Sanofi
Form 20-F
March 04, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

¨ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

or

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2015

Or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Or

¨ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

For the transition period from to

Commission File Number: 001-31368

Sanofi

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant s name into English)

France

(Jurisdiction of incorporation or organization)

54, Rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Karen Linehan, Executive Vice President Legal Affairs and General Counsel

54, Rue La Boétie, 75008 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class:	**Name of each exchange on which registered:**
American Depositary Shares, each representing one half of one ordinary share, par value 2 per share	New York Stock Exchange
Ordinary shares, par value 2 per share	New York Stock Exchange (for listing purposes only)
Contingent Value Rights	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

The number of outstanding shares of each of the issuer s classes of capital or common stock as of December 31, 2015 was:

Ordinary shares: 1,305,696,759

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES x NO ¨.

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. YES ¨ NO x.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer inRule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

	International Financial Reporting Standards as issued by	
U.S. GAAP ¨	the International Accounting Standards Board x	Other ¨

If Other has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ¨ Item 18 ¨

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x.

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Presentation of financial and other information

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS as adopted by the European Union, as of December 31, 2015.

Unless the context requires otherwise, the terms Sanofi, the Company, the Group, we, our or us refer to Sanofi and its consolidated subsid

All references herein to United States or U.S. are to the United States of America, references to dollars or $ are to the currency of the United States, references to France are to the Republic of France, and references to euro and are to the currency of the European Union member states (including France) participating in the European Monetary Union.

Brand names appearing in this annual report are trademarks of Sanofi and/or its affiliates, with the exception of:

- trademarks used or that may be or have been used under license by Sanofi and/or its affiliates, such as Actonel® a trademark of Actavis; Afrezza® a trademark of Mannkind Corporation; Aldurazyme® a trademark of the Joint Venture Biomarin/Genzyme LLC; Avilomics® a trademark of Avila Therapeutics Inc.; Cialis® OTC a trademark of Eli Lilly; Copaxone® a trademark of Teva Pharmaceuticals Industries; Cortizone-10® a trademark of Johnson & Johnson (except in the United States where it is a trademark of the Group); Fludara® and Leukine® trademarks of Alcafleu; Flutiform® a trademark of Jagotec AG; Gardasil® and Zostavax® trademarks of Merck & Co.; Hexyon® and Repevax® trademarks of Sanofi Pasteur MSD; RetinoStat® and UshStat®, trademarks of Oxford Biomedica; Spedra and Stendra® trademarks of Vivus Inc.; Squarekids® a trademark of Kitasato Daiichi Sankyo Vaccine Co., Ltd.; Zaltrap® a trademark of Regeneron in the United States;

- trademarks sold by Sanofi and/or its affiliates to a third party, such as Altace® a trademark of King Pharmaceuticals in the United States; Hyalgan® a trademark of Fidia Farmaceutici S.p.A.; Liberty®, Liberty® Herbicide, LibertyLink® Rice 601, LibertyLink® Rice 604 and StarLink® trademarks of Bayer; Maalox® a trademark of Novartis in the United States, Canada and Puerto Rico; and Sculptra® a trademark of Valeant; and,

- other third party trademarks such as Advantage® and Advantix® trademarks of Bayer; Atelvia® trademark of Actavis in the United States; DDAVP® a trademark of Ferring (except in the United States where it is a trademark of the Group); Enbrel® a trademark of Immunex in the United-States and of Wyeth on other geographical areas; GLAAS a trademark of Immune Design; Humalog®, Humulin , Mirioped, Basaglar® and Kwikpen® trademarks of Eli Lilly; iPhone® and iPod Touch® trademarks of Apple Inc.; Lactacyd® a trademark of Omega Pharma NV in the EU and several other European countries; Rituxan® a trademark of Biogen Idec Inc. in the United States and Canada, and Genentech in Japan; Unisom® a trademark of Johnson & Johnson on certain geographical areas (except in the United States and Israël where it is a trademark of the Group and Canada where it is a trademark of Paladin Labs Inc.); and Yosprala a trademark of Pozen Inc.

Not all trademarks related to investigational agents have been authorized as of the date of this annual report by the relevant health authorities; for instance Lyxumia® trade name has not been approved by the FDA.

The data relating to market shares and ranking information for pharmaceutical products, in particular as presented in Item 4. Information on the Company B. Business Overview B.6. Markets B.6.1. Marketing and distribution, are based on sales data from IMS Health MIDAS (IMS), retail and hospital, in Moving Annual Total September 2015, in constant euros (unless otherwise indicated).

