

Sanofi  
Form 20-F  
March 07, 2018  
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, 2017**

**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**

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(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:**

<b>Title of each class:</b>	<b>Name of each exchange on which registered:</b>
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, 2017 was:**

Ordinary shares: 1,254,019,904

**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



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**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, 2017.

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 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<sup>®</sup>, a trademark of Actavis; Afrezza<sup>®</sup>, a trademark of Mannkind Corporation; Aldurazyme<sup>®</sup>, a trademark of the Joint Venture Biomarin/Genzyme LLC; Avilomics<sup>®</sup>, a trademark of Avila Therapeutics, Inc.; Cialis<sup>®</sup> OTC, a trademark of Eli Lilly; Copaxone<sup>®</sup>, a trademark of Teva Pharmaceuticals Industries; Cortizone-10<sup>®</sup>, a trademark of Johnson & Johnson (except in the United States where it is a Sanofi trademark); Fludara<sup>®</sup> and Leukine<sup>®</sup>, trademarks of Alcafleu; Flutiform<sup>®</sup>, a trademark of Jagotec AG; RetinoStat<sup>®</sup> and UshStat<sup>®</sup>, trademarks of Oxford Biomedica; Spedra<sup>®</sup> and Stendra<sup>®</sup>, trademarks of Vivus Inc.; and Zaltrap<sup>®</sup> a trademark of Regeneron in the United States;

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

other third party trademarks such as Advantage<sup>®</sup> and Advantix<sup>®</sup>, trademarks of Bayer; Atelvia<sup>®</sup>, a trademark of Actavis in the United States; DDAVP<sup>®</sup>, a trademark of Ferring (except in the United States where it is a Sanofi trademark); Enbrel<sup>®</sup>, a trademark of Immunex in the United States and of Wyeth in other geographical areas; GLAAS<sup>®</sup>, a trademark of Immune Design; Humalog<sup>®</sup>, Humulin<sup>®</sup>, Miriope<sup>®</sup>, Basaglar<sup>®</sup> and Kwikpen<sup>®</sup>, trademarks of Eli Lilly; iPhone<sup>®</sup> and iPod Touch<sup>®</sup>, trademarks of Apple Inc.; Lactacyd<sup>®</sup>, a trademark of Omega Pharma NV in the EU and several other European countries; Rituxan<sup>®</sup>, a trademark of Biogen Idec, Inc. in the United States and Canada, and Genentech in Japan; Squarekids<sup>®</sup>, a trademark of Kitasato Daiichi Sankyo Vaccine Co., Ltd.; Unisom<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup> 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 excluding vaccines and in constant euros (unless otherwise indicated) on a November 2017 MAT (Moving Annual Total) basis. The data are mainly from IQVIA local sales audit, supplemented by country-specific sources.

Data relating to market shares and ranking information presented herein for our Consumer Healthcare products are based on sales data from Nicholas Hall (Q3 2017 MAT).

Data relating to market shares and ranking information presented herein for our vaccines business are based on internal estimates 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 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,

**Table of Contents**

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 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

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

<b>ADR</b>	American Depositary Receipt
<b>ADS</b>	American Depositary Share
<b>AFEP</b>	<i>Association française des entreprises privées</i> (French Association of Large Companies)
<b>AMF</b>	<i>Autorité des marchés financiers</i> (the French market regulator)
<b>ANDA</b>	Abbreviated New Drug Application
<b>BLA</b>	Biologic License Application
<b>BMS</b>	Bristol-Myers Squibb
<b>CEO</b>	Chief Executive Officer
<b>CER</b>	Constant exchange rates
<b>CGU</b>	Cash generating unit
<b>CHC</b>	Consumer Healthcare
<b>CHMP</b>	Committee for Medicinal Products for Human Use
<b>CVR</b>	Contingent value right
<b>ECB</b>	European Central Bank
<b>EFPIA</b>	European Federation of Pharmaceutical Industries and Associations
<b>EMA</b>	European Medicines Agency
<b>EU</b>	European Union
<b>FDA</b>	US Food and Drug Administration
<b>GAVI</b>	Global Alliance for Vaccines and Immunisation
<b>GBU</b>	Global Business Unit
<b>GLP-1</b>	Glucagon-like peptide-1
<b>GMP</b>	Good manufacturing practice
<b>Hib</b>	Haemophilus influenzae type b
<b>HSE</b>	Health, Safety and Environment
<b>IASB</b>	International Accounting Standards Board
<b>ICH</b>	International Council for Harmonization
<b>IFPMA</b>	International Federation of Pharmaceutical Manufacturers & Associations
<b>IFRS</b>	International Financial Reporting Standards
<b>IPV</b>	Inactivated polio vaccine
<b>ISIN</b>	International Securities Identification Number
<b>J-MHLW</b>	Japanese Ministry of Health, Labor and Welfare
<b>LSD</b>	Lysosomal storage disorder
<b>MEDEF</b>	<i>Mouvement des entreprises de France</i> (French business confederation)
<b>MS</b>	Multiple sclerosis
<b>NASDAQ</b>	National Association of Securities Dealers Automated Quotations
<b>NDA</b>	New Drug Application
<b>NHI</b>	National Health Insurance (Japan)
<b>NYSE</b>	New York Stock Exchange
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>OPV</b>	Oral polio vaccine

<b>OTC</b>	Over the counter
<b>PhRMA</b>	Pharmaceutical Research and Manufacturers of America
<b>PMDA</b>	Pharmaceuticals and Medical Devices Agency (Japan)
<b>PRV</b>	Priority Review Voucher
<b>PTE</b>	Patent Term Extension
<b>QIV</b>	Quadrivalent influenza vaccine
<b>R&amp;D</b>	Research and development
<b>ROA</b>	Return on assets
<b>SA</b>	<i>Société anonyme</i> (French public limited corporation)
<b>SEC</b>	US Securities and Exchange Commission
<b>SPC</b>	Supplementary Protection Certificate
<b>TSR</b>	Total shareholder return
<b>UNICEF</b>	United Nations Children's Emergency Fund
<b>US</b>	United States of America
<b>WHO</b>	World Health Organization



**Table of Contents****TABLE OF CONTENTS****PART I**

<b>Item 1.</b>	<u>IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS</u>	1
<b>Item 2.</b>	<u>OFFER STATISTICS AND EXPECTED TIMETABLE</u>	1
<b>Item 3.</b>	<u>KEY INFORMATION</u>	1
	<u>A. Selected Financial Data</u>	1
	<u>B. Capitalization and Indebtedness</u>	3
	<u>C. Reasons for Offer and Use of Proceeds</u>	3
	<u>D. Risk Factors</u>	4
<b>Item 4.</b>	<u>INFORMATION ON THE COMPANY</u>	19
	<u>A. History and Development of the Company</u>	20
	<u>B. Business Overview</u>	20
	<u>C. Organizational Structure</u>	68
	<u>D. Property, Plant and Equipment</u>	69
<b>Item 4A.</b>	<u>UNRESOLVED STAFF COMMENTS</u>	73
<b>Item 5.</b>	<u>OPERATING AND FINANCIAL REVIEW AND PROSPECTS</u>	74
	<u>A. Operating results</u>	74
	<u>B. Liquidity and Capital Resources</u>	128
	<u>C. Off-Balance Sheet Arrangements / Contractual Obligations and Other Commercial Commitments</u>	132
<b>Item 6.</b>	<u>DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES</u>	134
	<u>A. Directors and Senior Management</u>	134
	<u>B. Compensation</u>	160
	<u>C. Board Practices</u>	180
	<u>D. Employees</u>	186
	<u>E. Share Ownership</u>	188
<b>Item 7.</b>	<u>MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS</u>	193
	<u>A. Major Shareholders</u>	193
	<u>B. Related Party Transactions</u>	194
	<u>C. Interests of Experts and Counsel</u>	194
<b>Item 8.</b>	<u>FINANCIAL INFORMATION</u>	195
	<u>A. Consolidated Financial Statements and Other Financial Information</u>	195
	<u>B. Significant Changes</u>	198
<b>Item 9.</b>	<u>THE OFFER AND LISTING</u>	200
	<u>A. Offer and Listing Details</u>	200
	<u>B. Plan of Distribution</u>	201
	<u>C. Markets</u>	201
	<u>D. Selling Shareholders</u>	201
	<u>E. Dilution</u>	201

	<u>F. Expenses of the Issue</u>	201
<b>Item 10.</b>	<u>ADDITIONAL INFORMATION</u>	202
	<u>A. Share Capital</u>	202
	<u>B. Memorandum and Articles of Association</u>	202
	<u>C. Material Contracts</u>	214
	<u>D. Exchange Controls</u>	215
	<u>E. Taxation</u>	215
	<u>F. Dividends and Paying Agents</u>	219
	<u>G. Statement by Experts</u>	219
	<u>H. Documents on Display</u>	219
	<u>I. Subsidiary Information</u>	219
<b>Item 11.</b>	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	220
<b>Item 12.</b>	<u>DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES</u>	224

## PART II

<b>Item 13.</b>	<u>DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES</u>	231
<b>Item 14.</b>	<u>MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS</u>	231
<b>Item 15.</b>	<u>CONTROLS AND PROCEDURES</u>	231
<b>Item 16A.</b>	<u>AUDIT COMMITTEE FINANCIAL EXPERT</u>	232
<b>Item 16B.</b>	<u>CODE OF ETHICS</u>	232
<b>Item 16C.</b>	<u>PRINCIPAL ACCOUNTANTS FEES AND SERVICES</u>	232
<b>Item 16D.</b>	<u>EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES</u>	232
<b>Item 16E.</b>	<u>PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS</u>	233
<b>Item 16F.</b>	<u>CHANGE IN REGISTRANT S CERTIFYING ACCOUNTANT</u>	233
<b>Item 16G.</b>	<u>CORPORATE GOVERNANCE</u>	233
<b>Item 16H.</b>	<u>MINE SAFETY DISCLOSURE</u>	234

## PART III

<b>Item 17.</b>	<u>FINANCIAL STATEMENTS</u>	235
<b>Item 18.</b>	<u>FINANCIAL STATEMENTS</u>	235
<b>Item 19.</b>	<u>EXHIBITS</u>	235

**Table of Contents**

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, 2017, 2016 and 2015 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2017, 2016 and 2015 have been prepared in compliance with IFRS issued by the International Accounting

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Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2017. 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, 2017.

Sanofi reports its financial results in euros.

**Table of Contents**

## ITEM 3. KEY INFORMATION

## SELECTED CONDENSED FINANCIAL INFORMATION

<i>( million, except per share data)</i>	As of and for the year ended December 31,				
	2017	2016	2015	2014	2013
<b>IFRS Income statement data<sup>(a)</sup></b>					
Net sales <sup>(b)</sup>	35,055	33,821	34,060	31,380	30,693
Gross profit	24,593	24,006	23,942	21,769	20,989
Operating income	5,803	6,534	5,624	6,064	4,982
Net income excluding the exchanged/held-for-exchange Animal Health business	3,912	4,486	4,512	4,392	3,797
Net income attributable to equity holders of Sanofi	8,434	4,709	4,287	4,390	3,716
<b>Basic earnings per share ( ¢):</b>					
Net income excluding the exchanged/held-for-exchange Animal Health business	3.02	3.42	3.38	3.25	2.75
Net income attributable to equity holders of Sanofi	6.71	3.66	3.28	3.34	2.81
<b>Diluted earnings per share ( ¢):</b>					
Net income attributable to equity holders of Sanofi	6.66	3.63	3.25	3.30	2.77
<b>IFRS Balance sheet data</b>					
Goodwill and other intangible assets	53,344 <sup>(e)</sup>	51,166 <sup>(e)</sup>	51,583 <sup>(e)</sup>	53,740	52,529
Total assets	99,826	104,672	102,321	97,392	96,055
Outstanding share capital	2,508	2,544	2,603	2,620	2,641
Equity attributable to equity holders of Sanofi	58,089	57,554	58,049	56,120	56,904
Long term debt	14,326 <sup>(e)</sup>	16,815 <sup>(e)</sup>	13,118 <sup>(e)</sup>	13,276	10,414
Cash dividend paid per share ( ¢)	3.03 <sup>(g)</sup>	2.96	2.93	2.85	2.80

Cash dividend paid per share (\$) <sup>(f)/(h)</sup>	3.63 <sup>(g)</sup>	3.12	3.19	3.46	3.86
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- (a) *The results of the Animal Health business, and the gain on the divestment of that business, are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); see Notes D.1. and D.36 to our consolidated financial statements.*
- (b) *Following a change in accounting presentation in 2016, VaxServe sales of non-Sanofi products are included in **Other revenues**. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note B.13.) to our consolidated financial statements.*
- (c) *Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,256.9 million shares in 2017, 1,286.6 million shares in 2016, 1,306.2 million shares in 2015, 1,315.8 million shares in 2014, and 1,323.1 million shares in 2013.*
- (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. 1,266.8 million shares in 2017, 1,296.0 million shares in 2016, 1,320.7 million shares in 2015, 1,331.1 million shares in 2014, and 1,339.1 million shares in 2013.*
- (e) *As reported, excluding the Animal Health business presented in the line items, **Assets held for sale or exchange** and **Liabilities related to assets held for sale or exchange** as of December 31, 2015, December 31, 2016 and December 31, 2017.*
- (f) *Each American Depositary Share, or ADS, represents one half of one share.*
- (g) *Dividends for 2017 will be proposed for approval by the shareholders at the Annual General Meeting scheduled for May 2, 2018.*
- (h) *Based on the relevant year-end exchange rate.*

**Table of Contents**

## ITEM 3. KEY INFORMATION

**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 2013 through March 2018 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.

<i>(U.S. dollar per euro)</i>	<b>Period- end Rate</b>	<b>Average Rate<sup>(a)</sup></b>	<b>High</b>	<b>Low</b>
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
2017	1.20	1.14	1.20	1.04
Last 6 months 2017				
September	1.18	1.19	1.20	1.17
October	1.16	1.18	1.18	1.16
November	1.19	1.17	1.19	1.16
December	1.20	1.18	1.20	1.17
2018				
January	1.24	1.22	1.25	1.19
February	1.22	1.23	1.25	1.22
March <sup>(b)</sup>	1.24	1.23	1.24	1.22

*(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 March 02, 2018, we have used European Central Bank Rates for the period from March 05, 2018 through March 6, 2018.*

*(b) In each case, measured through March 6, 2018.*

On March 6, 2018 the European Central Bank Rate was 1.24 per euro.

**B. Capitalization and Indebtedness**

N/A

**C. Reasons for Offer and Use of Proceeds**

N/A



**Table of Contents**

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, invalidated 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 by country. This protection may not be sufficient to maintain effective product exclusivity because of local differences in the patents, in national laws, 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.

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

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.

In addition, if we lose patent protection 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 overpaid for 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 secured against the sale of generic clopidogrel during the course of the litigation.

In certain cases to terminate or avoid patent litigation, we or our collaborators may be required to obtain licenses from the holders of third-party intellectual property rights that already 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 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 for more information). If third parties obtain a preliminary or permanent injunction or if we fail to obtain a required license for a country where a valid third-party intellectual property rights as confirmed by a court of law exist, 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 have increased the proportion of biological therapeutics in our pipeline relative to traditional small molecule pharmaceutical products. Typically, the development, manufacture, sale and distribution of biological therapeutics is complicated by third-party intellectual property rights (otherwise known as freedom to operate (FTO) issues), to a greater extent than for the development, manufacture, sale and distribution of small molecule therapeutics,

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**Table of Contents**

## ITEM 3. KEY INFORMATION

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. In addition, 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 to be approved, it could reduce our sales and/or profitability of that product.

However, through our presence as a manufacturer of generics and biosimilars, we will also utilize patent challenge strategies against other innovators' patents similar to those of long-established generic companies, though 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 regard to their nature, scope and level from the types of product liability claims that we have handled in the past. Substantial damages have been awarded and/or settlements agreed 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 Company will be successful in defending against these claims or will not face additional claims in the future.

Often establishing the full side effect profile of a pharmaceutical drug goes beyond data derived from preapproval clinical studies which may only involve 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 over time following interactions with regulatory authorities, including restrictions of therapeutic indications, new contraindications, warnings or precautions and occasionally even the suspension or withdrawal of a product marketing authorization. Following any of these events, 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 pharmaceuticals 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 we have 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 Company'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

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**Table of Contents**

## ITEM 3. KEY INFORMATION

to the regulatory authorities. Regulatory processes differ from one jurisdiction and regulatory 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 it 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 pharmaceutical 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 at times 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 a considerable time. This system may result in negative risk/benefit assessments and 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 reviews and data analyses can lead to the issuance of recommendations by government agencies, health professional and patient or other specialized organizations regarding the use of products; for example, a recommendation to limit the patient population of a drug's indication, the imposition of marketing restrictions, or the suspension or withdrawal of the product can result in a reduction in sales volume as well as an increased risk of litigation.

Moreover, to monitor our compliance with applicable regulations, the FDA, the EMA and comparable agencies in other jurisdictions routinely conduct inspections of our facilities and may identify potential deficiencies. We have received notices of deficiencies and FDA Warning Letters in the past following the inspection of some of our facilities and may receive such letters in the future. In 2016, manufacturing deficiencies were observed by the FDA at our fill and finish facility specialized in biologics in Le Trait, France, during a routine cGMP inspection, and the FDA issued a form 483 ( Inspectional Observations ) listing manufacturing deficiencies. These cGMP deficiencies led the FDA to issue a Complete Response Letter in October 2016, delaying the approval of sarilumab (Kevzara®) until May 2017. More generally, if we fail to adequately respond to Warning Letters identifying a deficiency following an inspection, or fail to comply with applicable regulatory requirements at all or within the targeted timeline, we could be subject to enforcement, remedial and/or punitive actions by the FDA, the EMA or other regulatory authorities.

In addition, in order to comply with our duty to report adverse events and safety signals to regulatory authorities, we must regularly train our employees and third parties (such as external

sales forces and distributor employees) on regulatory matters. If we fail to train these people, or fail to train them appropriately, or they do not comply with contractual requirements, we may be exposed to the risk that safety events are not reported or not reported in a timely manner in breach of our reporting obligations.

To the extent that new regulations raise the costs of obtaining and maintaining product authorizations, or limit the economic value of a new product to its originator, the growth prospects of our industry and of Sanofi would be diminished. Approximately 50% of our current development portfolio consists of biological products that may in the future bring new therapeutic responses to current unmet medical needs, but that may also lead to more regulatory and technical constraints. Regulations applicable to biologics are often more complex and extensive than the regulations applicable to other pharmaceutical products. Biologics are also costly investments from an industrial standpoint as biological products are complex to produce. These constraints and costs could adversely affect our business, results of operations and financial condition.

**Claims and investigations relating to compliance, competition law, marketing practices, pricing, data privacy and other legal matters could adversely affect our business, results of operations and financial condition.**

Our industry is heavily regulated. Our business covers an extremely wide range of activities worldwide and involves numerous partners. We have adopted a Code of Ethics (the Code) that requires employees to comply with applicable laws and regulations, as well as the specific principles and rules of conduct set forth in the Code. We also have policies and procedures designed to help ensure that we, our employees, officers, agents, intermediaries and other third parties comply with applicable laws and regulations (including the US Foreign Corrupt Practices Act (FCPA), the UK Bribery Act, the OECD Anti-Bribery Convention, the French Anti-Corruption measures law (Sapin II) and other anti-bribery laws and regulations).

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

Any failure to comply directly or indirectly (including as a result of a business partner's breach) with the laws and regulations applicable to us, including new regulations, could lead to substantial liabilities and harm the Company's reputation. Governments and regulatory authorities around the world have been strengthening implementation and enforcement activities in recent years, including in relation to anti-bribery, anti-corruption, and data privacy legislation. Sanofi and certain of its subsidiaries are under investigation or could become the subject of additional investigations by various government entities and the Company is defending a number of lawsuits relating to pricing and marketing practices (including, for example, whistleblower litigation in the United States). The Company also faces litigation and government

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**Table of Contents**

ITEM 3. KEY INFORMATION

investigations or audits, including allegations of corruption, claims related to employment matters, patent and intellectual property disputes, consumer law claims and tax audits. See Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings and Note D.22. to our consolidated financial statements included at Item 18 of this annual report. Responding to such investigations is costly and distracts management's attention from our business.

Unfavorable outcomes in any of these matters, or in similar matters to be faced in the future, could preclude the commercialization of products, harm our reputation, negatively affect the profitability of existing products and subject us to substantial fines (including treble damages and fines based on our sales), punitive damages, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls, monitoring or self-reporting obligations, or exclusion from government reimbursement programs or markets. All of this could have a material adverse effect on our business, results of operations or financial condition.

These risks may encourage us to enter into settlement agreements and those settlements may involve significant monetary payments and/or criminal penalties and may include admissions of wrongdoing. Settlement of healthcare fraud cases in the United States may require companies to enter into a Corporate Integrity Agreement, which is intended to regulate company behavior for a specified period of years.

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

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

For example, governmental authorities are increasingly looking to facilitate generic and biosimilar competition to existing products through new regulatory proposals intended to achieve, or resulting in, changes to the scope of patent or data exclusivity rights and use of accelerated regulatory pathways for generic and biosimilar drug approvals. Such regulatory proposals could make patent prosecution for new products more difficult and time consuming or could adversely affect the exclusivity period for our products (see We rely on our patents and 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 above).

This new competitive environment and the potential regulatory changes may further limit the exclusivity enjoyed by innovative

products on the market and directly impact pricing, access and reimbursement levels, which may adversely affect our business and future results. See Item 4. Information on the Company B. Business Overview B.6. Markets

B.6.2. Competition and B.6.3. Regulatory framework .

In addition to international tax law and regulatory changes such as the OECD Base Erosion and Profit Shifting initiatives and EU directives to be adopted, changes in tax frameworks, tax reforms and other changes to the way existing tax laws are applied in jurisdictions and major countries where Sanofi and its subsidiaries and affiliates operate could affect our income, our effective tax rate, and consequently our future net income. This particularly applies to the recently enacted US tax reform for which IRS comments, guidelines and regulations are still to come. These changes may cover matters such as taxation of our operations, intercompany transactions, internal restructuring and more generally taxable income, tax rates, indirect taxation, transfer pricing, R&D tax credits, taxation of intellectual property, dividend taxation, controlled companies or a restriction in certain forms of tax relief. Any of these changes could have a material adverse effect on our business and future results. Additionally, due to the complexity of the fiscal environment, the ultimate resolution of any tax matters may result in payments greater or lesser than amounts accrued.

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

### Risks Relating to Our Business

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

Discovering and developing a new product is a costly, lengthy and uncertain process. To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products to compensate for decreasing sales of products facing patent expiry and regulatory data exclusivity, or competition from new products of competitors that are perceived as being superior or equivalent. We must pursue both early stage research and early and late development stages in order to propose a sustainable and well-balanced portfolio of products. In 2017, we spent 5,472 million on research and development, amounting to 15.6% of our net sales.

Our industry is driven by the need for constant innovation, but we may spread ourselves across too many areas of inquiry to be successful and may not be able to improve internal research productivity sufficiently to sustain our pipeline. We may also fail to invest in the right technology platforms, therapeutic areas, and product classes, or fail to build a robust pipeline and fulfill unmet medical needs in a timely manner. Fields of discovery, particularly



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**Table of Contents**

ITEM 3. KEY INFORMATION

biotechnology, are highly competitive and characterized by significant and rapid technological changes. Numerous companies are working on the same targets and a product considered as promising at the very beginning of its development may become less attractive if a competitor addressing the same unmet need reaches the market earlier.

The research and development process can take generally up to 15 years from discovery to commercial product launch. This process is conducted in various stages in order to test, along with other features, the efficacy, effectiveness and safety of a product. There can be no assurance that any of these product candidates will be proven safe or effective. See Item 4. Information on the Company B. Business Overview B.5. Global Research & Development . Accordingly, there is a substantial risk at each stage of development including clinical studies that we will not achieve our goals of safety and/or efficacy and that we will have to abandon a product in which we have invested substantial amounts of money and human resources, even in late stage development (Phase III). More and more trials are designed with clinical endpoints of superiority; failure to achieve those endpoints could damage the product's reputation and our overall program. Decisions concerning the studies to be carried out can have a significant impact on the marketing strategy for a given product. Multiple in-depth studies can demonstrate that a product has additional benefits, facilitating the product's marketing, but such studies are expensive and time consuming and may delay the product's submission to health authorities for approval. Our ongoing investments in new product launches and research and development for future products could therefore result in increased costs without a proportionate increase in revenues, which would negatively affect our operating results and profitability.

In 2015 we announced that we had up to 18 new medicines and vaccines on track to arrive on the market between 2014-2020, including six key launches. As of the end of 2017, all of those six products have already been approved or launched: Toujeo<sup>®</sup>, Praluent<sup>®</sup>, Dengvaxia<sup>®</sup>, Soliqua 100/33 / Suliqua , Kevzara<sup>®</sup> and Dupixent<sup>®</sup>. However, there can be no assurance that all of the products approved will achieve commercial success.

Following (or in some cases contemporaneously with) review of a product for a marketing authorization, the medical need served by the product and the corresponding reimbursement are evaluated by governmental agencies and/or third-party payers, requiring in some cases additional studies, including comparative studies, which may effectively delay marketing, change the population which the new product treats, and add to its development costs.

After marketing approval of our products, other companies or investigators, whether independently or with our authorization, may conduct studies or analysis beyond our control that may ultimately report results negatively affecting our sales either permanently or temporarily, it may take time for us to address the reported findings, leading

among other things to a material adverse impact on sales.

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

The commercial success of our existing products and our product candidates depends in part on their pricing and the conditions under which our products are reimbursed. Our products continue to be subject to increasing price and reimbursement pressure due, *inter alia*, to:

price controls imposed by governments in many countries;

increased public attention to the price of drugs and particularly price increases, limiting our ability to set the price, or to manage or increase the price of our products based upon their value;

removal of a number of drugs from government reimbursement schemes (for example products determined to be less cost-effective than alternatives);

partial reimbursement of patient populations within a labelled indication;

increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates;

increase in cost containment policies (including budget limitations) related to health expenses;

governmental and private health care provider policies that favor prescription of generic medicines or substitution of branded products with generic medicines;

more demanding evaluation criteria applied by Health Technology Assessment (HTA) agencies when considering whether to cover new drugs at a certain price level;

more governments using international reference pricing to set or manage the price of drugs based on an external benchmark of a product's price in other countries;

aggressive pricing strategies by some of our competitors; and

entry of new consumer healthcare competitors offering online sales.

In addition to the pricing pressures they exert, governmental and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies (including exclusive formularies), managing prescribing via various conditions (including prior authorisations and step edits) or otherwise discouraging physicians from prescribing our products (see also The concentration of the US payer market exposes us

to greater pricing pressure (below).

In the United States, the federal Affordable Care Act has increased the government's role with respect to price, reimbursement, and coverage levels for healthcare services and products within the large government healthcare sector. This law also imposed rebates and fees on pharmaceutical companies. Some US states are also

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**Table of Contents**

ITEM 3. KEY INFORMATION

considering legislation that could affect transparency practices, the marketing and prices of drugs, and access to drugs. US federal and state officials, including the new administration, are continuing to focus on the cost of health coverage and health care although future policy, including the nature and timing of any changes (including to the Affordable Care Act), remains unclear, creating multiple risks for the sector. Legislation was introduced in over 26 states in 2017 which will require price transparency and reporting of certain manufacturer information. This trend will continue into 2018 where we anticipate legislation to be filed in at least 20 states and more laws to be enacted around the United States.

Government price reporting obligations are complex, and we face risks related to the reporting of pricing data that could affect the reimbursement of and discount provided for our products to US government healthcare programs.

We encounter similar cost containment issues in countries outside the United States. In certain countries, including countries in the European Union, China and Canada, the coverage of prescription drugs, and pricing and levels of reimbursement, are subject to governmental control. For example, in Europe various authorities are developing the use of tenders for expensive products and are considering joint procurement mechanisms to negotiate lower prices. See also below Global economic conditions and an unfavorable financial environment could have negative consequences for our business .

We are also unable to predict the availability or level of reimbursement and related restrictions for our product candidates.

Price negotiations in a country may result in a price that is incompatible with the global price positioning of our products, which may lead us not to launch the product in that country, damaging our image and resulting in a decrease in initially anticipated sales.

Finally, our operating results may also be affected by parallel imports, particularly within the European Union, whereby distributors engage in arbitrage based on national price differences to buy products in low cost markets for resale in higher cost markets.

**The concentration of the US market exposes us to greater pricing pressure.**

In the United States, price is increasingly important to managed care organizations (MCOs) and pharmacy benefit managers (PBMs), and as the MCOs/PBMs grow in size following market consolidation, pharmaceutical companies have faced increased pressure in pricing and usage negotiations, and competition among pharmaceutical companies to have their products included in the care providers' formularies is robust. This can lead to price discounts or rebates in connection with the placement of products. Exclusion of one of our drugs from a formulary can significantly reduce sales in the MCO/PBM patient population. For example, since 2014, we have increased the level of rebates negotiated for

Lantus® in order to maintain favorable formulary positions with key payers in the US. Despite these efforts, in 2016, CVS and UnitedHealthcare (a PBM and MCO, respectively) decided that effective January 1, 2017 and April 1, 2017, respectively, Lantus®/Toujeo® would be excluded from commercial and MMC (Medicaid Managed Care) template formularies covering millions of people, thereby increasing the costs of Lantus®/Toujeo® to patients covered by the affected PBM/MCO (absent a co-pay assistance or other applicable program), and thus in turn reducing the patient population likely to purchase Lantus®/Toujeo®.

Also, some payers in the United States have put in place significant restrictions on the usage of Praluent®, which has resulted in significant out-of-pocket expenditures for Medicare patients.

In addition, distributors have increased their capacity to negotiate price and other terms as a consequence of the growing number of mergers of retail chains and distributors, resulting in consolidation of the distribution channel.

Due to these pressures on our prices, our revenues and margins are, and could continue to be, negatively affected.

### **We may lose market share to competing therapeutic options, biosimilar or generic products.**

We are faced with intense competition from generic products, biosimilars and brand-name drugs including from retail chains and distributors.

Doctors or patients may choose competitors' products over ours or alternative therapeutic options such as surgery if they perceive them to be safer, more reliable, more effective, easier to administer or less expensive, which could cause our revenues to decline and adversely affect our results of operations.

The success of any product also depends on our ability to educate patients when permissible and promote our products to healthcare providers by providing them with innovative data about the product and its uses including through the use of digital tools. If these education efforts are not effective, we may not be able to increase the sales of our products or realize the full value of our investment in their development.

We may not be able to anticipate precisely the date of market entry of generics or biosimilars or the potential impact on our sales, both of which depend on numerous parameters. The introduction of a generic version of a branded medicine typically results in a significant and rapid reduction in net sales for the branded product because generic manufacturers typically offer their unbranded versions at significantly lower prices, resulting in adverse price and volume effects for our genericized products. Also mandatory price regulations apply in certain countries to off-patent products and classes of products, and generics prices are taken into account for international reference pricing and tenders. Substitution is often permitted for generic products that are considered to be interchangeable or clinically identical. With respect to biosimilars, in

**Table of Contents**

ITEM 3. KEY INFORMATION

the United States only biosimilars that refer to an innovator drug that was approved under a Biologics License Application may be designated as interchangeable with the original biologic, and only in circumstances where specific criteria are met. In many European countries, automatic substitution of biologics is officially prohibited or not recommended. Nevertheless competition, including from non-substitutable biosimilars, would likely result in a decrease in prices, additional rebates, increased promotion efforts and lower margins.

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

These trends are exacerbated by applicable legislation which encourages the use of generic products to reduce spending on prescription drugs in many countries such as the United States, France and Germany. Therefore, the market for our products could also be affected if a competitor's innovative drug in the same market were to become available as a generic because a certain number of patients can be expected to switch to a lower-cost alternative therapy. We expect this generic competition to continue and to affect more of our products, including those with relatively modest sales.

**The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition, delay the launch of new products and negatively impact our image.**

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. Third parties supply us with a portion of our raw materials, active ingredients and medical devices, which exposes us to the risk of a supply shortage or interruption in the event that these suppliers are unable to manufacture our products to Sanofi quality standards or if they experience financial difficulties. Further, some raw materials essential to the manufacture of our products are not widely available from sources we consider reliable; for example, we have approved only a limited number of suppliers of heparins for use in the manufacture of Lovenox®. Any of these factors could adversely affect our business, operating results or financial condition. See Item 4. Information on the Company B. Business Overview B.8. Production and Raw Materials for a description of these outsourcing arrangements.

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

We must also be able to produce sufficient quantities of our products to satisfy demand. We may have difficulties transforming and adapting our existing plants to manufacture new products, including biologics, and scaling up production of our products currently under development once they are approved. Our biological products, in particular, are subject to the risk of manufacturing stoppages or the risk of loss of inventory because of the difficulties inherent in the processing of biological materials and the potential difficulties in accessing adequate amounts of raw materials meeting required standards. These difficulties may also be encountered during testing, which is a mandatory requirement for the products to be released. Effective insurance coverage for biological products may also be difficult to obtain in the event of contaminated batches as the cause of the contamination can be difficult to ascertain (for the impact on our financial statements see Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on the Company's results of operations and financial results. below)

Additionally, specific conditions must be respected both by Sanofi and our customers for the storage and distribution of many of our biological products. For example, cold storage for certain vaccines and insulin-based products is required. Failure to adhere to these requirements may result in lost product inventory or products becoming out of specification, which in turn may result in efficacy or safety issues for patients.

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

When manufacturing disruptions occur, we may not have alternate manufacturing capacity, particularly for certain biologics. In the event of manufacturing disruptions, our ability to use backup facilities or set up new facilities is more limited because biologics are more complex to manufacture. Even though we aim to have backup sources of supply whenever possible, including by manufacturing backup supplies of our principal active ingredients at additional facilities when practicable, we cannot be certain they will be sufficient if our principal sources become unavailable. Switching sources and manufacturing facilities requires significant time.

Supply shortages generate even greater negative reactions when they occur with respect to life saving medicines with limited or no viable therapeutic alternatives. Shortages of products can have a negative impact on the confidence of patients, customers and professional healthcare providers and the image of Sanofi and may lead to lower product revenues. Government authorities and regulators in the United States, in the European Union and other

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**Table of Contents**

ITEM 3. KEY INFORMATION

agencies worldwide are also considering measures to reduce these risks, such as through Supply Risk Management Plans for some products with high medical need, e.g. the French decree of July 2016 concerning the preparation of shortage management plans ( *plans de gestion des pénuries* ). It cannot be ruled out that these ongoing initiatives may generate additional costs for Sanofi if they result in a requirement to establish backup supply channels or to increase inventory levels to avoid shortages.

We are sometimes required to use animals to test our products in the development phase and to test our vaccines before distributing them. Animal testing activities have been the subject of controversy and adverse publicity. Testing on animals can be vital for the development or commercialization of a product. If applicable regulations were to ban this practice or if, due to pressure from animal welfare groups, we were no longer able to source animals to perform such tests, it would be difficult and in some cases impossible to develop or distribute our products in certain jurisdictions under the applicable marketing authorizations.

**We rely on third parties for the discovery, manufacture and marketing of some of our products.**

Our industry is both highly collaborative and competitive, whether in the discovery and development of new products, in-licensing, the marketing and distribution of approved products, or manufacturing activities. We expect that we will continue to rely on third parties for key aspects of our business and we need to ensure our attractiveness as a potential partner.

We conduct a number of significant research and development programs and market some of our products in collaboration with other biotechnology and pharmaceutical companies. For example, we currently have a global strategic collaboration with Regeneron on monoclonal antibodies. With Alnylam, we have an agreement to develop and commercialize treatments for rare genetic diseases (See Item 4. Information on the Company B. Business Overview ). In addition we may also rely on partners to design and manufacture medical devices, notably for the administration of our products.

If disruptions or quality concerns were to arise in the third-party supply of raw materials, active ingredients or medical devices or if our partners were unable to manufacture a product, this could also adversely affect our ability to sell our products in the quantities demanded by the market and could damage our reputation and relationships with our customers. See also The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition, delay the launch of new products and negatively impact our image above.

When we research and market our products through collaboration arrangements, we are also subject to the risk that we may not



adequately manage our alliance. For instance, we may not properly manage the decision making process with our partners. Decisions may also be under the control of or subject to the approval of our collaboration partners, who may have views that differ from ours. We are also subject to the risk that our partners may not perform effectively, which could have a detrimental effect when the performance of certain key tasks or functions is the responsibility of our collaboration partners. Failures in the development process or differing priorities may adversely affect the activities conducted through the collaboration arrangements.

Any conflicts or difficulties that we may have with our partners during the course of these agreements or at the time of their renewal or renegotiation, or any disruption in the relationships with our partners, may affect the development, the launch and/or the marketing of certain of our products or product candidates and may cause a decline in our revenues or otherwise negatively affect our results of operations.

**A substantial share of the revenue and income of Sanofi continues to depend on the performance of certain flagship products.**

We generate a substantial share of our revenues from the sale of certain key products (see Item 5. Operating and Financial Review and Prospects Results of Operations Year ended December 31, 2017 compared with year ended December 31, 2016 Net Sales Pharmaceuticals segment ). Lan<sup>®</sup> is particularly important; it was Sanofi's leading product with revenues of 4,622 million in 2017, representing 13.2% of Sanofi's net sales for the year. Lan<sup>®</sup> is a flagship product of the Diabetes franchise. Accounting for market trends, we announced in November 2017 that we now project a cumulative annual negative growth rate of 6% to 8% for our global Diabetes franchise for the period from 2015 to 2018. Nevertheless our actual sales may differ from these expectations given the numerous underlying assumptions (for example the outlook for insulin glargine sales, the introduction of one or several generic glargines and their penetration of the market, or the market uptake of our new products).

The launch of new medicines and vaccines in other therapeutic areas and the performance of our other businesses may not be sufficient to reduce the relative contribution of our Diabetes franchise to our overall performance. As regards products recently launched or under development in our R&D portfolio for which we have an alliance arrangement with a partner, the terms of the alliance agreements may require us to share profits and losses arising from commercialization of such products with our partners. This differs from the treatment of revenue and costs generated by other products for which we have no alliance agreement, and such profit sharing may deliver a lower contribution to our financial results.

**Table of Contents**

ITEM 3. KEY INFORMATION

Our flagship products benefit from certain intellectual property protections such as patents and exclusivity periods but patent and proprietary rights, even if they are not challenged, are subject to expiration dates. Expiration of effective intellectual property protections for our products typically results in the entry of one or more lower-priced generic competitors, often leading to a rapid and severe decline in revenues on those products (for information on the expected impact of biosimilar entry on the market see [We may lose market share to competing therapeutic options, biosimilar or generic products](#) above).

Furthermore, in general, if one or more of our flagship products were to encounter problems such as material product liability litigation, unexpected side effects, recall, regulatory proceedings, publicity affecting doctor or patient confidence, pressure from existing competitive products, or changes in labeling, or if a new, more effective treatment were introduced, or if there were a reduction in sales or a decline in sales growth of one or more of our flagship products, the adverse impact on our business, results of operations and financial condition could be significant.

**We are subject to the risk of non-payment by our customers<sup>(1)</sup>.**

We run the risk of delayed payments or even non-payment by our customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies. This risk is accentuated by recent concentrations among distributors, as well as by uncertainties around global credit and economic conditions, in particular in emerging markets. The United States poses particular customer credit risk issues because of the concentrated distribution system: our three main customers represented respectively 9%, 5% and 4% of our consolidated net sales in 2017. We are also exposed to large wholesalers in other markets, particularly in Europe. An inability of one or more of these wholesalers to honor their debts to us would adversely affect our financial condition (see Note D.34. to our consolidated financial statements included at Item 18 of this annual report).

In some countries, some customers are public or subsidized health systems. The economic and credit conditions in these countries may lead to an increase in the average length of time needed to collect on accounts receivable or the ability to collect 100% of receivables outstanding. Because of this context, we may need to reassess the recoverable amount of our debts in these countries during future financial years (see also [Item 5. Operating and Financial Review and Prospects](#) [Liquidity and Capital Resources](#) [Liquidity](#) ).

**Global economic conditions and an unfavorable financial environment could have negative consequences for our business<sup>(2)</sup>.**

Over the past several years, growth of the global pharmaceutical market has become increasingly tied to global economic growth. In this context, a substantial and lasting slowdown of the global economy, major national economies or emerging markets could negatively affect growth in the global pharmaceutical market and, as a result, adversely affect our business.

Unfavorable economic conditions have reduced the sources of funding for national social security systems, leading to austerity measures including heightened pressure on drug prices, increased substitution of generic drugs, and the exclusion of certain products from formularies.

Further, our net sales may be negatively impacted by the continuing challenging global economic environment, as high unemployment, increases in cost-sharing, and lack of developed third-party payer systems in certain regions may lead some patients to switch to generic products, delay treatments, skip doses or use other treatments to reduce their costs. In the United States there is a consistent increase in the number of patients in the Medicaid program, under which sales of pharmaceuticals are subject to substantial rebates and, in many US states, to formulary restrictions limiting access to brand-name drugs, including ours. Also, as a result of the insurance coverage mandate that came into effect in the United States in 2015, some employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees.

