworks, difficulties in recruiting qualified personnel or maintaining required internal control systems, 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")), and compliance issues including corruption and fraud (see "— Claims and investigations relating to compliance, competition law, marketing practices, pricing as well as other legal matters, could adversely affect our business, results of operations and financial condition").

Also as a global healthcare leader, we are exposed to a number of risks inherent in sectors in which, in the past, we have been less active such as the generic and consumer healthcare sectors whose business models and trade channels are different from the traditional pharmaceutical activity in particular regarding promotional efforts and trade terms.

Our strategic objectives may not be fully realized.

Our strategy is focused on four key priorities in order to deliver sustainable long-term growth and maximize shareholder returns: grow a global healthcare leader with synergistic businesses, 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.

The Group concentrates its efforts around identified businesses to meet significant growth objectives. There is no guarantee that we will meet these objectives or that these businesses, such as Emerging Markets or innovative products, will grow in line with anticipated growth rates. A failure to continue to expand our business in these areas could affect our results of operations or financial condition.

The successful launch of a new pharmaceutical product involves substantial investment in sales and marketing activities. In November 2014, we announced our intent to launch up to 18 new medicines and vaccines between 2014-2020; however there can be no assurance that these product candidates will be approved, with the requested indications, or if at all, and if approved, will achieve commercial success. The success of a product also depends on our ability to successfully produce and launch it. The strategy of launch that we may develop (notably in terms of timing, pricing, market access, marketing efforts and dedicated sales forces) may not deliver the benefits that we expect. The relevant competitive environment may also have evolved at the time of the actual launch, modifying our initial expectations. The need to prioritize the allocation of financial resources and sales forces may cause delays in the expected launch of some of our products.

Our success depends in part on our senior management team and other key employees and our ability to attract, integrate and retain key personnel and qualified individuals in the face of intense competition.

We depend on the expertise of our senior management team and other key employees. In addition, we rely heavily on recruiting and retaining talented people to help us meet our strategic objectives. We face intense competition for qualified individuals for senior management positions, or in specific geographic regions or in specialized fields such as clinical development, biosciences and devices. In addition, our ability to hire qualified personnel also depends in part on our ability to reward performance, incentivize our employees and to pay competitive compensation. Laws and regulations on executive compensation may restrict our ability to attract, motivate and retain the required level of talented people. The inability to attract, integrate and/or retain highly skilled personnel, in particular those in leadership positions, may weaken our succession plans, may materially adversely affect the implementation of our strategy and our ability to meet our strategic objectives and could ultimately impact our business or 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/or the imposition of civil or criminal penalties and civil damages.

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 and reputation.

Although we maintain property, business interruption and casualty insurance that we believe is in accordance with customary industry practices, this insurance may not be adequate to fully cover all potential hazards incidental to our business.

Environmental liabilities and costs related to compliance with applicable regulations 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 — B.10. 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 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 — B.10. Health, Safety and Environment (HSE)."

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 and our employees could suffer serious harm which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Financial Markets[(3)]

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 Japanese yen, and to currencies in Emerging Markets. In 2014, 34% of our net sales were realized in the United States, 34% in Emerging Markets (including countries that are or may in future be subject to exchange controls) and 6% in Japan. 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. For more information concerning our exchange rate exposure, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk."

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 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 issue new shares and existing shareholders have the right to subscribe for a portion of

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(3) 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.

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.

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

As of December 31, 2014, L'Oréal held approximately 8.96% of our issued share capital, accounting for approximately 16.28% 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 greater 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.

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. To our knowledge, L'Oréal, our largest shareholder, 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.

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 on file with the SEC as Annex B to Amendment No. 2 to the Registration Statement on Form F-4 filed with the Securities and Exchange Commission on March 24, 2011. Pursuant to the CVR agreement, each holder of a CVR is entitled to receive cash payments upon the achievement of certain milestones, if any, based on the achievement of certain aggregate net sales thresholds by Lemtrada® (alemtuzumab for treatment of multiple sclerosis). See "Item 10. Additional Information — C. Material Contracts — The Contingent Value Rights Agreement."

CVR holders are subject to additional risks, including:

- the public market for the CVRs may not be active 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;
- no payment will be made on the CVRs without the achievement of certain agreed upon milestones. As such, it may be difficult to value the CVRs and accordingly it may be difficult or impossible to resell the CVRs;
- 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 rank at parity with our other unsecured unsubordinated indebtedness;
- we are not prohibited from acquiring the CVRs, whether in open market transactions, private transactions or otherwise and we have already purchased CVRs on several occasions (for more information see "Item 5. Operating and Financial Review and Prospects — Liquidity and Capital Resources — Liquidity.");
- we may, under certain circumstances, purchase and cancel all outstanding CVRs; and
- while we have agreed to use diligent efforts (as defined in the CVR agreement), until the CVR agreement is terminated, to achieve each of the remaining Lemtrada® related CVR milestones set forth in the CVR agreement, we are not required to take all possible actions to achieve these goals. The two first milestones were not met and there can be no assurance that the product sales milestone #1 or the other product sales milestones will be achieved. The failure to achieve the sales milestones would have an adverse effect on the value, if any, of the CVRs.