While we believe that the IMS sales data we present below are generally useful comparative indicators for our industry, they may not precisely match the sales figures published by the companies that sell the products (including our company and other pharmaceutical companies). In particular, the rules used by IMS to attribute the sales of a product covered by an alliance or license agreement do not always exactly match the rules of the agreement.

In order to allow a reconciliation with our basis of consolidation as defined in Item 5. Operating and Financial Review and Prospects Presentation of Net Sales, IMS data shown in the present document have been adjusted and include:

(i) sales as published by IMS excluding Sanofi sales generated by the vaccines business, equating to the scope of our pharmaceutical operations;

(ii) IMS sales of products sold under alliance or license agreements which we recognize in our consolidated net sales but which are not attributed to us in the reports published by IMS; and

(iii) adjustments related to the exclusion of IMS sales for products which we do not recognize in our consolidated net sales but which are attributed to us by IMS.

Data relative to market shares and ranking information presented herein for our Consumer Health Care products, are based on sales data from Nicholas Hall.

Data relative to market shares and ranking information presented herein for our vaccines business are based on internal estimates unless stated otherwise.

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Data relative to market shares and ranking information presented herein for our animal health business are based on sales data from Vetnosis unless stated otherwise.

Product indications described in this annual report are composite summaries of the major indications approved in the product s principal markets. Not all indications are necessarily available in each of the markets in which the products are approved. The summaries presented herein for the purpose of financial reporting do not substitute for careful consideration of the full labeling approved in each market.

Cautionary statement regarding forward-looking statements

This annual report contains forward-looking statements. We may also make written or oral forward-looking statements in our periodic reports to the Securities and Exchange Commission on Form 6-K, in our annual report to shareholders, in our offering circulars and prospectuses, in press releases and other written materials and in oral statements made by our officers, directors or employees to third parties. Examples of such forward-looking statements include:

- projections of operating revenues, net income, business net income, earnings per share, business earnings per share, capital expenditures, cost savings, restructuring costs, positive or negative synergies, dividends, capital structure or other financial items or ratios;
- statements of our profit forecasts, trends, plans, objectives or goals, including those relating to products, clinical trials, regulatory approvals and competition; and
- statements about our future events and economic performance or that of France, the United States or any other countries in which we operate.

This information is based on data, assumptions and estimates considered as reasonable by the Company as at the date of this annual report and undue reliance should not be placed on such statements.

Words such as believe, anticipate, plan, expect, intend, target, estimate, project, predict, forecast, guideline, should and intended to identify forward-looking statements but are not the exclusive means of identifying such statements.

Forward-looking statements involve inherent, known and unknown, risks and uncertainties associated with the regulatory, economic, financial and competitive environment, and other factors that could cause future results and objectives to differ materially from those expressed or implied in the forward-looking statements.

Risk factors which could affect the future results and cause actual results to differ materially from those contained in any forward-looking statements are discussed under Item 3. Key Information D. Risk Factors . Additional risks, not currently known or considered immaterial by the Group, may have the same unfavorable effect and investors may lose all or part of their investment.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments.