Our Consumer Healthcare business could also be adversely impacted by difficult economic conditions that limit the financial resources of our customers.

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

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

*(1) Information in this section is supplementary to Notes B.8.8. (with respect to information required by IFRS 7), D.10 and D.34 to our consolidated financial statements included at Item 18 of this annual report.*

*(2) Information in this section is supplementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report, with respect to information required by IFRS 7.*

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**Table of Contents**

## ITEM 3. KEY INFORMATION

**Counterfeit versions of our products harm our business.**

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

**Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, business or reputational harm.**

Our business depends heavily on the use of information technologies. Certain key areas such as research and development, production and sales are to a large extent dependent on our information systems (including cloud-based computing) or those of third-party providers (including for the storage and transfer of critical, confidential, sensitive or personal information regarding our patients, clinical trials, vendors, customers, employees, collaborators and others). We and our third-party service providers use secure information technology systems for the protection of data and threat detection. However, there can be no assurance that our efforts or those of our third-party service providers to implement adequate security and control measures would be sufficient to protect against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyber-attack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

We commercialize a number of devices using new information technologies which, if they malfunction or are compromised, could lead to a risk of harm to patients (see Product liability claims could adversely affect our business, results of operations and financial condition above), including the unavailability of our products.

**The expansion of social media platforms and new technologies present risks and challenges for our business and reputation.**

We increasingly rely on social media and new technologies to communicate about our products and diseases or to provide health services. The use of these media requires specific attention, monitoring programs and moderation of comments. For example, patients may use these channels to comment on the effectiveness

of a product and to report an alleged adverse event. When such questions arise, the nature of evidence-based health care and restrictions on what pharmaceutical manufacturers may say about their products are not always well suited to

rapidly defending Sanofi or the public's legitimate interests in the face of the political and market pressures generated by social media and rapid news cycles, and this may result in commercial harm, overly restrictive regulatory actions and erratic share price performance. In addition, unauthorized communications, such as press releases or posts on social media, purported to be issued by Sanofi, may contain information that is false or otherwise damaging and could have an adverse impact on our stock price. Negative or inaccurate posts or comments about Sanofi, our business, directors or officers on any social networking website could seriously damage our reputation. In addition, our employees and partners may use social media and mobile technologies inappropriately, which may give rise to liability for Sanofi, or which could lead to breaches of data security, loss of trade secrets or other intellectual property or public disclosure of sensitive information, including information about our employees, clinical trials or customers or other information. Such uses of social media and mobile technologies could have a material adverse effect on our reputation, business, financial condition and results of operations.

**Impairment charges or write-downs in our books and changes in accounting standards could have a significant adverse effect on Sanofi's results of operations and financial results.**

Substantial value is allocated to intangible assets and goodwill resulting from business combinations, as disclosed at Note D.4. to our consolidated financial statements included in this annual report at Item 18, which could be substantially written down in value upon indications of impairment (primarily relating to pharmacovigilance, discontinued research and development projects, patent litigation and the launch of competing products), with adverse effects on our financial condition and the value of our assets.

If any of our strategic equity investments decline in value and remain below cost for an extended period, we may be required to write down our investment. We own a significant stake in Regeneron Pharmaceuticals, Inc. (22.2% of its share capital as of December 31, 2017), which is listed on NASDAQ and has been accounted for using the equity method since 2014. Any material deterioration in Regeneron's share price or financial performance would be an indicator that the value of our investment might have become impaired. This would require us to perform an impairment test, which could have a negative impact on our financial statements.

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

**Table of Contents**

ITEM 3. KEY INFORMATION

The financial environment and in particular the economic difficulties affecting Russia, Venezuela and the Middle East could also negatively affect the value of our assets (see Global economic conditions and an unfavorable financial environment could have negative consequences for our business above and Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition below).

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

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

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

**Risks Relating to Sanofi's Structure and Strategy**

**Our strategic objectives for long-term growth may not be fully realized.**

In November 2015, we outlined our strategic roadmap for the period 2015-2020. Our long term strategy rests on four pillars: reshape our portfolio, deliver outstanding launches, sustain innovation in R&D and simplify our organization.

We may not be able to fully realize our strategic objectives and, even if we are able to do so, these strategic objectives may not deliver the expected benefits or within the expected timeline.

We are looking to reshape our portfolio through acquisitions and divestitures and may not reach this objective if we are unable to identify opportunities, or enter into agreements in a timely manner or on sufficiently attractive terms. In addition, we may fail to (i) adopt the best strategy for our acquisitions/ divestitures or (ii) compete successfully in an

intensively competitive, increasingly focused market environment (see [We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments](#) below and [Our research and development efforts may not succeed in adequately renewing our product portfolio](#) above). We may also not have the necessary flexibility to appropriately reallocate resources toward our priority businesses.

The successful launch of a new pharmaceutical product involves substantial investment in sales and marketing activities. In 2015 we announced that we have up to 18 new medicines and vaccines on track to arrive on the market between 2014-2020 including six key launches. As of the end of 2017, all of those six products have already been approved or launched: Toujeo<sup>®</sup>, Praluent<sup>®</sup>, Dengvaxia<sup>®</sup> and Soliqua 100/33 / Suliqua, Kevzara<sup>®</sup> and Dupixent<sup>®</sup>. However there can be no assurance that all of our new products will achieve commercial success. We may also encounter failures or delays in our launch strategy. For example, Dengvaxia<sup>®</sup> sales suffer from political changes and economic volatility in Latin America and also from the recommendation to update the label at the end of 2017 following new clinical studies. In the Philippines, this resulted in the suspension of the dengue vaccination campaign in December 2017, and the temporary suspension of the Dengvaxia<sup>®</sup> license in early 2018, following a decision of the regulatory authority. In addition, the level of Praluent<sup>®</sup> sales reflects the implementation of utilization management restrictions by payers in the United States and limited market access in Europe which have hampered our launch strategy. The launch strategy we develop (in terms of timing, pricing, market access, marketing efforts and dedicated sales forces) may not deliver the benefits that we expect. The competitive environment for a given product may also have changed by the time of the actual launch, modifying our initial expectations. The need to prioritize the allocation of resources may also cause delays in the expected launch of some of our products.

Sustaining innovation in R&D is inherently risky due to the high rate of failure and we may not be able to allocate our resources to obtain optimal results (see also [Our research and development efforts may not succeed in adequately renewing our product portfolio](#) above).

Our ongoing simplification of our global organization through the implementation, starting from January 2016, of five global business units (GBUs) to meet significant growth objectives requires substantial attention from our management. There is no guarantee that this new organization will enable Sanofi to concentrate its efforts around the businesses most likely to deliver growth, or that these GBUs will grow in line with anticipated growth rates or deliver the expected benefits.

Failure to support and grow our marketed products, successfully execute the launches of newly approved products, advance our late-stage pipeline or manage the change of our organization would have an adverse impact on our business, prospects and results of operations.

**[We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments.](#)**

We pursue a strategy of selective acquisitions, in-licensing and collaborations in order to reinforce our pipeline and portfolio. The implementation of this strategy depends on our ability to identify

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**Table of Contents**

ITEM 3. KEY INFORMATION

business development opportunities and execute them at reasonable cost and on acceptable financing terms. Moreover, entering into in-licensing or collaboration agreements generally requires the payment of significant milestones well before the relevant products reach the market, without any assurance that such investments will ultimately become profitable in the long term (see Note D.21.1. to the consolidated financial statements included at Item 18 of this annual report and also We rely on third parties for the discovery, manufacture and marketing of some of our products above).

For newly acquired activities or businesses our growth objectives could be delayed or ultimately not realized, and expected synergies could be adversely impacted if:

we are unable to quickly or efficiently integrate those activities or businesses;

integration takes longer than expected;

key employees leave; or

we have higher than anticipated integration costs.

In January 2017, we completed the acquisition of Boehringer Ingelheim's consumer healthcare (CHC) business in exchange for our Animal Health business (Merial), but the expected benefits of the transaction may never be fully realized or may take longer to realize than expected.

In January 2018, we announced our intent to acquire Bioverativ and Ablynx. Completion of the transactions is subject to a number of risks and uncertainties. These include (but not limitatively): (i) our ability to complete the transactions on the terms proposed or within the expected time-frame; (ii) our ability to obtain the required regulatory clearances; and (iii) the possibility that competing offers may be made.

We may miscalculate the risks associated with business development transactions at the time they are made or not have the resources or ability to access all the relevant information to evaluate them properly, including with regard to the potential of research and development pipelines, manufacturing issues, compliance issues, or the outcome of ongoing legal and other proceedings. It may also take a considerable amount of time and be difficult to implement a risk analysis and risk mitigation plan after the acquisition of an activity or business is completed due to lack of historical data. As a result, risk management and coverage of such risks, particularly through insurance policies, may prove to be insufficient or ill-adapted.



Because of the active competition among pharmaceutical groups for such business development opportunities, there can be no assurance of our success in completing these transactions when such opportunities are identified.

**The globalization of our business exposes us to increased risks in specific areas.**

We continue to focus on emerging markets. However, difficulties in operating in emerging markets, a significant decline in the anticipated growth rate in these regions or an unfavorable movement of the exchange rates of these countries' currencies against the euro could impair our ability to take advantage of these growth opportunities and could affect our business, results of operations or financial condition (see also Global economic conditions and an unfavorable financial environment could have negative consequences for our business above).

The expansion of our activities in emerging markets also exposes us to more volatile economic conditions, political instability, competition from multinational or locally based companies that are already well established in these markets, the inability to adequately respond to the unique characteristics of emerging markets (particularly with respect to their underdeveloped judicial systems and regulatory frameworks), difficulties in recruiting qualified personnel or maintaining the necessary internal control systems, potential exchange controls, weaker intellectual property protection, higher crime levels (particularly with respect to counterfeit products (see Counterfeit versions of our products harm our business above)), and compliance issues including corruption and fraud (see Claims and investigations relating to compliance, competition law, marketing practices, pricing and other legal matters could adversely affect our business, results of operations and financial condition above). We may also face compliance and internal control systems issues in mature markets due to increased competition and more complex and stringent regulations.

As a global healthcare leader, we are exposed to a number of risks inherent in sectors in which we were previously less active such as consumer healthcare. The business models and trade channels in consumer healthcare, in particular regarding promotional efforts and trade terms for example, are different from those in our traditional pharmaceuticals business.

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

We depend on the expertise of our senior management team and other key employees. In addition, we rely heavily on recruiting and retaining talented people to help us meet our strategic objectives. We face intense competition for qualified individuals for senior management positions, or in specific geographic regions or in specialized fields such as clinical development, biosciences and devices. In addition, our ability to hire qualified personnel also depends in part on our ability to reward performance, incentivize our employees and to pay competitive compensation. Laws and regulations on executive compensation may restrict our ability to attract, motivate and retain the required level of talented people.

**Table of Contents**

ITEM 3. KEY INFORMATION

The inability to attract, integrate and/or retain highly skilled personnel, in particular those in leadership positions, may weaken our succession plans, may materially adversely affect the implementation of our strategy and our ability to meet our strategic objectives and could ultimately adversely impact our business or results of operations.

**Environmental Risks of Our Industrial Activities**

**Risks from the handling of hazardous materials could adversely affect our results of operations.**

Manufacturing activities, such as the chemical manufacturing of the active ingredients in our products and the related storage and transportation of raw materials, products and waste, expose us to various risks, including:

fires and/or explosions;

storage tank leaks and ruptures; or

discharges or releases of toxic or pathogen substances.

These operating risks can cause personal injury, property damage and environmental contamination, and may result in the shutdown of affected facilities and/or the imposition of civil, administrative, criminal penalties and/or civil damages.

The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results and reputation.

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

**Environmental liabilities and costs related to compliance with applicable regulations may have a significant adverse effect on our results of operations.**

The environmental laws of various jurisdictions impose actual and potential obligations on our Company to remediate contaminated sites. These obligations may relate to sites:

that we currently own or operate;

that we formerly owned or operated; or

where waste from our operations was disposed.

These environmental remediation obligations could significantly reduce our operating results. Sanofi accrues provisions for remediation when our management believes the need is probable and that it is reasonably possible to estimate the cost. See Item 4. Information on the Company B. Business Overview B.10. Health, Safety and Environment (HSE) for additional information regarding our environmental policies. In particular, our provisions for these obligations may be insufficient if the

assumptions underlying these provisions prove incorrect or if we are held responsible for additional, currently undiscovered contamination. These judgments and estimates may later prove inaccurate, and any shortfalls could have a material adverse effect on our results of operations and financial condition.

We are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former Sanofi subsidiaries have been named as potentially responsible parties or the equivalent under the US Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (also known as Superfund), and similar statutes in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligation, we and/or our subsidiaries may retain responsibility for environmental liabilities at some of the sites of our predecessor companies, or of subsidiaries that we demerged, divested or may divest. We have disputes outstanding regarding certain sites no longer owned by the Company. An adverse outcome in such disputes might have a significant adverse effect on our operating results. See Note D.22.d) to the consolidated financial statements included at Item 18 of this annual report and Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings.

Environmental regulations are evolving. For example, in Europe, new or evolving regulatory regimes include REACH, CLP/GHS, SEVESO, IPPC/IED, the Waste Framework Directive, the Emission Trading Scheme Directive, the Water Framework Directive, the Directive on Taxation of Energy Products and Electricity and several other regulations aimed at preventing global warming. Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to our Company and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants, site restoration and compliance to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures as well as other costs and liabilities, thereby adversely affecting our business, results of operations or financial condition. For more detailed information on environmental issues, see Item 4. Information on the Company B. Business Overview B.10. Health, Safety and Environment (HSE).

**Natural disasters prevalent in certain regions in which we do business could affect our operations.**

Some of our production sites are located in areas exposed to natural disasters, such as earthquakes, floods and hurricanes. In the event of a major disaster we could experience severe destruction or interruption of our operations

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

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**Table of Contents**

## ITEM 3. KEY INFORMATION

**Risks Related to Financial Markets<sup>(1)</sup>****Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition.**

Because we sell our products in numerous countries, our results of operations and financial condition could be adversely affected by fluctuations in currency exchange rates. We are particularly sensitive to movements in exchange rates between the euro and the US dollar, the Japanese yen, and to currencies in emerging markets. In 2017, 33.8% of our net sales were realized in the United States; 29.3% in Emerging Markets (see the definition in Item 5. Operating and Financial Review and Prospects A/ Operating results ), including countries that are, or may in future become, subject to exchange controls or hyper-inflation; and 5.1% in Japan. While we incur expenses in those currencies, the impact of currency exchange rates on these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate and when technically feasible, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations or financial condition. For more information concerning our exchange rate exposure, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

**Risks Relating to an Investment in Our Shares or ADSs****Foreign exchange fluctuations may adversely affect the US dollar value of our ADSs and dividends (if any).**

Holders of ADSs face exchange rate risk. Our ADSs trade in US dollars and our shares trade in euros. The value of the ADSs and our shares could fluctuate as the exchange rates between these currencies fluctuate. If and when we pay dividends, they would be denominated in euros. Fluctuations in the exchange rate between the euro and the US dollar will affect the US dollar amounts received by owners of ADSs upon conversion by the depositary of cash dividends, if any. Moreover, these fluctuations may affect the US dollar price of the ADSs on the New York Stock Exchange (NYSE) whether or not we pay dividends, in addition to any amounts that a holder would receive upon our liquidation or in the event of a sale of assets, merger, tender offer or similar transaction denominated in euros or any foreign currency other than US dollars.

**Persons holding ADSs rather than shares may have difficulty exercising certain rights as a shareholder.**

Holders of ADSs may have more difficulty exercising their rights as a shareholder than if they directly held shares. For example, if we

issue new shares and existing shareholders have the right to subscribe for a portion of them, the depositary is allowed, at its own discretion, to sell for their benefit that right to subscribe for new shares instead of making that right

available to ADS holders. Also, holders of ADSs must instruct the depositary how to vote their shares. Because of this extra procedural step involving the depositary, the process for exercising voting rights will take longer for holders of ADSs than for holders of shares. ADSs for which the depositary does not receive timely voting instructions will not be voted at any meeting.

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

As of December 31, 2017, L Oréal held approximately 9.43% of our issued share capital, accounting for approximately 16.88% of the voting rights (excluding treasury shares) of Sanofi. See Item 7. Major Shareholders and Related Party Transactions A. Major Shareholders. Affiliates of L Oréal currently serve on our Board of Directors. To the extent L Oréal continues to hold a large percentage of our share capital and voting rights, it will remain in a position to exert greater influence in the appointment of the directors and officers of Sanofi and in other corporate actions that require shareholders approval.

**Sales of our shares may cause the market price of our shares or ADSs to decline.**

Sales of large numbers of our shares, or a perception that such sales may occur, could adversely affect the market price for our shares and ADSs. To our knowledge, L Oréal, our largest shareholder, is not subject to any contractual restrictions on the sale of the shares it holds in our Company. L Oréal does not consider its stake in our Company as strategic.

**Risks Relating to Our Contingent Value Rights (CVRs)**

**In addition to the risks relating to our shares, CVR holders are subject to additional risks.**

In connection with our acquisition of Genzyme, we issued CVRs under a CVR agreement entered into by and between us and American Stock Transfer & Trust Company, the trustee (see also Note D.18. to the consolidated financial statements included at Item 18 of this annual report). A copy of the form of the CVR agreement is on file with the SEC as Annex B to Amendment No. 2 to the Registration Statement on Form F-4 filed with the Securities and Exchange Commission on March 24, 2011. Pursuant to the CVR agreement, each holder of a CVR is entitled to receive cash payments upon the achievement of certain milestones, if any, based on the achievement of certain cumulative net sales

*(1) Information in this section is supplementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report with respect to information required by IFRS 7.*

**Table of Contents**

ITEM 3. KEY INFORMATION

thresholds by Lemtrada® (alemtuzumab for treatment of multiple sclerosis). See Item 10. Additional Information C. Material Contracts The Contingent Value Rights Agreement.

CVR holders are subject to additional risks, including:

the public market for the CVRs may not be active or the CVRs may trade at low volumes, both of which could have an adverse effect on the resale price, if any, of the CVRs;

the market price and trading volume of the CVRs may be volatile;

no payment will be made on the CVRs without the achievement of certain agreed upon milestones. As such, it may be difficult to value the CVRs and accordingly it may be difficult or impossible to resell the CVRs;

if net sales do not exceed the thresholds set forth in the CVR agreement for any reason within the time periods specified therein, no payment will be made under the CVRs and the CVRs will expire without value;

since the US federal income tax treatment of the CVRs is unclear, any part of any CVR payment could be treated as ordinary income and required to be included in income prior to the receipt of the CVR payment;

any payments in respect of the CVRs rank at parity with our other unsecured unsubordinated indebtedness; we are not prohibited from acquiring the CVRs, whether in open market transactions, private transactions or otherwise and we have already purchased CVRs on several occasions (for more information see Item 5. Operating and Financial Review and Prospects Liquidity and Capital Resources Liquidity. );

we may, under certain circumstances, purchase and cancel all outstanding CVRs; and

while we have agreed to use diligent efforts (as defined in the CVR agreement), until the CVR agreement is terminated, to achieve each of the remaining Lemtrada® related CVR milestones set forth in the CVR agreement, we are not required to take all possible actions to achieve these goals. On July 5, 2016 Sanofi disclosed that, based upon actual sales of Lemtrada® in Qualifying Major Markets and in other markets during the respective applicable periods since the Product Launch, Product Sales Milestone #1 has not been met. On February 7, 2018, Sanofi disclosed that, based upon actual sales trends to date, it does not expect that product sales milestones #2, #3 and #4 will be met. Failure to achieve the remaining sales milestones could have an adverse effect on the value of the CVRs (see also Note D.22.c to the consolidated financial statements included at Item 18 of the annual report regarding the ongoing CVR Trustee Claim).



**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

Item 4. Information on the Company

**Introduction**

Sanofi is a leading global healthcare company, focused on patient needs and engaged in the research, development, manufacture and marketing of therapeutic solutions.

In the remainder of this section:

A product is referred to either by its international non-proprietary name (INN) or its brand name, which is generally exclusive to the company that markets it. In most cases, the brand names of our products, which may vary from country to country, are protected by specific registrations. In this document, products are identified by their brand names used in France and/or in the US.

For our Pharmaceuticals activity, unless otherwise stated, all market share percentages and rankings are calculated based on consolidated national pharmaceutical sales data, excluding vaccines and in constant euros, on a November 2017 MAT (Moving Annual Total) basis. The data are mainly from IQVIA local sales audit supplemented by various other country-specific sources e.g. Knobloch (Mexico), GERS (France hospital channel), HMR (Portugal), Reveal (Sweden). Market share data for the Consumer Healthcare business are from Nicholas Hall, Q3 2017 MAT.

For our Vaccines activity, market share percentages and rankings are based on our own estimates. These estimates have been made from information in the public domain collated from various sources, including statistical data collected by industry associations and information published by our competitors.

Sanofi has three principal activities: Pharmaceuticals, Consumer Healthcare (CHC) and Vaccines via Sanofi Pasteur. These activities are operating segments within the meaning of the IFRS 8 accounting standard (see Note D.35. to our consolidated financial statements included in Item 18 of this annual report). We exited the Animal Health business on January 1, 2017 when we closed a transaction with Boehringer Ingelheim (BI) in most markets to swap our Animal Health business for BI's Consumer Healthcare business.

We invest in the following activities (see B. Business Overview B.1. Strategy below): Rare Diseases, Multiple Sclerosis, Oncology, Immunology, Diabetes, Cardiovascular, Established Prescription Products<sup>(1)</sup>, Consumer Healthcare, Generics, and Vaccines. Unlike our Vaccines and Consumer Healthcare activities, which are operating segments within the meaning of IFRS 8, our Rare Diseases, Multiple Sclerosis, Oncology, Immunology, Diabetes, Cardiovascular, Established Prescription Products and

Generics activities are franchises whose performance is monitored primarily on the basis of net sales; the products sold by each of those franchises are included in our Pharmaceuticals operating segment. We are also active in emerging markets selling products from our three activities; the performance of our Emerging Markets<sup>(2)</sup> operations is monitored primarily on the basis of net sales.

For a presentation of the net sales of our activities for the year ended December 31, 2017, refer to Item 5 Results of Operations Year Ended December 31, 2017 Compared with Year Ended December 31, 2016 .

The most important pharmaceutical products marketed by us are described below.

Rare Diseases: a portfolio of enzyme replacement therapies including Cerezyme<sup>®</sup> for Gaucher disease; Myozyme<sup>®</sup> and Lumizyme<sup>®</sup> for Pompe disease; and Fabrazyme<sup>®</sup> for Fabry disease; Cerdelga<sup>®</sup>, an oral ceramide analog for Gaucher disease and Aldurazyme<sup>®</sup> for mucopolysaccharidosis Type 1 (MPS 1).

Multiple sclerosis: Aubagio<sup>®</sup>, a once-daily oral immunomodulator; and Lemtrada<sup>®</sup>, a monoclonal antibody. Both products were developed to treat patients with relapsing forms of multiple sclerosis.

Oncology: Jevtana<sup>®</sup>, a taxane derivative, indicated for patients with prostate cancer; Taxotere<sup>®</sup>, a taxoid representing a cornerstone therapy for several cancer types; Eloxatin<sup>®</sup>, a platinum agent, which is a key treatment for colorectal cancer; Thymoglobulin<sup>®</sup>, a broad immunosuppressive and immunomodulating agent; Mozobil<sup>®</sup>, a hematopoietic stem cell mobilizer for patients with hematologic malignancies; and Zaltrap<sup>®</sup>, a recombinant fusion protein, indicated for patients with metastatic colorectal cancer that is resistant to or has progressed following an oxaliplatin-containing regimen.

Immunology: Dupixent<sup>®</sup> (dupilumab), a monoclonal antibody against the Interleukin-4 alpha receptor, indicated for adults with moderate-to-severe atopic dermatitis; and Kevzara<sup>®</sup> (sarilumab), a monoclonal antibody against the Interleukin-6 receptor, indicated for adults with moderate to severe rheumatoid arthritis.

Diabetes: Lantus<sup>®</sup> (insulin glargine), a long-acting human insulin analog which is the world-leading brand in the insulin market; Toujeo<sup>®</sup> (insulin glargine 300 U/mL); Amaryl<sup>®</sup>, an oral once-daily sulfonylurea; Apidra<sup>®</sup>, a rapid-acting human insulin analog; Insuman<sup>®</sup>, a range of rapid-acting or intermediate-acting human

*(1) Established Prescription Products comprises mature products including Plavix<sup>®</sup>, Lovenox<sup>®</sup>, Aprovel<sup>®</sup>, Renagel<sup>®</sup> and Renvela<sup>®</sup>.*

*(2) World excluding the US, Canada, Western & Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico*

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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

insulins; Lyxumia<sup>®</sup>/Adlyxin<sup>®</sup> (lixisenatide), a once-daily GLP-1 receptor agonist; Soliqua 100/33 / Suliqua , a once-daily combination of insulin glargine and lixisenatide; and Admelog<sup>®</sup> / Insulin lispro Sanofi<sup>®</sup> (insulin lispro), a rapid-acting insulin.

Cardiovascular diseases: Praluent<sup>®</sup>, a cholesterol-lowering drug that inhibits PCSK9; and Multaq<sup>®</sup>, an anti-arrhythmic drug in atrial fibrillation.

Established Prescription Products: Plavix<sup>®</sup>, an anti-platelet agent indicated for a number of atherothrombotic conditions; Lovenox<sup>®</sup>, a low molecular weight heparin for the prophylaxis and treatment of venous thromboembolism and of acute coronary syndrome; Aprovel<sup>®</sup> and CoAprovel<sup>®</sup>, anti-hypertensives; Renagel<sup>®</sup> and Renvela<sup>®</sup>, oral phosphate binders for use in patients undergoing dialysis; Synvisc<sup>®</sup> and Synvisc-One<sup>®</sup>, viscosupplements used to reduce pain in patients suffering from osteoarthritis of certain joints; Stilnox<sup>®</sup>, for the short-term treatment of insomnia; and Allegra<sup>®</sup>, a long-lasting (12- and 24-hour) non-sedating prescription anti-histamine for the treatment of seasonal allergic rhinitis (hay fever) and uncomplicated hives.

Generics: our pharmaceuticals portfolio also includes a wide range of generics. In October 2016, we announced our intention to initiate a carve-out process in order to divest our European Generics business. Our Consumer Healthcare (CHC) activity is supported by four strategic categories: Allergy Cough & Cold, Pain, Digestive and Nutritionals. On January 1, 2017, we acquired BI's CHC business in most markets.

Our Vaccines activity is operated through Sanofi Pasteur. We sell leading vaccines in five areas: pediatric vaccines, influenza vaccines, adult and adolescent booster vaccines, meningitis vaccines, and travel and endemic vaccines. At the end of December 2016, Sanofi Pasteur and MSD ended their vaccines joint venture in Europe and integrated their respective European vaccines business into their own operations.

We obtained regulatory approval for two new products (Dupixent<sup>®</sup> and Kevzara<sup>®</sup>) in the US and in the EU in 2017. We also obtained regulatory approval in the US for Admelog<sup>®</sup>, a follow-on insulin lispro, which was also approved in the EU as a biosimilar under the proprietary name Insulin lispro Sanofi<sup>®</sup>.

Collaborations are essential to our business and a certain number of our products, whether on the market or under development, are in-licensed products relying on third-party rights or technologies.

## **A/ History and Development of the Company**

The current Sanofi corporation was incorporated under the laws of France in 1994 as a *société anonyme*, a form of limited liability company, for a term of 99 years. Since May 2011, we have operated under the commercial name Sanofi (formerly known as Sanofi-Aventis). Our registered office is located at 54, rue La Boétie, 75008 Paris, France, and our main telephone number is

+33 1 53 77 40 00. Our principal US subsidiary's office is located at 55 Corporate Drive, Bridgewater, NJ 08807; telephone: +1 (908) 981 5000.

### **Main changes since 2011**

On April 4, 2011, following a tender offer, we acquired control of Genzyme, a US biotechnology company headquartered in Cambridge, Massachusetts.

At the end of December 2016, Sanofi Pasteur and MSD ended their vaccines joint venture in Europe and integrated their respective European vaccines business into their own operations.

On January 1, 2017, Sanofi and Boehringer Ingelheim (BI) successfully closed in most markets a transaction to swap Sanofi's Animal Health business for BI's CHC business.

## **B/ Business overview**

### **B.1. Strategy**

#### **The market context for Sanofi**

A number of fundamental trends point to a positive outlook for the pharmaceutical industry. The global population is growing and aging. Unmet medical needs remain high. The industry has increased R&D productivity, and has returned to consistently launching a high number of innovative medicines. Patients around the world, and a rising middle class in emerging markets, are demanding better care, empowered by access to new information. It is a particularly exciting time scientifically and technologically, with the promise of genomics being realized, immuno-oncology transforming cancer treatments, big data generating new insights into disease, and digital technologies helping to transform care delivery.

At the same time, funding challenges, budget tightening and affordability will continue to put the entire Healthcare value chain under significant pressure. Even though we believe that the pharmaceutical portion will remain a fundamentally attractive business, the bar for innovation will most likely continue to rise. Innovation must have demonstrable benefit to the system. Payers will continue to put scrutiny on prices and reimbursement and will demand demonstration of real life outcomes, coupled with more innovative pricing and contracting practices.

Biosimilars are now firmly part of the competitive landscape in both the US and Europe. More focused competitors are building leadership positions in their priority therapy areas.

#### **Implementing the strategic roadmap**

To compete and win in this market, we are implementing our 2020 strategic roadmap, announced in November 2015. We have made significant progress against each of the four pillars of that strategy in 2017: reshape the portfolio,

deliver outstanding launches, sustain innovation in R&D, and simplify the organization.

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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

**Reshape the portfolio**

To reshape the portfolio, we segmented our businesses focusing on three targets: to sustain leadership, build competitive positions, and explore strategic options.

**Sustain leadership**

**Diabetes and Cardiovascular Diseases.** We remain committed to fighting the global epidemic of diabetes and to treating cardiovascular disease, the leading cause of death globally. Our three priorities over the next few years are to develop the insulin franchise with Lantus®, Toujeo®, and Soliqua 100/33 / Suliquala and other selected insulins; strengthen our pipeline; and lead the market shift to managing diabetes outcomes. In 2017, notable product achievements included continued global momentum behind Toujeo®; the launch of Soliqua 100/33/Suliqua™ in the US and Europe; approval in the US and Europe of our insulin lispro biosimilar; and ongoing development of our future assets (including sotagliflozin in Phase III, epeglenatide in Phase III, and our co-agonist drug candidates in Phase I and II). We are also committed to lead the market shift to managing diabetes outcomes. In 2016, we established Onduo, our diabetes solutions joint venture with world-class partner Verily. We have also made investments in several Integrated Care solutions across various geographies.

In cardiovascular, we have the opportunity to transform the management of hypercholesterolemia through Praluent®, developed jointly with Regeneron. In a challenging payer environment, we continue to work on securing access for patients to this important medication. We look forward to the results of the ODYSSEY cardiovascular outcomes study of 18,000 patients, which will be released in the first quarter of 2018.

**Vaccines.** Our growth will be driven by leading products in flu and by pediatric combinations. Demand typically exceeds supply, so a key priority for us is to produce more. We are investing to secure and expand flu and pediatric capacity. In 2017, to expand our vaccine product portfolio we (i) completed the acquisition of Protein Sciences, adding Flublok® (the only recombinant protein-based influenza vaccine approved by the US) to our influenza vaccine portfolio and (ii) agreed a collaboration with Medimmune to develop and commercialize a monoclonal antibody for the prevention of respiratory syncytial virus (RSV). In addition, our European business has been consolidated and simplified with dissolution of the joint venture with MSD.

**Rare Diseases.** We continue to sustain our market share leadership in rare genetic diseases through the patient-centered approach unique to Sanofi Genzyme, alongside product differentiation and market access. We continue to grow the market through screening expansion. We also expect to advance our strong pipeline, where four of our assets have received breakthrough or fast-track designation from the FDA. In January 2018, we and Alnylam restructured our RNAi therapeutics

alliance: we now have broader rights to fitusiran (in development for the treatment of people with hemophilia A and B), while Alnylam has broader rights to its investigational RNAi therapeutics programs for the treatment of ATTR amyloidosis, including patisiran and ALN-TTRsc02.

**Consumer Healthcare.** On January 1, 2017, Sanofi and Boehringer Ingelheim (BI) successfully closed in most markets a transaction to swap Sanofi's Animal Health and BI's CHC businesses. With this transaction, we acquired BI's CHC business in most markets and enhanced our position in four strategic categories: Allergy Cough & Cold, Pain, Digestive and Nutritionals. Since then, we have successfully integrated BI's CHC business; rejuvenated management of the Consumer Healthcare business; and defined a growth model and target operating model. We have also launched portfolio complexity reduction programs and identified key areas for internal and external growth.

**Emerging Markets.** We are the pharmaceutical industry leader in emerging markets and a major multinational player in the BRIC-M countries (Brazil, Russia, India, China and Mexico).

#### **Build competitive positions**

**Multiple Sclerosis.** We already have a competitive position in multiple sclerosis. We will continue to maximize our support to these products through life cycle management in a competitive market and we intend to strengthen our portfolio. Investing for the future, we have signed a licensing agreement with Principia to develop their experimental oral treatment (Bruton's tyrosine kinase inhibitor) that shows promise in multiple sclerosis and, potentially, other central nervous system diseases.

**Oncology.** We are rebuilding our oncology portfolio. We intend to maximize our clinical assets, particularly isatuximab (an anti-CD38 monoclonal antibody in late stage development for multiple myeloma) and cemiplimab (a PD-1 inhibitor derived from our alliance with Regeneron, in development for first line treatment of non small cell lung cancer, second line treatment of cervical cancer, the treatment of basal cell carcinoma and the treatment of advanced cutaneous squamous cell carcinoma). In January 2018, we announced that we and Regeneron will accelerate and expand investment in the clinical development of cemiplimab in oncology, and dupilumab in Type 2 allergic diseases.

**Immunology.** We have the cornerstones of an important new franchise in immunology through Kevzara® (for rheumatoid arthritis) and Dupixent® (developed in several indications including atopic dermatitis, asthma and nasal polyposis). Both drugs were developed in collaboration with Regeneron and both were launched in 2017. We aim to lead in atopic dermatitis with Dupixent®, which was the first in class biologic to reach the market. An important milestone was achieved with the dupilumab Phase III study in uncontrolled persistent asthma which met its two primary endpoints; we filed for this indication and we expect to receive a decision from the FDA by October 20, 2018. Also in





**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

2017 we entered into a research collaboration and global exclusive licensing agreement with Ablynx, focused on Nanobody<sup>®</sup>-based therapeutics for the treatment of various immune-mediated inflammatory diseases.

**Explore strategic options**

**Animal Health.** We have fully exited the Animal Health business through the swap with BI.

**Generics in Europe.** As announced, we carefully reviewed all options for our European Generics business. We announced the divestment earlier this year and signing of definitive transaction agreements<sup>(1)</sup> on the divestiture of European Generics is expected in the third quarter of 2018.

**Deliver outstanding launches**

Our second strategic priority is to deliver outstanding launches of new medicines and vaccines. We have focused the organization on six major product launches: Toujeo<sup>®</sup>, Praluent<sup>®</sup>, Dengvaxia<sup>®</sup>, Soliqua 100/33/ Suliqua , Kevzara<sup>®</sup>, and Dupixent<sup>®</sup>.

In 2017 we launched Dupixent<sup>®</sup>, the first and only biologic medicine for the treatment of adults with moderate-to-severe atopic dermatitis. Dupixent<sup>®</sup> uptake to date is being driven by high patient need, healthcare professional engagement and initial market access. Also in 2017, we launched Kevzara<sup>®</sup> for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

We continued the global launch and ramp-up of Toujeo<sup>®</sup> in diabetes; Praluent<sup>®</sup> for hypercholesterolemia; and Soliqua 100/33/ Suliqua , a combination of lixisenatide and insulin glargine treatment for diabetes, whose market access in the US is progressing.

Dengvaxia<sup>®</sup> uptake will most likely be impacted by product label updates to reflect new analysis of long-term data, which found differences in Dengvaxia<sup>®</sup> performance based on prior dengue infection.

**Sustain innovation in R&D**

Our strategy depends on continued innovation in R&D. We continue to strengthen our R&D pipeline, increasing the number of high-quality projects in the early stage pipeline and replenishing the late development pipeline as products launch. Having delivered real improvements in development productivity, we are now particularly focused on improving research productivity. We have aligned the R&D organization with the new Global Business Unit structure, reorganized research into thematic clusters, continued to build capability in translational science, and recruited important new talent.

We have moved and rebalanced our portfolio towards biologics especially through our collaboration with Regeneron for monoclonal

antibodies. At the same time, we have worked internally to develop our own proprietary platforms such as multi-specific antibodies to go from a mono-targeting to a multi-targeting world.

Our R&D investments will follow our business priorities, focusing on those businesses where we aim to sustain leadership and build competitive positions.

### **Simplify the organization**

We are creating a more agile organization through a strategic cost savings program, which has delivered 1.5 billion from 2015 to 2017:

Simplification via the implementation in 2016 of a new Global Business Unit structure, integrating global franchises and country-level commercial and medical organizations for each of our major businesses (Sanofi Genzyme; Diabetes and Cardiovascular; General Medicines and Emerging Markets; Sanofi Pasteur and Consumer Healthcare), and via the creation of Global Functions (Finance, Human Resources, Information Technology and Solutions, etc);

Operational improvement and productivity efforts in Industrial Affairs;

Product portfolio streamlining in our Established Products franchise; and

Resizing of sales forces to reflect evolving market dynamics.

In parallel, we have made reinvestment decisions scaled to the needs of the business and have continued to strengthen our Medical Affairs and External Affairs functions. We have also united the different parts of the Company behind a single vision, a common set of values and a shared culture.

## **B.2. Main pharmaceutical products**

The sections below provide additional information on our main products. Our intellectual property rights over our pharmaceutical products are material to our operations and are described at B.7. Patents, Intellectual Property and Other Rights below. As disclosed in Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Patents of this annual report, we are involved in significant litigation concerning the patent protection of a number of these products. For more information on sales performance, see Item 5. Operating and Financial Review and Prospects Results of Operations .

### **a) Rare Diseases**

Our Rare Diseases business is focused on products for the treatment of rare genetic diseases and other rare chronic debilitating diseases, including lysosomal storage disorders (LSDs), a group of metabolic disorders caused by enzyme deficiencies.

*(1) Following completion of the dialogue with employee representatives.*

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

**Cerezyme®**

Cerezyme® (imiglucerase for injection) is an enzyme replacement therapy used to treat Gaucher disease, an inherited, potentially life-threatening LSD. It is estimated that Gaucher disease occurs in approximately one in 120,000 newborns in the general population and one in 850 in the Ashkenazi Jewish population worldwide, but the incidence and patient severity vary among regions.

Cerezyme® is the only therapy with a 25-year history of reducing, relieving and reversing many of the symptoms and risks of Type 1 and Type 3 (in certain markets) Gaucher disease. Cerezyme® is administered by intravenous infusion over one or two hours.

The principal markets for Cerezyme® are the US, Germany, Italy, France and Turkey.

**Cerdelga®**

Cerdelga® (eliglustat) is the first and only first-line oral therapy for Gaucher disease Type 1. A potent, highly specific ceramide analogue inhibitor of GL-1 synthesis with broad tissue distribution, Cerdelga® has demonstrated efficacy in the treatment of naive Gaucher disease patients and in patients who switch from enzyme replacement therapy (ERT).

Cerdelga® was approved by the FDA in August 2014 and by the European Commission in January 2015; the product is now available in several European countries. It was approved in Japan in March 2015 and launched in the same year. Regulatory submissions are ongoing in other countries.

The largest market for Cerdelga® and for Gaucher disease overall is the US.

**Myozyme® and Lumizyme®**

Myozyme® and Lumizyme® (alglucosidase alfa) are enzyme replacement therapies used to treat Pompe disease, an inherited, progressive and often fatal LSD. Pompe disease occurs in approximately one in 40,000 newborns worldwide, but the incidence and patient severity vary among regions.

Myozyme® has been marketed since 2006 in the US and the EU and is approved in more than 70 countries. Outside the US, Myozyme® is marketed for patients with both infantile- and late-onset disease. Lumizyme® has been marketed in the US since June 2010. Initially designed specifically to treat patients with late-onset Pompe disease and patients

over eight years of age without evidence of cardiac hypertrophy, on August 1, 2014 it was approved for infantile-onset Pompe disease.

Myozyme<sup>®</sup> and Lumizyme<sup>®</sup> are administered by intravenous infusion once every two weeks. Both products are recombinant forms of the same human enzyme.

The principal markets for Myozyme<sup>®</sup> are the US, Germany, Italy, the Netherlands and the UK.

### **Fabrazyme<sup>®</sup>**

Fabrazyme<sup>®</sup> (agalsidase beta) is an enzyme replacement therapy used to treat Fabry disease, an inherited, progressive and potentially life threatening LSD. Fabry disease occurs in approximately one in 35,000 newborns worldwide, but the incidence and patient severity vary among regions.

Fabrazyme<sup>®</sup> has been marketed in the EU since 2001 and in the US since 2003, and is approved in more than 70 countries. Fabrazyme<sup>®</sup> is administered by intravenous infusion once every two weeks.

The principal markets for Fabrazyme<sup>®</sup> are the US, Japan, France, Italy and the UK.

### **Aldurazyme<sup>®</sup>**

Aldurazyme<sup>®</sup> (laronidase) is the first and only approved treatment for mucopolysaccharidosis type 1 (MPS 1). A human recombinant enzyme therapy with over 13 years of clinical post-marketing experience, Aldurazyme<sup>®</sup> has been shown to be safe and effective in symptomatic MPS 1 patients of all phenotypes. MPS 1 occurs in approximately one per 100,000 live births worldwide, but the incidence and patient severity vary among regions. Aldurazyme<sup>®</sup> is administered once weekly as an intravenous infusion

The principal markets for Aldurazyme<sup>®</sup> are the US, France, the UK, Japan and Germany.

## **b) Multiple Sclerosis**

Multiple sclerosis (MS) is an autoimmune disease in which a person's immune system attacks the central nervous system, damaging myelin, the protective sheath that covers nerve fibers. This causes a break in communication between the brain and the rest of the body, ultimately destroying the nerves themselves, and causing irreversible damage. More than 2.5 million people suffer from MS worldwide.

Our MS franchise consists of Aubagio<sup>®</sup> (teriflunomide), a once-daily, oral immunomodulator, and Lemtrada<sup>®</sup> (alemtuzumab), a monoclonal antibody. Both products have been developed to treat patients with relapsing forms of MS.

### **Aubagio<sup>®</sup>**

Aubagio<sup>®</sup> (teriflunomide), a small molecule immunomodulatory agent with anti-inflammatory properties, reversibly inhibits dihydroorotate dehydrogenase, a mitochondrial enzyme involved in the de novo pyrimidine synthesis required for activated lymphocytes to multiply. The exact mechanism by which teriflunomide exerts its therapeutic effect in MS is unknown but may involve a reduction in the number of activated lymphocytes in the central nervous system. Aubagio<sup>®</sup> is a once-daily oral therapy. Aubagio<sup>®</sup> has shown significant efficacy across key measures of MS disease activity, including slowing the progression of physical disability, reducing relapses, and reducing the number of brain lesions as detected by magnetic resonance imaging (MRI).



**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

Aubagio® is the first and only oral MS therapy to significantly slow the progression of disability in two Phase III trials (TEMPO and TOWER). Consistent with its effect on slowing disability progression, Aubagio® is the only oral therapy shown to prevent or delay a second clinical attack in patients who have experienced initial neurological symptoms suggestive of MS (TOPIC trial).

Ongoing development efforts include the TeriKIDS study to assess the safety and efficacy of teriflunomide in children (10-17 years old) and global post-marketing registries for pregnancy.

Aubagio® was granted marketing authorization by the FDA in September 2012 for the treatment of patients with relapsing forms of MS, and by the European Commission in August 2013 for the treatment of adult patients with relapsing remitting MS. Aubagio® is now approved in more than 70 countries around the world.

In 2017, Sanofi reached settlement with all 20 generic Aubagio® ANDA first filers granting each a royalty-free license to enter the United States market on March 12, 2023. See Item 8. Financial Information A. Consolidated financial statements and other financial information .

The principal markets for Aubagio® in terms of sales are the US, Germany, France, the UK, Canada, Spain and Italy.

**Lemtrada®**

Lemtrada® (alemtuzumab) is a humanized monoclonal antibody targeting the CD52 antigen. The exact mechanism by which alemtuzumab exerts its therapeutic effect in MS is unknown. Research suggests immunomodulatory effects through the selective depletion and repopulation of T and B lymphocytes, resulting in a resetting of the immune system. Lemtrada® is administered as two short courses 12 months apart; for the majority of patients no further treatment is necessary, making Lemtrada® the only disease-modifying therapy (DMT) that can provide long term durable efficacy in the absence of continuous dosing.

Lemtrada® was able to show statistically significant improvement across many key measurements of MS disease activity including improvement in physical disability, reducing relapses, and reducing the number of brain lesions as detected by MRI. Lemtrada® is the first and only approved DMT to show an improvement in six-month confirmed disability improvement (CDI) against an active comparator (CARE MS II study). Lemtrada® was also able to reduce brain volume loss over six years to levels seen in healthy controls, despite the majority of Lemtrada® patients



receiving no treatment after the initial two treatment courses (extension of CARE MS I and II studies).

In September 2013, Lemtrada<sup>®</sup> was granted marketing authorization by the European Commission for treatment of adult patients with relapsing forms of MS with active disease defined by clinical or imaging features. In November 2014, the FDA approved Lemtrada<sup>®</sup> for the treatment of patients with relapsing forms of multiple sclerosis. Because of its safety profile, the FDA approval

limited use of Lemtrada<sup>®</sup> to patients who have had an inadequate response to two or more drugs indicated for the treatment of MS and included a black-box warning on potential side effects. Lemtrada<sup>®</sup> is only available in the US through a restricted program called the Lemtrada<sup>®</sup> Risk Evaluation and Mitigation Strategy (REMS) Program. Lemtrada<sup>®</sup> is currently approved in more than 60 countries with additional marketing applications under review by regulatory authorities globally.

Alemtuzumab is being evaluated in a Phase III study to assess the safety and efficacy in pediatric patients with relapsing remitting form of multiple sclerosis.

The principal markets for Lemtrada<sup>®</sup> in terms of sales are the US, the UK, Germany, Spain, Canada and Italy.

Bayer Healthcare receives contingent payments based on alemtuzumab global sales revenue. For additional information, see Note D.18. to the consolidated financial statements included at Item 18 of this annual report.

### **c) Immunology**

Our Immunology franchise consists of Dupixent<sup>®</sup> (dupilumab), the first and only biologic medicine for the treatment of adults with moderate-to-severe atopic dermatitis (AD), and Kevzara<sup>®</sup> (sarilumab) for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA).

#### **Dupixent<sup>®</sup>**

Dupixent<sup>®</sup> (dupilumab), a human monoclonal antibody, binds to the interleukin-4 receptor (IL-4R) and has been shown to specifically inhibit overactive signaling of two key proteins, IL-4 and IL-13, which are believed to be major drivers of the persistent underlying inflammation in atopic dermatitis, and certain other allergic or atopic diseases.

Atopic dermatitis, a form of eczema, is a chronic inflammatory disease with symptoms often appearing as a rash on the skin. Moderate-to-severe atopic dermatitis is characterized by rashes sometimes covering much of the body, and can include intense, persistent itching and skin dryness, cracking, redness, crusting and oozing. Itch is one of the most burdensome symptoms for patients and can be debilitating.

The global LIBERTY AD clinical trial program, which included nearly 3,000 patients, examined the use of Dupixent<sup>®</sup> either alone or with topical corticosteroids in patients with inadequately controlled moderate-to-severe AD. In all these studies, Dupixent<sup>®</sup> alone or with topical corticosteroids met the primary and key secondary endpoints.

Dupixent<sup>®</sup> comes in a pre-filled syringe and can be self-administered as a subcutaneous injection every other week after an initial loading dose. Dupixent<sup>®</sup> can be used with or without topical corticosteroids.

Dupixent<sup>®</sup> was granted marketing authorization by the FDA in March 2017 for the treatment of adults with moderate-to-severe atopic



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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

dermatitis whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Dupixent<sup>®</sup> was evaluated by the FDA with Priority Review. This followed the FDA's 2014 Breakthrough Therapy designation for Dupixent<sup>®</sup> for inadequately controlled moderate-to-severe AD. In September 2017, the European Commission approved Dupixent<sup>®</sup> for use in adults with moderate-to-severe AD who are candidates for systemic therapy. Applications for regulatory approval have also been submitted in several other countries and are being reviewed.

Dupixent<sup>®</sup> is available in the US (since April 2017) and in Germany (since December 2017).

Dupixent<sup>®</sup> is developed and commercialized in collaboration with Regeneron Pharmaceuticals, Inc. For additional information on the commercialization of this product, see Item 5. Financial Presentation of Alliances Alliance Arrangements with Regeneron .

Dupilumab is currently being evaluated in a broad range of clinical development programs for diseases that are driven by Type 2 inflammation, including uncontrolled persistent asthma (we filed for this indication and we expect to receive a decision from the FDA by October 20, 2018), adolescent and pediatric atopic dermatitis, pediatric asthma, nasal polyps and eosinophilic esophagitis. See B.5. Global Research & Development

There are ongoing patent infringement proceedings in several countries initiated by Sanofi and Regeneron against Amgen and Immunex relating to Dupixent<sup>®</sup>. See Note D.22.b) to the consolidated financial statements included at Item 18 of this annual report and Item 8. Financial Information B. Significant changes of this annual report for more information.

**Kevzara<sup>®</sup>**

Kevzara<sup>®</sup> (sarilumab) is a human monoclonal antibody that binds to the interleukin-6 receptor (IL-6R) and has been shown to inhibit IL-6R mediated signaling. IL-6 is a cytokine in the body that, in excess and over time, can contribute to the inflammation associated with rheumatoid arthritis.

Rheumatoid arthritis is a chronic inflammatory autoimmune disease which carries substantial burden. In RA, the immune system attacks the tissues of the joints, causing inflammation, pain, and eventually joint damage and disability. RA most often strikes people between 30 and 60 years old; however, it can occur in adults at any age.

The global SARIL-RA clinical development program, which evaluated Kevzara<sup>®</sup>, incorporated data from more than 3,300 adults with moderately to severely active RA who had an inadequate response to previous treatment regimens. In two pivotal Phase 3 clinical trials (MOBILITY study in methotrexate inadequate responders and TARGET study in inadequate responders to anti-TNF treatment), Kevzara<sup>®</sup> plus background disease modifying anti-rheumatic drugs (DMARDs) demonstrated statistically significant, clinically-meaningful improvements.

In May 2017, the FDA approved Kevzara<sup>®</sup> for the treatment of adult patients with moderately to severely active RA who have had

an inadequate response or intolerance to one or more DMARDs, such as methotrexate. In June 2017, the European Commission granted marketing authorization for Kevzara<sup>®</sup> in combination with methotrexate for the treatment of moderately to severely active RA in adult patients who have responded inadequately to or who are intolerant to one or more DMARDs, such as methotrexate.

Kevzara<sup>®</sup> was launched in Canada in February 2017, in the US in June 2017, and in Germany, the Netherlands and the UK during the second half of 2017.

Kevzara<sup>®</sup> is developed and commercialized in collaboration with Regeneron Pharmaceuticals, Inc. For additional information on the commercialization of this product, see Item 5. Financial Presentation of Alliances Alliance Arrangements with Regeneron .

Sarilumab is being evaluated in Phase II studies in children and adolescents with polyarticular-course juvenile idiopathic arthritis (JIA) and with systemic JIA.

#### **d) Oncology**

##### **Jevtana<sup>®</sup>**

Jevtana<sup>®</sup> (cabazitaxel), a cytotoxic agent, is a semi-synthetic taxane promoting tubulin assembly and stabilizing microtubules, approved in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

Jevtana<sup>®</sup> was granted marketing authorization by the FDA in June 2010, by the European Commission in March 2011, and in Japan in July 2014. The product is now approved in over 85 countries.

The main countries contributing to sales of Jevtana<sup>®</sup> in 2017 were the US, France, Germany, Japan, Italy and Spain.

##### **Taxotere<sup>®</sup>**

Taxotere<sup>®</sup> (docetaxel), a taxoid class derivative, inhibits cancer cell division by essentially freezing the cell's internal skeleton, which is comprised of microtubules. Microtubules assemble and disassemble during a cell-division cycle. Taxotere<sup>®</sup> promotes their assembly and blocks their disassembly, thereby preventing many cancer cells from dividing, which ultimately results in destroying many cancer cells.

Taxotere<sup>®</sup> is available in more than 90 countries as an injectable solution. It has been approved for use in 11 indications in five different tumor types (breast, prostate, gastric, lung, and head and neck).

Generics of docetaxel have been launched globally.

Sanofi is involved in Taxotere<sup>®</sup> product litigation in the US. See Note D.22.a) to the consolidated financial statements included at Item 18 of this annual report.



**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

**Eloxatin®**

Eloxatin® (oxaliplatin) is a platinum-based cytotoxic agent. Eloxatin®, in combination with infusional administration of two other chemotherapy drugs, 5-fluorouracil/leucovorin (the FOLFOX regimen), is approved by the FDA for adjuvant treatment of people with stage III colon cancer who have had their primary tumors surgically removed. This approval was based on evidence of an improvement in disease-free survival after four years.

Eloxatin® is in-licensed from Debiopharm and is marketed in more than 70 countries worldwide.

Generics of oxaliplatin have been launched globally.

**Thymoglobulin®**

Thymoglobulin® (anti-thymocyte Globulin) is a polyclonal anti-human thymocyte antibody preparation that acts as a broad immunosuppressive and immunomodulating agent. The product's primary mechanism of action is T-cell depletion, which is complemented by a host of other immunomodulating effects. Thymoglobulin® is currently marketed in over 65 countries. Depending on the country, Thymoglobulin® is indicated for the treatment and/or prevention of acute rejection in organ transplantation; immunosuppressive therapy in aplastic anemia; and the treatment and/or prevention of Graft-versus-Host Disease (GvHD) after allogeneic hematopoietic stem cell transplantation.

The main countries contributing to Thymoglobulin® sales in 2017 were the US, China, France, Japan and South Korea.

**Mozobil®**

Mozobil® (plerixafor injection) is a hematopoietic stem cell mobilizer indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

The largest market for Mozobil® is the US.

## Zaltrap®

Zaltrap® (aflibercept/ziv-aflibercept) is a recombinant fusion protein which acts as a soluble decoy receptor that binds to Vascular Endothelial Growth Factor-A (VEGF-A), Vascular Endothelial Growth Factor-B (VEGF-B) and placental growth factor (PlGF), preventing the bound VEGF from binding to their native receptors. VEGF-A is one of the mediators contributing to angiogenesis. VEGF-B and PlGF, related growth factors in the VEGF family, may contribute to tumor angiogenesis as well.

The FDA approved Zaltrap® in August 2012 for use in combination with FOLFIRI (chemotherapy regimen made of 5-fluorouracil/leucovorin/irinotecan), in patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. To avoid confusion with Eylea®, the

FDA assigned a new name, ziv-aflibercept, to the active ingredient. The European Commission approved Zaltrap® (aflibercept) in February 2013 to treat mCRC that is resistant to or has progressed after an oxaliplatin-containing regimen.

Zaltrap® is now approved in more than 70 countries worldwide. For additional information on Zaltrap® commercialization, see Item 5 Financial Presentation of Alliances Alliance Arrangements with Regeneron .

The principal markets for Zaltrap® are France, Germany, the US, Spain and Italy.

## e) Diabetes

The prevalence of diabetes is expected to increase significantly by 2030, reflecting multiple socio-economic factors including sedentary lifestyles, excess weight and obesity, unhealthy diet and an aging population.

Our main diabetes products are Lantus® and Toujeo®, long acting analogs of human insulin; Apidra®, a rapid acting analog of human insulin; Insuman®, a range of human insulin; Adlyxin®/Lyxumia® (lixisenatide), a once-daily injectable prandial GLP-1 receptor agonist; Soliqua 100/33 / Suliqua , an injectable once-daily insulin glargine and lixisenatide combination; and Admelog®/Insulin lispro Sanofi®, follow-on/biosimilar of insulin lispro, a rapid-acting insulin analog.

## Lantus®

Lantus® (insulin glargine) is a long-acting analog of human insulin, indicated for once-daily subcutaneous administration in the treatment of adult patients with type 2 diabetes who require basal insulin for the control of hyperglycemia, and for adult and pediatric patients (label extension for pediatric use was granted in the EU in 2012) aged two years and over with type 1 diabetes.

Lantus® is the most-studied basal insulin, with 16 years of clinical evidence in diabetes treatment and a well-established safety profile.

Lantus® can be administered subcutaneously using syringes or specific pens including:

Lantus® SoloSTAR®, a pre-filled disposable pen available in over 120 countries worldwide, that combines a low injection force of up to 80 units per injection with ease of use; and

AllSTAR<sup>®</sup>, a reusable insulin pen developed specially for people with diabetes in emerging markets, indicated for use with Sanofi's insulin portfolio. AllSTAR<sup>®</sup> is currently available in a dozen countries, mostly in emerging markets.

Lantus<sup>®</sup> is available in over 130 countries worldwide. The leading countries for sales of Lantus<sup>®</sup> in 2017 were the US, China, France and Germany.

A biosimilar of Lantus<sup>®</sup> from Eli Lilly and Company (Lilly) was launched in most European markets under the name Abasaglar<sup>®</sup> in



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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

2015; the same product was launched in the US in December 2016 as Basaglar<sup>®</sup>. It has also been launched in Japan and in several other countries worldwide. The FDA has granted tentative approval for Merck's follow-on glargine insulin, it was approved by the EMA in January 2017 but has not launched as of yet. Mylan's application for its follow-on glargine insulin is under FDA regulatory review and received a CHMP positive opinion in January 2018.

There are ongoing patent infringement proceedings in the US against Merck and Mylan. See Note D.22.b) to the consolidated financial statements included at Item 18 of this annual report and Item 8. Financial Information B. Significant changes of this annual report for more information.

**Toujeo<sup>®</sup>**

Toujeo<sup>®</sup> (insulin glargine 300 units/mL) has been granted marketing authorization by the FDA (February 2015); the European Commission (April 2015); and the Ministry of Health, Labor and Welfare (J-MHLW) in Japan, where its approved brand name is Lantus<sup>®</sup> XR (June 2015).

Toujeo<sup>®</sup> is available in Toujeo<sup>®</sup> SoloSTAR<sup>®</sup>, a disposable prefilled pen which contains 450 units of insulin glargine and requires one third of the injection volume to deliver the same number of insulin units as Lantus<sup>®</sup> SoloSTAR<sup>®</sup>. The maximum single injection dose of 80 IU meets the needs of the vast majority of patients on basal insulin in the US, who require 80 IU or less per day.

Toujeo<sup>®</sup> has now been launched in more than 40 countries. Toujeo<sup>®</sup> is currently pending marketing authorization with other health authorities around the world. The principal markets for Toujeo<sup>®</sup> are the US, Germany, Russia, Spain and Japan.

**Apidra<sup>®</sup>**

Apidra<sup>®</sup> (insulin glulisine) is a rapid-acting analog of human insulin, indicated for the treatment of adults with type 1 or type 2 diabetes for supplementary glycemetic control. Apidra<sup>®</sup> has a more rapid onset and shorter duration of action than fast-acting human insulin and can be used in combination with long-acting insulins such as Lantus<sup>®</sup> for supplementary glycemetic control at mealtimes. Apidra<sup>®</sup> can be administered subcutaneously using syringes or specific pens including the Apidra<sup>®</sup> SoloSTAR<sup>®</sup> disposable pen.

Apidra<sup>®</sup> is available in over 100 countries worldwide. The principal markets are the US, Germany, Japan, Italy and France.

## Insuman®

Insuman® (human insulin) is a range of insulin solutions and suspensions for injection and is indicated for diabetes patients when treatment with insulin is required. Human insulin is produced by recombinant DNA technology in *Escherichia coli* strains. Insuman® is supplied in vials, cartridges, and pre-filled disposable pens (SoloSTAR®). The Insuman® range is comprised of rapid-acting insulin solutions (Insuman® Rapid and Insuman® Infusat)

that contain soluble insulin, an intermediate-acting insulin suspension (Insuman® Basal) that contains isophane insulin, and combinations of fast-acting and intermediate-acting insulins in various proportions (Insuman® Comb).

Insuman® is principally sold in emerging markets.

## Adlyxin®/Lyxumia®

Adlyxin® or Lyxumia® (lixisenatide) is a once-daily injectable prandial GLP-1 receptor agonist and is indicated for the treatment of adults with type 2 diabetes to achieve glycemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycemic control.

In February 2013, the European Commission granted marketing authorization in Europe for Lyxumia®. On completion of pricing and reimbursement discussions, Sanofi initiated a phased launch of Lyxumia® in most EU countries. Lixisenatide was approved by the FDA in July 2016 under the brand name of Adlyxin® after the results of the ELIXA trial demonstrated cardiovascular safety in type 2 diabetes patients with high cardiovascular risk; Adlyxin® was launched in the US in January 2017. Lixisenatide is approved under the proprietary name Lyxumia® in more than 60 countries and marketed in over 40. Lixisenatide was in-licensed from Zealand Pharma A/S.

## Soliqua 100/33 / Suliqua

Soliqua 100/33 or Suliqua is a once-daily fixed-ratio combination of insulin glargine 100 Units/mL, a long-acting analog of human insulin, and lixisenatide, a GLP-1 receptor agonist. It has been studied in a Phase III program of more than 1,900 patients.

The FDA approved Soliqua 100/33 in November 2016 for the treatment of adults with type 2 diabetes inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide. Soliqua 100/33 is now available in the US (since January 2017) in a single pre-filled pen for once-daily dosing covering 15 to 60 units of insulin glargine 100 units/mL and 5 to 20 mcg of lixisenatide using SoloSTAR® technology, the most frequently used disposable insulin injection pen platform in the world.

In January 2017, the European Commission granted marketing authorization in Europe for Suliqua (the product's brand name in Europe) for use in combination with metformin for the treatment of adults with type 2 diabetes to improve glycemic control when this has not been provided by metformin alone or metformin combined with another oral glucose-lowering medicinal product or with basal insulin. In Europe, Suliqua is available in two pens providing different dosing options. Within Europe, Suliqua was launched in the Netherlands in May 2017 and in Hungary and Sweden in November 2017.

Applications for regulatory approval have also been submitted in several other countries and are being reviewed.



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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

**Admelog<sup>®</sup> / Insulin lispro Sanofi<sup>®</sup>**

Admelog<sup>®</sup> or Insulin lispro Sanofi<sup>®</sup> is a rapid-acting insulin similar to Humalog<sup>®</sup>, another insulin lispro 100 Units/mL. Admelog<sup>®</sup> was approved by the FDA in December 2017, and was also granted marketing authorization as a biosimilar (under the proprietary name Insulin lispro Sanofi<sup>®</sup>) by the European Commission in July 2017. It is used to improve blood sugar control in adults with Type 2 diabetes and adults and children (3 years and older) with Type 1 diabetes. The Admelog<sup>®</sup> clinical development program involved more than 1,000 adults living with type 1 or type 2 diabetes.

Admelog<sup>®</sup> comes in both vials and the SoloStar pen, and was launched in the US in January 2018.

**Integrated Care Solutions**

Sanofi and Verily Life Sciences LLC (formerly Google Life Sciences), an Alphabet company, announced in September 2016 the launch of Onduo, a joint venture created through Sanofi and Verily's diabetes-focused collaboration. The joint venture is based in Cambridge, Massachusetts (United States). Onduo's mission is to help people with diabetes live full, healthy lives by developing comprehensive solutions that combine devices, software, medicine, and professional care to enable simple and intelligent disease management.

**f) Cardiovascular Diseases**

**Praluent<sup>®</sup>**

Praluent<sup>®</sup> (alirocumab) is a human monoclonal antibody (mAb) that blocks the interaction of proprotein convertase subtilisin/kexin type 9 (PCSK9) with low-density lipoprotein (LDL) receptors, increasing the recycling of LDL receptors and reducing LDL cholesterol levels.

Praluent<sup>®</sup> has been extensively studied through the ODYSSEY Phase III program with 16 global trials including more than 23,500 patients in more than 40 countries to evaluate the product's efficacy and safety across various high cardiovascular risk patients (due to but not limited to diabetes, family hypercholesterolemia or previous cardiovascular events) including patients with heterozygous familial hypercholesterolemia (HeFH), patients with primary hypercholesterolemia uncontrolled on statins and/or other lipid-modifying therapies, post acute coronary syndrome

(ACS) patients and as a monotherapy for patients who are unable to tolerate an effective dose of statins.

The effect of Praluent® on cardiovascular morbidity and mortality within the post ACS patient population is being investigated in the ODYSSEY OUTCOMES trial. Results are expected in the first quarter of 2018.

Praluent® has been granted marketing authorization by the FDA (July 2015), the European Commission (September 2015) and the Japanese Ministry of Health, Labor and Welfare (J-MHLW) (July 2016). Praluent® is indicated as an adjunct to diet and

maximally tolerated statin therapy in certain adult patients with uncontrolled LDL cholesterol. Praluent® is available in 75 mg and 150 mg dose injections for self-administration every two weeks.

Praluent® has been approved in more than 50 countries and launched in more than 30 countries including the US, Canada, Japan, Germany, the UK, Spain, Mexico and the UAE.

Praluent® is developed and commercialized in collaboration with Regeneron Pharmaceuticals, Inc. For additional information on the commercialization of this product, see Item 5. Financial Presentation of Alliances Alliance Arrangements with Regeneron .

There are ongoing patent infringement proceedings in several countries initiated against us and Regeneron Pharmaceuticals, Inc. by Amgen relating to Praluent® in which Amgen has requested injunctive reliefs. See Note D.22.b) to the consolidated financial statements included at Item 18 of this annual report.

### Multaq®

Multaq® (dronedarone) is an oral multichannel blocker with anti-arrhythmic properties for prevention of atrial fibrillation recurrences. Multaq® is among the most extensively studied anti-arrhythmic drugs in atrial fibrillation: it demonstrated a unique cardiovascular outcome benefit in the ATHENA study and effective rhythm control in the EURIDIS and ADONIS studies which was confirmed in real world investigations.

There are ongoing patent infringement proceedings in the US. For further information, see Item 8 Information on Legal or Arbitration Proceedings Multaq® Patent Litigation .

### g) Established Prescription Products

#### Plavix® / Iscover®

Plavix® or Iscover® (clopidogrel bisulfate), a platelet adenosine diphosphate (ADP) receptor antagonist with a rapid onset of action that selectively inhibits platelet aggregation induced by ADP, is indicated for the prevention of atherothrombotic events in patients with a history of recent myocardial infarction (MI), recent ischemic stroke or established peripheral arterial disease (PAD).

Plavix® is indicated for patients with acute coronary syndrome (ACS):

For patients with non-ST-segment elevation ACS, including unstable angina/nonQ-wave myocardial infarction, Plavix® has been shown to decrease the rate of a combined endpoint of cardiovascular death, MI or stroke, as well as the rate of a combined endpoint of cardiovascular death, MI, stroke, or refractory ischemia. This applies equally to patients who are to be managed medically, and those who are to be managed with percutaneous coronary intervention (with or without stent) or coronary artery bypass grafting.



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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

For patients with ST-segment elevation acute myocardial infarction, Plavix<sup>®</sup> has been shown to reduce the rate of death from any cause and the rate of a combined endpoint of death, re-infarction or stroke. Plavix<sup>®</sup> is also indicated in combination with acetylsalicylic acid (ASA) for the prevention of atherothrombotic and thromboembolic events in atrial fibrillation, including stroke.

CoPlavix<sup>®</sup> / DuoPlavin<sup>®</sup>, a fixed-dose combination of clopidogrel bisulfate and ASA, is indicated for the prevention of atherothrombotic events in adult patients with acute coronary syndrome who are already taking both clopidogrel and ASA.

Plavix<sup>®</sup> or Iscover<sup>®</sup> are marketed in more than 80 countries. For additional information on the commercialization of these products, see Item 5. Financial Presentation of Alliances Alliance Arrangements with Bristol-Myers Squibb .

A number of generics have been launched in Europe, the US and other markets. In Japan, generics were launched in June 2015 for the stroke indication, in October 2015 for MI and in December 2016 for the PAD indication, the last protected indication.

Plavix<sup>®</sup> is the leading anti-platelet in the Chinese market. The main countries contributing to sales of Plavix<sup>®</sup> / Iscover<sup>®</sup> in 2017 were China and Japan.

Sanofi is involved in Plavix<sup>®</sup> product litigation in the US. See Note D.22.a) to the consolidated financial statements included at Item 18 of this annual report.

**Lovenox<sup>®</sup> / Clexane<sup>®</sup>**

Lovenox<sup>®</sup> or Clexane<sup>®</sup> (enoxaparin sodium) is registered for a wider range of clinical indications than any other low molecular weight heparin (LMWH). Its comprehensive clinical dossier has demonstrated a favorable risk-benefit ratio, notably in the prophylaxis and treatment of venous thromboembolism and in the treatment of acute coronary syndrome. In the prevention of venous thromboembolism, the use of Lovenox<sup>®</sup> continues to grow, particularly in prophylaxis of deep vein thrombosis (DVT) in patients hospitalized for an acute medical condition.

In the US, three enoxaparin generics have been approved in addition to our own authorized generic. In the EU, the European Commission granted marketing authorizations to two enoxaparin biosimilars in September 2016. In 2017, two enoxaparin biosimilars were launched in Germany and one in the UK and Italy. One national marketing authorization has been granted in Poland where this biosimilar is available. We expect biosimilars to be launched in

additional countries.

Lovenox<sup>®</sup> or Clexane<sup>®</sup> is marketed in more than 100 countries.

### **Aprovel<sup>®</sup> / Avapro<sup>®</sup> / Karvea<sup>®</sup>**

Aprovel<sup>®</sup> or Avapro<sup>®</sup> or Karvea<sup>®</sup> (irbesartan) is an anti-hypertensive belonging to the class of angiotensin II receptor antagonists. These highly effective and well tolerated antagonists act by blocking the effect of angiotensin II, the hormone responsible for blood vessel contraction, thereby enabling blood pressure to return to normal. In addition to Aprovel<sup>®</sup> / Avapro<sup>®</sup> / Karvea<sup>®</sup>, we also market CoAprovel<sup>®</sup> / Avalide<sup>®</sup> / Karvezide<sup>®</sup>, a fixed-dose combination of irbesartan and hydrochlorothiazide (HCTZ), a diuretic that increases the excretion of water and sodium by the kidneys and provides an additional blood pressure lowering effect.

Aprovel<sup>®</sup> and CoAprovel<sup>®</sup> tablets are available in a wide range of dosages to fit the needs of patients with different levels of hypertension severity.

Aprovel<sup>®</sup> is indicated as a first-line treatment for hypertension and for the treatment of nephropathy in hypertensive patients with type 2 diabetes. CoAprovel<sup>®</sup> is indicated for patients whose blood pressure is not adequately controlled with a monotherapy, but also as initial therapy in patients at high risk or with markedly high baseline blood pressure or who are likely to need multiple drugs to achieve their blood pressure goals.

A fixed-dose combination with amlodipine (Aprovasc<sup>®</sup>) has been launched in several emerging market countries.

Aprovel<sup>®</sup> and CoAprovel<sup>®</sup> are marketed in more than 80 countries. For additional information on the commercialization of this product, see Item 5. Financial Presentation of Alliances Alliance Arrangements with Bristol-Myers Squibb. In Japan, the product is licensed to Shionogi Co. Ltd and BMS KK. BMS KK has sublicensed the agreement to Dainippon Pharma Co. Ltd.

A number of generics have been launched in Europe, the US and other markets.

The main countries contributing to sales of Aprovel<sup>®</sup> / Avapro<sup>®</sup> / Karvea<sup>®</sup> in 2017 were China and Japan.

### **Renagel<sup>®</sup> and Renvela<sup>®</sup>**

Renagel<sup>®</sup> (sevelamer hydrochloride) and Renvela<sup>®</sup> (sevelamer carbonate) are oral phosphate binders used by chronic kidney disease (CKD) patients on dialysis as well as late stage CKD patients in Europe to treat a condition called hyperphosphatemia, or elevated phosphorus levels, which is associated with heart and bone disease. Renvela<sup>®</sup> is a second-generation buffered phosphate binder.

In the US, there are an estimated 395,000 dialysis patients, approximately 90% of whom receive a phosphate binder. There are an estimated 350,000 dialysis patients in the EU and 65,000 in Brazil. In the EU, Renvela<sup>®</sup> is also approved to treat CKD patients not on dialysis.

Renagel<sup>®</sup> and Renvela<sup>®</sup> are marketed in more than 85 countries. In Japan and several Pacific Rim countries, Renagel<sup>®</sup> is marketed by Chugai Pharmaceutical Co., Ltd and its sublicensee, Kyowa Hakko Kirin Co., Ltd.

In the US, five sevelamer carbonate tablets generics and one sevelamer carbonate powder generic have been approved. In





**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

October 2017, Sanofi launched an authorized generic of Renvela<sup>®</sup> / Renagel<sup>®</sup> on the US market. Generics of sevelamer carbonate are currently marketed in various European countries. As of December 31, 2017, there are no generics of sevelamer hydrochloride approved in either Europe or in the US. We anticipate the first approvals of generics of sevelamer hydrochloride in the US in 2018.

The main countries contributing to sales of Renagel<sup>®</sup> and Renvela<sup>®</sup> in 2017 were the US, France, China, Saudi Arabia and Canada,

**Allegra<sup>®</sup> / Telfast<sup>®</sup>**

Allegra<sup>®</sup> or Telfast<sup>®</sup> (fexofenadine hydrochloride) is a long-lasting (12- and 24-hour) non-sedating prescription anti-histamine for the treatment of seasonal allergic rhinitis (hay fever) and uncomplicated hives. It offers patients significant relief from allergy symptoms without causing drowsiness.

We also market Allegra-D<sup>®</sup> 12 Hour and Allegra-D<sup>®</sup> 24 Hour, anti-histamine/decongestant combination products with an extended-release decongestant for effective non-drowsy relief of seasonal allergy symptoms, including nasal congestion. This combination is marketed in Japan under the Dellegra<sup>®</sup> brand name.

Generics of most forms of Allegra<sup>®</sup> / Telfast<sup>®</sup> have been approved in our major markets.

In the US, the Allegra<sup>®</sup> family moved to over-the-counter (OTC) use in adults and children aged two and over in 2011. Allegra<sup>®</sup> was also launched on the OTC market in Japan in November 2012, though it also remains available on prescription. See B.3. Consumer Healthcare below.

Allegra<sup>®</sup> / Telfast<sup>®</sup> is marketed in approximately 80 countries. The largest market for prescriptions of Allegra<sup>®</sup> is Japan, where competing generics entered the market in early 2013.

**Stilnox<sup>®</sup> / Ambien<sup>®</sup> / Myslee<sup>®</sup>**

Stilnox<sup>®</sup> (zolpidem tartrate) is indicated for the short-term treatment of insomnia. Stilnox<sup>®</sup> rapidly induces sleep that is qualitatively close to natural sleep and devoid of certain side effects that are characteristic of the benzodiazepine class as a whole. Its action lasts for a minimum of six hours and it is generally well tolerated, allowing the patient to

awaken without notably impaired attention, alertness or memory throughout the day.

Stilnox<sup>®</sup> is marketed in over 100 countries. It is available under the brand name Ambien<sup>®</sup> / Ambien<sup>®</sup>CR in the US and Myslee<sup>®</sup> in Japan, where it is co-promoted jointly with Astellas.

Stilnox<sup>®</sup> and Ambien CR<sup>®</sup> are subject to generic competition in most markets, including the US, Europe and Japan.

In 2017, the main countries contributing to Stilnox<sup>®</sup> / Ambien<sup>®</sup> / Myslee<sup>®</sup> sales were Japan and the US.

### **Synvisc<sup>®</sup> / Synvisc-One<sup>®</sup>**

Synvisc<sup>®</sup> and Synvisc-One<sup>®</sup> (hylan G-F 20) are viscosupplements used to treat pain associated with osteoarthritis. Synvisc<sup>®</sup> is indicated for the treatment of pain associated with osteoarthritis of the knee, hip, ankle, and shoulder joint in countries that have adopted CE marking, and for pain due to knee osteoarthritis in the US. Synvisc-One<sup>®</sup> is approved for use in patients with osteoarthritis of the knee in the US and countries that require CE marking. Currently the main viscosupplementation market is for the treatment of pain associated with osteoarthritis of the knee.

Synvisc<sup>®</sup> is a triple-injection product and Synvisc-One<sup>®</sup> a single-injection product. Both are administered directly into the intra-articular space of the joint to temporarily restore synovial fluid.

In 2017, the main countries contributing to Synvisc<sup>®</sup> and Synvisc-One<sup>®</sup> sales were the US, Mexico, Brazil and Canada.

### **Depakine<sup>®</sup>**

Depakine<sup>®</sup> (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 40 years and remains a reference treatment for epilepsy worldwide.

Depakine<sup>®</sup> is also a mood stabilizer, registered in the treatment of manic episodes associated with bipolar disorder<sup>(1)</sup>.

Depakine<sup>®</sup> is marketed in over 100 countries. We no longer hold any rights to Depakine<sup>®</sup> in the US, and sodium valproate generics are available in most markets.

Sanofi is involved in product litigation related to Depakine<sup>®</sup>. See Note D.22.a) to the consolidated financial statements included at Item 18 of this annual report.

## **h) Generics**

As announced, we carefully reviewed all options for our European Generics business in 2016. Following that detailed review of the business, we have taken a definitive decision to initiate a carve-out process of our generics business in Europe. Signing of definitive transaction agreements<sup>(2)</sup> on the divestiture of European Generics is expected in the third quarter of 2018. We have also confirmed our commitment to our Generics business in other parts of the world, and will further focus on emerging markets in order to develop this business in those countries.

## **B.3. Consumer healthcare**

With the strategic transaction between Boehringer Ingelheim (BI) and Sanofi, closed in most markets on January 1, 2017, Sanofi acquired BI's CHC business in most markets. The deal enhanced our position in four strategic categories Allergy Cough & Cold, Pain, Digestive and Nutritionals and enabled us to achieve critical scale and strengthen our geographical presence.

*(1) In some countries this indication is branded differently (eg Depakote® in France).  
(2) Following completion of the dialogue with employee representatives.*

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

Our CHC sales are supported by a range of products including the following brands:

Allergy Cough & Cold

Allegra<sup>®</sup> is a range of fexofenadine HCl based products. Fexofenadine is an antihistamine for relief from allergy symptoms including sneezing, runny nose, itchy nose or throat, and itchy, watery eyes. Allegra<sup>®</sup> OTC is mainly sold in the US, Brazil, Australia, Japan, India and in more than 80 countries across the world.

Xyzal<sup>®</sup> Allergy 24H is an oral antihistamine (levocetirizine dihydrochloride) for the relief of symptoms associated with seasonal and year-round allergies. Two formulations of Xyzal<sup>®</sup> are now approved for OTC use: 5 mg tablets for age 6 and older, and 0.5 mg/mL oral solution for age 2 and older. The product was made available in the US in 2017.

Mucosolvan<sup>®</sup> is a cough brand with many different formulations. The main product is a syrup which can be taken by adults and children in accordance with local dosing recommendations and registrations. It contains the mucoactive agent ambroxol; this stimulates synthesis and release of surfactant. It is sold in Germany, Russia, Philippines and various countries in Europe and Asia.

Pain

Doliprane<sup>®</sup> offers a range of paracetamol/acetaminophen-based products for pain and fever with a wide range of dosage options and pharmaceutical forms, and is sold mainly in France and various African countries.

The Buscopan<sup>®</sup> range (hyoscine butylbromide) has an antispasmodic action that specifically targets the source of abdominal pain and discomfort. It is sold across the globe.

Digestive

Dulcolax® products offer a range of constipation solutions from predictable overnight relief to comfortable natural-feeling relief. The products are sold in over 80 countries. Dulcolax® tablets contain the active ingredient bisacodyl, which works directly on the colon to produce a bowel movement.

Enterogermina® is a probiotic in the form of a drinkable suspension in 5 ml bottles or capsules containing two billion *Bacillus clausii* spores, and also powder sachets (six billion spores). Enterogermina® is indicated for the maintenance and restoration of intestinal flora in the treatment of acute or chronic intestinal disorders. Enterogermina® is sold primarily in Europe and in Latin America and parts of Asia.

Essentiale® is a natural soybean remedy to improve liver health. It is composed of essential phospholipids extracted from highly purified soya and contains a high percentage of phosphatidylcholine, a major component of the cell membrane. Essentiale® is used in fatty liver disease and is sold mainly in Russia, Eastern Europe, various countries in Southeast Asia, and China.

Zantac® products are for the prevention and relief of heartburn. Zantac® is sold in the US and Canada.

#### Nutritionals

Pharmaton® is a range of products which contain vitamins, minerals and standardized Ginseng Extract G115. Pharmaton® is sold mainly in Latin America, the Middle East and Southeast Asia.

#### Other

Gold Bond® offers a broad range of products including daily body lotions, anti-itch products, moisturizing and soothing lotions, body and foot creams and powders for eczema. Gold Bond® is only sold in the US.

### **B.4. Vaccine products**

Sanofi Pasteur, the vaccines division of Sanofi, is a world leader in the vaccine industry providing more than one billion doses of vaccines each year and making it possible to immunize more than 500 million people worldwide per year against diseases such as polio or influenza.

In Europe, Sanofi Pasteur's vaccine products were historically developed and marketed by Sanofi Pasteur MSD (SPMSD), a joint venture that served 19 countries, created in 1994 and held equally by Sanofi Pasteur and Merck & Co., Inc. (Merck). The vaccines market having undergone significant changes since the creation of SPMSD, Sanofi Pasteur and Merck decided to adjust their strategic priorities and terminated the SPMSD joint venture at the end of December 2016, reintegrating their European vaccine activities into their own operations. We successfully reintegrated our European vaccine portfolios into our company's operations which allowed us to drive significant growth.

Sanofi Pasteur is a key supplier to publicly funded international markets such as UNICEF, the Pan American Health Organization (PAHO) and the Global Alliance for Vaccines and Immunization (GAVI).

The Sanofi Pasteur portfolio includes the following vaccines:

#### **a) Polio, Pertussis and Hib pediatric vaccines**

Sanofi Pasteur is one of the key players in pediatric vaccines in both developed and emerging markets, with a broad portfolio of standalone and combination vaccines protecting against up to six diseases in a single injection. Due to the diversity of immunization schedules throughout the world, vaccines vary in composition according to regional specificities.

Pentaxim<sup>®</sup>, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b (Hib), was first marketed in 1997. To date, almost 300 million doses of Pentaxim<sup>®</sup> have been distributed in over

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

100 countries, and the vaccine has been included in the national immunization programs of 24 countries.

Hexaxim<sup>®</sup> is the only fully liquid, ready-to-use 6-in-1 (hexavalent) pediatric vaccine that provides protection against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. In 2013, the EMA approved this hexavalent pediatric vaccine in the EU, where it is sold under the brand name Hexyon<sup>®</sup> in Western Europe and under the brand name Hexacima<sup>®</sup> in Eastern Europe. The rollout of this new hexavalent vaccine began in July 2013 in Germany and has since ramped up significantly, with 30 countries having launched Hexaxim<sup>®</sup> in their public or private immunization programs. In December 2014, the WHO granted prequalification status to Hexaxim<sup>®</sup> in a one-dose vial presentation. Hexaxim<sup>®</sup> is the only combination vaccine including acellular pertussis (acP) and inactivated polio vaccines (IPV) currently prequalified by the WHO.

In 2017, Sanofi Pasteur in partnership with Merck made its PR5i hexavalent combination vaccine available on the market under the trademark Vaxelis<sup>®</sup>. The PR5i hexavalent combination vaccine is under regulatory review in the US. PR5i antigens are manufactured by Sanofi Pasteur (diphtheria, tetanus, pertussis (5acP) and polio (IPV)), and by Merck (Hib and hepatitis B).

Pentacel<sup>®</sup>, a pediatric combination vaccine protecting against five diseases (diphtheria, tetanus, pertussis, polio and Hib), was launched in the US in 2008. Supply limitations have been lifted.

Quadracel<sup>®</sup>, launched in the US in January 2017, is a combination vaccine against diphtheria, tetanus, pertussis and polio. It is used as a booster to be administered as the fifth dose in the primary series of vaccines, allowing children to complete the entire childhood schedule with as few injections as possible.

Shan5<sup>®</sup>, developed by Shantha, is a fully-liquid 5-in-1 vaccine protecting against five diseases (diphtheria, tetanus, pertussis, polio and hepatitis B). Following improvements made to key manufacturing steps in the production of the antigen components of the vaccine, Shan5<sup>®</sup> regained its prequalification from the WHO (which provides access to the product in low-income countries) in May 2014, and was launched in the Indian market in the last quarter of 2014. Shan5<sup>®</sup> has been retained for the GAVI/UNICEF tender for the 2017-2019 period.

Sanofi Pasteur is the world's leading developer and manufacturer of polio vaccines, with both oral polio vaccines (OPVs) and injectable inactivated polio vaccines (IPVs) in its portfolio. Sanofi Pasteur's polio production capacity and historic commitment have enabled us to serve as an important industrial partner in helping to achieve the goal of



worldwide polio eradication. The combined use of OPVs and IPV is expected to improve the level of protection in countries threatened by the possible resurgence of polio. In November 2013, GAVI announced its support for the introduction of IPV in the national immunization programs of the world's 71 poorest countries. The WHO expert group on immunization recommended that all countries introduce at least one dose of IPV in their routine immunization schedule by the first half of 2016. In September 2014, Nepal became the first GAVI supported country to introduce IPV. By the end of 2016, all 71 eligible countries had been approved for IPV support and 53

had completed their introductions, with the remaining countries to complete their introductions in the next several years. Sanofi Pasteur continues to partner with public health authorities, supplying much-needed vaccines and making substantial efforts to register Imovax<sup>®</sup> Polio, Shan IPV Polio and bivalent OPV in an impressive number of countries in record time. As of today, polio remains endemic in three countries: Afghanistan, Pakistan and Nigeria.

## **b) Influenza Vaccines**

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines, with over 200 million doses delivered in 2017. In recent years, demand for influenza vaccine has experienced strong growth in many countries, particularly in the US, Brazil and Mexico. Sanofi Pasteur expects the global demand for influenza vaccines to continue to grow within the next decade due to increased disease awareness, growth in emerging markets, and expanded recommendations by governmental and advisory bodies to be vaccinated against seasonal influenza.

Sanofi Pasteur has two distinct influenza vaccines that are sold globally: Fluzone<sup>®</sup> and Vaxigrip<sup>®</sup>.

Fluzone<sup>®</sup> High-Dose vaccine, launched in the US in 2010, was specifically designed to generate a more robust immune response against influenza in people aged 65 and older and provide greater protection against influenza. In November 2014, the FDA changed the prescribing information for Fluzone<sup>®</sup> High-Dose to document its superior clinical benefit compared to the standard Fluzone<sup>®</sup> dose (the high-dose vaccine was 24% more effective than standard Fluzone<sup>®</sup> in a large-scale efficacy study).

Fluzone<sup>®</sup> Quadrivalent is a quadrivalent inactivated influenza vaccine containing two type A antigens and two type B antigens. Compared to the trivalent influenza vaccine, the addition of a second B strain to the vaccine provides increased protection against the most prevalent circulating strains. Fluzone<sup>®</sup> Quadrivalent/FluQuadri<sup>®</sup> is available in 24 countries for children aged over six months, adolescents and adults.

Vaxigrip<sup>®</sup> is a trivalent vaccine licensed in over 150 countries globally for people aged six months and over. A quadrivalent formulation of Vaxigrip<sup>®</sup> (QIV) for people aged 3 years and over was licensed in 2016 and launched in more than 20 countries in 2017. Vaxigrip<sup>®</sup> QIV in the 6 to 35 months age group was approved in Europe in December 2017.

In 2017, Sanofi completed the acquisition of Protein Sciences, a vaccines biotechnology company. Through the acquisition, Sanofi Pasteur added to its US portfolio Flublok<sup>®</sup> (a quadrivalent influenza vaccine for adults age 18 and over), the only recombinant protein-based influenza vaccine approved by the FDA.

## **c) Adult Booster Vaccines**

Many countries now recommend pertussis immunization for adolescents and adults. These recommendations, combined with immunization awareness initiatives, have led to increased pertussis vaccination rates in these populations in recent years.



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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

Adacel<sup>®</sup> is the first trivalent adolescent and adult booster offering protection against diphtheria, tetanus and pertussis. It also reduces exposure from infants who are not immunized or only partially immunized.

Repevax<sup>®</sup> (also marketed under the trademark Adacel-Polio<sup>®</sup>) is a combination vaccine that provides protection against diphtheria, tetanus, pertussis and polio.

**d) Meningitis and Pneumonia Vaccines**

Menactra<sup>®</sup> is the first quadrivalent conjugate vaccine against meningococcal meningitis, which is considered the deadliest form of meningitis in the world. Menactra<sup>®</sup> is now indicated for people aged nine months through 55 years in the US, Canada, several Middle Eastern countries such as Saudi Arabia, and numerous other countries in all regions of the world. In most markets, a conjugated quadrivalent vaccine like Menactra<sup>®</sup> offers the best value proposition by protecting against four of the most common serogroups: A, C, Y, and W-135.

**e) Travel and Endemic Vaccines**

Sanofi Pasteur provides a wide range of travel and endemic vaccines including hepatitis A, typhoid, cholera, yellow fever, and Japanese encephalitis, as well as rabies vaccines and immunoglobulins. These vaccines and immunoglobulins are used in endemic settings in the developing world and are the foundation for important partnerships with governments and organizations such as UNICEF. They are also used by travelers and military personnel in industrialized countries and in endemic areas.

In 2009, Shantha launched Shanchol<sup>®</sup>, the first oral cholera vaccine produced in India for use in children and adults. Shanchol<sup>®</sup> received WHO prequalification in 2011. In 2013, the first oral cholera vaccine stockpile (which Shanchol<sup>®</sup> is part of) was created by the WHO, to respond to outbreaks and vaccine needs in areas of heightened risk.

IMOJEV<sup>®</sup>, a Japanese encephalitis vaccine, was launched in Australia and Thailand in 2012. In 2014, IMOJEV<sup>®</sup> obtained an extension of indication for use in children aged nine months and over, and obtained WHO prequalification. IMOJEV<sup>®</sup> has been rolled out in endemic countries throughout Asia.

As regards yellow fever, we shipped a significant part of the outbreak prevention stockpile in record time in 2016 to support our WHO/UNICEF/GAVI partners in their fight against expansion of the ongoing outbreak, confirming our key role in combatting this important public health threat.

## f) Dengue

Dengue fever constitutes a major public health and economic burden in the endemic areas of the Asia-Pacific region and in Latin America. More than 100 countries, representing nearly half of the world's population, are at risk. Over the last 50 years, the incidence of the disease has increased 30-fold, an alarming rate given there

was no specific treatment available. In response to this global threat, which can impact children, adolescents and adults, the WHO has set ambitious objectives to reduce the burden of the disease on society. One of these objectives is to reduce morbidity by 25% and mortality by 50% by 2020. Surveillance data from some endemic countries indicate that between 70 and 90 percent of people will have been exposed to dengue at least once by the time they reach adolescence. Following 20 years of innovative research and collaboration with local at-risk communities and dengue scientists around the world, Sanofi Pasteur has developed a dengue vaccine candidate and embarked on a global, multinational clinical development program.

Dengvaxia<sup>®</sup> has been approved in 19 countries to date: Argentina, Australia, Bangladesh, Bolivia, Brazil, Cambodia, Costa Rica, El Salvador, Guatemala, Honduras, Indonesia, Malaysia, Mexico, Paraguay, Peru, the Philippines (temporarily suspended for one year in December 2017: see below), Singapore, Thailand and Venezuela. Dengvaxia<sup>®</sup> is currently indicated in most of the countries for individuals aged 9 or older living in a dengue-endemic area. In this indicated population, Dengvaxia<sup>®</sup> has been shown to prevent 93% of severe disease and 80% of hospitalizations due to dengue over the 25-month phase of the large-scale clinical studies conducted in 10 countries in Latin America and Asia where dengue is widespread.

On November 29, 2017 Sanofi announced results of a new analysis of long-term Dengvaxia<sup>®</sup> data which found differences in vaccine performance based on prior dengue infection. Sanofi proposed that health authorities update information provided to physicians and patients on its dengue vaccine requesting that healthcare professionals assess the likelihood of prior dengue infection in an individual before vaccinating with Dengvaxia<sup>®</sup>. For individuals who have not been previously infected by dengue virus, vaccination with Dengvaxia<sup>®</sup> should not be recommended. This update is being implemented in any relevant countries (excluding the Philippines).

Based on up to six years of clinical data, the new analysis evaluated long-term safety and efficacy of Dengvaxia<sup>®</sup> in people who had been infected with dengue prior to vaccination and those who had not. The analysis confirmed that Dengvaxia<sup>®</sup> provides persistent protective benefit against dengue fever in those who had prior infection. For those not previously infected by dengue virus, however, the analysis found that in the longer term, more cases of severe disease could occur following vaccination upon a subsequent dengue infection.

Dengvaxia<sup>®</sup> had already been launched in two public vaccination programs: one in Parana State (Brazil), and one public program targeting students in public schools in the Philippines. In December 2017, the Philippines put the Dengvaxia<sup>®</sup> vaccine campaign on hold and temporarily suspended the Dengvaxia license for one year. Brazil's Parana state has continued with the program.

In the Philippines Sanofi has bought back unused doses of Dengvaxia<sup>®</sup> following the announcement of label update in November.

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

**B.5. Global research & development**

The mission of Sanofi's R&D organization is to discover and develop therapies that prevent, treat or cure diseases. Our day-to-day commitment is to respond to patients' needs and to provide them with adapted therapeutic solutions in order to improve their well-being and extend their lives.

Sanofi R&D is a global organization integrating all R&D activities across three major segments: Pharmaceuticals, Vaccines and Consumer Healthcare.

To carry out our mission and maximize its impact, we strive to bring innovation to patients and to build a pipeline of high value projects. Our approach is neutral to the source of innovation, whether it comes from internal research or external partners.

Medical value, scientific quality and operational effectiveness are the three drivers that underpin our strategy. The focus is on projects that have the potential to provide the best added medical value to patients and payers and to reduce healthcare costs for society.

By using a translational medicine approach, ensuring that research hypotheses are validated in humans as early as possible, R&D can translate basic research findings into medical practice more quickly and efficiently and improve the scientific quality of our projects.

**B.5.1. Pharmaceuticals**

***B.5.1.1. Organization***

Our Global R&D organization is committed to responding to the real needs of patients by providing them with safe, cost-effective and appropriate therapeutic solutions, improving their access to treatment and delivering better health outcomes. In offering new solutions to patients, it is vital to understand the complexity of human diseases, to sustain innovation and to foster scientific excellence without losing sight of the need for operational efficiency.

To meet these challenges, Sanofi R&D has evolved towards an integrated organization encompassing a wide range of therapeutic areas aligned with the Global Business Units (GBUs), which are dedicated to supporting our commercial

operations and reflect our strengths and expertise as well as the most pressing health issues.

For Pharmaceuticals, six therapeutic areas (TAs) have been rolled out:

Diabetes, Cardiovascular and Metabolism

Oncology

Immunology & Inflammation

Multiple Sclerosis, Neurology & Gene Therapy

Infectious Diseases

Rare Diseases

These TAs drive a portfolio of R&D projects, ensuring a strategically coherent approach and flawless implementation.

Each TA has its own experts who are responsible for analyzing medical needs, defining project strategy and development plans, and leading the Global Project Teams.

Our R&D Operations department handles all operational activities and delivers effective development through integrated, collaborative project teams. Those teams harness high caliber functional expertise and the most appropriate technologies across chemical, biological and pharmaceuticals operations, translational medicine and early development and clinical sciences.

In Research, a dedicated, integrated platform has been introduced that works across multiple disease areas and methods. This platform drives collaboration with internal and external partners to translate human biology research and state-of-the art technologies and processes into novel drug targets and world-class safe and effective drugs.

Sanofi's R&D operations are concentrated in three major hubs: North America, Germany and France. These hubs help build our scientific intelligence network and facilitate connections and knowledge-sharing between in-house scientists, and with external partners and scientific communities, in order to accelerate our research activities.

#### ***B.5.1.2. Governance***

Global Project Teams (GPTs) are responsible for developing project strategy and driving the execution of projects through functional sub-teams. GPTs are led by a Global Project Head (GPH) who works in collaboration with a Project Manager (PM), and are built around core functional team members representing each department collaborating in the development project.

Various committees assess product and project development across the R&D value chain, carry out in-depth scientific review, make go and no-go decisions and determine portfolio priorities.

Projects are assessed using two key criteria which allow management to rapidly understand how the portfolio is performing in terms of innovation, unmet medical needs, risk and value:

relative medical value, which encompasses the extent of the unmet need, the market dynamics and the likelihood of getting satisfactory market conditions; and

science translation, which includes the level of innovation and translatability of the science including likelihood of development success.

The clinical portfolio is the result of decisions taken during these reviews, plus compounds entering the portfolio from the discovery phase or from third parties via acquisition, collaboration or alliances.

As described at Item 3. Key Information D. Risk Factors Risks Relating to Our Business research and development efforts may not succeed in adequately renewing the product portfolio and Risks Relating to the Group Structure and Strategy We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments , our product development efforts are subject to the risks and uncertainties inherent in any new product development program.

**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

**B.5.1.3. Products**

The clinical portfolio for new products as of February 7, 2018 can be summarized as follows; where several indications are being developed for one product, each indication is regarded as a separate project and specified individually in the table below.

For information related to Kevzara<sup>®</sup>, Praluent<sup>®</sup>, Aubagio<sup>®</sup> and Lemtrada<sup>®</sup>, see Item 4. Information on the Company B. Business Overview B.2. Main Pharmaceutical Products .

	<b>Phase I</b>	<b>Phase II</b>	<b>Phase III /registration</b>
<b>Diabetes</b>	SAR438335	SAR425899	SAR341402 (T1 & T2 Diabetes)
		sotagliflozin (WHF <sup>(a)</sup> in Diabetes)	sotagliflozin (T1 & T2 Diabetes)
<b>Oncology</b>	SAR408701	SAR566658 (TNBC <sup>(d)</sup> )	efpeglenatide (T2 Diabetes) isatuximab (3L RRMM <sup>(f)</sup> ICARIA)
	SAR439459	cemiplimab (BCC <sup>(e)</sup> )	isatuximab (1-3L RRMM <sup>(g)</sup> IKEMA)
	SAR439859		isatuximab (1L NDMM <sup>(h)</sup> IMROZ)
	SAR439459+cemiplimab		cemiplimab (2L CC <sup>(i)</sup> )
	SAR439859+palbociclib		cemiplimab (1L NSCLC <sup>(j)</sup> )
	isatuximab+cemiplimab (RRMM <sup>(b)</sup> )		cemiplimab (CSCC <sup>(k)</sup> )
	isatuximab+CyBord (NDMM <sup>(c)</sup> )		
<b>Cardiovascular &amp;</b>	SAR247799	mavacamten	Praluent <sup>®</sup> (post ACS)



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<b>Metabolism</b>	SAR440181	SAR407899	
<b>Immunology &amp;</b>	SAR439794	SAR156597	dupilumab (asthma adults, 12+ years)
<b>Inflammation</b>	SAR440340	GZ389988	dupilumab (asthma, 6-11 years)
		dupilumab (EE <sup>(l)</sup> )	Dupixent <sup>®</sup> (AD pediatrics <sup>(o)</sup> )
		Kevzara <sup>®</sup> (pcJiA <sup>(m)</sup> )	dupilumab (nasal polyposis)
<b>Multiple Sclerosis</b>	SAR442168	Kevzara <sup>®</sup> (sJiA <sup>(n)</sup> ) venglustat (GPD <sup>(p)</sup> )	Aubagio <sup>®</sup> (RMS ped. <sup>(q)</sup> )
<b>Neurology</b>	SAR228810	SAR422459	Lemtrada <sup>®</sup> (RRMS ped. <sup>(r)</sup> )
<b>Ophthalmology</b>	UshStat <sup>®</sup>		
<b>Infectious diseases</b>		ferroquine (combo OZ439)	
<b>Rare diseases</b>		olipudase alfa	GZ402666
		venglustat (Gaucher type3)	fitusiran
		venglustat (Fabry)	

*(a) Worsening Heart Failure*

*(b) Relapsing and/or Refractory Multiple Myeloma*

*(c) Newly Diagnosed Multiple Myeloma*

*(d) Triple Negative Breast Cancer*

*(e) Basal Cell Carcinoma*

*(f) 3<sup>rd</sup> Line Relapsing and/or Refractory Multiple Myeloma*

*(g) 1<sup>st</sup>-3<sup>rd</sup> Line Relapsing and/or Refractory Multiple Myeloma*

*(h) 1<sup>st</sup> Line Newly Diagnosed Multiple Myeloma*

*(i) 2<sup>nd</sup> Line Cervical Cancer*

*(j) 1<sup>st</sup> Line Non-Small Cell Lung Cancer*

*(k) Cutaneous Squamous Cell Carcinoma*

*(l) Eosinophilic Esophagitis*

*(m) Polyarticular Juvenile Idiopathic Arthritis*

*(n) Systemic Juvenile Idiopathic Arthritis*

*(o) Atopic Dermatitis*

*(p) Gaucher related Parkinson's Disease*

*(q) Relapsing Multiple Sclerosis pediatric*

*(r) Relapsing Remitting Multiple Sclerosis pediatric*

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

Phase I studies are the first studies performed in humans, who are mainly healthy volunteers, except for studies in oncology, where Phase I studies are performed in patients. Their main objective is to assess the tolerability, the pharmacokinetic profile (the way the product is distributed and metabolized in the body and the manner by which it is eliminated) and where possible the pharmacodynamic profiles of the new drug (i.e. how the product may react on some receptors).

Phase II studies are early controlled studies in a limited number of patients under closely monitored conditions to show efficacy and short-term safety and to determine the dose and regimen for Phase III studies.

Phase III studies have the primary objective of demonstrating or confirming the therapeutic benefit and the safety of the new drug in the intended indication and population. They are designed to provide an adequate basis for registration.

**a) Diabetes**

**Sotagliflozin (SAR439954)**, an oral dual inhibitor of SGLT1/2, is in-licensed from Lexicon. Results of the Phase III program in type 1 diabetes were released in 2017. We expect to file for approval in the US in type 1 diabetes during the first half of 2018. A large Phase III program is currently ongoing to investigate the use of sotagliflozin for the treatment of type 2 diabetes. A Phase II study in diabetic patients with worsening heart failure is ongoing.

**Efpeglenatide (SAR439977)** is a long-acting GLP1 receptor agonist derived from our license agreement with Hanmi Pharmaceuticals. A Phase III development program in type 2 diabetes was initiated in December 2017.

**Rapid Acting Insulin (SAR341402)** is in Phase III for the treatment of type 1 and type 2 diabetes.

**Dual GLP-1/glucagon receptor (SAR425899)** entered Phase IIb in December 2016 for the treatment of patients with type 2 diabetes. Completion of Phase IIb is expected in the first quarter of 2018.

**Dual GLP-1/GIP receptor agonist (SAR438335)** is currently in Phase I for the treatment of patients with type 2 diabetes.

## b) Cardiovascular & Metabolism

**Mavacamten (SAR439152)**, a myosin inhibitor derived from our partnership with MyoKardia, has achieved proof of concept in treatment of obstructive hypertrophic cardiomyopathy in 2017 and will start a registration Phase IIb/III study in the second quarter of 2018.

**SAR407899**, a novel Rho-kinase inhibitor, started a Phase IIa Proof of concept study in October 2017 in patients with microvascular angina. Results are expected in January 2019.

**SAR440181**, an allosteric activator of cardiac myosin ATPase (positive inotrope) small molecule designed to treat dilated

cardiomyopathy and derived from our partnership with MyoKardia, completed Phase Ia in 2017 and is starting Phase Ib in 2018.

**SAR247799**, a S1P1 agonist, entered Phase I in August 2016 in the treatment of cardiovascular diseases.

## c) Oncology

### Products in development

**Isatuximab (SAR650984)** is a monoclonal antibody which selectively binds to CD38, a cell surface antigen expressed in multiple myeloma cancer cells, and other hematological malignancies. Isatuximab is a collaboration compound derived from the Collaboration and License Agreement with ImmunoGen. Isatuximab kills tumor cells via multiple biological mechanisms including:

antibody-dependent cellular-mediated cytotoxicity (ADCC);

complement-dependent cytotoxicity (CDC);

antibody-dependent cellular phagocytosis (ADCP); and

direct induction of apoptosis (pro-apoptosis) without cross-linking.

Isatuximab also inhibits CD38 ectoenzymatic activity and the expansion of immune-suppressive regulatory T cells and myeloid derived suppressor cells.

The program is currently in Phase III clinical development.

There are multiple studies ongoing in multiple myeloma (MM), including three pivotal Phase III trials.

The **ICARIA-MM** Phase III trial compares isatuximab in combination with pomalidomide and dexamethasone against pomalidomide and dexamethasone in patients with relapsed and refractory multiple myeloma.

The Phase III **IKEMA** trial is a randomized, open label, multicenter study assessing the clinical benefit of isatuximab combined with carfilzomib (Kyprolis®) and dexamethasone versus carfilzomib with dexamethasone in patients with relapsed and/or refractory multiple myeloma previously treated with one to three prior lines.

The Phase III **IMROZ** trial is a randomized, open-label, multicenter study assessing the clinical benefit of isatuximab in combination with bortezomib (Velcade<sup>®</sup>), lenalidomide (Revlimid<sup>®</sup>) and dexamethasone versus bortezomib, lenalidomide and dexamethasone in patients with newly diagnosed multiple myeloma not eligible for transplant.

A Phase I study in combination with cyclophosphamide, bortezomib and dexamethasone is ongoing in the treatment of adult patients newly diagnosed with MM not eligible for transplant.

A Phase I/II study in combination with cemiplimab in the treatment of patients suffering from RRMM should be initiated in the first quarter of 2018.

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

**Cemiplimab (SAR439684)**, a PD-1 inhibitor derived from our alliance with Regeneron, is currently in Phase IIb to support registration in the treatment of cutaneous squamous cell carcinoma. The dossier was filed end of February 2018.

A Phase II program in the treatment of basal cell carcinoma was initiated in July 2017.

Additional Phase III studies are also running in different indications:

in the first-line treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1, versus Platinum Based Chemotherapy; and

in the treatment of patients with recurrent or metastatic platinum-refractory cervical cancer. In this study, cemiplimab is assessed versus investigator's choice chemotherapy.

**SAR566658** is an antibody drug conjugate (ADC) loaded with a maytansinoid derivative DM4 (huDS6-SPDB-DM4) targeting CA6. CA6 is a tumor specific epitope highly expressed on some solid tumors. The product is currently in Phase II in the treatment of triple-negative breast cancer.

**SAR439859** is a potent, orally bioavailable, and selective estrogen receptor (ER) inhibitor that belongs to the SERD class of compounds. SAR439859 antagonizes the binding of estradiol to ER but also promotes the transition of ER to an inactive conformation that leads to receptor degradation (98%) at sub-nanomolar concentrations in tumor cells harboring either wild type or mutant ER. The compound is in Phase I in the treatment of metastatic breast cancer, in monotherapy and in combination with palbociclib.

**SAR439459** is a monoclonal antibody which inhibits the activity of transforming growth factor beta (TGF $\beta$ ). TGF $\beta$  regulates several biological processes (including wound healing, embryonic development, and malignant transformation) by controlling many key cellular functions including proliferation, differentiation, survival, migration, and epithelial mesenchyme transition. TGF $\beta$  is expected to alleviate the suppressive tumor microenvironment and allow checkpoint modulators, such as anti-programmed cell death 1 (PD-1), to better induce immune responses and thus increase the proportion of patients benefitting from anti-PD-1 treatment. The compound is in Phase I in the treatment of advanced solid tumors in monotherapy and in combination with cemiplimab.

**SAR408701** is an antibody drug conjugate (ADC) that binds to CEACAM-5, a membrane glycoprotein originally identified as a surface marker on adenocarcinomas of the human gastrointestinal tract. A study is ongoing to evaluate the activity of the drug in the treatment of non-small-cell lung cancer, colorectal cancer and gastric cancer. In addition, there is an active Phase I trial in Japan.

### Product discontinued in 2017

**SAR428926**, an antibody drug conjugate (ADC) binding to Lysosomal Associated Membrane Protein 1 (LAMP1), was discontinued in November 2017. The product was in Phase I.

### Collaborations

Sanofi Oncology has a large number of collaborations and alliances to support its R&D portfolio.

In 2015, we entered into a strategic collaboration and license agreement with Regeneron focusing on cancer immunotherapy. The objective of the collaboration is to generate high value development candidates in the emerging field of immuno-oncology, providing us with an opportunity to expand and accelerate our development pipeline and build a strong position in one of the most attractive segments of the oncology market. To date cemiplimab (SAR439684), a PD-1 inhibitor monoclonal antibody derived from this collaboration, has entered Phase III clinical development.

Also in 2015, we entered into an exclusive strategic collaboration with the German biotech company BioNTech (Mainz) in the field of active immunization. The goal of the alliance is to discover and develop messenger RNA (mRNA) therapeutics for cancer immunotherapy by leveraging the scientific expertise of the two organizations. The first clinical candidate is expected to enter clinical trials in 2018.

These two ambitious alliances have the potential to address some of the unmet medical needs that remain in cancer treatment.

Sanofi Oncology has also established various alliances with leading academic cancer centers such as Institut Gustave Roussy, Institut Curie and the Dana Farber Cancer Institute, and with biotechnology companies like Immunogen and Evotec. We will also be partnering with the Foundation of the US National Institutes of Health (FNIH) in the Partnership for Accelerating Cancer Therapies (PACT).

In 2016, we entered into a collaboration with Innate Pharma to develop innovative bispecific antibody formats engaging natural killer (NK) cells to kill tumor cells, and a collaboration with Warp Drive Bio to develop drugs targeting human oncogenes including RAS. Both these collaborations are in line with our ongoing commitment to the discovery and development of new cancer drugs and therapeutic strategies that will make a difference in the lives of cancer patients.

### d) Immunology & Inflammation

#### Main products in Phase III and in the registration phase

**Dupilumab (SAR231893)**, an interleukin-4 receptor alpha antagonist, is a human monoclonal antibody of the IgG4 subclass that binds to the IL-4Ra subunit and inhibits IL-4 and IL-13 signaling. Dupilumab is jointly developed with Regeneron in several indications:

**Atopic dermatitis:** the product was approved by the FDA in March 2017 and by the European Commission in September 2017, and launched under the trade name Dupixent<sup>®</sup>. Several Phase III pediatric studies (6 months to 5 years, 6 to 11 years and 12-17 years) are currently ongoing.



**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

**Asthma:** the Phase III program in adults and children over 12 years was completed in 2017 and the dossier is currently in the submission phase. A Phase III study in children (6-11 years) is ongoing.

**Nasal polyposis:** the Phase III program consists of two pivotal trials of respectively 24 and 52 weeks. Their objective is to evaluate the efficacy of dupilumab compared to placebo on a background of mometasone furoate nasal spray (MFNS) in reducing nasal congestion/obstruction (NC) severity and endoscopic nasal polyp score (NPS) in patients with bilateral nasal polyposis. In addition the studies will evaluate as key secondary endpoints the reduction in computed tomography (CT) scan opacification of the sinuses, improvement in loss of smell and patient reported quality of life, and reduction in need for steroids or surgery.

**Eosinophilic esophagitis:** Positive results were obtained in the proof-of-concept study in 2017 and discussions are currently ongoing with the US health authorities regarding the Phase III program.

**Main products in early stage**

**SAR156597** (humanized bi-specific monoclonal antibody targeting the cytokines IL-4 and IL-13) is in Phase IIA for the treatment of diffuse systemic sclerosis. Sanofi decided in 2017 to stop the development of the compound in idiopathic pulmonary fibrosis.

**GZ389988** (TrkA) is a small molecule which inhibits binding of nerve growth factor (NGF) to its primary tyrosine receptor kinase A (TrkA), and is being developed as a treatment for symptoms resulting from osteoarthritis. The Phase IIA program initiated in August 2016 was completed in 2017 and the next steps are under discussion.

**SAR440340**, a human anti-IL33 monoclonal antibody derived from our alliance with Regeneron, has completed Phase I. Several Phase II studies are expected to start in 2018, in moderate-to-severe asthma, in atopic dermatitis and in chronic obstructive pulmonary disease.

**SAR439794**, a TLR4 agonist, entered Phase I in September 2016 for the treatment of peanut allergy.

**Product discontinued in 2017**

**SAR100842**, an LPA1 receptor antagonist, developed in systemic scleroderma, was discontinued in Phase IIa in September 2017.

#### e) Multiple Sclerosis, Neurology & Ophthalmology

##### Multiple sclerosis

**SAR442168 (PRN2246)**, an orally administered Bruton's tyrosine kinase (BTK) inhibitor which was designed to access the brain and

spinal cord by crossing the blood-brain barrier and impact immune cell and brain cell signaling, started Phase I development in October 2017 in the treatment of multiple sclerosis.

##### Neurology

**Venglustat (GZ402671)**, an orally administered brain penetrant glucosylceramide synthase (GCS) inhibitor, has completed Part 1 (dose escalation phase) of a Phase II study in patients with early-stage Parkinson's disease carrying a  $\beta$ -glucocerebrosidase (GBA) gene mutation (GBA-PD) or other prespecified variant. Part 2 (treatment phase) of the study is due to start in early 2018. The product is also being developed in some rare disease indications described below.

**SAR228810**, an anti-protofibrillar Abeta monoclonal antibody, has completed the Phase I program in mild cognitive impairment due to Alzheimer's Disease (AD) and in mild AD. The next steps of development are under discussion. Biomarker studies are being performed.

##### Ophthalmology

**SAR422459** is a gene therapy product which uses a lentivector gene delivery technology to introduce a functional ABCR gene into photoreceptors in patients with autosomal recessive Stargardt's disease, an orphan inherited condition that leads to progressive vision loss from childhood. The product is currently in Phase IIA.

**UshStat® (SAR421869)** is a gene therapy product which uses a lentivector gene delivery technology to introduce a functional MYO7A gene into the photoreceptors and retinal pigment epithelium (RPE) cells in patients with Usher 1B syndrome, an orphan inherited condition that leads to progressive visual field constriction and vision loss from childhood. A Phase I/IIA clinical study is ongoing.

##### Product discontinued in 2017

**GZ402668 (GLD52)**, an IgG1 monoclonal antibody binding to CD52 (a cell surface antigen present at high levels on T and B lymphocytes) has been discontinued for further development in multiple sclerosis (MS) after Phase I due to strategic reprioritization.

#### f) Infectious Diseases

**Ferroquine (OZ439)** is a first in class combination for malaria, developed in collaboration with Medicines for Malaria Venture (MMV). Ferroquine is a new 4 amino quinoline being developed for the treatment of acute uncomplicated malaria, and is active against chloroquine sensitive and chloroquine resistant Plasmodium strains. Due to its long half-life it has the potential to be part of single dose cure regimens for the treatment of both



**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

*P. vivax* and *P. falciparum* malaria. OZ439 is a synthetic peroxide antimalarial drug candidate from MMV designed to provide a single dose oral cure in humans. A Phase IIB clinical study of the combination of the two products, conducted in adults and children with *P. falciparum* malaria, started in July 2015 in Africa and in October 2017 in Asia.

**g) Rare Diseases****Main products in Phase III and in the registration phase**

**Alnylam collaboration:** In October 2012, Genzyme entered into an exclusive license agreement with Alnylam, covering the ALN-TTR programs in the Asia-Pacific-Japan region. ALN-TTR01 and ALN-TTR02 Phase I results were published in the *New England Journal of Medicine* in August 2013. Results showed that RNAi therapeutics targeting transthyretin (TTR) achieved rapid, dose-dependent, durable, and specific knockdown of TTR, the disease-causing protein in TTR-mediated amyloidosis (ATTR). Genzyme's exclusive territory rights for the ALN-TTR programs were extended to the rest of the world excluding North America and Western Europe on January 14, 2014. The January 2014 agreement also included exclusive rights for Sanofi to opt into future Alnylam rare disease pipeline programs including fitusiran for which we exercised a regional option in September 2015 and then stepped up to a co-development, co-commercialization option on November 14, 2016. On January 6, 2018, the parties executed a strategic restructuring of the alliance to streamline and optimize development and commercialization of certain products. Specifically:

Sanofi will obtain global rights to fitusiran, currently in development for hemophilia A and B. Alnylam will receive royalties based on net sales of fitusiran products.

Alnylam will obtain global rights to its ATTR therapeutics programs, including patisiran and ALN-TTRsc02. Sanofi will receive royalties based on net sales of these ATTR amyloidosis products.

With respect to other products, the material terms of the 2014 Agreement remain unchanged.

**Fitusiran (SAR439774)** Alnylam (ALN-AT3): This is a program for development of a siRNA therapeutic to treat hemophilia (A and B), using a novel approach targeting antithrombin (AT) with AT

knockdown leading to increase in thrombin generation. The Phase III program (ATLAS) is being initiated with dosing of the first patients expected towards the end of the first quarter of 2018.

**GZ402666 (Neo GAA)** is a second generation enzyme replacement therapy targeting the treatment of Pompe disease. The Phase III program was launched in November 2016, with the COMET study targeting treatment naïve late onset Pompe disease patients. The Phase II mini-COMET study has enrolled its first patient in October 2017, targeting treatment experienced infantile onset Pompe disease patients.

### Main products in early stage

**GZ402665 (rhASM) olipudase alfa** is an enzyme replacement therapy targeting the treatment of non-neurological manifestations of acid sphingomyelinase deficiency (ASMD), also known as Niemann-Pick B disease. An open label pivotal Phase I/II study in the pediatric population has been expanded to include additional younger patients. The Phase II/III trial to support registration in the adult population started enrolling patients in 2016.

**Venglustat/GZ402671 (GCS inhibitor)** is in development in Fabry Disease, Gaucher Disease type 3 (GD3) and Autosomal Dominant Polycystic Kidney Disease (ADPKD). The extension study of the Phase II trial for the treatment of Fabry disease is ongoing to understand the long term effects of venglustat therapy in Fabry patients. An observational study for the evaluation of Fabry Disease (PRO - Patient Reported Outcome) started in January 2017 and was fully enrolled by October 2017. A Phase II study in Gaucher disease type 3 (LEAP) is ongoing, and the first patient enrolled is about to reach one-year treatment. A Phase III pivotal study (SAVE-PKD) in rapidly progressive Autosomal Dominant Polycystic Kidney Disease (ADPKD) patients is planned to start in 2018.

### B.5.2. Vaccines

Our Vaccines R&D is focused on developing new prophylactic vaccines and improving existing ones.

The Sanofi Pasteur R&D portfolio includes 13 vaccines currently in advanced development as shown in the table below. The portfolio is well balanced, with five vaccine products for novel targets and eight vaccines which are enhancements of existing vaccine products.

**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

<b>PHASE I</b>	<b>PHASE II</b>	<b>PHASE III</b>	<b>REGISTRATION</b>
<b>Respiratory Syncytial Virus</b>	<b>Tuberculosis</b>	<b>Fluzone® QIV HD</b>	<b>VaxiGrip® QIV IM</b>
RSV infant vaccine	Recombinant subunit vaccine	Quadrivalent inactivated influenza vaccine High dose	Quadrivalent inactivated influenza vaccine (6-35 months)
<b>Herpes Simplex virus Type 2</b>	<b>HIV</b>	<b>Men QuadTT</b>	<b>PR5i</b>
HSV-2 vaccine	Prevention of HIV infections in at-risk adults	Advanced generation meningococcal ACYW conjugate vaccine	DTP-HepB-Polio-Hib <sup>(b)</sup>  Pediatric hexavalent vaccine (US)
	<b>SP0232(8) mAb<sup>(a)</sup></b>	<b>Pediatric pentavalent vaccine</b>	
	Respiratory syncytial virus monoclonal antibody	DTP-Polio-Hib <sup>(b)</sup>  Japan	
	<b>Rabies VRVg</b>		
	Purified vero rabies vaccine		
	<b>Adacel®+</b>		

Tdap booster

**Shan6**

DTP-HepB-Polio-Hib<sup>(b)</sup>

Pediatric hexavalent  
vaccine

*(a) Partnered and/or in collaboration Sanofi may have limited or shared rights on some of these products*

*(b) D=Diphtheria, T=Tetanus, P=Pertussis, Hib=Haemophilus influenzae b, HepB=Hepatitis B.*

## Enhancements of Existing Vaccines

**Influenza vaccine:** To sustain our global leadership in the development of influenza vaccines, our R&D efforts are focused on innovative approaches. In line with our drive to develop quadrivalent flu vaccines (see B.4. Vaccine Products ), in August 2017 we completed the acquisition of Protein Sciences, a vaccines biotechnology company that has developed the baculovirus expression system technology (BEST) platform for the production of recombinant proteins. Protein Sciences has used this platform to develop and commercialize Flublok<sup>®</sup> Quadrivalent, a recombinant influenza vaccine indicated for active immunization of adults aged 18 and older against seasonal influenza.

**Meningitis vaccine:** *Neisseria meningitidis* bacteria are a leading cause of meningococcal disease in the US, Europe, the African meningitis belt and other endemic regions such as Brazil and Australia. Sanofi Pasteur is developing an advanced generation quadrivalent conjugated meningococcal vaccine. This vaccine uses an alternative technology to diphtheria conjugation as currently used in the commercialized vaccine. Phase II clinical trial results have demonstrated its safety and immunogenicity. The project is currently in Phase III.

**Rabies vaccine:** VRVg (VerorabVax<sup>®</sup>) is a next generation human rabies vaccines under development, aiming to replace worldwide both Sanofi Pasteur vaccines currently commercialized (Imovax<sup>®</sup> Rabies and Verorab). It will offer a purified human rabies vaccine, produced without animal or human material on vero cell. The recent data of the US Phase II clinical trial (VRV11) performed in healthy adults in post-exposure regimen with administration of HRIG, showed a clear dose ranging effect, leading us to consider

the highest dose for the next phase III studies. Overall, VRVg (high dose) shows similar safety profile and at least equivalent immune response to Imovax<sup>®</sup> Rabies.

**Pediatric pentavalent vaccine for the Japanese market:** Sanofi Pasteur, in partnership with Kitasato (KDSV) and Daiichi Sankyo (DS), is developing a pediatric pentavalent vaccine for the Japanese market. The vaccine includes diphtheria, tetanus and acellular pertussis (DTaP) from KDSV, and inactivated polio (IPV) and Hib from Sanofi Pasteur. It is anticipated that this product, to be distributed by DS, will be the first pentavalent pediatric combination vaccine in the Japanese market. It would serve as a primary series and booster vaccine for Japanese children up to two years old. The project is currently in Phase III.

**PR5i (hexavalent vaccine):** Sanofi Pasteur is co-developing with Merck & Co., Inc. (Merck) a hexavalent combination vaccine (PR5i 6-in-1 vaccine) to protect against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. A license application for this vaccine was submitted to the European Medicines Agency (EMA) by Sanofi Pasteur MSD (SPMSD) in January 2015. On December 17, 2015 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending marketing authorization for the product, to be commercialized as Vaxelis<sup>®</sup> in the European Union. On February 19, 2016, SPMSD was granted marketing authorization for Vaxelis<sup>®</sup>, and commercialization began in 2017 through a partnership between Merck and Sanofi Pasteur. A Biologics License

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Application was submitted to the US FDA in August 2014, and on November 2, 2015 the FDA issued a Complete Response Letter (CRL) for PR5i which is to be commercialized through a partnership of Merck and Sanofi



**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

Pasteur. Sanofi Pasteur and Merck are currently reviewing the CRL and plan to further communicate with the FDA. PR5i is expected to be the first hexavalent vaccine in the US market.

**Shan 6** is a cost-effective, all-in-one liquid hexavalent combination vaccine being developed for the Indian market and WHO pre-qualification. It comprises a detoxified whole-cell pertussis component as well as diphtheria toxoid, tetanus toxoid, Haemophilus influenza type b PRP-T, inactivated poliovirus types 1, 2, and 3 and hepatitis B virus components. A Phase I/II trial was initiated in India in October 2016, and Phase III preparations are underway.

**Adacel+ (Pertussis vaccine):** To sustain our global leadership in the development of pertussis vaccines, our R&D efforts are focused on developing an improved Tdap (tetanus toxoid, diphtheria toxoid, and 5-component Acellular pertussis containing formulation), for use in individuals aged 10 and over in the US market. The new formulation is being tested in Phase II trials.

**New Vaccine Targets**

**Tuberculosis:** Statens Serum Institute (SSI) of Denmark has granted Sanofi Pasteur a license to its technology for the use of certain fusion proteins in the development of a tuberculosis vaccine. The candidate vaccine is made up of recombinant protein units. Results from a 2008 Phase I trial found that the candidate vaccine was safe when administered to healthy adults living in a region of high endemic tuberculosis. A Phase I/II study in infants was initiated in South Africa in July 2013. A Phase II proof of concept study was initiated in young adolescents in South Africa in March 2014. Results are expected in 2018.

**Herpes Simplex Virus:** Herpes simplex virus type 2 is a member of the herpes virus family and as such establishes life-long infections, with latent virus established in neural ganglia. Although antivirals currently exist to treat infections, no vaccine exists, greatly limiting options in disease management. Our vaccine candidate is a live attenuated virus and is being assessed as a therapeutic and possibly prophylactic vaccine to reduce recurrence and transmission. In 2014, Sanofi Pasteur signed a contract with Immune Design Corp. to collaborate on the development of a therapeutic herpes simplex virus vaccine by exploring the potential of various combinations of agents.

**HIV:** Due to the enormity of the disease burden in developing countries and the potential for initial licensing of an efficacious vaccine in the developing world, Sanofi Pasteur is working in a pox-protein public-private partnership (P5) to document efficacy of a pox-protein based HIV prophylactic vaccine in South Africa. Specifically, following the modest success of RV144 (the first trial to show supporting evidence that vaccines could lower the risk of contracting HIV), the P5 partnership adopted a pox-protein based vaccine candidate as potentially providing greater protection for

South Africa and conducted a Phase I/II study (HVTN 100). This study met all pre-specified safety and immunogenicity criteria and supported moving the vaccine regimen to a pivotal efficacy study (HVTN702), which started on October 26, 2016 in South Africa and will continue until 2021. HVTN702 will not only assess the vaccine's

safety and efficacy, it will also help in discovering immune correlates of protection.

**RSVi:** Respiratory Syncytial Virus (RSV) is the most common cause of bronchiolitis in young children. Globally, RSV accounts for 22%-40% of lower tract respiratory illnesses, 50%-90% of bronchiolitis cases and 19%-40% of pneumonia cases, and causes up to 199,000 deaths each year. It is estimated that in the US alone, about 172,000 RSV hospitalizations occur each year in children under 5 years of age, resulting in significant healthcare costs. Sanofi Pasteur has signed a Cooperative Research and Development Agreement (CRADA) with the US National Institutes of Health (NIH) to develop a live attenuated RSV vaccine for routine immunization in infants aged 4 months and older. The lead candidate(s) are currently under Phase 1 evaluation in healthy infants without previous RSV exposure. In addition, in March 2017 Sanofi Pasteur announced an agreement with MedImmune to develop and commercialize a monoclonal antibody (SP0232, also known as MEDI8897) which has been engineered to have a long half-life so that only one dose would be needed for the entire RSV season. It is currently being investigated in a Phase IIb study in preterm infants. MEDI8897 received fast-track designation from the FDA in 2015.

**Zika:** Sanofi Pasteur entered into a Cooperative Research and Development Agreement (CRADA) with the Walter Reed Army Institute of Research (WRAIR) on a Zika vaccine project in 2016. The Biomedical Advanced Research and Development Authority (BARDA) of the US Department of Health and Human Services had agreed to provide \$43.2 million in funding for the manufacture of the inactivated Zika vaccine and the Phase I-II clinical trials. In August 2017, BARDA informed Sanofi Pasteur that it had decided to limit its funding to a case definition and surveillance study as well as any activities required to advance our vaccine development to a point where development would be indefinitely paused but could be restarted if the epidemic re-emerges. Consequently, Sanofi does not intend to continue development of, or seek a license from WRAIR for, the Zika vaccine candidate at this time. One of the ways Sanofi Pasteur will continue to contribute to the field of knowledge on Zika is by completing, with partial BARDA support, the ongoing case definition and surveillance study; this will provide guidance on Zika epidemiology and diagnosis that can be applicable to any vaccine subsequently developed to prevent the disease.

***Clostridium difficile* (C.diff) Toxoid vaccine:** We announced in December 2017 that we had decided to discontinue clinical development of our experimental C.diff vaccine.

**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

**B.5.3. R&D expenditures for late stage development**

Expenditures on research and development amounted to 5,472 million in 2017. Based on our new segment reporting model<sup>(1)</sup>, that comprised 4,056 million in the Pharmaceuticals segment; 123 million in the Consumer Healthcare segment; 557 million in the Vaccines segment; and 736 million allocated to Other, representing R&D support function costs that have been verticalized as part of the reorganization of Sanofi. Research and development expenditures were the equivalent of about 15.6% of net sales in 2017, compared to 15.3% in 2016 and about 14.9% in 2015. The stability in R&D expenditure as a percentage of sales

over the past three years is attributable to active management of the portfolio and close cost control, and has been achieved despite a greater proportion of products being in late stage development. Based on our previous segment reporting model<sup>(2)</sup>, under which we present our comparative analysis, preclinical research in the Pharmaceuticals segment<sup>(3)</sup> amounted to 1,218 million in 2017 compared to 1,094 million in 2016 and 1,072 million in 2015. Of the remaining 3,617 million relating to clinical development in the Pharmaceuticals segment<sup>(3)</sup> (3,523 million in 2016 and 3,458 million in 2015), the largest portion was generated by Phase III or post-marketing studies, reflecting the cost of monitoring large scale clinical trials.

Compound	Entry into Phase III <sup>(a)</sup> (month/year)	Compound Patent Term <sup>(b)</sup>			Comments
		US	EU	Japan	
SAR341402	August 2017	N/A	N/A	N/A	Phase III program ongoing in type 1 and 2 diabetes
insulin aspart sotagliflozin (SAR439954)	November 2015	2028	2027	2027	Phase III program ongoing in Type 1 & 2 diabetes. Dossier filing in type 1 diabetes is expected during the first half of 2018
efpeglenatide	December 2017	2028	2028	2028	

(SAR439977)					Phase III program ongoing in Type 2 diabetes
dupilumab	October 2014	2027	2029	2029	Dossier approved in Atopic Dermatitis (AD) in adults, Phase III program ongoing in AD in children and adolescents. Dossier submitted in Asthma for adults and children over 12 years old, Phase III program ongoing in Asthma for children (six-11 years)
(SAR231893)					
GZ402666	November 2016	2029	2028	2028	Phase III program ongoing in Nasal polyposis Phase III program ongoing in Pompe Disease
isatuximab	December 2016	2028	2027	2027	Phase III program ongoing in relapsing refractory multiple myeloma and in newly diagnosed multiple myeloma. A first filing is expected in 2018
(SAR650984)					
cemiplimab	May 2017				Phase III program ongoing in non-small cell lung cancer and cervical cancer
(SAR439684)					
fitusiran	Expected	2033	2033	2033	A biological license application in cutaneous squamous cell carcinoma was filed end of February 2018 in the US Phase III program initiated with dosing of the first patient expected the first quarter of 2018
(SAR439774)	Q1 2018				

(a) First entry into Phase III in any indication.

(b) Subject to any future supplementary protection certificates and patent term extensions.

(1) For more information see Item 5 A.1.5 Segment Information below.

(2) For more information see Item 5 A.2.3 Segment Results below.

(3) Includes the Consumer Healthcare business and an allocation of global support function costs. For more information see Item 5 A.2.3 Segment Results below.

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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

With respect to the compound patent information set out above, investors should bear in mind the following additional factors:

The listed compound patent expiration dates do not reflect possible extensions of up to five years available in the US, the EU, and Japan for pharmaceutical products. See B.7. Patents, Intellectual Property and Other Rights Patent Protection for a description of supplementary protection certificates and patent term extensions.

Depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product.

Regulatory exclusivity tied to the protection of clinical data is complementary to patent protection, and may provide more efficacious or longer lasting marketing exclusivity than a compound's patent estate. See B.7. Patents, Intellectual Property and Other Rights Regulatory Exclusivity for additional information. In the United States the data protection generally runs five years from first marketing approval of a new chemical entity extended to seven years for an orphan drug indication and twelve years from first marketing approval of a biological product. In the EU and Japan the corresponding data protection periods are generally ten years and eight years, respectively.

**B.6. MARKETS**

A breakdown of revenues by business segment and by geographical region for 2017, 2016, and 2015 can be found at Note D.35. to our consolidated financial statements included at Item 18 of this annual report.

The following market shares and ranking information are based on consolidated national pharmaceutical sales data (excluding vaccines), in constant euros, on a November 2017 MAT (Moving Annual Total) basis. The data are mainly from IQVIA local sales audit supplemented by various other country-specific sources including Knobloch (Mexico), GERS (France hospital channel), HMR (Portugal) and Reveal (Sweden). Market share data for the Consumer Healthcare business are from Nicholas Hall, Q3 2017 MAT. For more information on market shares and rankings see Presentation of Financial and Other Information at the beginning of this Annual Report on Form 20-F.

**B.6.1. Marketing and Distribution**

We have a commercial presence in approximately 100 countries, and our products are available in more than 170 countries. Our main markets in terms of net sales are respectively:

Emerging Markets (see definition in Information on the Company Introduction above): Sanofi is the leading healthcare company in emerging markets. Sanofi is the fifth largest pharmaceutical company in China.

The US: we rank twelfth with a market share of 3.7%.

Europe: we are the second largest pharmaceutical company in France where our market share is 7.2% and we rank fourth in Germany with a 4.4% market share.

Other countries: our market share in Japan is 1.6%.

A breakdown of our aggregate net sales by geographical region is presented in Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2017 Compared with Year Ended December 31, 2016.

Although specific distribution patterns vary by country, we sell prescription drugs primarily to wholesale drug distributors, independent and chain retail drug outlets, hospitals, clinics, managed-care organizations and government institutions. Rare disease products are also sold directly to physicians. With the exception of Consumer Healthcare products, our drugs are ordinarily dispensed to patients by pharmacies upon presentation of a doctor's prescription.

We use a range of channels from in-person to digital to disseminate information about and promote our products among healthcare professionals and patients, ensuring that the channels not only cover our latest therapeutic advances but also our established prescription products, which satisfy patient needs in some therapy areas. We regularly advertise in medical journals and exhibit at major medical congresses. In some countries, products are also marketed directly to patients by way of television, radio, newspapers and magazines, and digital channels (such as the internet). National education and prevention campaigns can be used to improve patients' knowledge of their conditions.

Our sales representatives, who work closely with healthcare professionals, use their expertise to promote and provide information on our drugs. They represent our values on a day-to-day basis and are required to adhere to a code of ethics and to internal policies in which they receive training.

Although we market most of our products through our own sales forces, we have entered into and continue to form partnerships to co-promote/co-market certain products in specific geographical areas. Our major alliances are detailed at Item 5. Operating and Financial Review and Prospects Financial Presentation of Alliances. See also Item 3. Key Information D. Risk Factors We rely on third parties for the discovery, manufacture and marketing of some of our products.

Our vaccines are sold and distributed through multiple channels including physicians, pharmacies, hospitals, private companies and distributors in the private sector, and governmental entities and non-governmental organizations in the public and international donor markets.



**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

**B.6.2. Competition**

The pharmaceutical industry continues to experience significant changes in its competitive environment.

There are four types of competition in the prescription pharmaceutical market:

competition between pharmaceutical companies to research and develop new patented products or address unmet medical needs;

competition between different patented pharmaceutical products marketed for the same therapeutic indication;

competition between original and generic products or between original biological products and biosimilars, at the end of regulatory exclusivity or patent protection; and

competition between generic or biosimilar products.

We compete with other pharmaceutical companies in all major markets to develop innovative new products. We may develop new technologies and new patented products wholly in-house, but we also enter into collaborative R&D agreements in order to access new technologies. See Note D.21. to our consolidated financial statements included in Item 18 of this annual report.

Sanofi is the fifth largest pharmaceutical company globally by sales. Our prescription drugs compete in all major markets against patented drugs from major pharmaceutical companies. Our competitors in key businesses include: Novo Nordisk, Boehringer Ingelheim and Merck in diabetes; Lilly in diabetes, immunology and oncology; Bristol-Myers Squibb in immunology and oncology; Novartis in diabetes, multiple sclerosis, and oncology; Shire in rare diseases; Pfizer in rare diseases and oncology; Biogen, Teva and Merck Serono in multiple sclerosis; Bayer in multiple sclerosis and oncology; Roche in multiple sclerosis, immunology and oncology; AstraZeneca in diabetes, cardiovascular disease and oncology; and Amgen in cardiovascular disease.



Following our acquisition of Boehringer Ingelheim's consumer healthcare business, our share of the global consumer healthcare market in 2017 was 4.2%. Other key competitors include Johnson & Johnson, Pfizer, GlaxoSmithKline, Bayer and Reckitt Benckiser as well as local players, especially in emerging markets.

Our generics business competes with multinational corporations such as Teva, Sandoz (a division of Novartis), Mylan and local players, especially in emerging markets.

In our Vaccines business we are one of the top four players, competing primarily with large multinational players including Merck, GlaxoSmithKline, and Pfizer.

We also face competition from generic drugs that enter the market when our patent protection or regulatory exclusivity expires, or when we lose a patent infringement lawsuit (see B.7. Patents, Intellectual Property and Other Rights below). Similarly, when a

competing patented drug from another pharmaceutical company faces generic competition, those generic products can also affect the competitive environment of our own patented product. See Item 3. Key Information D. Risk factors Risks relating to our business .

Competition from producers of generics has increased sharply in response to healthcare cost containment measures and to the increased number of products for which patents or regulatory exclusivity have expired.

Generics manufacturers who have received all necessary regulatory approvals for a product may decide to launch a generic version before the patent expiry date, even in cases where the owner of the original product has already commenced patent infringement litigation against the generics manufacturer. Such launches are said to be at risk for the promoter of the generic product because it may be required to pay damages to the owner of the original product in the context of patent infringement litigation; however, these launches may also significantly impair the profitability of the pharmaceutical company whose product is challenged.

Drug manufacturers also face competition through parallel trading, also known as reimportation. This takes place when drugs sold abroad under the same brand name as in a domestic market are imported into that domestic market by parallel traders, who may repackage or resize the original product or sell it through alternative channels such as mail order or the internet. This situation is of particular relevance to the EU, where these practices have been encouraged by the current regulatory framework. Parallel traders take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices.

Finally, pharmaceutical companies face illegal competition from falsified drugs. The WHO estimates that falsified products account for 10% of the market worldwide, rising to 30% in some countries. All therapeutic areas are affected, also including vaccines. However, in markets where powerful regulatory controls are in place, falsified drugs are estimated to represent less than 1% of market value.

### **B.6.3. Regulatory Framework**

#### ***B.6.3.1. Overview***

The pharmaceutical and health-related biotechnology sectors are highly regulated. National and supranational health authorities administer a vast array of legal and regulatory requirements that dictate pre-approval testing and quality standards to maximize the safety and efficacy of a new medical product. These authorities also regulate product labeling, manufacturing, importation/exportation and marketing, as well as mandatory post-approval commitments that may include pediatric development.



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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

The submission of an application to a regulatory authority does not guarantee that a license to market will be granted. Furthermore, each regulatory authority may impose its own requirements during the course of the product development and application review. It may refuse to grant approval and require additional data before granting approval, even though the same product has already been approved in other countries. Regulatory authorities also have the authority to request product recalls, product withdrawals and penalties for violations of regulations based on data that are made available to them.

Product review and approval can vary from six months or less to several years from the date of application depending upon the country. Factors such as the quality of data, the degree of control exercised by the regulatory authority, the review procedures, the nature of the product and the condition to be treated, play a major role in the length of time a product is under review.

The International Council for Harmonization (ICH) continues to implement its reform mandate.

The aims are to reinforce the foundations of the ICH; expand harmonization globally beyond the traditional ICH members, i.e. the three founding members (EU, Japan, US) plus Canada and Switzerland as observers; and facilitate the involvement of additional regulators and industry associations around the world. There are now nine regulatory agencies (including China, Brazil and South Korea) and six industry associations as full ICH members and 24 organizations (including nine regulatory authorities from around the world) with observer status.

International collaboration between regulatory authorities continues to develop with the implementation of confidentiality arrangements and memoranda of understanding between both ICH and non-ICH regulatory authorities. Examples include work-sharing on Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) inspections, as well as regular interactions between the US and the EU in the form of clusters (i.e. pediatrics, oncology, advanced therapy medicinal products, vaccines, pharmacogenomics, orphan drugs, biosimilars, and blood products). In 2017 the United States and the EU completed an exchange of letters to amend the Pharmaceutical Annex to the 1998 US-EU Mutual Recognition Agreement. Under this agreement, US and EU regulators will be able to utilize each other's good manufacturing practice for inspections of pharmaceutical manufacturing facilities.

In addition to the joint efforts listed above, Free Trade Agreements (FTAs) have proven to be one of the best ways to open up foreign markets to exporters and to allow for discussions on harmonization topics for regulatory authorities. Some agreements, such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), are international in nature, while others are between specific countries. The requirements of many countries (including Japan and several EU Member States) to negotiate selling prices or reimbursement rates for pharmaceutical products with government regulators significantly extend the time to market

entry beyond the initial marketing approval. While marketing authorizations for new pharmaceutical products in the EU have been largely centralized within the European Commission in collaboration with the EMA, pricing and

reimbursement remain a matter of national competence.

**In the EU**, there are three main procedures for applying for marketing authorization:

The centralized procedure is mandatory for drugs derived from biotechnologies; new active substances designed for human use to treat HIV, viral diseases, cancer, neurodegenerative diseases, diabetes and auto-immune diseases; orphan drugs; and innovative products for veterinary use. When an application is submitted to the EMA, the scientific evaluation of the application is carried out by the Committee for Medicinal Products for Human Use (CHMP) and a scientific opinion is prepared. This opinion is sent to the European Commission which adopts the final decision and grants an EU marketing authorization. Such a marketing authorization is valid throughout the EU and the drug may be marketed within all EU Member States.

If a company is seeking a national marketing authorization in more than one Member State, two procedures are available to facilitate the granting of harmonized national authorizations across member states: the mutual recognition procedure or the decentralized procedure. Both procedures are based on the recognition by national competent authorities of a first assessment performed by the regulatory authority of one Member State.

National authorizations are still possible, but are only for products intended for commercialization in a single EU Member State or for line extensions to existing national product licenses.

Generic products are subject to the same marketing authorization procedures. A generic product must contain the same active medicinal substance as a reference product approved in the EU. Generic applications are abridged: generic manufacturers only need to submit quality data and demonstrate that the generic drug is bioequivalent to the originator product (i.e. performs in the same manner in the patient's body), but do not need to submit safety or efficacy data since regulatory authorities can refer to the reference product's dossier. Generic product applications can be filed and approved in the EU only after the originator product eight-year data exclusivity period has expired. Further, generic manufacturers can only market their generic products after a 10- or 11-year period has elapsed from the date of approval of the originator product. In the case of orphan drugs, generic product applications may not be filed before the expiry of a 10- or 12-year period from the date of approval of the originator product.

Another relevant aspect in the EU regulatory framework is the sunset clause under which any marketing authorization ceases to be valid if it is not followed by marketing within three years or if marketing is interrupted for a period of three consecutive years.

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

In 2017, the EMA recommended 92 medicines for marketing authorization (versus 81 in 2016), including 35 new active substances.

Among the 92 medicines recommended, 19 (21%) had an orphan designation (versus 17 in 2016 and 18 in 2015), providing medicines for patients with rare diseases. Seven medicines were evaluated under accelerated assessment in 2017 (also seven in 2016 and five in 2015); this mechanism is reserved for medicines that have the potential to address unmet medical needs. Three medicines were recommended for a conditional marketing authorization; this is one of the EMA's early access routes to patients, and is intended for medicines that address an unmet medical need and that target seriously debilitating, life-threatening or rare diseases, or are intended for use in emergency situations in response to a public health threat.

Post-authorization safety monitoring of pharmaceutical products is carefully regulated in Europe. EU pharmaceutical legislation for medicinal products describes the respective obligations of the marketing authorization holder (MAH) and of the regulatory authorities to set up a system for pharmacovigilance in order to collect, collate and evaluate information about suspected adverse reactions.

It is possible for the regulatory authorities to withdraw products from the market for safety reasons. Responsibilities for pharmacovigilance rest with the regulatory authorities of all the EU Member States in which the marketing authorizations are held. In accordance with applicable legislation, each EU Member State has a pharmacovigilance system for the collection and evaluation of information relevant to the risk-benefit balance of medicinal products. The regulatory authority regularly monitors the safety profile of the products available in its territory, takes appropriate action where necessary, and monitors the compliance of MAHs with their pharmacovigilance obligations. All relevant information is shared between the regulatory authorities and the MAH, in order to allow all parties involved in pharmacovigilance activities to fulfill their obligations and responsibilities.

The pharmacovigilance legislation was amended in 2012. The amendments aimed to further strengthen the protection of patient health by promoting prompt and appropriate regulatory action on European medicines. In particular, the amendments included major changes to notification requirements: MAHs of human medicines now have to notify EU regulators of any action to withdraw a product from a market, together with the reason for this action. Changes also included the creation of a Pharmacovigilance Risk Assessment Committee (PRAC), a scientific advisory committee at EMA level, with a key role in the assessment of all aspects of risk management relating to the use of medicinal products for human use approved in the European Economic Area (EEA). This includes measures relating to the

detection, assessment, minimization and communication of the risk of adverse reactions, having due regard to the therapeutic effect of the medicinal product. This committee is also responsible for the design and evaluation of post-authorization safety studies (PASS) and pharmacovigilance audits.

In Europe, the PRAC has performed reviews of marketed products (by class or on ad hoc basis) through various procedures. For Sanofi, 182 products underwent PRAC review through signal and referral procedures from July 2012 to December 2017, generating 112 labeling variations (14 new variations in 2017) and five additional risk minimization measures. In only two cases for Sanofi (Myolastan<sup>®</sup>, and methadone oral solutions containing povidone) did the review lead to the product being withdrawn from the EU market.

The EU pharmacovigilance legislation also strengthens the legal basis for regulators to require post-authorization safety and efficacy studies throughout the life cycle of a medicinal product, with regulatory supervision of protocols and results. Such studies are aimed at collecting data to enable the safety or efficacy of medicinal products to be assessed in everyday medical practice. The granting of marketing authorization is conditional on such studies being performed. Consequently, the pharmaceutical industry now has to build the need for PASS and post-authorization efficacy studies (PAES) into development and life cycle management plans. Sanofi has put in place robust processes to ensure that PASS and PAES can be properly implemented as required, either as part of a Risk Management Plan (RMP) or following a health authority request.

A further requirement introduced by the EU pharmacovigilance legislation is for pharmaceutical companies to prepare Periodic Safety Update Reports (PSURs). These are not limited to safety data, but instead present a critical analysis of the risk-benefit balance of a medicinal product, taking into account new or emerging information in the context of cumulative information on risks and benefits.

There is in addition a legal requirement for an enhanced adverse reaction collection and management system (EudraVigilance) that delivers better health protection through simplified reporting, higher quality data, and improved search, analysis and tracking functionalities. Associated with this is a legal requirement for MAHs to monitor EudraVigilance data, to the extent to which they have access to such data. On November 22, 2017, the EMA launched a new and improved version of EudraVigilance with enhanced functionalities to support the fulfilment of these pharmacovigilance obligations. Alongside the launch, simplified electronic reporting of suspected adverse reactions related to medicines by national Competent Authorities and MAHs to EudraVigilance became mandatory. On February 22, 2018, the legal requirement for MAHs to monitor EudraVigilance data and inform the EMA and national competent authorities of validated signals became applicable for active substances included in the List of medicinal products under additional monitoring , for a one-year pilot period.

The database of medicinal products aims to deliver structured and quality assured information on medicinal products authorized in the EU that incorporates the terminology adopted in the EU for products, substances, and organizations underpinning pharmacovigilance and regulatory systems. Since January 1, 2015,

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**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

MAHs have been required to notify the EMA of any new marketing authorizations within 15 calendar days from the date of authorization, and to notify the EMA of any change in the terms of a marketing authorization as soon as possible within 30 calendar days following the date on which the changes were authorized.

The EMA's medical literature monitoring (MLM) service was launched on September 1, 2015 to monitor selected medical literature for reports of suspected adverse drug reactions containing certain active substances, and to enter reports in the EudraVigilance database.

There is a legal requirement for the EMA to set up a repository for Periodic Safety Update Reports (PSURs) and for EMA assessment reports on PSURs in order to facilitate centralized PSUR reporting and to enhance access to data and information, thereby supporting risk/benefit assessments of medicines. The PSUR Repository achieved full functionality in June 2015 and its use in the EU became mandatory on June 13, 2016.

**In the US**, applications for approval are submitted for review to the FDA, which has broad regulatory powers over all pharmaceutical and biological products that are intended for sale and marketing in the US. To commercialize a product in the US, a new drug application (NDA) under the Food, Drug and Cosmetic (FD&C) Act, or a Biological License Application (BLA) under the Public Health Service (PHS) Act, must be submitted to the FDA for filing and pre-market review. Specifically, the FDA must decide whether the product is safe and effective for its proposed use; if the benefits of the drug's use outweigh its risks; whether the drug's labeling is adequate; and if the manufacturing of the drug and the controls used for maintaining quality are adequate to preserve the drug's identity, strength, quality and purity. Based upon this review, the FDA can require post-approval commitments and requirements. Approval for a new indication of a previously approved product requires submission of a supplemental NDA (sNDA) for a drug or a supplemental BLA (sBLA) for a biological product.

Sponsors wishing to market a generic drug can file an Abbreviated NDA (ANDA) under 505(j) of the FD&C Act. These applications are abbreviated because they are generally not required to include data to establish safety and effectiveness, but need only demonstrate that their product is bioequivalent (i.e. performs in humans in the same manner as the originator's product). Consequently, the length of time and cost required for development of generics can be considerably less than for the innovator's drug. The ANDA pathway in the US can only be used for generics of drugs approved under the FD&C Act.

The FD&C Act provides another abbreviated option for NDA approved products, which is a hybrid between an NDA and ANDA called the 505(b)(2) pathway. This 505(b)(2) pathway enables a sponsor to rely on the FDA's findings that the reference product is safe and effective, based on the innovator's preclinical and clinical data.

The FDA Center for Drug Evaluation and Research (CDER) approved 46 novel drugs in 2017 (versus 22 in 2016, 45 in 2015, 41 in 2014, and 27 in 2013). Designations and pathways to expedite drug development and review include Fast Track (18/46 = 39%), Breakthrough Therapy (17/46 = 37%), Accelerated approval (6/46 = 13%) and Priority

Review (28/46 = 61%). Of the 46 novel drugs approved in 2017, 61% were designated in one or more expedited categories.

CDER identified 15 of the 46 novel drugs approved in 2017 (33%) as First-in-Class, one indicator of the innovative nature of a drug. Approximately 39% of the novel drugs approved in 2017 were approved to treat rare or orphan diseases that affect 200,000 or fewer Americans.

**In Japan**, the regulatory authorities can require local clinical studies, though they also accept multi-national studies. In some cases, bridging studies have been conducted to verify that foreign clinical data are applicable to Japanese patients and obtain data to determine the appropriateness of the dosages for Japanese patients. The Japanese Ministry of Health, Labor and Welfare (J-MHLW) has introduced a new National Health Insurance (NHI) pricing system. Reductions in NHI prices of new drugs every two years are compensated by a Premium for a maximum of 15 years. A Premium is granted in exchange for the development of unapproved drugs or off-label indications with high medical needs. Once an official request for development of an unapproved drug or off-label indication has been made, the pharmaceutical companies must file literature-based reports within six months or submit a clinical trial notification for registration within one year after the official development request. For unapproved drugs with high medical needs, clinical trials in Japanese patients are generally required. Otherwise, a fine equivalent to 105% (with 5% representing interest) of sales based on the premium would have to be paid back to the government.

To promote the development of innovative drugs and bring them into early practical use in Japan ahead of the world, the Sakigake (a Japanese term meaning forerunner) review designation program was introduced in April 2015. The Pharmaceuticals and Medical Devices Agency (PMDA) will review designated products on a priority basis with the aim of reducing their review time from the normal 12 months to six months.

Based on the NHI price system, the Premium classification will be restricted to new products from companies which conduct R&D on pharmaceuticals truly conducive to the improvement of healthcare quality, i.e. (i) pediatric/orphan drugs and (ii) drugs to treat diseases that cannot be adequately controlled with existing drugs. From 2019, all prescription product prices will be reviewed annually instead of once every two years, but price cuts will actually be conducted only for a limited number of products with big gaps between their official reimbursement prices and market prices



**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

(e.g. generic drugs and long-listed original products). On the other hand, prices of products that are rapidly adopted after approvals for new indications may from 2017 be reviewed four times a year.

The PMDA has set a target for 80% (as opposed to the current 50%) of all applications to be reviewed in 12 months for products with standard review status and in nine months for products with priority review status by the end of 2018.

The PMDA also plans to eliminate the review lag between the filing and approval of drugs and medical devices relative to the FDA by the end of 2020.

The Pharmaceuticals and Medical Devices Act was implemented on November 25, 2014. There are three major objectives. The first objective is to strengthen safety measures for drugs and medical devices. In particular, MAHs must prepare a package insert based on the latest knowledge and notify the J-MHLW before placing products on the market or when revisions are made. The second objective is to accelerate the development of medical devices. The third-party accreditation system will be expanded to specially controlled generic medical devices (i.e. Class III devices). Consequently, the PMDA can accelerate the review of innovative medical devices. The third objective is accelerated commercialization of regenerative medicinal products.

The term Regenerative Medicinal Products used in the law includes cellular and tissue-based products and gene therapies. This concept is similar to Advanced Therapy Medicinal Products (ATMPs) in the EU. The law allows for conditional regulatory approval based on confirmation of probable efficacy and safety in small-scale clinical trials, followed up by comprehensive studies to confirm safety and efficacy in a wider population that would then lead to a regular (full) approval.

For new drugs and biosimilar products with approval applications submitted on or after April 2013, Japan has implemented an RMP (Risk Management Plan), similar to the EU Pharmacovigilance system.

For generic products, the data necessary for filing are similar to EU and US requirements. Companies only need to submit quality data, and data demonstrating bioequivalence to the originator product, unless the drug is administered intravenously. Clinical Trial Data (CTD) submission for generics has been mandatory since March 2017.

***B.6.3.2. Biosimilars***

Products can be referred to as biologics when they are derived from natural sources, including blood products or products manufactured within living cells (such as antibodies). Most biologics are complex molecules or mixtures of molecules which are difficult to characterize and require physico-chemical-biological testing, and an understanding of and control over the manufacturing process.

The concept of generics is not scientifically appropriate for biologics due to their high level of complexity. Consequently the

concept of biosimilar products is more appropriate. A full comparison of the purity, safety and efficacy of the biosimilar product against the reference biological product should be undertaken, including assessment of physical-chemical-biological, non-clinical and clinical similarity.

**In the EU**, the regulatory framework for developing and evaluating biosimilar products has been in place since 2005. The CHMP has issued several product/disease specific guidelines for biosimilar products including guidance on preclinical and clinical development of biosimilars of Low Molecular Weight Heparin (LMWH) and of insulins. Starting in 2011 and continuing through 2017, the CHMP has been engaged in revising most of the existing biosimilar guidelines (general overarching guidelines, quality, and non-clinical and clinical product-specific guidelines).

While the CHMP has adopted a balanced approach for all biosimilars, allowing evaluation on a case-by-case basis in accordance with relevant biosimilar guidelines, it has also indicated that in specific circumstances, a confirmatory clinical trial may not be necessary. This applies if similar efficacy and safety can clearly be deduced from the similarity of physicochemical characteristics, biological activity/potency, and pharmacokinetic and/or pharmacodynamic profiles of the biosimilar and the reference product. With respect to vaccines, the CHMP currently takes the view that it is at present unlikely that these products can be characterized at the molecular level, and that each vaccine product must be evaluated on a case-by-case basis.

In February 2017, the EMA launched a tailored scientific advice pilot project to support step-by-step development of new biosimilars, based on a review of the quality, analytical and functional data already available. This pilot will encompass six scientific advice requests. The EMA will analyze the outcome after completing the pilot.

In 2017, the EMA and the European Commission published an information guide for healthcare professionals to provide them with reference information on the science and regulation underpinning the use of biosimilar medicines.

**In the US**, the Patient Protection and Affordable Care Act (Affordable Care Act), signed into law in March 2010, amended the Public Health Service Act to create an abbreviated licensure pathway (351k) for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-licensed biological product.

In 2017 the FDA published for consultation two biosimilar draft guidance documents: *Considerations in Demonstrating Interchangeability with a Reference Product* and *Statistical Approaches to Evaluate Analytical Similarity*.

As of the date of this annual report nine biosimilar products have been approved by the FDA. Five of those nine products were approved in 2017. To date no biosimilar products have been deemed interchangeable.

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**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

**In Japan**, guidelines defining the regulatory approval pathway for follow-on biologics were finalized in March 2009. These guidelines set out the requirements on preclinical, clinical and Chemistry, Manufacturing and Control (CMC) data to be considered for the development of the new application category of biosimilars. Unlike the CHMP guidelines, the main scope of the Japanese guidelines includes recombinant proteins and polypeptides, but not polysaccharides such as LMWH.

Many regulatory authorities worldwide have in place, or are in the process of developing, a regulatory framework for biosimilar development and approval. It should be noted that although many emerging markets are basing their regulations and guidance on WHO or EMA documentation, some markets have approved biosimilars under an existing regulatory framework that is not specific to biosimilars.

***B.6.3.3 Regenerative Medicine***

The US Center for Biologics Evaluation and Research (CBER) has established the Regenerative Medicine Advanced Therapy (RMAT) designation program, as authorized in section 3033 of the 21st Century Cures Act. This program aims to facilitate an efficient development program, expedite review of innovative regenerative medicine therapies, and provide more timely access to potentially life-saving products. Products granted the RMAT designation are eligible for increased early interactions with FDA, including all the benefits available to breakthrough therapies. As of October 31, 2017, FDA had granted 11 RMAT designations.

In 2017, the FDA published two final guidance documents that are part of a comprehensive policy framework to address how the agency plans to support and expedite the development of regenerative medicine products, including human cells, tissues, and cellular and tissue-based products (HCT/Ps). These guidance documents build upon the FDA's risk-based, flexible regulatory framework, and underscore the agency's commitment to help bring new and innovative treatment options to patients. The first guidance (Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use) is intended to provide clarity in the determination of whether HCT/Ps are subject to the FDA's premarket review requirements. The second guidance (Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception) is intended to provide clarity as to whether an establishment may qualify for an exception from the requirements under Part 1271 of the Code of Federal Regulations (CFR) Title 21 by meeting the exception in 21 CFR 1271.15(b).

Novel regenerative medicine therapies approved by the CBER in 2017 include the first three gene therapies: Novartis AG's chimeric antigen receptor T-cell (CAR-T) therapy Kymriah (tisagenlecleucel) followed by Kite Pharma Inc.'s CAR-T therapy Yescarta (axicabtagene ciloleucel), both for oncology indications, and Spark Therapeutics Inc.'s Luxturna (voretigene neparvovec-rzyl) for inherited vision loss.

***B.6.3.4 Generics***

**In the EU** 20 positive opinions were issued under the centralized procedure for generics in 2017 (versus 16 in 2016 and 21 in 2015). Most of the generics applications for chemical entities use the mutual recognition and decentralized procedures. Pricing systems for generics remain at national level in the EU.

**In the US**, to help the FDA ensure that participants in the US generic drug system comply with US quality standards and to increase the likelihood that American consumers get timely access to low cost, high quality generic drugs, the FDA and the industry have jointly agreed to a comprehensive program (Generic Drug User Fee Amendments) to supplement traditional appropriated funding, focused on safety, access, and transparency. For the period October 1, 2016 through September 30, 2017 the FDA planned to review and act on 90% of original ANDA submissions within 10 months from the date of submission. For this period, 763 ANDAs were approved, 174 received tentative approval and 1603 complete responses were issued.

**In Japan**, the 2014 reforms to the NHI price system included a new special price reduction rule for long-listed drugs. The rule was introduced in April 2014. It reduced the NHI prices of long-listed drugs whose generic replacement rates are less than 20% five years after their first generics join the NHI price list. Reductions are 2.0% in the first NHI price revision, 1.75% if the substitution rate is 20% or higher but less than 40%, and 1.5% if the rate is 40% or higher but less than 60%.

Under the new price system, NHI prices of first generics (previously set at 60%) were set at 50% of the price of the originator product. A 40% rule is applied to oral first generics once more than ten products with the same ingredients have obtained listing.

In addition, a maximum Sakigake premium of 20% was introduced in April 2016 for Sakigake-designated products, which have new mechanisms of action and obtain approval in Japan ahead of the rest of the world.

#### ***B.6.3.5. Medical Devices***

**In the EU**, there is no pre-market authorization by a regulatory authority. Instead there is a Conformity Assessment Procedure (for medium and high risk devices), possibly involving an independent third party Notified Body (NB) depending on the classification of the device. Once certified, medical devices have to bear the CE-mark, allowing them to circulate freely in the EU/EFTA (European Free Trade Association) countries and Turkey.

To align legal requirements across the EU Member States and to strengthen the protection of public health, two new Regulations came into force in 2017 replacing older EU Directives.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices came into force on May 26, 2017 with a transition period of three years.

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**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices came into force on May 26, 2017 with a transition period of five years.

**In the US**, the FDA Center for Devices and Radiological Health (CDRH) is responsible for regulating firms that manufacture, repackage, relabel and/or import medical devices sold in the US. The CDRH also regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

Medical devices are classified into Class I, II, and III based on their risks and the regulatory controls necessary to provide reasonable assurance of safety and effectiveness. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval. Low and moderate risk devices (Class I and II) can also be classified through the de novo pathway if certain conditions are met.

The basic regulatory requirements that manufacturers of medical devices distributed in the US must comply with are: Establishment Registration; Medical Device Listing; Premarket Notification 510(k) (unless exempt) or Premarket Approval; Investigational Device Exemption; Quality System Regulation; Labeling Requirements and Medical Device Reporting.

***B.6.3.6. OTC drugs***

**In the EU**, four European centralized prescription to OTC (Rx-to-OTC) switches have occurred since 2009. For nationally authorized products, switches follow national rules for OTC classification. In 2017, a European platform for non-prescription medicines was launched to harmonize non-prescription status and to facilitate the switching environment.

**In the US**, the FDA approved one prescription to OTC switch in 2017: Sanofi Consumer Healthcare's Xyzal<sup>®</sup> Allergy 24HR (levocetirizine dihydrochloride).

**In Japan**, the J-MHLW drug safety committee set new rules in 2013 on the details of safety evaluations for drugs newly switched from prescription to OTC, following the passage of a bill to revise the Pharmaceutical Affairs Law (PAL). The J-MHLW gives the green light for online sales of such OTC drugs if no safety concerns arise during an

initial three-year safety evaluation period. During this three-year evaluation period, drugs that moved from prescription to OTC are categorized as products that require

pharmacist consultations when purchased. Under the new rules, the J-MHLW requires marketing authorization holders to submit interim reports upon completion of their post marketing surveillance (PMS).

The PMS needs to cover 3,000 patients for oral drugs and 1,000 patients for topical drugs. Based on these interim reports and other reports on adverse events, the J-MHLW performs the first evaluation on whether there are any safety concerns three years after the launch. If no safety concerns are identified during this three-year safety evaluation period, the classification of these Rx-to-OTC switches will be downgraded to Category 1 OTC drugs, i.e. drugs which do not require pharmacist consultation and can be sold online. The J-MHLW performs the second safety evaluation one year after the transfer to Category 1 OTC drugs. If no safety concerns are identified, the classification of the Category 1 OTC drugs will be downgraded to Category 2 OTC drugs, i.e. drugs that can be handled by pharmacists but also by registered salespersons.

Generic OTC drugs can be filed after completion of the three-year PMS period and will be approved in seven months.

The J-MHLW launched a new panel in April 2016 to pick up Rx-to-OTC switch candidates. Under the new scheme, the MHLW accepts requests for Rx-to-OTC switch candidates from various stakeholders such as medical societies, consumers, and pharmaceutical companies, and then these requests are publicly reviewed by the new panel in order to minimize pressures from medical societies. Based on its deliberations, the panel refers shortlisted requests to the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) committee on nonprescription drugs, which effectively makes decisions on marketing approval for OTCs.

#### ***B.6.3.7. Transparency and public access to documents***

##### **Transparency regarding regulatory information, clinical trials and associated regulatory decision-making**

Over the last several years the pharmaceutical industry has been subject to growing pressure for greater transparency about clinical trials (conduct and results). Regulatory authorities are also being pressed for more openness and transparency, for example by making more comprehensive disclosures about the rationale and basis of regulatory decisions on medicinal products, so as to enhance the credibility of the regulatory process. This is a significant driver of the transparency initiatives undertaken in several countries.

Pharmaceutical manufacturers have committed to publishing protocols, study information and results of clinical studies conducted with their products in publicly accessible registries. In addition, both ICH and non-ICH countries often impose mandatory disclosure of clinical trials information.

From a regulatory perspective, ambitious initiatives have been undertaken by the major regulatory authorities and Sanofi has processes in place to address these initiatives.

EU pharmaceutical legislation for medicinal products requires national regulatory authorities and the EMA to actively publish information concerning authorization and supervision of medicinal

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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

products. The EMA has introduced a series of initiatives aimed at improving the transparency of its activities, such as improving the format of the European Public Assessment Report and web-published product approvals, withdrawals and rejections. In addition, there is an increased focus on comparative efficacy and effectiveness. The new EU pharmacovigilance legislation aims at giving greater transparency, especially with regard to communication of safety issues (e.g. public hearings, specific European web portals with information on medicinal products). Finally, patients and consumers are increasingly involved in the work of the EMA's scientific committees.

The EMA has committed to continuously extend its approach to transparency. A key goal in this process is the proactive publication of clinical trial data for medicines once the decision-making process on an application for an EU-wide marketing authorization is complete.

In 2014, the EMA adopted Policy 70 for publication of clinical trial reports. The policy came into force on January 1, 2015. It applies to clinical reports contained in any new marketing authorization applications for centralized marketing authorizations; to post-authorization procedures for existing centrally authorized medicinal products; and to article 58 applications (medicines that are intended exclusively for markets outside the EU).

For post-authorization procedures for existing centrally authorized medicinal products, the effective date was July 1, 2015 for extension of indication and line extension applications submitted as of that date.

The policy is being implemented in two phases:

The first phase concerns the publication of clinical reports only, the data from which will be accessible on the EMA website.

In the second phase, the EMA will endeavor to find the most appropriate way to make Individual Patient Data (IPD) available, in compliance with privacy and data protection laws.

In order to operationalize EMA Policy 70, Sanofi launched an internal project to define, develop, implement and control a sustainable process, supported by associated tools and documents, as well as resourcing, training and communication plans to manage clinical documents and data redaction in compliance with Policy 70. In 2016, the EMA Policy 70 process was fully transitioned to the business operational teams. Awareness communication is ongoing not only for current submissions, but also to streamline the process for ongoing and future studies.

**In the US**, the FDA launched a Transparency Initiative in June 2009. The objective of the initiative was to render the FDA much more transparent and open to the American public by providing the public with useful, user-friendly information about agency activities and decision making.

The FDA Transparency Initiative has three phases: Phase I Improving the understanding of the FDA basics (completed with ongoing updates); Phase II Improving the FDA's disclosure of information to the public (ongoing); and Phase III Improving the FDA's transparency to regulated industry (ongoing). Proposals to improve transparency and access to information have been released for consultation for both Phase II and Phase III. Some of the less controversial proposals have been implemented; others, such as proactive release of information that the Agency has in its possession, may require revisions to US federal regulations.

In September 2016, the US Department of Health and Human Services, National Institute of Health (NIH) published Final Rule under Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) on the Dissemination of Clinical Trial Information. The Final Rule requires registration and results submission for applicable clinical trials (ACTs); clarifies and expands registration data elements; expands scope of results reporting requirements to include trials of unapproved products; clarifies and expands results data elements; and revises Quality Control (QC) and posting process.

Additionally, in January 2018, the FDA launched a new pilot program to evaluate whether disclosing certain information included within clinical study reports ( CSRs ) of approved drugs is beneficial to the public. CSRs are scientific reports prepared by the sponsor to summarily address a drug's efficacy and safety, and include information related to the methods and results of clinical trials supporting the drug. Traditionally, this information has only been released following submission of a Freedom of Information Act ( FOIA ) request. Under the pilot program, the Agency will continue to protect from disclosure trade secrets and confidential commercial information, as required by law.

**In Japan**, the J-MHLW/PMDA actively publishes information concerning approvals of medicinal products (ethical drugs, nonprescription drugs, and quasi-drugs) and medical devices. For ethical drugs discussed at the J-MHLW's Pharmaceutical Affairs and Food Sanitation Council, the redacted clinical trials data modules 1 and 2 (except for commercial confidential information and personal data) have been made publicly available on the PMDA website.

### Transparency regarding Health Care Professionals

**In the EU**, there is no harmonized approach regarding transparency for Health Care Professionals (HCPs). For transparency purposes, there is increased external scrutiny of interactions between pharmaceutical companies and HCPs at national level, with legal provisions or healthcare industry voluntary undertakings in some countries (such as the UK, Denmark, France and Portugal).

The European Federation of Pharmaceutical Industries Association (EFPIA) released in mid-2013 a Code on Disclosure of Transfers of Value from Pharmaceutical Companies to HCPs and Healthcare



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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

Organizations (HCOs), the EFPIA HCP/HCO Disclosure Code . EFPIA members are required to comply with this Code and transpose it into their national codes.

The Code includes stricter rules on hospitality and gifts, with the requirement for member associations to include a threshold on hospitality and the prohibition of gifts in their national codes.

**In the US**, the Physician Payments Sunshine Act, or Sunshine Act , was passed as part of the Affordable Care Act. The law is designed to bring transparency to financial relationships between physicians, teaching hospitals, and the pharmaceutical industry. Manufacturers and group purchasing organizations (GPOs) must report certain payments or transfers of value including payments for research, publication support, travel, honoraria and speaking fees, meals, educational items like textbooks and journal reprints whether made directly to a physician or teaching hospital or indirectly through a third party. The law also requires manufacturers and GPOs to report physicians or members of their immediate family who have an ownership interest in the company. Reports are made to the Centers for Medicare and Medicaid Services, a government agency.

**In Japan**, the Japan Pharmaceutical Manufacturers Association (JPMA) member companies started releasing information on their funding of healthcare professionals in 2013 and patient groups in 2014 under the trade group s voluntary guidelines to boost financial transparency. Under the JPMA s transparency guidelines for the relations between companies and medical institutions, its members currently report their payments in five categories: R&D, academic research support, manuscript/writing fees, provision of information, and other expenses.

***B.6.3.8. Other new legislation proposed or pending implementation***

In the **US**, in August 2017 the Food and Drug Reauthorization Act (FDARA) was signed into law. The law reauthorized user fee collection for the next five years for drugs (PDUFA VI), devices (MDUFA IV), generics (GDUFA II) and biosimilars (BsUFA II) and reflects a move to a more stable funded program. In addition to user fees, FDARA focuses on modifications and improvements of the regulation of drugs, devices and generics.

**In China**, since the initial programmatic regulatory reform initiative started in 2015, most of the country s regulatory processes have been adapted to bring them into line with other major regulatory agencies. These include establishing predictable pathways and timelines (including conditional approvals); a Marketing Application Holder system; risk-based inspections; and clinical trial processes that allow companies developing innovative drugs to conduct

clinical trials simultaneously with other countries (International Multicenter Clinical Trials). The China Food and Drug Administration (CFDA) has also established a system for intellectual property protection.

### Clinical trial regulation in the EU

The Clinical Trial Regulation ((EU) 536/2014) of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, was published in the Official Journal of the EU on May 28, 2014.

Pharmaceutical companies and academic researchers will be required to post the results of all their European clinical trials in a publicly-accessible database.

The legislation streamlines the rules on clinical trials across Europe, facilitating cross-border cooperation to enable larger, more reliable trials, as well as trials of products for rare diseases. It simplifies reporting procedures, and gives the European Commission the authority to perform audits. Once a clinical trial sponsor has submitted an application dossier to a Member State, the Member State will have to respond to it within fixed deadlines.

One of the main objectives of the European Commission in introducing the clinical trial regulation was to simplify the clinical trial approval process. The new legislation was drafted in the more stringent form of a regulation rather than as a directive, so as to achieve better harmonization between countries without interfering with Member States competencies in terms of ethical issues.

The major points are:

The timeline for approving a clinical trial proposal is set at 60 days without questions (and a maximum of 99 with questions and clock stops). This can be seen as a setback for the industry, as the Commission's proposal was based on 41 days without questions and a maximum of 74 days including all possible delays. In the case of advanced therapy medicinal products, the timeline can be extended by another 50 days, making 110 days in total.

To make both the reference state and the relevant Member States comply with the timelines, the legislation includes the concept of tacit approval. The fact that this feature was accepted by all parties can be seen as a positive outcome for the industry.

Selection of reference Member State by the sponsor was maintained.

As regards transparency requirements for clinical trial data submitted through a single EU submission portal and stored in a Union-level database, the new clinical trial regulation allows for protection of personal data of patients and commercially confidential information, which is in line with the industry data sharing laid out in Policy 70 (see previous section). The new regulation cannot be implemented until the single EU submission portal and database is fully operational. Work on the EU database and portal progressed during 2017, but due to technical difficulties with the development of the IT systems the portal's go-live date was postponed. An audit will be carried out in 2018, and the EMA will provide further information on timelines after the audit. According to an EMA assessment report in 2017,



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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

development remains in line with a schedule that would allow the EU Clinical Trial Regulation to enter into force in the second half of 2019.

**Falsified medicines**

The EU has reformed the rules for importing active substances for medicinal products for human use into the EU (Directive 2011/62/EU). Since January 2013, all imported active substances must have been manufactured in compliance with GMP standards or standards at least equivalent to GMP. The manufacturing standards in the EU for active substances are those specified in Q7 as issued by the International Council for Harmonization (ICH). With effect from July 2, 2013, such compliance must be confirmed in writing by the competent authority of the exporting country, except for countries with waivers. Written confirmation must also confirm that the plant where the active substance was manufactured is subject to control and enforcement of GMP at least equivalent to that in the EU.

Several implementing measures for the Falsified Medicines Directive have been adopted. A common EU logo for online pharmacies was adopted in June 2014, giving Member States until July 2015 to prepare for its application. Detailed rules for the safety features appearing on the outer packaging of medicinal products for human use have been adopted, meaning that all prescription drugs or reimbursed drugs commercialized on the European market will have to be serialized by February 2019.

**Nagoya Protocol**

The Nagoya Protocol came into force in October 2014 and is intended to create greater legal certainty and transparency for both providers and users of genetic resources by:

establishing more predictable conditions for access to genetic resources; and

helping to ensure benefit-sharing when genetic resources leave the contracting party providing the genetic resources.

In the EU, the European Commission published the implementation Act in 2015 (Regulation 2015/1866).

It states that the pharmaceutical industry has to implement compliance procedures for non-human biological materials used in the discovery, development, manufacturing and packaging of medicinal products.

The Sanofi Nagoya Ready Project was launched in 2015 to ensure compliance with international treaties on the sustainable use of biodiversity. The Nagoya Ready Project Team has ensured that Sanofi is prepared for compliance with the Nagoya Protocol and ready for full implementation. A Nagoya Expert Group reporting to the Bioethics

Committee will continue to monitor the international implementation of the protocol and provide appropriate support and advice to the relevant Sanofi teams.

**In Japan**, the relevant ministries are currently considering local measures for the ratification of the Nagoya Protocol. The schedule for ratification has yet to be determined. The details of local measures for the implementation of the Nagoya Protocol cannot be disclosed due to ongoing discussion, but the relevant ministries are considering a framework where terms and conditions can be set for mutual agreement and a consent can be obtained in advance from providers in accordance with laws and regulations in a source country when genetic resources from the source country are used in Japan.

#### NDA electronic clinical trial data submission (eCTD)

**In the EU**, electronic submission for marketing authorization and variation applications has already been in place for many years. To

allow secure submission over the Internet for all types of eCTD applications for human medicines, the EMA launched the eSubmission Gateway, which is now mandatory for all eCTD submissions through the centralized procedure, in order to improve efficiency and decrease costs for applicants.

As of July 1, 2015, companies are obliged to use electronic application forms provided by the EMA for all centralized marketing authorization applications for human and veterinary medicines. From January 2016, the use of electronic application forms became mandatory for all other EU marketing authorization procedures (i.e. mutual recognition and decentralized procedures, and national submissions).

**In Japan**, electronic submission of CDISC-based clinical data will become mandatory after the transition period that runs from October 2016 to March 2020, allowing the authority to efficiently store and analyze the data to improve its efficacy and safety predictions.

Such mandatory electronic submissions are expected to be limited to clinical trial data for new drugs newly filed for regulatory approval. The necessity for electronic submission for Phase I trial data will likely be decided on a case-by-case basis, while pharmaceutical companies will be required to file nonclinical toxicity study data in one of the Standard for the Exchange on Non clinical Data (SEND) formats in due course.

#### Brexit

The United Kingdom's decision to withdraw from the European Union ( Brexit ) has triggered a need to adapt regulatory activities in the region. Early in 2017, the EMA established a working group to explore options to (re)distribute across the remaining network the workload related to human (and veterinary) medicines and inspections currently managed by the UK.

The risk-based methodology leverages the diverse expertise in the network and takes into account the workload associated with the regulation of medicines. The EMA will communicate details of the methodology and next steps in early 2018.

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

The EMA has conducted Industry Stakeholder meetings to discuss the various issues related to Brexit and is continuing to release regulatory and procedural guidance for pharmaceutical companies in order to facilitate preparation for Brexit.

To safeguard continuity of operations and secure timely execution of its core tasks, the EMA has launched a Business Continuity Plan (BCP). The BCP defines priority levels for EMA activities according to their impact on public health and the ability of the EMA to manage the tasks in light of the human resources available. Some regulatory activities are already temporarily suspended, or output is temporarily reduced, such as for instance work on the Transparency Policy 70 project.

In November 2017, following a predetermined procedure, it was decided that the EMA will relocate to Amsterdam in the Netherlands. The EMA's collaboration with the Netherlands commenced promptly and agreement has been reached on a joint governance structure, with plans to progress activities within five work streams relating to temporary and permanent premises, staff relocation, financial and legal aspects, and external communication.

Sanofi has set up an internal Brexit Task Force to proactively address issues triggered by Brexit.

**B.6.4. Pricing & Reimbursement**

Rising overall healthcare costs are leading to efforts to curb drug expenditures in most markets in which we operate. Increasingly, these efforts result in pricing and market-access controls for pharmaceuticals. The nature and impact of these controls vary from country to country, but some common themes are reference pricing, systematic price reductions, formularies, volume limitations, patient co-pay requirements, and generic substitution. In addition, governments and third-party payers are increasingly demanding comparative/relative effectiveness data to support their decision-making process. They are also increasing their use of emerging healthcare information technologies such as electronic prescribing and health records to enforce transparency and tight compliance with these regulations and controls. As a result, the environment in which pharmaceutical companies must operate in order to make their products available to patients and providers who need them continues to grow more complex each year.

While a drive to expand healthcare coverage has become a noticeable feature in many regions, providing opportunities for industry, it has also brought pressure on these new budgets, bringing with it a wave of price and volume control measures. Many countries and regions have increased pressure on pricing through joint procurement and negotiation.

National production, whether through a policy of industrialization, through technology transfer agreements or through preferential conditions for local production, is equally a growing issue.

Significant trends:

In the United States there is increased scrutiny on the price of branded pharmaceutical products, and therefore heightened sensitivity to patient exposure to high out-of-pocket expense.

Private health insurance is offered widely as part of employee benefit packages, and is the main source of access to subsidized healthcare provision. Some individuals purchase private health plans directly, while publicly-subsidized programs provide cover for retirees, the poor, the disabled, uninsured children, and serving or retired military personnel. Double-coverage can occur. Public health insurances include:

Medicare, which provides health insurance for retirees and for people with permanent disabilities. The basic Medicare scheme (Part A) provides hospital insurance only and the vast majority of retirees purchase additional cover through some or all of three other plans named Part B, Part C and Part D. Part D enables Medicare beneficiaries to obtain outpatient drug subsidies. Almost two-thirds of all Medicare beneficiaries have enrolled in Part D plans.

Medicaid, which provides health insurance for those on low incomes.

Managed Care Organizations (MCOs) combine the functions of health insurance, delivery of care, and administration. MCOs use specific provider networks and specific services and products. There are three types of managed care plans: Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), and Point of Service (POS) plans.

Pharmacy benefit managers (PBMs) serve as intermediaries between insurance companies, pharmacies and manufacturers to secure lower drug costs for commercial health plans, self-insured employer plans, Medicare Part D plans, and federal and state government employee plans.

In the United States, the federal Affordable Care Act has increased the government's role with respect to price, reimbursement, and coverage levels for healthcare services and products within the large government healthcare sector. This law also imposed rebates and fees on pharmaceutical companies. Legislation was introduced in over 26 states in 2017 which would require price transparency and reporting of certain manufacturer information. Legislation has been passed in Nevada (requiring detailed reporting to the state on information for all drugs essential for treating diabetes) and in California (requiring advance price notification and detailed information for any drugs with a WAC increase of 16% or more over a two year period). This trend will continue into 2018 where we anticipate legislation to be filed in at least 20 states and more laws to be enacted around the country. US federal and state officials, including the Trump administration, are continuing to focus on the cost of health coverage and health care although the future policy, including the nature and timing of any changes to the Affordable Care Act, remains unclear.

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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

In October 2017, the President signed an Executive Order directing federal agencies to modify how the ACA is implemented and announced the Administration would no longer fund cost sharing subsidies paid to health insurance exchange plans. However, health insurance exchanges remain a minor percentage of the payor mix using branded pharmaceuticals, and so the impact of these changes appears limited. Currently, while there is the potential for additional disruptions to the ACA exchange markets via administrative or congressional action, full repeal or other wholesale changes to the law appear unlikely in the near term. Drug pricing-related policies continue to be a focus for the government, however, so there is no assurance that additional adverse policy changes could arise.

Affordable access for patients is critical to our industry's success; however, the cost of access via third party intermediaries—Pharmaceutical Benefit Managers (PBMs), Health Plans and Government Markets—is calling into question the integrity of the healthcare system and the sustainability of our business.

As the US approached the so-called "Patent Cliff" major market insurers realized the traditional business revenue model was threatened and there was an immediate shift to a model that would increase enrollment and cut costs. In recent years mergers and acquisitions have been the largest source of payer revenue growth, as acquired patients translate to increased demand.

With a decline in generic conversion and no further scope for consolidation, payers are seeking alternative methods to cut costs. As payers consolidate they can leverage their size and market share to demand higher rebates in return for increased access. If a manufacturer is reluctant to offer a higher rebate, the insurer will resort to interventions to enforce formulary controls.

As a soft measure to control access, payers use step therapy (to ensure use of low-cost therapies) and prior authorization (to require proof of medical necessity). For example, some US payers have placed significant restrictions on usage of Praluent<sup>®</sup>, which has resulted in significant out-of-pocket expenditures for Medicare patients.

A more extreme tactic, initially provoked by pharma coupons, is adding a product to an exclusion list; this means that (i) a patient has to pay out of pocket and (ii) manufacturer coupons are rejected at the pharmacy. For example, since 2014, we have increased the level of rebates granted for Lantus<sup>®</sup> in order to maintain favorable formulary positions with key payers in the US. Despite these efforts, in 2016 CVS and UnitedHealthcare (a PBM and MCO, respectively) decided that effective January 1, 2017 and April 1, 2017, respectively, Lantus<sup>®</sup> and Toujeo<sup>®</sup> will be excluded from the formulary across the commercial and MMC (Medicaid Managed Care) template formularies covering approximately 34.7 million people, thus reducing the potential patient populations to whom Lantus<sup>®</sup> may be prescribed.



US insurers have prioritized the need to control costs in specialty categories, and will maximize exclusions and protocols to achieve

savings. There is a particular focus on all chronic disease states, which will limit the ability of new entrants to achieve coverage without demonstration of comparative effectiveness. Finally, US insurers are quick to adopt Follow-On-Biologic (copycat) versions of branded drugs as a good enough alternative to leverage higher rebates as compared with incumbent products.

A new approach to copayments was adopted recently by some plans: the copay accumulator programs do not apply manufacturer copay coupons for specialty drugs to the patient's deductible and out-of-pocket maximum, which may lead to an increase in patients' overall costs.

In addition, distributors have increased their capacity to negotiate price and other terms as a consequence of the growing number of mergers of retail chains and distributors, resulting consolidation of the distribution channel.

In May 2017, Sanofi adopted pricing principles for the US (for more information, please see <https://www.sanofi.com/en/our-responsibility/documents-center/>)

The industry in China is going through a transformative period with many proposals on reform from the government. The first update of the NRDL (National Reimbursement Drug List) since 2009 occurred in 2017 and it has been announced that this will be done on a more regular basis going forward, to bring innovative medicines to the Chinese market earlier. The CFDA (China Food and Drugs Administration) has also made clear its intent to clear the backlog of regulatory reviews. Generics manufacturers are incentivized to submit originator bioequivalence data in order to access priority tendering, in a drive to modernize the generics industry and change their image as an affordable alternative to brands. The market itself is also due to transform through a series of smaller measures. For example, a two-invoice policy will simplify the supply chain, and tax reform has reallocated funds to poorer provinces for healthcare. While these can be viewed as positive, there are many uncertainties. Whatever the outcome, we can expect many other measures in the Chinese market following a call to step up the pace of reforms.

Recent trends in European policy have been towards joint procurement and joint negotiations, ignited by the controversy on funding Hepatitis C drugs. At the same time, political uncertainty, especially Brexit negotiations in the UK and tightening evaluation processes (e.g. the dissolution of the pricing committee in favor of an HTA committee in Greece, ultra-orphan drug quality adjusted life-year (QALY) thresholds and budget thresholds in the UK) are ever-present. However, with an increasing number of innovative products on the horizon, some countries have begun to address this, such as a dedicated budget for innovative medicines in Italy and the Accelerated Access Pathway in the UK.

While reforms in Japan were announced, several proposals were delayed until future reviews. However, some significant modifications were made to the Price Maintenance Premium and to the Foreign Price Adjustment. The final details are currently under preparation.

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

In South America, inflation continues to have a major effect on the sustainability of the industry in the region. Transparent tendering platforms have begun to appear in Colombia and Brazil while joint procurement actions are widening (brought about for HCV and oncology).

The Eurasian Economic Union (Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia) has moved forward with its plans for a single pharmaceutical market with a centralized system for product registration under a mutual recognition agreement. This should further streamline processes and also increase the region's negotiating power.

We believe that third-party payers will continue to act to curb the cost of pharmaceutical products. While the impact of those measures cannot be predicted with certainty, we are taking the necessary steps to defend the accessibility and price of our products in order to reflect the value of our innovative product offerings:

In compliance with local law we actively engage with our key stakeholders to define criteria for assessing the value of our products to them. These stakeholders, including physicians, patient groups, pharmacists, government authorities and third-party payers, can have a significant impact on market access for our products.

We continue to add flexibility and adaptability to our operations so as to better prepare, diagnose, and address issues in individual markets.

Conscious of the importance of recognizing the value of our products and the high cost of research and development, we continue to analyze innovative pricing and access strategies that balance patient access with appropriate rewards for innovation. Specifically, we are involved in risk-sharing agreements with payers, whereby part of the financial risk related to a treatment's success is carried by the marketing company. Those agreements provide that clinical efficacy be monitored after launch, for a specified period of time and patient population. The price and reimbursement level of the drug is then either confirmed or revised based on the post-marketing results.

We are also actively testing pilot models for affordability and access to healthcare, allowing wider access to therapies for populations that would otherwise be denied this.

**B.7. Patents, intellectual property and other rights**

## Patent Protection

We own a broad portfolio of patents, patent applications and patent licenses worldwide. These patents are of various types and may cover:

active ingredients;

pharmaceutical formulations;  
product manufacturing processes;

intermediate chemical compounds;

therapeutic indications/methods of use;

delivery systems; and

enabling technologies, such as assays.

Patent protection for individual products typically extends for 20 years from the patent filing date in countries where we seek patent protection. A substantial part of the 20-year life span of a patent on a new molecule (small molecule or biologic) has generally already passed by the time the related product obtains marketing authorization. As a result, the effective period of patent protection for an approved product's active ingredient is significantly shorter than 20 years. In some cases, the period of effective protection may be extended by procedures established to compensate regulatory delay in Europe (via Supplementary Protection Certificate or SPC), in the US (via Patent Term Extension or PTE) and in Japan (also via PTE).

Additionally, the product may benefit from the protection of patents obtained during development or after the product's initial marketing authorization. The protection a patent provides to the related product depends upon the type of patent and its scope of coverage, and may also vary from country to country. In Europe for instance, applications for new patents may be submitted to the European Patent Office (EPO), an intergovernmental organization which centralizes filing and prosecution. As of December 2017, an EPO patent application may cover the 38 European Patent Convention Member States, including all 28 Member States of the EU. The granted European Patent establishes corresponding national patents with uniform patent claims among the Member States. However, some older patents were not approved through this centralized process, resulting in patents having claim terms for the same invention that differ between the countries. Additionally, a number of patents prosecuted through the EPO may pre-date the European Patent Convention accession of some current European

Patent Convention Member States, resulting in different treatment in those countries.

In 2013, EU legislation was adopted to create a European Unitary Patent and a Unified Patent Court. However, it will only enter into force once the agreement on the Unified Patent Court is ratified by at least 13 Member States including France, Germany, and the United Kingdom. As of the date of this document, 14 countries including France have ratified the agreement, but ratification by the United Kingdom and Germany is still outstanding, and the process is impacted by Brexit.

The Unitary Patent will provide unitary protection within the participating states of the EU (when ratified by the Member States with the exception of Croatia, Spain, and Poland, not currently signatories of the agreement). The Unified Patent Court will be a specialized patent court with exclusive jurisdiction for litigation relating to European patents and Unitary Patents. The Court will be

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**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

composed of a central division (headquartered in Paris) and several local and regional divisions in the contracting Member States to the agreement. The Court of Appeal will be located in Luxembourg.

We monitor our competitors and vigorously seek to challenge patent infringements when such infringements would negatively impact our business objectives. See Item 8 A. Consolidated Financial Statements and Other Financial Information A.3. Information on Legal or Arbitration Proceedings Patents of this annual report.

The expiration or loss of a patent covering a new molecule, typically referred to as a compound patent, may result in significant competition from generic products and can result in a dramatic reduction in sales of the original branded product (see Item 3. Key Information D. Risk Factors ). In some cases, it is possible to continue to benefit from a commercial advantage through product manufacturing trade secrets or other types of patents, such as patents on processes, intermediates, compound structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulin, were historically relatively less reliant on patent protection and may in many cases have no patent coverage. It is nowadays increasingly frequent for novel vaccines and insulins also to be patent protected. Finally, patent protection is of comparatively lesser importance to our Consumer Healthcare and generics businesses, which rely principally on trademark protection.

**Regulatory Exclusivity**

In some markets, including the EU and the US, many of our pharmaceutical products may also benefit from multi-year regulatory exclusivity periods, during which a generic competitor may not rely on our clinical trial and safety data in its drug application. Exclusivity is meant to encourage investment in research and development by providing innovators with exclusive use, for a limited time, of the innovation represented by a newly approved drug product. This exclusivity operates independently of patent protection and may protect the product from generic competition even if there is no patent covering the product.

In the US, the FDA will not grant final marketing authorization to a generic competitor for a New Chemical Entity (NCE) until the expiration of the regulatory exclusivity period (five years) that commences upon the first marketing authorization of the reference product. The FDA will accept the filing of an Abbreviated New Drug Application (ANDA) containing a patent challenge one year before the end of this regulatory exclusivity period (see the descriptions of ANDAs in Product Overview Challenges to Patented Products below). In addition to the regulatory exclusivity granted to NCEs, significant line extensions of existing NCEs may qualify for an additional three years of regulatory exclusivity. Also, under certain limited conditions, it is possible to extend unexpired US regulatory and patent-related exclusivities by a pediatric extension. See Pediatric Extension , below.

In the US, a different regulatory exclusivity period applies to biological drugs. The Biologics Price Competition and Innovation Act of 2009 ( BPCIA ), was enacted on March 23, 2010 as part of the Affordable Care Act. The BPCIA introduced an approval pathway for biosimilar products. A biosimilar product is a biologic product that is highly

similar to the reference (or innovator) product notwithstanding minor differences in clinically inactive components, and which has no clinically meaningful differences from the reference product in terms of the safety, purity, and potency of the product. The BPCIA provides that an application for a biosimilar product that relies on a reference product may not be submitted to the FDA until four years after the date on which the reference product was first licensed, and that the FDA may not approve a biosimilar application until 12 years after the date on which the reference product was first licensed. US Federal and state officials, including the new Administration, are continuing to focus on the cost of health coverage and health care although the future policy, including the nature and timing of any changes to the Affordable Care Act, remains unclear.

In the EU, regulatory exclusivity is available in two forms: data exclusivity and marketing exclusivity. Generic drug applications will not be accepted for review until eight years after the first marketing authorization (data exclusivity). This eight-year period is followed by a two-year period during which generics cannot be marketed (marketing exclusivity). The marketing exclusivity period can be extended to three years if, during the first eight-year period, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which are deemed to provide a significant clinical benefit over existing therapies. This is known as the 8+2+1 rule.

In Japan, the regulatory exclusivity period varies from four years for medicinal products with new indications, formulations, dosages, or compositions with related prescriptions, to six years for new drugs

containing a medicinal composition, or requiring a new route of administration, to eight years for drugs containing a new chemical entity, to ten years for orphan drugs or new drugs requiring pharmaco-epidemiological study.

### Emerging Markets

One of the main limitations on our operations in emerging market countries is the lack of effective intellectual property protection or enforcement for our products. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP) required developing countries to amend their intellectual property laws to provide patent protection for pharmaceutical products since January 1, 2005. However, it also provided a limited number of developing countries with an extended period in which to achieve compliance with TRIP. Additionally, these same countries frequently do not provide non-patent exclusivity for innovative products. While the situation has gradually improved, the lack of protection for intellectual property rights or the lack of robust enforcement of intellectual property

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

rights poses difficulties in certain countries. Additionally, in recent years a number of countries facing health crises have waived or threatened to waive intellectual property protection for specific products, for example through compulsory licensing of generics. See Item 3. Key Information D. Risk Factors Risks Relating to Sanofi's Structure and Strategy The globalization of our business exposes us to increased risks in specific areas .

**Pediatric Extension**

In the US and the EU, under certain conditions, it is possible to extend a product's regulatory exclusivity for an additional period of time by providing data on pediatric studies.

In the US, the FDA may ask a company for pediatric studies if it has determined that information related to the use of the drugs in the pediatric population may produce health benefits. The FDA has invited us by written request to provide additional pediatric data on several of our main products. Under the Hatch-Waxman Act, timely provision of data meeting the FDA's requirements (regardless of whether the data supports a pediatric indication) may result in the FDA extending regulatory exclusivity and patent life by six months, to the extent these protections have not already expired (the so-called pediatric exclusivity ).

In Europe, a regulation on pediatric medicines provides for pediatric research obligations with potential associated rewards including extension of patent protection (for patented medicinal products) and six month regulatory exclusivity for pediatric marketing authorization (for off-patent medicinal products).

In Japan, there is no pediatric research extension of patent protection (for patented medicinal products). However, regulatory exclusivity may be extended from eight to ten years.

**Orphan Drug Exclusivity**

Orphan drug exclusivity may be granted in the US to drugs intended to treat rare diseases or conditions (affecting fewer than 200,000 patients in the US, or in some cases more than 200,000 with no expectation of recovering costs).

Obtaining orphan drug exclusivity is a two step process. An applicant must first seek and obtain orphan drug designation from the FDA for its drug for one or more indications. If the FDA approves a drug for the designated indication, the drug will generally receive orphan drug exclusivity for such designated indication.

Orphan drug exclusivity runs from the time of approval and bars approval of another application (ANDA, 505(b)(2), New Drug Application (NDA) or Biologic License Application (BLA)) from a different sponsor for the same drug in the same indication for a seven year period. Whether a subsequent application is for the same drug depends upon the chemical and clinical characteristics. The FDA may approve applications for the same drug for indications not protected by orphan exclusivity.

Orphan drug exclusivities also exist in the EU and Japan.

## Product Overview

We summarize below the intellectual property coverage (in some cases through licences) in our major markets of the marketed products described above at B.2. Main Pharmaceutical Products . In the discussion of patents below, we focus on active ingredient patents (compound patents) and for NCEs on any later filed patents listed, as applicable, in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book ) or in their foreign equivalents. For Biologics the Orange Book listing does not apply. These patents or their foreign equivalents tend to be the most relevant in the event of an application by a competitor to produce a generic or a biosimilar version of one of our products (see Challenges to Patented Products below). In some cases, products may also benefit from pending patent applications or from patents not eligible for Orange Book listing (for NCEs) (e.g. patents claiming industrial processes). In each case below, we specify whether the active ingredient is claimed by an unexpired patent. Where patent terms have been extended to compensate for US Patent and Trademark Office (USPTO) delays in patent prosecution (Patent Term Adjustment PTA) or for other regulatory delays, the extended dates are indicated below. The US patent expirations presented below reflect USPTO dates, and also reflect six month pediatric extensions when applicable. Where patent terms have expired we indicate such information and mention whether generics are on the market.

We do not provide later filed patent information relating to formulations already available as an unlicensed generic. References below to patent protection in Europe indicate the existence of relevant patents in most major markets in the EU. Specific situations may vary by country, most notably with respect to older patents and to countries that have only recently joined the EU.



**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

We additionally set out any regulatory exclusivity from which these products continue to benefit in the US, EU or Japan. Regulatory exclusivities presented below incorporate any pediatric extensions obtained. While EU regulatory exclusivity is intended to be applied throughout the EU, in some cases Member States have taken positions prejudicial to our exclusivity rights.

	United States	European Union	Japan
<b>Aldurazyme<sup>®</sup> (aronidase)</b>	Compound: November 2019  Later filed patents: ranging through July 2020 with PTA	Compound: November 2020 in some EU countries only  Later filed patent: November 2020 in some EU countries only	Compound: November 2020
<b>Allegra<sup>®</sup> (fexofenadine hydrochloride)</b>	Compound: expired Generics on the market Converted to over-the-counter	Compound: expired Generics on the market	Compound: expired Generics on the market Converted to over-the-counter
<b>Amaryl<sup>®</sup> (glimepiride)</b>	Compound: expired	Compound: expired	Compound: expired
<b>Apidra<sup>®</sup> (insulin glulisine)</b>	Compound: June 2018  Later filed patents: ranging through September 2027	Compound: September 2019 with SPC in most of the EU countries  Later filed patent: March 2022	Compound: May 2022 with PTE  Later filed patent: July 2022
<b>Aprovel<sup>®</sup> (irbesartan)</b>	Compound: expired	Compound: expired	Regulatory exclusivity: Expired Compound: expired Later filed patent: June 2021 with PTE
<b>Aubagio<sup>®</sup> (teriflunomide)<sup>(a)</sup></b>	Generics on the market Compound: expired Later filed patents: coverage ranging through February 2034 Regulatory exclusivity: September 2017	Generics on the market Compound: expired Later filed patent: coverage ranging through September 2030 Regulatory exclusivity: August 2023	Compound: expired Later filed patent: coverage ranging through March 2024

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<b>Cerdelga® (eliglustat)</b>	Compound: April 2022 (2026 with PTE if granted) Later filed patent: November 2030 (pending) Regulatory exclusivity: August 2019 Orphan drug exclusivity: August 2021	Compound: July 2022 (2027 with SPC if granted) Later filed patent: November 2030  Orphan drug exclusivity: January 2025	Compound: July 2022 (March 2025 with PTE) Later filed patent: November 2030 (pending) Regulatory exclusivity: March 2023
<b>Cerezyme® (imiglucerase) Depakine® (sodium valproate)</b>	Compound: expired Compound: N/A <sup>(b)</sup>	Compound: N/A Compound: N/A <sup>(b)</sup> Later filed patent: Depakine® Chronosphere formulation: Expired	Compound: N/A Compound: N/A <sup>(b)</sup> Later filed patent: Depakine® Chronosphere formulation: Expired

*(a) In 2017, Sanofi reached settlement with all 20 generic Aubagio® ANDA first filers granting each a royalty-free license to enter the United States market on March 12, 2023 (see Item 8. Financial Information).*

*(b) No rights to compounds in the US, EU and Japan.*

**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

	United States	European Union	Japan
<b>Dupixent® (dupilumab)</b>	Compound: October 2027 (Mar 2031 with PTE if granted) Later filed patents: coverage ranging through December 2033 with PTA Regulatory exclusivity: March 2029	Compound: October 2029 (September 2032 if SPC granted) Later filed patents: coverage ranging through September 2033 (pending) Regulatory exclusivity: September 2027	Compound: October 2029 (PTE to be determined once product is approved) Later filed patents: coverage ranging through September 2033 (pending) Regulatory exclusivity: January 2026
<b>Fabrazyme® (agalsidase beta)</b>	Compound: N/A Later filed patents: expired	Compound: N/A Later filed patents: expired	Compound: N/A Later filed patents: expired
<b>Insuman® (human insulin)</b>	Compound: N/A	Compound: N/A Later filed patent: August 2018	Compound: N/A
<b>Jevtana® (cabazitaxel)</b>	Compound: September 2021 with PTE and pediatric exclusivity Later filed patents: coverage ranging through April 2031 with pediatric exclusivity	Compound: expired  Later filed patents: coverage ranging through October 2030 (pending) Regulatory exclusivity: March 2021	Compound: March 2021 with PTE  Later filed patents: coverage ranging through October 2030 with PTE Regulatory exclusivity: July 2022
<b>Kevzara® (sarilumab)</b>	Compound: January 2028 with PTA Later filed patents: coverage ranging through March 2037	Compound: June 2027  Later filed patents: coverage ranging through March 2037	Compound: June 2027  Later filed patents: coverage ranging through March 2037

	(pending)	(pending)	(pending)
	Regulatory exclusivity: May 2029		
<b>Lantus® (insulin glargine)</b>	Compound: expired Later filed patents ranging through March 2028	Compound: Expired Later filed patents ranging through June 2023	Compound: expired Later filed patents ranging through June 2023
<b>Lemtrada® (alemtuzumab)</b>	Compound: expired Later filed patent: August 2029 with PTA	Compound: expired Later filed patent: September 2027 (pending)	Compound: expired Later filed patent: September 2027
<b>Lovenox® (enoxaparin sodium)</b>	Compound: N/A Generics on the market	Compound: expired	Compound: expired
<b>Lumizyme® / Myozyme® (alglucosidase alpha)</b>	Compound: N/A Later filed patents: coverage ranging through February 2023 with PTA Biologics regulatory exclusivity: April 2018	Compound: N/A Later filed patents: July 2021	Compound: N/A Later filed patents: coverage ranging through July 2021  Orphan drug exclusivity: expired
<b>Adlyxin®/Lyxumia® (lixisenatide)</b>	Compound: July 2020 (July 2025 with PTE if granted) Later filed patents: coverage ranging through August 2032 Regulatory exclusivity: July 2021	Compound: July 2020 <sup>(b)</sup> (2025 with SPC in most EU countries if granted) Later filed patents: November 2030 (pending) Regulatory exclusivity: February 2023	Compound: July 2024 with PTE  Later filed patents: November 2030 Regulatory exclusivity: June 2021

**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

	United States	European Union	Japan
<b>Mozobil® (plerixafor)</b>	Compound: N/A Later filed patents: coverage ranging through July 2023	Compound: N/A Later filed patent: July 2022 (2024 with SPC in some EU countries) Orphan drug exclusivity: August 2019	Compound: N/A Later filed patent: August 2026 with PTE Orphan drug exclusivity: December 2026
<b>Multaq® (dronedarone hydrochloride)</b>	Compound: expired Later filed patents: coverage ranging through June 2031	Compound: expired Later filed patent: June 2018 (2023 with SPC in most EU countries) Regulatory exclusivity: December 2019	Compound: expired Later filed patent: June 2018
<b>Soliqua100/33 / Suliqua (lixisenatide + insulin glargine)</b>	Compound: July 2020 (July 2025 with PTE if granted) Later filed patents: coverage ranging through November 2030 (pending) Regulatory exclusivity: July 2021	Compound: July 2020 (July 2025 with SPC in most EU countries if granted) Later filed patents: coverage ranging through January 2032 with SPC Regulatory exclusivity: January 2027	Compound: July 2024 with PTE Later filed patents: coverage ranging through November 2030 Regulatory exclusivity: to be determined
<b>Plavix® (clopidogrel bisulfate)</b>	Compound: expired Generics on the market	Compound: expired Generics on the market	Compound: expired
<b>Praluent® (alirocumab)</b>	Compound: December 2029 Later filed patents: coverage ranging through September 2032 (pending) Biologics regulatory exclusivity: July 2027 Compound: N/A	Compound: December 2029 (September 2030 if SPC granted) Later filed patents: coverage ranging through September 2032 (pending) Regulatory exclusivity: September 2025 Compound: N/A	Compound: November 2032 with PTE Later filed patents: coverage ranging through September 2032 Regulatory exclusivity: July 2024 Compound: N/A

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<b>Renagel® (sevelamer hydrochloride)</b>	Later filed patent: October 2020	Later filed patent: October 2020	Later filed patent: October 2020
<b>Renvela® (sevelamer carbonate)</b>	Compound: N/A Later filed patents: October 2025 (tablet) and December 2030 (sachet) Generics on the market	Compound: N/A Later filed patent: November 2025 (tablet) and September 2026 (sachet) Generics on the market	Compound: N/A Later filed patents: November 2025 (tablet) and September 2026 (sachet)
<b>Stilnox® (zolpidem tartrate)</b>	Compound: expired Generics on the market	Compound : expired Generics on the market	Compound : expired Later filed patent: Ambien® CR formulation (December 2019) not commercialized
<b>Synvisc® (Hylan G-F 20)</b>	Compound: expired	Compound: N/A	Compound: expired Regulatory exclusivity: July 2018
<b>Synvisc-One® (Hylan G-F 20)</b>	Compound: expired	Compound: N/A Later filed patent: December 2025	Compound: expired Later filed patent: December 2025

**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

	United States	European Union	Japan
<b>Toujeo® (insulin glargine)</b>	Compound: expired Later filed patents: coverage ranging through May 2031 Regulatory exclusivity: February 2018	Compound: expired Later filed patents: coverage ranging through May 2031 (pending)	Compound: expired Later filed patents: coverage ranging through July 2033 with PTE Regulatory exclusivity: July 2019
<b>Zaltrap® (afibercept)</b>	Compound: May 2020 (July 2022 with PTE if granted)  Later filed patents: coverage ranging through April 2032 (pending) Biologics regulatory exclusivity: November 2023	Compound: May 2020 (May 2025 with SPC in most EU countries, if granted)  Later filed patents: coverage ranging through April 2032 (pending)  Regulatory exclusivity: February 2023	Compound: May 2020 (May 2025 with PTE if granted)  Later filed patents: coverage ranging through April 2032 (pending)  Regulatory exclusivity: March 2023

*PTE: Patent Term Extension.*

*SCP: Supplementary Protection Certificate.*

*PTA: Patent Term Adjustment.*

Patents held or licensed by Sanofi do not in all cases provide effective protection against a competitor's generic version of our products. For example, notwithstanding the presence of unexpired patents, competitors launched generic versions of Allegra® in the US (prior to the product being switched to over-the-counter status) and Plavix® in the EU.

We caution the reader that there can be no assurance that we will prevail when we assert a patent in litigation and that there may be instances in which Sanofi determines that it does not have a sufficient basis to assert one or more of the patents mentioned in this report, for example in cases where a competitor proposes a formulation not appearing to fall within the claims of our formulation patent, a salt or crystalline form not claimed by our composition of matter patent, or an indication not covered by our method of use patent. See Item 3. Key Information D. Risk Factors 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 .

As disclosed in Item 8 of this annual report, we are involved in significant litigation concerning the patent protection of a number of our products.

### Challenges to Patented Products

#### Abbreviated New Drug Applications (ANDAs)

In the US, companies have filed Abbreviated New Drug Applications (ANDAs), containing challenges to patents related to a number of our products. An ANDA is an application by a drug manufacturer to receive authority to market a generic version of another company's approved product, by demonstrating that the purportedly generic version has the same properties as the original

approved product. ANDAs may not be filed with respect to drugs licensed as a biological. See B.6.3. Regulatory Framework B.6.3.2. Biosimilars above. An ANDA relies on the safety and other technical data of the original approved product, and does not generally require the generic manufacturer to conduct clinical trials (thus the name abbreviated new drug application), presenting a significant benefit in terms of time and cost. As a result of regulatory protection of our safety and other technical data, the ANDA may generally be filed only five years after the initial US original product marketing authorization. See Regulatory Exclusivity above. This period can be reduced to four years if the ANDA includes a challenge to a patent listed in the FDA's Orange Book. However, in such a case if the patent holder or licensee brings suit in response to the patent challenge within the statutory window, then the FDA is barred from granting final approval to an ANDA during the 30 months following the patent challenge (this bar is referred to in our industry as a 30-month stay ), unless, before the end of the 30 months, a court decision or settlement has determined either that the ANDA does not infringe the listed patent or that the listed patent is invalid and/or unenforceable.

FDA approval of an ANDA after this 30-month period does not resolve outstanding patent disputes, but it does remove the regulatory impediments to a product launch by a generic manufacturer willing to take the risk of later being ordered to pay damages to the patent holder.

The accelerated ANDA-type procedures are potentially applicable to many, but not all, of the products we manufacture. See B.6.3. Regulatory Framework 6.3.2. Biosimilars and Regulation above. We seek to defend our patent rights vigorously in these cases. Success or failure in the assertion of a given patent against a competing product is not necessarily predictive of the future success or failure in the assertion of the same patent or *a fortiori* the corresponding foreign patent against another competing product due to factors such as possible differences in the



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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

formulations of the competing products, intervening developments in law or jurisprudence, local variations in the patents and differences in national patent law and legal systems. See Item 3. Key Information D. Risk Factors 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 .

**Section 505(b)(2) New Drug Applications in the US**

Our products and patents are also subject to challenge by competitors via another abbreviated approval pathway, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. This provision expressly permits an applicant to rely, at least in part, on the FDA's prior findings of safety and effectiveness of a drug that has obtained FDA approval. The FDA may still require applicants to provide additional preclinical or clinical data to ensure that differences from the reference drug do not compromise safety and effectiveness. This pathway allows for approval for a wide range of products, especially for those products that represent only a limited change from an existing approved drug. The 505(b)(2) pathway is distinct from the ANDA pathway, which allows for approval of a generic product based on a showing that it is equivalent to a previously approved product.

A 505(b)(2) applicant is required to identify the reference drug on which it relies, as well as to certify to the FDA concerning any patents listed for the referenced product in the Orange Book. Specifically, the applicant must certify in the application that, for each patent that claims the drug or a use of the drug for which the applicant is seeking approval:

there is no patent information listed for the reference drug (paragraph I certification);

the listed patent has expired for the reference drug (paragraph II certification);

the listed patent for the reference drug has not expired, but will expire on a particular date and approval is sought after patent expiration (paragraph III certification); or

the listed patent for the reference drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the product for which the 505(b)(2) NDA is submitted (paragraph IV certification).

A paragraph III certification may delay the approval of an application until the expiration of the patent. A paragraph IV certification generally requires notification of the patent owner and the holder of the NDA for the referenced product. If the patent owner or NDA holder brings patent litigation against the applicant within the statutory window, a 30-month stay is entered on the FDA's ability to grant final approval to the 505(b)(2) applicant unless, before the end of the stay, a court decision or settlement determines the listed patent is invalid, not enforceable, and/or not infringed. A 505(b)(2) application may also be subject to non-patent

exclusivity, and the FDA may be prohibited from giving final approval to a 505(b)(2) application until the expiration of all applicable non-patent exclusivity periods.

In the EU, a generic drug manufacturer may only reference the data of the regulatory file for the original approved product after data exclusivity has expired. However, there is no patent listing system in Europe comparable to the Orange Book, which would allow the patent holder to prevent the competent authorities from granting marketing authorization by bringing patent infringement litigation prior to approval. As a result, generic products may be approved for marketing following the expiration of marketing exclusivity without regard to the patent holder's rights. Nevertheless, in most of these jurisdictions once the competing product is launched, and in some jurisdictions even prior to launch (once launch is imminent), the patent holder may seek an injunction against such marketing if it believes its patents are infringed. See Item 8 of this annual report.

## Trademarks

Our products are sold around the world under trademarks that we consider to be of material importance in the aggregate. Our trademarks help to identify our products and to protect the sustainability of our growth. Trademarks are particularly important to the commercial success of CHC and generics.

It is our policy to protect and register our trademarks with a strategy adapted to each product or service depending on the countries where they are commercialized: on a worldwide basis for worldwide products or services, or on a regional or local basis for regional or local products or services.

The process and degree of trademark protection vary country by country, as each country applies its own trademark laws and regulations. In most countries, trademark rights may only be obtained through formal trademark application and registration. In some countries, trademark protection can be based primarily on use. Registrations are granted for a fixed term (in most cases ten years) and are renewable indefinitely, except in some countries where maintenance of the trademarks is subject to their effective use.

When trademark protection is based on use, it covers the products and services for which the trademark is used. When trademark protection is based on registration, it covers only the products and services designated in the registration certificate. Additionally, in certain cases, we may enter into a coexistence agreement with a third party that owns potentially conflicting rights in order to avoid any risk of confusion and better protect and defend our trademarks.

Our trademarks are monitored and defended based on this policy and in order to prevent counterfeit, infringement and/or unfair competition.

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

**B.8. Production and Raw Materials**

Our policy is to manufacture the majority of our products in-house. There are three principal stages in our production process: the manufacture of pharmaceutical active ingredients, the transformation of those ingredients into drug products, and packaging those products.

Our general policy is to produce the majority of our active ingredients and principal drug products at our own plants in order to reduce our dependence on external suppliers. In some cases, however, we rely on third parties for the manufacture and supply of certain active ingredients, drug products and medical devices. Active ingredients are manufactured using raw materials sourced from suppliers who have been subject to rigorous selection and approval procedures, in accordance with international standards and our own internal directives. We have outsourced some of our production under supply contracts associated with acquisitions of products or businesses or with plant divestitures, or to establish a local presence to capitalize on growth in emerging markets. Our pharmaceutical subcontractors follow our general quality and logistics policies, as well as meeting other criteria. See Item 3. Key Information D. Risk Factors Risks Relating to Our Business .

At the start of 2017 we launched our Global External Manufacturing team, to enhance the way we manage relations with our third-party suppliers.

We also obtain active ingredients from third parties under collaboration agreements. This applies to the monoclonal antibodies developed with Regeneron.

Our pharmaceutical production sites are divided into three categories:

global sites, which serve all markets: located mainly in Europe, these facilities are dedicated to the manufacture of our active ingredients, injectable drug products, and a number of our main solid-form drug products;

regional sites, which serve markets at regional level, in Europe and particularly the BRIC-M countries (Brazil, Russia, India, China and Mexico), giving us a strong industrial presence in emerging markets; and

local sites, which serve their domestic market only.

Sanofi Pasteur produces vaccines at sites located in the United States, Canada, France, Mexico, China, Thailand, Argentina and India. The pharmaceutical site at Le Trait (France) also contributes to Sanofi Pasteur's industrial operations by making available its aseptic filling facilities.

All of our production facilities are good manufacturing practice (GMP) compliant, in line with international regulations.

Our principal sites are approved by the FDA:

the Biologics facilities in the United States (Allston, Framingham and Northborough), France (Lyon Gerland) and Belgium (Geel);

the Injectables facilities in France (Le Trait, Maisons-Alfort), Italy (Anagni), Ireland (Waterford), Germany (Frankfurt) and the United States (Ridgefield);

the Pharmaceuticals facilities in France (Ambarès and Tours), the United Kingdom (Haverhill and Holmes Chapel), and the United States (Saint Louis);

the Consumer Healthcare facilities in France (Compiègne), and the United States (Chattanooga); and

the Vaccines facilities in France (Marcy l'Étoile and Le Trait which handle filling and packaging of Fluzon® ID for the US market), the United States (Swiftwater), and Canada (Toronto).

Wherever possible, we seek to have multiple plants approved for the production of key active ingredients and our strategic finished products (this is the case with Lovenox®, for example).

In May 2010, Genzyme's Allston facility in the United States entered into a consent decree with the FDA following FDA inspections at the facility that resulted in observations and a warning letter raising Current Good Manufacturing Practices (CGMP) deficiencies. A consent decree is a court order entered into by agreement between a company and the government (in this case the FDA) that requires the company to take certain actions as set out in the decree. Under the terms of the consent decree, the Sanofi Genzyme facility at Allston was permitted to continue manufacturing during the remediation process subject to compliance with the terms of the consent decree.

The consent decree required Sanofi Genzyme to implement a plan to bring operations at the Allston facility into compliance with applicable laws and regulations. The plan had to address all deficiencies reported to Genzyme or identified as part of an inspection completed by a third-party expert in February 2011. This workplan was submitted to the FDA in April 2011 and accepted by the FDA in January 2012. Modifications to the remediation workplan were accepted by the FDA in March 2012 and April 2015.

The workplan was completed on March 31, 2016. The next step was a third-party certification process, which was finalized on June 30, 2017. In August 2017, the FDA conducted an inspection of the facility and delivered a favorable conclusion, following which certification was received on October 4, 2017.

The Allston facility is required to engage a third-party expert to audit its manufacturing operations for an additional period of at least five years.

More details about our manufacturing sites are given below at section D. Property, Plant and Equipment .

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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

**B.9. Insurance and Risk Coverage**

We are protected by four key insurance programs, relying not only on the traditional corporate insurance and reinsurance market but also on our captive insurance company, Carraig Insurance DAC (Carraig).

These four key programs cover Property & Business Interruption, General & Product Liability, Stock and Transit, and Directors & Officers Liability.

Carraig participates in our coverage for various lines of insurance including Property & Business Interruption, Stock and Transit, and General & Product Liability. Carraig is run under the supervision of the Irish regulatory authorities, is wholly-owned by Sanofi, and has sufficient resources to meet those portions of our risks that it has agreed to cover.

It sets premiums for our entities at market rates. Claims are assessed using the traditional models applied by insurance and reinsurance companies, and the company's reserves are regularly verified and confirmed by independent actuaries.

Our Property & Business Interruption program covers all our entities worldwide, wherever it is possible to use a centralized program operated by our captive insurance company. This approach shares risk between our entities, enabling us to set deductibles and guarantees that are appropriate to the needs of local entities. It also incorporates a prevention program, including a comprehensive site visit program covering our production, storage, research and distribution facilities and standardized repair and maintenance procedures across all sites. Specialist site visits are conducted every year to address specific needs, such as testing of sprinkler systems or emergency plans to deal with flooding risks.

The Stock and Transit program protects all goods owned by Sanofi while they are in transit nationally or internationally whatever the means of transport, and all our inventories wherever they are located. Sharing risk between our entities means that we can set deductibles at appropriate levels, for instance differentiating between goods that require temperature controlled distribution and those that do not. We have developed a prevention program with assistance from experts, implementing best practices in this area at our distribution sites. This program, which is led by our captive insurance company, has substantial capacity, largely to deal with the growth in sea freight which can lead to a concentration of value in a single ship.

Our General & Product Liability program was renewed in 2017 for all our subsidiaries worldwide wherever it was possible to do so, despite the increasing reluctance in the insurance and reinsurance market to cover product liability risks for large pharmaceutical groups. For several years, insurers have been reducing product liability cover because of the difficulty of insuring some products that have been subject to numerous claims. These products are excluded from the cover provided by insurers, and hence from the cover obtained by us on the insurance market. This applies to a

few of our products, principally those described in Note D.22.a) to our consolidated financial statements included at Item 18 in this annual report. Because of these market conditions we have increased, year by year, the extent to which we self-insure.

The principal risk exposure for our pharmaceutical products is covered with low deductibles at country level, the greatest level of risk being retained by our captive insurance company. The level of risk self-insured by Sanofi including via our captive reinsurance company enables us to retain control over the management and prevention of risk. Our negotiations with third-party insurers and reinsurers are tailored to our specific risks. In particular, they allow for differential treatment of products in the development phase, for the discrepancies in risk exposure between European countries and the United States, and for specific issues arising in certain jurisdictions such as generics coverage in the United States. Coverage is adjusted every year in order to take into account the relative weight of new product liability risks, such as those relating to rare diseases with very low exposure or to healthcare products which do not require marketing approval.

Our cover for risks that are not specific to the pharmaceutical industry (general liability) is designed to address the potential impacts of our operations.

For all lines of business of Carraig, outstanding claims are covered by provisions for the estimated cost of settling all claims incurred but not paid at the balance sheet date, whether reported or not, together with all related claims handling expenses. Where there is sufficient data history from Sanofi or from the market for claims made and settled, management with assistance from independent actuaries prepares an actuarial estimate of the company's exposure to unreported claims for the risks covered. The actuaries perform an actuarial valuation of the company's IBNR (Incurred But Not Reported) and ALAE (Allocated Loss Adjustment Expense) liabilities at year end. Two ultimate loss projections (based upon reported losses and paid losses respectively) are computed each year using the Bornhuetter-Ferguson method; these projections form the basis for the provisions set.

The Directors & Officers Liability program protects all legal entities under our control, and their directors and officers. Our captive insurance company is not involved in this program.

We also operate other insurance programs, but these are of much lesser importance than those described above.

All our insurance programs are backed by best in class insurers and reinsurers and are designed in such a way that we can integrate most newly acquired businesses on a continuous basis. Our cover has been designed to reflect our risk profile and the capacity available in the insurance market. By centralizing our major programs, we are able to provide world-class protection while reducing costs.

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

**B.10. Health, Safety and Environment**

Our manufacturing and research operations are subject to increasingly stringent health, safety and environmental (HSE) laws and regulations. These laws and regulations are complex and rapidly changing, and Sanofi invests the necessary sums in order to comply with them. This investment, which aims to respect health, safety and the environment, varies from year to year.

Applicable environmental laws and regulations may require us to eliminate or reduce the effects of chemical substance discharge at our various sites. The sites in question may belong to Sanofi, and may be currently operational, or may have been owned or operational in the past. In this regard, Sanofi may be held liable for the costs of removal or remediation of hazardous substances on, under or in the sites concerned, or on sites where waste from activities has been stored, without regard to whether the owner or operator knew of or under certain circumstances caused the presence of the contaminants, or at the time site operations occurred the discharge of those substances was authorized.

As is the case for a number of companies in the pharmaceutical, chemical and intense agrochemical industries, soil and groundwater contamination has occurred at some of our sites in the past, and may still occur or be discovered at others. In Sanofi's case, such sites are mainly located in the United States, Germany, France, Hungary, the Czech Republic, Italy and the United Kingdom. As part of a program of environmental surveys conducted over the last few years, detailed assessments of the risk of soil and groundwater contamination have been carried out at current and former Sanofi sites. In cooperation with national and local authorities, Sanofi regularly assesses the rehabilitation work required and carries out such work when appropriate. Long-term rehabilitation work is in progress or planned in Mount Pleasant, East Palo Alto and Portland in the United States; Barceloneta in Puerto Rico; Frankfurt in Germany; Brindisi in Italy; Dagenham in the United Kingdom; Ujpest in Hungary; Prague in the Czech Republic; Beaucaire, Valernes, Limay, Romainville, Neuville and Vitry in France; and on a number of sites divested to third parties and covered by contractual environmental guarantees granted by Sanofi.

We may also have potential liability for investigation and cleanup at several other sites. We have established provisions for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. In France specifically, we have provided the financial guarantees for environmental protection required under French regulations.



Potential environmental contingencies arising from certain business divestitures are described in Note D.22.d to the consolidated financial statements. In 2017, Sanofi spent 67 million on rehabilitating sites previously contaminated by soil or groundwater pollution.

Due to changes in environmental regulations governing site remediation, our provisions for remediation obligations may not be

adequate due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques involved, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations arising from the past involvement of Aventis in the chemical and agrochemical industries, it is impossible to quantify the future impact of these laws and regulations with precision. See Item 3.D. Risk Factors Environmental Risks of Our Industrial Activities .

We have established, in accordance with our current knowledge and projections, provisions for cases already identified and to cover contractual guarantees for environmental liabilities relating to sites that have been divested. In accordance with Sanofi standards, a comprehensive review is carried out once a year on the legacy of environmental pollution. In light of data collected during this review, we adjusted our provisions to approximately 685 million as of December 31, 2017 versus 732 million as of December 31, 2016. The terms of certain business divestitures, and the environmental obligations and retained environmental liabilities relating thereto are described in Note D.22. to our consolidated financial statements.

To our knowledge, Sanofi did not incur any liability in 2017 for non-compliance with current HSE laws and regulations that could be expected to significantly jeopardize its activities, financial situation or operating income. We also believe that we are in substantial compliance with current HSE laws and regulations and that all the environmental permits required to operate our facilities have been obtained.

Regular HSE audits are carried out by Sanofi in order to assess compliance with standards (which implies compliance with regulations) and to initiate corrective measures (47 internal audits performed by 85 auditors in 2017). Moreover, around 200 specific visits were performed jointly with experts representing our insurers.

Sanofi has implemented a worldwide master policy on health, safety and environment to promote the health and well-being of the employees and contractors working on its sites and respect for the environment. We consider this master policy to be an integral part of our commitment to social responsibility. In order to implement this master policy, Sanofi key requirements have been drawn up in the key fields of HSE management, HSE leadership, safety in the workplace, process safety, occupational hygiene, health in the workplace and protection of the environment.

## Health

From the development of compounds to the commercial launch of new drugs, Sanofi research scientists continuously assess the effect of products on human health. This expertise is made available to employees through two committees responsible for chemical and biological risk assessment. Sanofi's COVALIS Committee is responsible for the hazard determination and

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**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

classification of all active pharmaceutical ingredients and synthesis intermediates handled at Sanofi facilities. This covers all active ingredients handled in production at company sites or in processes sub-contracted for manufacture. Any important issues involving raw materials or other substances that lack established occupational exposure limits may also be reviewed. The COVALIS Committee determines the occupational exposure limits required within Sanofi. Our TRIBIO Committee is responsible for classifying all biological agents according to their degree of pathogenicity, and applies rules for their containment and the preventive measures to be respected throughout Sanofi. See Item 3. Key Information D. Risk Factors Environmental Risks of Our Industrial Activities Risks from the handling of hazardous materials could adversely affect our results of operations .

Appropriate occupational hygiene practices and programs are defined and implemented in each site. These practices consist essentially of containment measures for collective and individual protection against exposure in all workplaces where chemical substances or biological agents are handled. All personnel are monitored with an appropriate medical surveillance program, based on the results of professional risk evaluations linked to their duties.

In addition, dedicated resources have been created to implement the EU Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). To fully comply with the new European Regulation on Classification, Labeling and Packaging of chemicals, Sanofi has registered the relevant hazardous chemical substances with the European Chemicals Agency (ECHA).

**Safety**

Sanofi has rigorous policies to identify and evaluate safety risks and to develop preventive safety measures, and methods for checking their efficacy. Additionally, Sanofi invests in training that is designed to instill in all employees a sense of concern for safety, regardless of their duties. These policies are implemented on a worldwide scale to ensure the safety of all employees and to protect their health. Each project, whether in research, development or manufacturing, is subject to evaluation procedures, incorporating the chemical substance and process data communicated by the COVALIS and TRIBIO Committees described above. The preventive measures are designed primarily to reduce the number and seriousness of work accidents and to minimize exposures involving permanent and temporary Sanofi employees as well as our sub-contractors.

The French chemical manufacturing sites in Aramon, Sisteron and Vertolaye, as well as the plants located in the Hoechst Industry Park in Frankfurt, Germany, and the chemical production site in Budapest, Hungary, are listed Seveso III (from the name of the European directive that deals with potentially dangerous sites through a list of activities and substances associated with classification thresholds). In accordance with French law on technological risk prevention, the French sites are also subject to

heightened security inspections due to the toxic or flammable materials stored on the sites and used in the operating processes.

Risk assessments of processes and installations are drawn up according to standards and internal guidelines incorporating the best state of the art benchmarks for the industry. These assessments are used to fulfill regulatory requirements and are regularly updated. Particular attention is paid to any risk-generating changes such as process or installation changes, as well as changes in production scale and transfers between industrial or research units.

We have specialized process safety-testing laboratories that are fully integrated into our chemical development activities, apply methods to obtain the physico-chemical parameters of manufactured chemical substances (intermediate chemical compounds and active ingredients) and apply models to measure the effect of potentially leachable substances in the event of a major accident. In these laboratories the parameters for qualifying hazardous reactions are also determined, in order to define scale-up process conditions while transferring from development stage to industrial scale. All these data ensure that our risk assessments are relevant.

We believe that the safety management systems implemented at each site, the hazard studies carried out and the risk management methods implemented, as well as our third-party property insurance policies covering any third-party physical damage, are consistent with legal requirements and the best practices in the industry.

## Environment

We have committed to an ambitious policy aimed at limiting the direct and indirect impacts of our activities on the environment, throughout the life cycle of our products. We have identified five major environmental challenges relating to our businesses: greenhouse gas emissions and climate disruption; water; pharmaceuticals in the environment; waste; and biodiversity.

The initiatives already implemented since 2010 are continuing, and we have been keen to give them fresh impetus through the Planet Mobilization program. Reflecting our environment strategy out to 2025, the program sets more ambitious targets for reducing environmental impacts across the entire value chain. Planet Mobilization is a global project that involves all of the Company's resources in defining objectives and engaging with external partners.

Compared with 2015 figures, we are undertaking to halve our carbon emissions by the end of 2025 and reach carbon-neutral status by 2050 on our scope 1 & 2 (industrial, R&D and tertiary sites, including the medical rep fleet). We have also set ourselves the target of achieving sustainable water resource management, especially at sites which are under hydric stress. On this new scope, by the end of 2017, we had reduced CO<sub>2</sub> emissions by 7% and water consumption by 6%.

**Table of Contents**

## ITEM 4. INFORMATION ON THE COMPANY

Overall waste recycling at sites is already above 72% and is expected to be more than 90% by the end of 2025. The discharge rate had dropped to 8% at the end of 2017 and we have committed to move towards a maximum of 1% by 2025. Biodiversity management at sites is also a priority, with the aim of making all employees aware of this challenge and implementing risk assessment and management plans at priority sites.

Finally, we are pursuing the policy we began in 2010 of managing pharmaceutical products in the environment throughout their life cycles. At the end of 2017, all priority chemical sites had been evaluated and were shown to present no risk to the environment. The assessment program was extended to other sites, starting with the pharmaceutical production sites. In 2017, eight sites implemented the program.

In line with this approach, we have committed to the Roadmap AMR 2020 initiative, which aims to combat microbial resistance to antibiotics. The initiative brings together thirteen of the major players in the pharmaceutical industry, and will involve co-producing reference guides and methodologies for sustainable management of antibiotics in the pharmaceutical sector. The initiative includes a specific commitment with respect to antibiotic production sites that are operated by signatories or their suppliers, involving firstly the definition and deployment of a shared framework for managing potential waste, and secondly the establishment of environmental thresholds. (See Cautionary statement regarding forward-looking statements )

**C/ Organizational Structure****C.1. Significant Subsidiaries**

Sanofi is the holding company of a consolidated group consisting of over 300 companies. The table below sets forth our significant subsidiaries as of December 31, 2017. For a fuller list of the principal companies in our consolidated group, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

<b>Significant Subsidiary</b>	<b>Date of Incorporation</b>	<b>Country of Incorporation</b>	<b>Principal Activity</b>	<b>Financial and Voting</b>
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				<b>Interest</b>
Aventis Inc.	07/01/1968	United States	Pharmaceuticals	100%
Aventis Pharma SA	09/24/1974	France	Pharmaceuticals	100%
Genzyme Corporation	11/21/1991	United States	Pharmaceuticals	100%
Hoechst GmbH	07/08/1974	Germany	Pharmaceuticals	100%
Sanofi-Aventis Amérique du Nord	09/20/1985	France	Pharmaceuticals	100%
Sanofi-Aventis Deutschland GmbH	06/30/1997	Germany	Pharmaceuticals	100%
Sanofi-Aventis Europe	07/15/1996	France	Pharmaceuticals	100%
Sanofi-Aventis US LLC	06/28/2000	United States	Pharmaceuticals	100%
Sanofi-Aventis Participations SAS	02/25/2002	France	Pharmaceuticals	100%
Sanofi Pasteur SA	02/08/1989	France	Vaccines	100%
Sanofi Pasteur Inc.	01/18/1977	United States	Vaccines	100%
Sanofi Winthrop Industrie	12/11/1972	France	Pharmaceuticals	100%
Chattem, Inc.	11/11/1909	United States	Pharmaceuticals	100%

Since 2009, we have transformed Sanofi through numerous acquisitions (see A. History and Development of the Company above), in particular those of Genzyme in April 2011 and Meriel in September 2009. The financial effects of the Genzyme acquisition are presented in Note D.1.3. to our consolidated financial statements for the year ended December 31, 2013, included in our annual report on Form 20-F for that year. The financial effects of the Meriel acquisition are presented in Note D.1.3. to our consolidated financial statements for the year ended December 31, 2010, included in our annual report on Form 20-F for that year. On

January 1, 2017, Sanofi and Boehringer Ingelheim (BI) finalized the strategic transaction agreed in June 2016, involving the exchange of Sanofi's Animal Health business (Meriel) for BI's Consumer Healthcare business. The financial effects of this transaction are presented in Note D.1. to our consolidated financial statements, included at Item 18 of this annual report on Form 20 F. At the end of December 2016, Sanofi Pasteur and MSD (known as Merck in the United States and Canada) ended their Sanofi Pasteur MSD joint venture. The financial effects of the resulting divestment/acquisition are presented in Note D.1.2. to our consolidated

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**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

financial statements for the year ended December 31, 2016, included in our annual report on Form 20-F for that year.

In certain countries, we carry on some of our business operations through joint ventures with local partners. In addition, we have entered into worldwide collaboration agreements (i) with Regeneron, relating to Zaltrap<sup>®</sup>, human therapeutic antibodies such as Praluent<sup>®</sup> and antibodies in immunology such as Dupixent<sup>®</sup> and Kevzara<sup>®</sup>; and (ii) with BMS, relating to Plavix<sup>®</sup>. For further information, refer to Note C. to our consolidated financial statements, Principal Alliances .

**C.2. Internal Organization of Activities**

Sanofi and its subsidiaries collectively form a group organized around three activities: Pharmaceuticals, Consumer Healthcare and Human Vaccines (Vaccines).

During 2017, Sanofi gradually integrated the Consumer Healthcare operations of Boehringer Ingelheim (BI), acquired on January 1, 2017. Following the completion of the integration process and effective December 31, 2017, Consumer Healthcare business forms a distinct operating segment.

Within Sanofi, responsibility for research and development (R&D) in their respective fields rests with Sanofi SA and Genzyme Corporation in Pharmaceuticals, and with Sanofi Pasteur and Sanofi Pasteur, Inc. in Vaccines. However, within our integrated R&D organization, strategic priorities are set and R&D efforts coordinated on a worldwide scale. In fulfilling their role in R&D, the aforementioned companies subcontract R&D to those of their subsidiaries that have the necessary resources. They also license patents, manufacturing know-how and trademarks to certain of their French and foreign subsidiaries. Those licensee subsidiaries manufacture and distribute the majority of our products, either directly or via local distribution entities.

Our industrial property rights, patents and trademarks are mainly held by the following companies:

Pharmaceuticals: Sanofi, Aventis Pharma SA, Sanofi Biotechnology SAS (France), Sanofi-Aventis Deutschland GmbH (Germany) and Genzyme Corporation (US);

Vaccines: Sanofi Pasteur (France) and Sanofi Pasteur, Inc. (US).

For a description of our principal items of property, plant and equipment, see D. Property, Plant and Equipment below. Our property, plant and equipment is held mainly by the following companies:

in France: Sanofi Pasteur SA, Sanofi Chimie, Sanofi Winthrop Industrie, Sanofi, and Sanofi-Aventis Recherche & Développement;

in the United States: Sanofi Pasteur, Inc., Genzyme Corporation, and Genzyme Therapeutics Products LP;

in Canada: Sanofi Pasteur Limited;

in Germany: Sanofi-Aventis Deutschland GmbH;

in Belgium: Genzyme Flanders BVBA Holding Co; and

in Ireland: Genzyme Ireland Limited.

### C.3. Financing and Financial Relationships between Group Companies

The Sanofi parent company raises the bulk of the Company's external financing and uses the funds raised to meet, directly or indirectly, the financing needs of its subsidiaries. The parent company operates a cash pooling arrangement under which any surplus cash held by subsidiaries is managed centrally. There is also a centralized foreign exchange risk management system in place, whereby the parent company contracts hedges to meet the needs of its principal subsidiaries.

Consequently, at December 31, 2017, the Sanofi parent company held 94% of our external financing and 89% of our surplus cash.

Sanofi European Treasury Center SA (SETC), a 100%-owned Sanofi subsidiary incorporated in 2012 under the laws of Belgium, is dedicated to providing financing and various financial services to our subsidiaries.

## D/ Property, Plant and Equipment

### D.1. Overview

Our headquarters are located in Paris, France. See [D.4 Office Space](#) below.

We operate our business through office premises and research, production and logistics facilities in approximately 100 countries around the world. Our office premises house all of our support functions, plus operational representatives from our subsidiaries and the Company.

A breakdown of our sites by use and by ownership status (owned versus leasehold) is provided below. This breakdown is based on surface area. All surface area figures are unaudited.

#### Breakdown of sites by use

<i>Industrial</i>	60%
<i>Research</i>	12%
<i>Offices</i>	16%
<i>Logistics</i>	9%
<i>Other</i>	4%

**Breakdown of sites by ownership status**

<i>Leasehold</i>	<i>25%</i>
<i>Owned</i>	<i>75%</i>



**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

We own most of our research & development and production facilities, either freehold or under finance leases with a purchase option exercisable on expiration of the lease.

**D.2. Description of Our Sites**

**Sanofi industrial sites**

As part of the process of transforming Sanofi and creating Global Business Units, we are continuing to adapt the organization of the Industrial Affairs department in support of our new business model. Since June 2013, the Industrial Affairs department has been responsible for all production and quality operations within Sanofi. The department focuses on customer needs and service quality, the sharing of Sanofi Manufacturing System manufacturing practices, the development of a common culture committed to quality and the pooling of expertise within technology platforms, particularly in biological, injectable and pharmaceutical products. Since January 2016, the Industrial Affairs department has also been responsible for Sanofi Global HSE and Global Supply Chain.

At the end of 2017, we were carrying out industrial production at 79 sites in 36 countries:

8 sites for our Biologics operations;

9 sites for our Injectables operations;

37 sites for our Pharmaceuticals operations;

14 sites for our Consumer Healthcare operations;

11 sites for the industrial operations of Sanofi Pasteur in vaccines.

In 2017, we produced the following quantities:

Pharmaceuticals: 4,738 million units, comprising:

units manufactured and packaged: 3,072 million;

units packaged only: 320 million;

bulk products in unit equivalents: 379 million;

outsourced units: 976 million; and

Vaccines: 470 million containers (syringes and ampoules) filled, including outsourced production.

We believe that our production facilities are in compliance with all regulatory requirements, are properly maintained and are generally suitable for future needs. Nonetheless, we regularly inspect and evaluate those facilities with regard to environmental, health, safety and security matters, quality compliance and capacity utilization. For more information about our property, plant and equipment, see Note D.3 to our consolidated financial statements, included at Item 18 of this annual report, and section B.8 Production and Raw Materials above.

Production of biological, chemical and pharmaceutical products is the responsibility of our Industrial Affairs department, which is also in charge of most of our logistics facilities (distribution and storage centers).

Major drugs, active ingredients, specialties and medical devices are manufactured at the following sites:

**Production Sites: Biologics**

Belgium: Geel;

France: Lyon Gerland and Vitry-sur-Seine;

Germany: Frankfurt Insulin Biotech; and

United States: Allston, Framingham Biologics, Framingham Biosurgery and Northborough.

**Production Sites: Injectables**

China: Beijing;

France: Le Trait and Maisons-Alfort;

Germany: Frankfurt;

Hungary: Csanyikvölgy;

Ireland: Waterford;

Italy: Anagni;

Russia: Orel; and

United States: Ridgefield.

**Production Sites: Pharmaceuticals**

Algeria: Ain Benian and Oued Smar;

Bangladesh: Tongi;

Brazil: Campinas;

China: Hangzhou;

Colombia: Cali and Villa Rica;

Czech Republic: Prague;

United Arab Emirates: Dubai;

Egypt: Cairo;

France: Ambarès, Amilly, Aramon, Mourenx, Ploermel, Saint-Aubin-les-Elbeuf, Sisteron, Tours and Vertolaye;

Germany: Frankfurt Pharma & Chemistry

Hungary: Ujpest;

India: Goa, Ankleshwar Pharma & Chemistry;

70

**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

Indonesia: Jakarta;

Italy: Scoppito and Brindisi;

Japan: Kawagoe;

Pakistan: Karachi;

Romania: Bucharest;

Saudi Arabia: KAEC;

Singapore: Jurong;

South Africa: Waltloo;

Spain: Riells;

Tunisia: Megrine;

Turkey: Luleburgaz;

United Kingdom: Haverhill and Holmes Chapel; and  
**Production sites: Consumer Healthcare**

Major drugs for our Consumer Healthcare portfolio are manufactured at the following sites:

Australia: Virginia;

Brazil: Suzano;

France: Compiègne and Lisieux;

Germany: Cologne;

Hungary: Veresegyhás;

Italy: Origgio;

Japan: Narita;

Mexico: Ocoyoacac;

Poland: Rzeszow;

United States: Chattanooga; and

Vietnam: 3 sites in Ho Chi Minh City.

**Production Sites: Vaccines (Sanofi Pasteur)**

Argentina: Pilar;

Canada: Toronto;

China: Shenzhen;

France: Marcy l'Étoile, Val de Reuil and Neuville;

India: Hyderabad (Shantha);

Mexico: Ocoyoacac;

Thailand: Chachoengsao; and

United States: Swiftwater and Pearl River.

Sanofi Pasteur also has its own R&D and production sites, either freehold or under finance leases with a purchase option exercisable on expiration of the lease.

### Research & Development sites

In Pharmaceuticals, research and development activities are conducted at the following sites:

six operational sites in France: Chilly/Longjumeau, Marcy l Etoile, Montpellier, Strasbourg, and Vitry/ Alfortville;

two sites in the rest of Europe (Germany and the Netherlands), the larger of which is in Frankfurt (Germany);

four sites in the United States, the Bridgewater, Cambridge, Framingham/Waltham and Great Valley sites; and

in Asia, three sites in China ( Beijing, Shanghai and Chengdu) and a clinical research unit in Japan.  
Vaccines research and development sites are:

United States: Swiftwater, Cambridge, Orlando;

France: Marcy L Etoile/Lyon; and

Canada: Toronto.

### D.3. Acquisitions, capital expenditures and divestitures

The carrying amount of our property, plant and equipment at December 31, 2017 was 9 579 million. During 2017, we invested 1,394 million (see Note D.3. to our consolidated financial statements, included at Item 18 of this annual report), mainly in increasing capacity and improving productivity at our various production and R&D sites.

Our principal acquisitions, capital expenditures and divestitures in 2015, 2016 and 2017 are described in Notes D.2. ( Impact of changes in the scope of consolidation ), D.3. ( Property, plant and equipment ) and D.4. ( Goodwill and other intangible assets ) to our consolidated financial statements, included at Item 18 of this annual report.

As of December 31, 2017, our firm commitments in respect of future capital expenditures amounted to 508 million. The principal locations involved were: for the Pharmaceuticals segment, the industrial facilities at Frankfurt (Germany), Framingham and Allston (United States), Geel (Belgium), Cambridge (United States), Le Trait (France) and Vitry (France); and for the Vaccines segment, the facilities at Swiftwater (United States), Toronto (Canada) and

Marcy L. Étoile (France).

In the medium term and assuming no changes in the scope of consolidation, we expect to invest on average some 1.7 billion a year in property, plant and equipment. We believe that our own cash resources and the undrawn portion of our existing credit facilities will be sufficient to fund these expenditures.



## Table of Contents

### ITEM 4. INFORMATION ON THE COMPANY

Our principal ongoing investments are described below.

#### **Biologics**

In 2014, a dedicated **Biologics** platform was launched to develop synergies between Pharmaceuticals, Sanofi Pasteur, Sanofi Genzyme and our Biotherapeutics operations. This platform is helping us extend our footprint in biotechnologies by adopting a multi-disciplinary approach and improving capacity utilization. It also enables us to leverage our expertise in the production of biologics, from active ingredient to integrated manufacturing, including both the medicine itself and associated medical devices.

Three dedicated biotechnology hubs have been developed: Paris/Lyon (France), Frankfurt (Germany) and Boston (United States). Piloting this technology, which relies on cell or microbiological culture or the development of viral vectors, calls for highly specific knowledge and expertise backed by dedicated production platforms to support global product launches.

#### **Injectables**

The Frankfurt facility, our principal site for the manufacture of **diabetes** treatments, is now equipped with an additional aseptic filling unit that uses isolator technology. Toujeo<sup>®</sup>, launched in 2015, is among the diabetes products handled in this new filling unit. The Diabetes industrial network has a solid base in emerging markets, both in Russia with the Orel site (now our second largest insulin pen production site after Frankfurt) and at the Beijing site in China. As part of the integration of Shantha (India) into our Injectables platform, the Indian site uses our proprietary manufacturing technology to handle filling and packaging for insulin products.

Our prefilled syringes network mainly delivers Lovenox<sup>®</sup>/Clexane<sup>®</sup> from Le Trait (France) and Maisons Alfort (France) to global markets and from Csanyikvölgy (Hungary) to non-FDA/EMA regulated markets.

#### **Pharmaceuticals**

The development of our General Medicines & Emerging Markets platform is built on a network of over 30 regional and local industrial sites in 25 countries, supporting growth in those markets.

At Sidi Abdellah in Algeria we are building a new facility that will become our largest industrial complex in Africa, mainly producing dry and liquid formulations.

Our Industrial Affairs Department has an ongoing policy of adapting industrial facilities to market needs. As part of this process, during 2017 we sold our facilities at Tangshan (China), Dakar (Senegal) and Zenata (Morocco).

### Consumer Healthcare

The pharmaceutical industrial operations of our **Consumer Healthcare** (CHC) business are spread across a dedicated network. Global markets are supplied from our facilities at Compiègne (France), Origgio (Italy), Cologne (Germany) and Veresegyház (Hungary). Regional markets are supplied from our Suzano facility in Brazil, our Rzeszow facility in Poland and our ACE facility in Vietnam. Our facilities at Lisieux (France, production of Doliprane® for the French market), Hangzhou (China), Virginia (Australia), and the Chattem facility in Tennessee (United States), mainly supply their local markets. We have recently invested heavily in major projects intended to build a specialist CHC industrial network. This has included switching some CHC products from non-CHC facilities to the dedicated CHC network, transferring some liquid and effervescent formulations of CHC products to the Cologne site, and transforming the Origgio site into a facility dedicated to a single product family (Enterogermina®).

Our Industrial Affairs Department has an ongoing policy of adapting industrial facilities to market needs. As part of this process we have completed construction of our new facility in Ho Chi Minh City (Vietnam), which manufactures specialty pharmaceuticals and CHC products, and in 2017 sold our CHC facility at Hangzhou (China).

### Vaccines (Sanofi Pasteur)

Sanofi Pasteur's industrial operations are in a major investment phase, preparing for the upcoming growth of our influenza and Polio/Pertussis/Hib franchises. Major investments were launched during 2017 in France (including a new influenza building at Val-de-Reuil), Canada (a new pertussis building), the US and Mexico.

Our Industrial Affairs Department has an ongoing policy of adapting industrial facilities to market needs. As part of this process, we divested the facilities at Canton and Rockville (United States) during 2017.

### Innovation and culture of industrial excellence

In 2017, we highlighted industrial innovation in our various facilities by organizing our ninth annual round of Industrial Trophies, in five categories: Patient Needs, Technological Innovation, Operational Performance, Energy & Environment, and Young Industrial Innovation Talent.

The ambition of our Industrial Affairs department is to continue to raise quality standards in Sanofi's production activities, and to remain a world leader and a benchmark in the global pharmaceutical industry. To achieve this goal, all our activities share a common culture of industrial excellence, enshrined in the Sanofi Manufacturing System. This sets out a series of priorities (such as customer service, constant improvement, site network optimization and transverse optimization) that constitute our industrial vision and will be crucial to our mutual success.

### D.4. Office space

As part of the transformation of Sanofi and the implementation of the ONE SANOFI program, we are undertaking major real estate



**Table of Contents**

ITEM 4. INFORMATION ON THE COMPANY

programs with two core objectives: to bring our teams together on single sites in new workspaces that favor agility, cross-fertilization and communication; and to rationalize office space while achieving a responsible environmental footprint.

The many projects delivered in 2017 included completion of the master plan for the Lyon area (France) with the Carteret campus (1,500 people), plus new campuses in Sao Paulo (Brazil) and Tokyo Opera City (Japan) housing 1,100 and 1,500 people respectively.

This transformative approach to working practices provides strong support for our various operations to attain their objectives. The rollout plan extends to all regions via projects such as the master plan for the Boston area, Massachusetts (United States), under which Genzyme and Sanofi office space will be combined under a single roof in an environmentally-certified building to be delivered in 2018. A similar master plan is being rolled out in the Netherlands, to bring the teams from Gouda and Naarden together on a single site.

**Item 4A. Unresolved Staff Comments**

N/A

**Table of Contents**

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**ITEM 5. Operating and Financial Review and Prospects**

You should read the following discussion in conjunction with our consolidated financial statements and the notes thereto included in this annual report at Item 18.

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2017.

The following discussion contains forward-looking statements that involve inherent risks and uncertainties. Actual results may differ materially from those contained in such forward-looking statements. See **Cautionary Statement Regarding Forward-Looking Statements** at the beginning of this document.

Unless otherwise stated, all financial variations in this item are given on a reported basis.

**A/ Operating results**

**A.1. Significant operating information**

**A.1.1. 2017 Overview**

During 2017, we continued to progress towards our key strategic objectives: reorganizing our operations, successfully launching new products, enhancing innovation in R&D and streamlining our organization.

On January 1, 2017, Sanofi and Boehringer Ingelheim (BI) finalized the strategic transaction agreed in June 2016, involving the exchange of Sanofi's Animal Health business (Merial) for BI's Consumer Healthcare business. After final enterprise value adjustments, the exchange values of the two businesses effectively transferred during 2017 were determined to be 10,557 million for Sanofi's Animal Health business and 6,239 million for BI's Consumer Healthcare

business. The divestment of the Animal Health business generated an after-tax gain of 4,643 million in 2017 (see Note D.1. to our consolidated financial statements included at Item 18 of this annual report on Form 20-F).

During 2017, we gradually integrated BI's Consumer Healthcare business into our Consumer Healthcare Global Business Unit (GBU). Following completion of the integration process and with effect from December 31, 2017, we have identified our Consumer Healthcare activity as an operating segment, the financial information for which is reported separately to, and reviewed separately by, our Chief Executive Officer. Consequently, as of December 31, 2017 Sanofi has three operating segments: Pharmaceuticals, Consumer Healthcare and Human Vaccines (Vaccines) (see A.1.5. Segment Information below).

At the end of December 2016, Sanofi Pasteur and MSD (known as Merck in the United States and Canada) ended their European joint venture Sanofi Pasteur MSD (SPMSD). Under the terms of this transaction, we divested our share of the joint venture and acquired the vaccines portfolio that reverted to Sanofi. The additional net sales generated from January 1, 2017 onwards as a result of this transaction are reflected in our consolidated net sales for the year ended December 31, 2017.

During 2017, we continued our policy of securing research and development alliances and making targeted acquisitions. We entered into a license agreement with Principia Biopharma, Inc. to develop an oral drug candidate for the treatment of multiple sclerosis. In influenza vaccines, we completed the acquisition of Protein Sciences. We also entered into an agreement with MedImmune to develop and commercialize a vaccine for the prevention of respiratory diseases.

Our research and development efforts led to a number of compounds entering Phase III in 2017: dupilumab in the treatment of uncontrolled persistent asthma in children aged 6-11 and of atopic dermatitis in adolescents aged 12-17; isatuximab in the treatment of multiple myeloma; efglenatide in the treatment of diabetes; and cemiplimab in the treatment of non small cell lung cancer and as a second line treatment for cervical cancer. A number of products were launched during 2017 following the granting of regulatory approvals, including Dupixent® (moderate to severe atopic dermatitis in adults) in the United States and some European Union countries; Kevzara® (rheumatoid arthritis) in the United States and some European Union countries; and Soliqua™ 100/33 in the United States and Suliqua™ in Europe (insulin glargine 100 units/ml and lixisenatide 33 mcg/ml injectable solution) in diabetes.

In 2017, we also invested in our industrial facilities to deliver the production capacity needed for those products, including an extension to our vaccine facility at Val-de-Reuil (France) and a strategic alliance with Lonza to create a large-scale biologics production facility at Visp (Switzerland).

On November 29, 2017, following a new analysis of long-term clinical trial data which found differences in Dengvaxia® performance based on prior dengue infection, we proposed that national regulatory agencies in countries where the vaccine has been approved update the prescribing information, known as the label in many countries, and request that healthcare professionals assess the likelihood of prior dengue infection in an individual before vaccinating. Vaccination should only be recommended when the potential benefits outweigh the potential risks (in countries with a high burden of dengue disease). For individuals who have not been previously infected by dengue virus, vaccination is not recommended. The national regulatory agency in

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

the Philippines decided to suspend the dengue vaccination campaign in December 2017, and early in 2018 took the decision to suspend the marketing authorization of Dengvaxia® for a one-year period. In other countries, label updates are in progress (see A.2.1. Net Sales).

Net sales for the year ended December 31, 2017 were 35,055 million, 3.6% higher than in 2016. At constant exchange rates (CER)<sup>(1)</sup>, net sales were up 5.6%, reflecting the acquisition of BI's Consumer Healthcare business and the first-time consolidation of Sanofi's European vaccines business. At constant exchange rates and on a constant structure basis, net sales grew 0.5%, driven by Vaccines, the Multiple Sclerosis franchise, Dupixent®, and more generally by Emerging Markets.

*Net income attributable to equity holders of Sanofi* amounted to 8,434 million, 79.1% higher than in 2016 after taking account of the gain on divestment of the Animal Health business and the direct and indirect effects of US tax reform. Earnings per share was 6.71, up 83.3% on 2016. Business net income<sup>(2)</sup> was 6,964 million, 4.7% lower than in 2016, while business earnings per share<sup>(2)</sup> was 2.5% lower than in 2016 at 5.54.

As of December 31, 2017 we had reduced our debt, net of cash and cash equivalents<sup>(3)</sup> to 5,229 million, compared with 8,206 million as of December 31, 2016. The reduction in net debt was due largely to the receipt of a balancing cash payment as part of the transaction with BI. At the Annual General Meeting, to be held on May 2, 2018, the shareholders will be asked to approve a dividend of 3.03 per share for the 2017 financial year, representing a payout of 54.7% of our business net income.

**A.1.2. Impacts of competition from generics and biosimilars**

Some of our flagship products continued to suffer sales erosion in 2017 due to competition from generics and biosimilars. We do not believe it is possible to state with certainty what level of net sales would have been achieved in the absence of generic competition.

A comparison of our consolidated net sales for the years ended December 31, 2017 and 2016 (see Results of Operations Year Ended December 31, 2017 Compared with Year Ended December 31, 2016 below) for products affected by generic and biosimilar competition shows a loss of 1,570 million of net sales on a reported basis. Other parameters may have contributed to the loss of sales, such as a fall in the average price of certain products (e.g. Lantus®).

The table below sets forth the impact by product.

( million)	2017	2016	Change on a reported basis	Change on a reported basis (%)
Aprovel® Europe	115	127	(12)	-9.4%
Lantus® Europe	760	878	(118)	-13.4%
Lovenox® Europe	951	1,027	(76)	-7.4%
Plavix® Europe	150	162	(12)	-7.4%
Renagel®/Renvela® Europe	71	82	(11)	-13.4%
Ambien® United States	55	84	(29)	-34.5%
Lantus® United States	2,542	3,528	(986)	-27.9%
Lovenox® United States	58	54	4	+7.4%
Renagel®/Renvela® United States	645	764	(119)	-15.6%
Taxotere® United States	-	4	(4)	-100.0%
Allegra® Japan	146	174	(28)	-16.1%
Amaryl® Japan	27	36	(9)	-25.0%
Aprovel® Japan	89	82	7	+8.5%
Lantus® Japan	43	74	(31)	-41.9%
Myslee® Japan	95	110	(15)	-13.6%
Plavix® Japan	235	355	(120)	-33.8%
Taxotere® Japan	15	26	(11)	-42.3%
<b>Total excluding Emerging Markets</b>	<b>5,997</b>	<b>7,567</b>	<b>(1,570)</b>	<b>-20.7%</b>

(1) Non-GAAP financial measure: see definition under A.1.6. Presentation of Net Sales below

(2) Non-GAAP financial measure: see definition under A.1.5. Segment information 3/ Business Net Income below

(3) Non-GAAP financial measure: see definition under B. Liquidity and capital Resources below



**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

We expect the erosion caused by generic competition to continue in 2018, with a negative impact on our net income. The products likely to be impacted include those that already faced generic competition in 2017, but whose sales can reasonably be expected to be subject to further sales erosion in 2018: Aprovel<sup>®</sup>, Lantus<sup>®</sup>, Lovenox<sup>®</sup>, Plavix<sup>®</sup> and Renagel<sup>®</sup>/Renvela<sup>®</sup> in Europe; Ambien<sup>®</sup>, Lantus<sup>®</sup>, Lovenox<sup>®</sup>, Renagel<sup>®</sup>/Renvela<sup>®</sup> and Taxotere<sup>®</sup> in the United States; and Allegra<sup>®</sup>, Amaryl<sup>®</sup>, Aprovel<sup>®</sup>, Lantus<sup>®</sup>, Myslee<sup>®</sup>, Plavix<sup>®</sup> and Taxotere<sup>®</sup> in Japan.

In 2017, the aggregate consolidated net sales of these products in countries where generic competition currently exists or is expected in 2018 amounted to 5,997 million; this comprises 3,300 million in the United States (including 2,542 million in net sales of Lantus<sup>®</sup> and 645 million in net sales of Renagel<sup>®</sup>/Renvela<sup>®</sup>), 2,047 million in Europe, and 650 million in Japan. The negative impact on our 2018 net sales is likely to represent a substantial portion of this amount, but the actual impact will depend on a number of factors such as the actual launch dates of generic products in 2018, the prices at which they are sold, and potential litigation outcomes.

**A.1.3. Purchase Accounting Effects**

Our results of operations and financial condition for the years ended December 31, 2017, 2016 and 2015 have been significantly affected by our August 2004 acquisition of Aventis, our April 2011 acquisition of Genzyme and certain subsequent transactions. See Critical accounting and reporting policies Business combinations below for an explanation of the impact of business combinations on our results of operations.

The Genzyme business combination has generated significant amortization of intangible assets ( 857 million in 2017, 866 million in 2016 and 890 million in 2015) and impairment of intangible assets (expenses of 16 million in 2017, net reversal of 6 million in 2016 and expenses of 214 million in 2015). The Aventis business combination has also generated significant amortization expenses ( 365 million in 2017, 482 million in 2016 and 638 million in 2015).

In order to isolate the purchase accounting effects of all acquisitions and certain other items, we use a non-GAAP financial measure that we refer to as business net income<sup>(d)</sup>.

**A.1.4. Sources of Revenues and Expenses**

**Revenues.** Revenue arising from the sale of goods is presented in the income statement within *Net sales*. Net sales comprise revenue from sales of pharmaceutical products, human vaccines and active ingredients, net of sales returns,

of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Returns, discounts, incentives and rebates are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue.

See Note B.13.1. to our consolidated financial statements included at Item 18 of this annual report. We sell pharmaceutical products and vaccines directly, through alliances, and by licensing arrangements throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. When we sell products through alliances, the revenues reflected in our consolidated financial statements are based on the contractual arrangements governing those alliances. For more information about our alliances, see *Financial Presentation of Alliances* below. When our products are sold by licensing arrangements, we receive royalty income that we record in *Other revenues*. The sales of non-Sanofi products of our US based entity VaxServe are also presented in *Other revenues*; see Note B.13.2. to the consolidated financial statements included at Item 18 of this annual report.

**Cost of Sales.** Our cost of sales consists primarily of the cost of purchasing raw materials and active ingredients, labor and other costs relating to our manufacturing activities, packaging materials, payments made under licensing agreements and distribution costs. We have license agreements under which we manufacture, sell and distribute products that are patented by other companies and license agreements under which other companies distribute products that we have patented. When we pay royalties, we record them in *Cost of sales*.

**Operating Income.** Our operating income reflects our revenues, our cost of sales and the remainder of our operating expenses, the most significant of which are research and development expenses and selling and general expenses. For our operating segments, we also measure our results of operations through an indicator referred to as *Business Operating Income*, which we describe below under *Segment Information Business Operating Income of Segments*.

#### **A.1.5. Segment information**

##### ***1/ Operating segments***

In accordance with IFRS 8 (Operating Segments), the segment information reported by Sanofi is prepared on the basis of internal management data provided to the Chief Executive Officer, who is the chief operating decision maker. The performance of those segments is monitored individually using internal reports and common indicators. The operating segment disclosures required under IFRS 8 are provided in Notes D.35. and B.26. ( *Segment Information* ) to our consolidated financial statements, included at Item 18 of this annual report.

Sanofi acquired the Consumer Healthcare operations of BI on January 1, 2017, and during 2017 we gradually integrated those operations into our Consumer Healthcare Global Business Unit (GBU). Following completion of the integration process and with effect from December 31, 2017, we have identified our Consumer Healthcare business as an operating segment, the financial

*(1) Non-GAAP financial measure: see definition under A.1.5. Segment information 3/ Business Net Income below*

**Table of Contents**

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

information for which is reported separately to, and reviewed separately by, our Chief Executive Officer. Up to December 31, 2017, the results of the Consumer Healthcare business were included in the Pharmaceuticals segment, as described below.

Consequently, as of December 31, 2017 Sanofi has three operating segments: Pharmaceuticals, Consumer Healthcare and Human Vaccines (Vaccines).

The Pharmaceuticals segment comprises the commercial operations of the following global franchises: Specialty Care (Rare Diseases, Multiple Sclerosis, Oncology, Immunology), Diabetes & Cardiovascular, Established Prescription Products and Generics, together with research, development and production activities dedicated to our Pharmaceuticals segment. This segment also includes all associates whose activities are related to pharmaceuticals, in particular our share of Regeneron.

The Consumer Healthcare segment comprises, for all geographical territories, the commercial operations for our Consumer Healthcare products, together with research, development and production activities dedicated to those products.

The Vaccines segment comprises, for all geographical territories (including from January 1, 2017 certain European territories previously included in the Sanofi Pasteur MSD joint venture), the commercial operations of Sanofi Pasteur, together with research, development and production activities dedicated to vaccines.

Inter-segment transactions are not material.

In addition, during 2017 we finalized a complete realignment of our internal management reporting to match our managerial structure. As a result, the costs of our global functions (Medical Affairs, External Affairs, Finance, Human Resources, Legal Affairs, Information Solutions & Technologies, Sanofi Business Services, etc.) are now managed centrally at group-wide level and are no longer allocated to operating segments for internal management reporting purposes. For the year ended December 31, 2017 and subsequent years, the costs of those functions will be presented within the Other category. That category also includes other reconciling items such as retained commitments related to of divested activities.

Consequently, the analysis of our net sales performance provided below is presented using our new segment reporting model. Segmental results for the year ended December 31, 2017 are also presented using the new model. However, due to lack of available data and the complex and significant adjustments that would be required (in particular to our reporting tools), the comparative information has not been restated to reflect the changes arising from our new segment reporting model. We have therefore also presented segment results for 2017 and comparative periods using our previous segment reporting model.

## ***2/ Business Operating Income***

We report segment results on the basis of Business operating income . This indicator is used internally by our chief operating decision maker to measure the performance of each operating segment and to allocate resources. For a definition of business operating income , and a reconciliation between that indicator and ***Income before tax and investments accounted for using the equity method***, refer to Note D.35. to our consolidated financial statements.

## ***3/ Business net income***

We believe that understanding of our operational performance by our management and our investors is enhanced by reporting business net income . This non-GAAP financial measure represents business operating income, less net financial expenses and the relevant income tax effects. For prior year periods (2016 and 2015), Business net income consists of (i) Business net income excluding Animal Health , determined as described above and (ii) Animal Health business net income , determined on a similar and comparable basis.

We also report business earnings per share non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding.

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The table below reconciles our business operating income to our business net income for the years ended December 31, 2017, 2016 and 2015:

( million)	December 31, 2017	December 31, 2016	December 31, 2015
<b>Business operating income</b>	<b>9,343</b>	<b>9,285</b>	<b>9,313</b>
Financial income and expenses	(273)	(399) <sup>(a)</sup>	(381)
Income tax expense	(2,106)	(2,054)	(1,929)
<b>Business net income excluding Animal Health</b>	<b>6,964</b>	<b>6,832</b>	<b>7,003</b>
Animal Health business net income	-	476	368
<b>Business net income</b>	<b>6,964</b>	<b>7,308</b>	<b>7,371</b>

(a) This amount does not include the 457 million impairment loss charged against Sanofi's equity investment in Alnylam.

Business net income is defined as *Net income attributable to equity holders of Sanofi* determined under IFRS, excluding the following items:

amortization and impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature);

fair value remeasurement of contingent consideration relating to business combinations or divestments;

other impacts associated with acquisitions (including impacts of acquisitions on investments accounted for using the equity method);

restructuring costs and similar expenses<sup>(1)</sup>;

other gains and losses (including gains and losses on major disposals of non-current assets)<sup>(2)</sup>;

other costs and provisions related to litigation<sup>(2)</sup>;

the tax effects of the items listed above;

the effects of major tax disputes;

the 3% tax levied on the distribution of dividends to equity holders of Sanofi;

the direct and indirect effects of the US tax reform enacted on December 22, 2017, and the consequences of the French Constitutional Council ruling of October 6, 2017 on the additional 3% levy on dividends paid out in cash;

those Animal Health items that are not included in business net income<sup>(3)</sup>;

the portion attributable to non-controlling interests of the items listed above; and

the impairment loss taken in 2016 against our equity investment in Alnylam, which reflected a decline in the market value of that investment as of December 31, 2016 relative to its historical cost, most of the decline having occurred when Alnylam decided to discontinue the revusiran development program on October 5, 2016.

Business net income also includes Sanofi's share of the business net income of Sanofi Pasteur MSD from the date when Sanofi and MSD announced their intention to end their joint venture.

*(1) Presented in the line item **Restructuring costs and similar expenses** in the consolidated income statement.*

*(2) Presented in the line item **Other gains and losses, and litigation** in the consolidated income statement.*

*(3) Comprises (i) impact of the discontinuation of depreciation and impairment of property, plant & equipment with effect from the start date of application of IFRS 5 (Discontinued and Held-for-Sale Operations) included in business net income; (ii) impact of the amortization and impairment of intangible assets until the start date of IFRS 5 application; (iii) costs directly incurred as a result of the divestment; and (iv) tax effects of items (i) to (iii).*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The table below reconciles our business net income to *Net income attributable to equity holders of Sanofi*:

<i>( million)</i>	<b>2017<sup>(a)</sup></b>	<b>2016<sup>(a)</sup></b>	<b>2015<sup>(a)</sup></b>
<b>Net income attributable to equity holders of Sanofi</b>	<b>8,434</b>	<b>4,709</b>	<b>4,287</b>
Amortization of intangible assets <sup>(b)</sup>	1,866	1,692	2,137
Impairment of intangible assets	293	192	767
Fair value remeasurement of contingent consideration	159	135	(53)
Expenses arising from the impact of acquisitions on inventories	166	-	-
Restructuring costs and similar items	731	879	795
Impairment loss charged against the equity investment in Alnylam	-	457	-
Other gains and losses, and litigation <sup>(c)</sup>	215	(211)	-
Tax effects of the items listed above <sup>(d)</sup> :	(1,126)	(841)	(1,331)
<i>related to amortization and impairment of intangible assets</i>	<i>(719)</i>	<i>(694)</i>	<i>(1,019)</i>
<i>related to fair value remeasurement of contingent consideration</i>	<i>4</i>	<i>(24)</i>	<i>(39)</i>
<i>expenses arising from the impact of acquisitions on inventories</i>	<i>(52)</i>	<i>-</i>	<i>-</i>
<i>restructuring costs and similar expenses</i>	<i>(134)</i>	<i>(95)</i>	<i>(273)</i>
<i>other tax effects</i>	<i>(225)</i>	<i>(28)</i>	<i>-</i>
Other tax items <sup>(e)</sup>	742	113	111
Share of items listed above attributable to non-controlling interests	(4)	(22)	(25)
Investments accounted for using the equity method: restructuring costs and expenses arising from the impact of acquisitions	131	(9)	191
Items relating to the Animal Health business <sup>(f)</sup>	(4,643)	162	492
Other Sanofi Pasteur MSD items <sup>(g)</sup>	-	52	-
<b>Business net income</b>	<b>6,964</b>	<b>7,308</b>	<b>7,371</b>
Average number of shares outstanding (million)	1,256.9	1,286.6	1,306.2
Basic earnings per share (in euros)	6.71	3.66	3.28
Reconciling items per share (in euros)	(1.17)	2.02	2.36
Business earnings per share (in euros)	5.54	5.68	5.64

- (a) *The results of the Animal Health business for 2016, and the gain arising on the divestment of that business in 2017, are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations).*
- (b) *Includes amortization expense generated by the remeasurement of intangible assets in connection with business combinations: 1,726 million in 2017 and 1,550 million in 2016.*
- (c) *For 2017, this line item mainly comprises a provision for a vendor's liability guarantee relating to a past divestment, and for 2016, the pre-tax gain on the divestment of Sanofi's interest in the Sanofi Pasteur MSD joint venture.*
- (d) *For 2017, this line includes the impact of changes in corporate income tax rates, mainly in France (25% standard rate effective as of January 1, 2022). For 2016, this line includes the impact on deferred tax assets and liabilities arising from the reconciling items (in particular amortization and impairment of intangible assets, and restructuring costs) as a result of changes in corporate income tax rates, mainly in France (28% standard rate effective January 1, 2020) and in Japan.*
- (e) *For 2017, this line comprises (i) the direct and indirect effects of the US tax reform (negative impact of 1,193 million) and (ii) the consequences of the French Constitutional Council ruling of October 6, 2017 on the additional 3% levy on dividends paid out in cash (positive impact of 451 million).*
- (f) *For 2017, this line shows the gain arising on the divestment of the Animal Health business. For 2016, this line shows the elimination of (i) the impact of the discontinuation of depreciation and impairment of property, plant & equipment with effect from the start date of IFRS 5 application and included in business net income; (ii) the impact of the amortization and impairment of intangible assets until the start date of IFRS 5 application; (iii) costs directly incurred as a result of the divestment; and (iv) tax effects of items (i) to (iii).*
- (g) *For 2016, this line shows the elimination of Sanofi's share of the business net income of Sanofi Pasteur MSD from the date when Sanofi and Merck announced their intention to end their joint venture.*

The most significant reconciling items between our business net income and **Net income attributable to equity holders of Sanofi** relate to (i) the purchase accounting effects of our acquisitions and business combinations, particularly the amortization and

impairment of intangible assets (other than software and other rights of an industrial or operational nature), and (ii) the impacts of events regarded as non-recurring, where the amounts involved are particularly significant. We believe that excluding those non-cash or



**Table of Contents**

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

non-recurring charges enhances an investor's understanding of our underlying economic performance, because we do not consider that the excluded charges reflect the combined entity's ongoing operating performance. Rather, we believe that each of the excluded charges reflects the decision to acquire the businesses concerned.

The principal purchase accounting effects of acquisitions and business combinations on net income are:

amortization and net impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature), net of taxes and non-controlling interests; and

the incremental cost of sales incurred on the workdown of acquired inventories remeasured at fair value, net of taxes.

We believe (subject to the limitations described below) that disclosing our business net income enhances the comparability of our operating performance, for the following reasons:

the elimination of charges related to the purchase accounting effect of our acquisitions and business combinations (particularly amortization and impairment of finite-lived intangible assets, other than software and other rights of an industrial or operational nature) enhances the comparability of our ongoing operating performance relative to our peers in the pharmaceutical industry that carry those intangible assets (principally patents and trademarks) at low book values either because they are the result of in-house research and development that has already been expensed in prior periods or because they were acquired through business combinations that were accounted for as poolings-of-interest;

the elimination of selected items such as the incremental cost of sales arising from the workdown of acquired inventories remeasured at fair value in business combinations, major gains and losses on disposals, and costs and provisions associated with major litigation and any other major non-recurring items, improves comparability from

one period to the next; and

the elimination of restructuring costs and similar items enhances comparability because those costs are incurred in connection with reorganization and transformation processes intended to optimize our operations.

We remind investors, however, that business net income should not be considered in isolation from, or as a substitute for, *Net income attributable to equity holders of Sanofi* reported in accordance with IFRS. In addition, we strongly encourage investors and potential investors not to rely on any single financial measure but to review our financial statements, including the notes thereto, carefully and in their entirety.

We compensate for the material limitations described above by using business net income only to supplement our IFRS financial reporting and by ensuring that our disclosures provide sufficient

information for a full understanding of all adjustments included in business net income.

Because our business net income is not a standardized measure, it may not be directly comparable with the non-GAAP financial measures of other companies using the same or a similar non-GAAP financial measure.

#### **A.1.6. Presentation of Net Sales**

In the discussion below, we present our consolidated net sales for 2017, 2016 et 2015. We analyze our net sales among various categories, including by business, product and geographical region. In addition to reported net sales, we analyze non-GAAP financial measures designed to isolate the impact on our net sales of currency exchange rates and changes in the structure of our group.

When we refer to changes in our net sales at constant exchange rates (CER), that means that we have excluded the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for the previous period.

When we refer to changes in our net sales on a constant structure basis, that means that we eliminate the effect of changes in structure by restating the net sales for the previous period as follows:

by including sales generated by entities or product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we make the acquisition;

similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and

for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

#### **A.1.7. Financial Presentation of Alliances**

We have entered into a number of alliances for the development, co-promotion and/or co-marketing of our products. We believe that a presentation of our two principal alliances is useful to an understanding of our financial statements.

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The financial impact of the alliances on the Company's income statement is described in Results of Operations Year Ended December 31, 2017 Compared with Year Ended December 31, 2016 and Year Ended December 31, 2016 Compared with Year Ended December 31, 2015, in particular in Net Sales, Other Revenues, Share of Profit from Investments Accounted for using the Equity Method and Net Income Attributable to Non-Controlling Interests.

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**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

***I/ ALLIANCE ARRANGEMENTS WITH REGENERON PHARMACEUTICALS INC. (Regeneron)******Collaboration agreement on the discovery, development and commercialization of human therapeutic antibodies***

In November 2007, Sanofi and Regeneron signed new agreements (amended in November 2009) for the discovery, development and commercialization of fully human therapeutic antibodies. Sanofi having decided not to extend the discovery agreement, that agreement expired on December 31, 2017. Under the 2009 amended agreements Sanofi committed to funding the discovery and pre-clinical development of fully human therapeutic antibodies by a maximum of \$160 million per year through 2017. Sanofi had an option to develop and commercialize antibodies discovered by Regeneron pursuant to the collaboration. Following the signature in July 2015 of the immuno-oncology collaboration agreement described below, \$75 million (spread over three years) was reallocated to that new agreement.

If the option was exercised, Sanofi co-develops and co-commercialize the antibody with Regeneron and is responsible for funding. Sanofi and Regeneron share co-promotion rights and profits on sales of the co-developed antibodies. On receipt of the first positive Phase III trial results for any such antibody, the subsequent Phase III costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under those arrangements are recognized by Sanofi as a reduction in the line item ***Research and development expenses***. Once a product begins to be commercialized, and provided that the share of quarterly results under the agreement represents a profit, Sanofi is entitled to an additional profit-share (capped at 10% of Regeneron's share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration. In addition, Sanofi may be required to make milestone payments based on aggregate sales of all antibodies. As of December 31, 2017 the cumulative development costs incurred by the two parties were 5.2 billion (comprising 2.9 billion funded 100% by Sanofi, and 2.3 billion funded 80% by Sanofi and 20% by Regeneron, amounts translated into euros at the closing US dollar exchange rate). On the earlier date of (i) 24 months before the scheduled launch date or (ii) the first positive Phase III trial results, Sanofi and Regeneron share the commercial expenses of the antibodies co-developed under the license agreement. Sanofi recognizes all the sales of those antibodies. Profits and losses arising from commercial operations in the United States are split 50/50. Outside the United States, Sanofi is entitled to between 55% and 65% of profits depending on sales of the antibodies, and bears 55% of any losses. The share of profits and losses attributable to Regeneron under the agreement is recognized in the line items ***Other operating income*** or ***Other operating expenses***, which are components of operating income. In addition, Regeneron is entitled to receive payments of up to \$250 million contingent on the attainment of specified levels of sales outside the United States.

Praluent<sup>®</sup>, Dupixent<sup>®</sup>, Kevzara<sup>®</sup>, and REGN3500 (SAR 440340) will continue to be developed, and commercialized as applicable, with Regeneron under the Antibody License and Collaboration Agreement (LCA), following the expiry of the Discovery Agreement.

Immuno Oncology (IO) Discovery and Development Agreement and IO Licence and Collaboration Agreement (IO LCA)

On July 1, 2015, Sanofi and Regeneron entered into a new global collaboration to discover, develop and commercialize new antibody cancer treatments in the emerging field of immuno-oncology. As part of the agreements, the two companies are jointly developing a programmed cell death protein 1 (PD-1) inhibitor antibody currently in Phase IIb in the treatment of cutaneous squamous cell carcinoma and in Phase III for non-small cell lung cancer and cervical cancer, and expect to initiate clinical trials with new therapeutic candidates based on ongoing innovative preclinical programs. Sanofi made an upfront payment of \$640 million to Regeneron. The two companies will then invest approximately \$1 billion from discovery through proof of concept (POC) development (usually a Phase IIa study) of monotherapy and novel combinations of immuno-oncology antibody candidates to be funded 25% by Regeneron (\$250 million) and 75% by Sanofi (\$750 million). Under the terms of the IO Discovery and Development Agreement, Sanofi is entitled to an additional share of profits of up to 50% of the clinical development costs initially funded by Sanofi. That additional profit-share is capped at 10% of the share of Regeneron's quarterly profits arising under the agreement.

Under the terms of the IO LCA Sanofi and Regeneron also committed to provide additional funding of no more than \$650 million on a 50/50 basis (\$325 million per company) for the development of REGN2810, a PD-1 inhibitor antibody. In January 2018, Sanofi and Regeneron announced an agreement to increase the PD1 development budget from the previously disclosed \$650 million to \$1.64 billion, which will continue to be shared 50-50. In addition, Sanofi will make a one-time milestone payment of \$375 million to Regeneron in the event that sales of a PD-1 product and any other collaboration antibody sold for use in combination with a PD-1 product were to exceed, in the aggregate, \$2 billion in any consecutive 12-month period. Finally, the two companies agreed to reallocate \$75 million (spread over three years) to immuno-oncology antibody research and development from Sanofi's \$160 million annual contribution to their existing antibody collaboration, which has not been extended. Beyond the committed funding, additional funding will be allocated as programs enter post-POC development.

Under the terms of the IO Discovery and Development Agreement, Sanofi can exercise opt-in rights to further development and commercialization under the IO LCA for candidates derived from the program.

Once Sanofi has exercised its opt-in rights for a candidate, future development of that candidate will be conducted either by Sanofi and Regeneron.

**Table of Contents**

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Where development is conducted by Sanofi, the entire cost of developing that candidate will be funded by Sanofi, and Regeneron will reimburse half of those costs, subject to a cap of 10% of Regeneron's quarterly profits.

Where development is conducted by Regeneron, the two parties will share the development costs equally.

**Investor agreement**

In January 2014, Sanofi and Regeneron amended the investor agreement that has existed between the two companies since 2007 (the Amended Investor Agreement). Under the terms of the amendment, Sanofi accepted various restrictions. Sanofi is bound by certain standstill provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron or acquiring more than 30% of Regeneron's capital stock (consisting of the outstanding shares of common stock and the shares of Class A stock). This prohibition will remain in place until the earlier of (i) the later of the fifth anniversaries of the expiration or earlier termination of the Zaltrap® collaboration agreement with Regeneron (related to the development and commercialization of Zaltrap®) or the collaboration agreement with Regeneron on monoclonal antibodies (see Collaboration agreement on the discovery, development and commercialization of human therapeutics antibodies above), each as amended and (ii) other specified events.

Sanofi has also agreed to vote as recommended by Regeneron's Board of Directors, except that it may elect to vote proportionally with the votes cast by all of Regeneron's other shareholders with respect to certain change-of-control transactions, and to vote in its sole discretion with respect to liquidation or dissolution, stock issuances equal to or exceeding 20% of the outstanding shares or voting rights of Regeneron's Class A Stock and Common Stock (taken together), and new equity compensation plans or amendments if not materially consistent with Regeneron's historical equity compensation practices.

As soon as it had passed the threshold of 20% ownership of the capital stock, Sanofi exercised its right under the Amended Investor Agreement to designate an independent director, who was appointed to the Board of Directors of Regeneron. The interest held by Sanofi in Regeneron has been accounted for using the equity method since April 2014.

On the conditions set out in the Amended Investor Agreement entered into in January 2014, Sanofi's right to designate a Regeneron board member was contingent on Sanofi maintaining its percentage share of Regeneron's outstanding capital stock (measured on a quarterly basis) at a level no lower than the highest percentage level previously achieved,

with the maximum requirement capped at 25%. In addition, Sanofi's interest in Regeneron is subject to a clause restricting Sanofi's ability to sell shares of Regeneron's capital stock, which has been amended by the letter agreement of January 2018 (the 2018 Letter Agreement see below).

In November 2015, the Independent Designee (as defined in the Amended Investor Agreement) designated by Sanofi as an independent director resigned from the Regeneron Board of Directors. At Sanofi's request, pursuant to the Amended Investor Agreement, Regeneron appointed N. Anthony Tony Coles, M.D. to its Board of Directors in January 2017 as a successor Sanofi designee.

The Amended Investor Agreement also gives Sanofi the right to receive certain reasonable information as may be agreed upon by the parties and which will facilitate Sanofi's ability to account for its investment in Regeneron using the equity method of accounting under IFRS.

In January 2018, **Sanofi and Regeneron** announced (i) amendments to their collaboration agreement on the discovery, development and commercialization of human therapeutic antibodies; (ii) amendments to their IO licence and collaboration agreement on the development of cemiplimab in the field of immuno-oncology; and (iii) a limited waiver and amendment of the Amended Investor Agreement pursuant to the 2018 Letter Agreement.

The announcement included a series of amendments to the collaboration agreements relating to the funding of additional programs to develop REGN2810 in extended indications, and of additional programs on Dupixent® and IL33 (REGN3500).

The \$650 million development budget for the PD-1 inhibitor antibody will be increased to \$1.64 billion through 2022, funded equally by the two companies (i.e. from \$325 million to \$820 million for each partner).

The additional programs on Dupixent® and IL33 (REGN3500) will focus on extending the current range of indications and finding new indications, and improving co-morbidity between multiple pathologies.

Pursuant to the 2018 Letter Agreement, Regeneron has agreed to grant a limited waiver of the lock-up and the obligation to maintain the Highest Percentage Threshold in the Amended and Restated Investor Agreement between the companies, so that Sanofi may elect to sell a small percentage of the Regeneron common stock it owns to fund a portion of the cemiplimab and dupilumab development expansion. This waiver will allow Sanofi to sell in private transactions to Regeneron up to an aggregate of 1.4 million shares of Regeneron common stock through the end of 2020. If Regeneron decides not to purchase the shares, Sanofi will be allowed to sell those shares on the open market, subject to certain volume and timing limitations. Upon expiration of the limited waiver under the 2018 Letter Agreement, the Amended Investor Agreement will be amended to define Highest Percentage Threshold as the lower of (i) 25% of Regeneron outstanding shares of Class A Stock and Common Stock (taken together) and (ii) the higher of (a) Sanofi's percentage ownership of Class A Stock and Common Stock (taken together) on such termination date and (b) the highest percentage ownership of Regeneron

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**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

outstanding shares of Class A Stock and Common Stock (taken together) Sanofi attains following such termination date.

**2/ ALLIANCE ARRANGEMENTS WITH BRISTOL-MYERS SQUIBB (BMS)**

Two of Sanofi's leading products were jointly developed with BMS: the anti-hypertensive agent irbesartan (Aprovel®/Avapro®/Karvea®) and the anti-atherothrombosis treatment clopidogrel bisulfate (Plavix®/Iscover®).

On September 27, 2012, