Sanofi
Form 20-F
March 03, 2017
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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
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016
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, 2016 was:

Ordinary shares: 1,292,022,324

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES 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 .

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 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 in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer 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:

U.S. GAAP | International Financial Reporting Standards as issued by the International Accounting Standards Board | 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 .

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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, 2016.

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 US 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 Sanofi trademark); 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.; and 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®, a trademark of Actavis in the United States; DDAVP®, a trademark of Ferring (except in the United States where it is a Sanofi trademark); Enbrel®, a trademark of Immunex in the United States and of Wyeth in other geographical areas; GLAAS®, a trademark of Immune Design; Humalog®, Humulin , Mirioper, 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; Squarekids®, a trademark of Kitasato Daiichi Sankyo Vaccine Co., Ltd.; Unisom® a trademark of Johnson & Johnson in certain geographical areas (except in the United States and Israel where it is a Sanofi trademark 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, the 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 mainly on sales data from QuintilesIMS (MIDAS) on Moving Annual Total September 2016, in constant euros (unless otherwise indicated), supplemented by country-specific sources.

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 relating to market shares and ranking information presented herein for our Consumer Healthcare products are based on sales data from Nicholas Hall.

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

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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 Sanofi 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 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

Principal abbreviations used in the Annual Report on Form 20-F

ADR	American Depositary Receipt
ADS	American Depositary Share
AFEP	*Association française des entreprises privées* (French Association of Large Companies)
AMF	*Autorité des marchés financiers* (the French market regulator)
ANDA	Abbreviated New Drug Application
BLA	Biologic License Application
BMS	Bristol-Myers Squibb
CEO	Chief Executive Officer
CER	Constant exchange rates
CGU	Cash generating unit
CHC	Consumer Healthcare
CHMP	Committee for Medicinal Products for Human Use
CVR	Contingent value right
ECB	European Central Bank
EMA	European Medicines Agency
EU	European Union
FDA	US Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunisation
GBU	Global Business Unit
GLP-1	Glucagon-like peptide-1
GMP	Good manufacturing practice
Hib	Haemophilus influenzae type b
HSE	Health, Safety and Environment
IASB	International Accounting Standards Board
ICH	International Council for Harmonization
IFRS	International Financial Reporting Standards
IPV	Inactivated polio vaccine
ISIN	International Securities Identification Number
J-MHLW	Japanese Ministry of Health, Labor and Welfare
LSD	Lysosomal storage disorder
MEDEF	*Mouvement des entreprises de France* (French business confederation)
MS	Multiple sclerosis
NASDAQ	National Association of Securities Dealers Automated Quotations
NDA	New Drug Application
NHI	National Health Insurance (Japan)
NYSE	New York Stock Exchange
OECD	Organisation for Economic Co-operation and Development
OPV	Oral polio vaccine
OTC	Over the counter
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PRV	Priority Review Voucher
PTE	Patent Term Extension
QIV	Quadrivalent influenza vaccine
R&D	Research and development
ROA	Return on assets
SA	*Société anonyme* (French public limited corporation)
SEC	US Securities and Exchange Commission
SPC	Supplementary Protection Certificate
TSR	Total shareholder return
UNICEF	United Nations Children s Fund
US	United States of America
WHO	World Health Organization

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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, 2016, 2015 and 2014 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2016, 2015 and 2014 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, 2016. 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, 2016.

Sanofi reports its financial results in euros.

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ITEM 3. KEY INFORMATION

SELECTED CONDENSED FINANCIAL INFORMATION

(million, except per share data)	As of and for the year ended December 31, 2016	2015	2014	2013	2012[a]
IFRS Income statement data					
Net sales[b]	33,821	34,060	31,380	30,693	34,743
Gross profit	24,006	23,942	21,769	20,989	24,859
Operating income	6,534	5,624	6,064	4,982	6,430
Net income excluding the held-for-exchange Animal Health business	4,486	4,512	4,392	3,797	-
Net income attributable to equity holders of Sanofi	4,709	4,287	4,390	3,716	4,888
Basic earnings per share ([c]):					
Net income excluding the held-for-exchange Animal Health business	3.42	3.38	3.25	2.75	-[a]
Net income attributable to equity holders of Sanofi	3.66	3.28	3.34	2.81	3.70
Diluted earnings per share ([d]):					
Net income attributable to equity holders of Sanofi	3.63	3.25	3.30	2.77	3.68
IFRS Balance sheet data					
Goodwill and other intangible assets	51,166[e]	51,583[e]	53,740	52,529	58,265
Total assets	104,672	102,321	97,392	96,055	100,399
Outstanding share capital	2,544	2,603	2,620	2,641	2,646
Equity attributable to equity holders of Sanofi	57,554	58,049	56,120	56,904	57,352
Long term debt	16,815[e]	13,118[e]	13,276	10,414	10,719
Cash dividend paid per share ([f])	2.96[g]	2.93	2.85	2.80	2.77
Cash dividend paid per share ($)[f][h]	3.12[g]	3.19	3.46	3.86	3.65

*(a) For 2012, the lines **Net sales**, **Gross profit**, and **Operating Income** include the Animal Health business. For the other periods (2013 to 2016), the net results of the Animal Health business are presented in a separate line item, **Net income/(loss) of the held-for-exchange Animal Health business**, in the consolidated income statements.*

*(b) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards (see Notes A.5. and B.14.). The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.5.).*

(c) Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,286.6 million shares in 2016, 1,306.2 million shares in 2015, 1,315.8 million shares in 2014, 1,323.1 million shares in 2013 and 1,319.5 million shares in 2012.

(d) 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., 1,296.0 million shares in 2016, 1,320.7 million shares in 2015, 1,331.1 million shares in 2014, 1,339.1 million shares in 2013 and 1,329.6 million shares in 2012.

*(e) As reported, excluding the Animal Health business clarified in the line item, **Assets held for sale or exchange and liabilities related to assets held for sale or exchange** as of December 31, 2015 and December 31, 2016.*

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

(g) Dividends for 2016 will be proposed for approval at the annual general meeting scheduled for May 10, 2017.

(h) 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 2017 expressed in US dollars per euro. The information concerning the US 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 US 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[(a)]**	**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
2016	1.06	1.10	1.15	1.04
Last 6 months				
2016				
September	1.12	1.12	1.13	1.12
October	1.10	1.10	1.12	1.09
November	1.06	1.08	1.11	1.09
December	1.06	1.05	1.08	1.04
2017				
January	1.08	1.06	1.08	1.04
February	1.06	1.07	1.08	1.06
March[(b)]	1.05	1.05	1.05	1.05

(a) 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 24, 2017, we have used European Central Bank Rates for the period from February 27, 2017 through March 2, 2017.

(b) In each case, measured through March 2, 2017.

On March 2, 2017 the European Central Bank Rate was 1.05 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 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 conclude 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 addition, if we lose patent protection in patent litigation as a result of an adverse court decision or a settlement, we face the risk that government and private third-party payers and purchasers of pharmaceutical products may claim damages alleging they have over-reimbursed or payed a drug. For example, in Australia, our patent on clopidogrel was ultimately held invalid. Following this decision, the Australian Government is seeking damages for its alleged over-reimbursement of clopidogrel drugs due to the preliminary injunction we had obtained against the sale of generic clopidogrel during the course of the litigation.

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. We have increased the proportion of biological therapeutics in our pipeline relative to traditional small molecule pharmaceutical products. Typically, biological therapeutics face third party intellectual property rights, otherwise known as freedom to operate (FTO) issues, more than small molecule therapeutics because of the types of patents allowed by national patent offices. Further, our ability to successfully challenge third party patent rights is dependent on the laws of national courts. Certain countries have laws that provide stronger bases for challenging third party patent rights compared to the laws that are available to challenge patents in other countries. Therefore, we may be able to invalidate a certain third party patent in one country but not invalidate counterpart patents in other countries. Third parties may also request a preliminary or a permanent 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 that country. For example, Sanofi is currently party to patent infringement proceedings in several countries initiated against us and Regeneron by Amgen relating to Praluent® in which Amgen has requested injunctive relief (see Note D.22.b) to the consolidated financial statements

included at Item 18 of this annual report and Item 8 B. of this annual report for more information). If third parties 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 if we 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 value of the patent 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

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further at risk sales and order removal of 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 US 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 above. 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 our business, results of operations and financial condition below). If a biosimilar version of one of our products were approved, it could reduce our sales and/or profitability of that product.

However, with our presence as a manufacturer of generics and 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.

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