20-F 1 d246196d20f.htm 20-F

Table of Contents

# 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, 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 ☒ 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 ☒.

Table of Contents

**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 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® 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™, Miriopen®, 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.

Table of Contents

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.

Table of Contents

# 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 marcheś 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 |

Table of Contents

# Table of contents

## Part I



## Part II



## Part III

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.