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ABBREVIATIONS

Abbreviations used in the Form 20-F

ADR/ADS	American Depositary Receipt/American Depositary Share
AFEP	*Association francaise des entreprises privees* (French association of large companies)
AMF	*Autorité des marches financiers* (the French market regulator)
ANDA	Abbreviated New Drug Application
ECB	European Central Bank
BLA	Biologic License Application
BMS	Bristol-Myers Squibb
CGU	Cash generating unit
CHC	Consumer Health Care
CHMP	Committee for Medicinal Products for Human Use
CNS	Central Nervous System
COSO	Committee of Sponsoring Organizations of the Treadway Commission
COVALIS	Health risk prevention committee
CSR	Corporate Social Responsibility
CVMP	Committee for Medicinal Products for Veterinary Use
CVR	Contingent Value Right
ECHA	European Chemicals Agency
ECOVAL	Internal committee for assessing the environmental risks of our pharmaceutical products
EMA	European Medicines Agency
EMTN	Euro Medium Term Note
EPA	U.S. Environmental Protection Agency
EPS	Earnings per share
EU	European Union
FCPA	U.S. Foreign Corrupt Practices Act
FCPE	*Fonds commun de placement d entreprise* (Corporate investment funds)
FDA	U.S. Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunisation
GLP-1	Glucagon-like peptide-1
GMP	Good Manufacturing Practice
GRI	Global Reporting Initiative
HSE	Health, Safety and Environment
IASB	International Accounting Standards Board
IFRS	International Financial Reporting Standards
ILO	International Labor Organisation
LEED	Leadership in Energy and Environmental Design
LSD	Lysosomal storage disorder
MEDEF	*Mouvement des entreprises de France* (French business confederation)
NASDAQ	National Association of Securities Dealers Automated Quotations
NDA	New Drug Application
OECD	Organisation for Economic Co-operation and Development
OTC	Over The Counter
PaHO	Pan American Health Organisation
PRAC	Pharmacovigilance Risk Assessment Committee
R&D	Research & Development
REACH	Registration, Evaluation, Authorization and restriction of Chemicals
ROA	Return on assets
SEC	U.S. Securities and Exchange Commission
TRIBIO	Internal biological risk committee
TSR	Total Shareholder Return
TSU	Therapeutic Strategic Unit
UNICEF	United Nations Children s Fund
USDA	United States Department of Agriculture
WHO	World Health Organization

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Item 1. Identity of Directors, Senior Management and Advisers

PART I

Item 1. Identity of Directors, Senior Management and Advisers

N/A

Item 2. Offer Statistics and Expected Timetable

N/A

Item 3. Key Information

A. Selected Financial Data

SUMMARY OF SELECTED FINANCIAL DATA

The tables below set forth selected consolidated financial data for Sanofi. These financial data are derived from the Sanofi consolidated financial statements. The Sanofi consolidated financial statements for the years ended December 31, 2015, 2014 and 2013 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2015, 2014 and 2013 have been

prepared in compliance with IFRS issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2015. The term IFRS refers collectively to international accounting and financial reporting standards (IAS and IFRS) and to interpretations of the interpretations committees (SIC and IFRIC) mandatorily applicable as of December 31, 2015.

Sanofi reports its financial results in euros.

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Item 2. Offer Statistics and Expected Timetable

SELECTED CONDENSED FINANCIAL INFORMATION

(million, except per share data)	As of and for the year ended December 31, 2015	2014	2013	2012	2011
IFRS Income statement data[a]					
Net sales	34,542	31,694	30,966	34,947[a]	33,389[a]
Gross profit	23,942	21,769	20,989	24,859[a]	24,193[a]
Operating income	5,624	6,064	4,982	6,430[a]	5,861[a]
Net income excluding the held-for-exchange Animal Health business	4,512	4,392	3,797	-[a]	-[a]
Net income attributable to equity holders of Sanofi	4,287	4,390	3,716	4,888	5,646
Basic earnings per share ( ):					
Net income excluding the held-for-exchange Animal Health business	3.38	3.25	2.75	-[a]	-[a]
Net income attributable to equity holders of Sanofi	3.28	3.34	2.81	3.70	4.27
Diluted earnings per share ( ):					
Net income attributable to equity holders of Sanofi	3.25	3.30	2.77	3.68	4.26
IFRS Balance sheet data					
Goodwill and other intangible assets	51,583[d]	53,740	52,529	58,265	62,221
Total assets	102,321	97,392	96,055	100,399	100,672
Outstanding share capital	2,603	2,620	2,641	2,646	2,647
Equity attributable to equity holders of Sanofi	58,049	56,120	56,904	57,352	56,193
Long term debt	13,118[d]	13,276	10,414	10,719	12,499
Cash dividend paid per share ( )	2.93[f]	2.85	2.80	2.77	2.65
Cash dividend paid per share ($)[e]/[g]	3.19[f]	3.46	3.86	3.65	3.43

(a) Including the Animal Health business, the net income/loss of which is presented in a separate line item, ***Net income/(loss) of the held-for-exchange Animal Health business****, in the consolidated income statements for 2015, 2014 and 2013 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report). For 2012 and 2011, it is not practicable to provide information excluding the Animal Health business without unreasonable effort or expense.*

(b) Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,306.2 million shares in 2015, 1,315.8 million shares in 2014, 1,323.1 million shares in 2013, 1,319.5 million shares in 2012 and 1,321.7 million shares in 2011.

