Sanofi
Form 20-F
March 11, 2015

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(Mark One)

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

or

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

For the fiscal year ended December 31, 2014
or

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

or

o **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, 2014 was:

Ordinary shares: 1,319,367,445

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

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 o NO ý.

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 ý No o

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 o No o

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 ý	Accelerated filer o	Non-accelerated filer o

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

U.S. GAAP o	International Financial Reporting Standards as issued by the International Accounting Standards Board ý	Other o

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 o Item 18 o

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 o No ý.

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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, 2014.

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

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® a trademark of Oxford Biomedica; Spedra and Stendra trademarks of Vivus Inc.; Squarekids® a trademark of Kitasato Daiichi Sankyo Vaccine Co., Ltd.; Stargen a trademark of Oxford Biomedica; 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 Farmeceutici 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 and Miriopen® 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.); UshStat® a trademark of Oxford BioMedica; 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, for calendar year 2014, 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.

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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 vaccines business are based on internal estimates unless stated otherwise.

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 similar expressions are 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 used in the Form 20-F

ADR/ADS	American Depositary Receipt/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
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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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, 2014, 2013 and 2012 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2014, 2013 and 2012 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, 2014. 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, 2014.

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Sanofi reports its financial results in euros.

SELECTED CONDENSED FINANCIAL INFORMATION

	As of and for the year ended December 31,				
(€ million, except per share data)	**2014**	**2013(a)**	**2012(a)**	**2011**	**2010**
IFRS Income statement data [(b)]:					
Net sales	33,770	32,951	34,947	33,389	32,367
Gross profit	23,080	22,315	24,859	24,193	24,638
Operating income	6,143	5,105	6,430	5,861	6,535
Net income attributable to equity holders of Sanofi	4,390	3,716	4,888	5,646	5,467
Basic earnings per share (€)[b)/(c)]:					
Net income attributable to equity holders of Sanofi	3.34	2.81	3.70	4.27	4.19
Diluted earnings per share (€)[b)/(d)]:					
Net income attributable to equity holders of Sanofi	3.30	2.77	3.68	4.26	4.18
IFRS Balance sheet data:					
Goodwill and other intangible assets	53,740	52,529	58,265	62,221	44,411
Total assets	97,392	96,055	100,399	100,672	85,264
Outstanding share capital	2,620	2,641	2,646	2,647	