(c) Based on the weighted average in each period of the number of shares outstanding plus stock options and restricted shares with a potentially dilutive effect; i.e., 1,320.8 million shares in 2015, 1,331.1 million shares in 2014, 1,339.1 million shares in 2013, 1,329.6 million shares in 2012 and 1,326.7 million shares in 2011.

(d) Excluding the Animal Health business which is presented in separate line items, ***Assets held for sale or exchange*** *and* ***Liabilities related to assets held for sale or exchange.***

(e) Each American Depositary Share, or ADS, represents one half of one share.

(f) Dividends for 2015 will be proposed for approval at the annual general meeting scheduled for May 4, 2016.

(g) Based on the relevant year-end exchange rate.

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SELECTED EXCHANGE RATE INFORMATION

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2011 through March 2016 expressed in U.S. dollars per euro. The information concerning the U.S. dollar exchange rate is based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York (the Noon Buying Rate). We provide the

exchange rates below solely for your convenience. We do not represent that euros were, could have been, or could be, converted into U.S. dollars at these rates or at any other rate. For information regarding the effect of currency fluctuations on our results of operations, see Item 5. Operating and Financial Review and Prospects and Item 11. Quantitative and Qualitative Disclosures about Market Risk.

(U.S. dollar per euro)	**Period-end Rate**	**Average Rate[1]**	**High**	**Low**
2011	1.30	1.40	1.49	1.29
2012	1.32	1.29	1.35	1.21
2013	1.38	1.33	1.38	1.28
2014	1.21	1.32	1.39	1.21
2015	1.09	1.10	1.20	1.05
Last 6 months				
2015				
September	1.12	1.12	1.14	1.11
October	1.10	1.12	1.14	1.10
November	1.06	1.07	1.10	1.06
December	1.09	1.09	1.10	1.06
2016				
January	1.08	1.09	1.10	1.07
February	1.09	1.11	1.14	1.09
March[2]	1.09	1.09	1.09	1.09

(1) *The average of the Noon Buying Rates on the last business day of each month during the relevant period for the full year average, and on each business day of the month for the monthly average. The latest available Noon Buying Rate being February 26, 2016, we have used European Central Bank Rates for the period from February 29, 2016 through March 3, 2016.*

(2) *In each case, measured through March 3, 2016.*

On March 3, 2016 the European Central Bank Rate was 1.0901 per euro.

B. Capitalization and Indebtedness

N/A

C. Reasons for Offer and Use of Proceeds

N/A

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Item 3. Key Information

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. Investors should carefully consider all the information set forth in the following risk factors before deciding to invest in any of the Company s securities. 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 other 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 when we assert or defend our patents.

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 validity or coverage before the patent 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 and/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. Third parties may also request a preliminary injunction in a country from a court of law to prevent us from marketing a product if they consider that we infringe their patent rights in the country. If they obtain a

preliminary or permanent injunction from a court of law or if we fail to obtain a required license for a country where the valid third-party intellectual property right as confirmed by a court of law, 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 a third party 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 of our small molecule and biological pharmaceutical products (see Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings for additional information). 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.

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. Governments may adopt more permissive approval frameworks (for example, shortening the duration of data exclusivity, or narrowing the scope of new products receiving data exclusivity) which could allow competitors to obtain broader marketing approval for biosimilars including as a substitutable product, increasing competition for our products (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

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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.

If our patents and/or proprietary rights to our products were limited or circumvented, our financial results could be materially and adversely affected.

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

Product liability is a significant risk for any pharmaceutical company, and our product liability exposure could increase given that liability claims relating to our 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 a recall or a withdrawal, pharmaceutical companies can face significant product liability claims.

Furthermore, we commercialize several devices (some of which use new technologies) which, if they malfunction, could cause unexpected damage and lead to product liability claims (see Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, business or reputational harm.).

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. 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 cases where we self-insure, the legal costs that we would bear for handling such claims and potential indemnifications to be paid to claimants could have a negative impact on our financial condition.

Due to insurance conditions, even when the Group has insurance coverage, recoveries from insurers may not be totally successful. Moreover, insolvency of an insurer could affect our ability to recover claims on policies 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 materially 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 required approvals.

Obtaining marketing authorization is a long and highly regulated process requiring us to present extensive documentation and data 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 which can evolve over time, 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 including post-marketing studies to which we have committed as a condition of approval. In addition, 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. This system may result in additional market authorization suspensions or withdrawals. All of these requirements have increased the costs associated with maintaining regulatory approvals and achieving reimbursement for our products. Post-regulatory approval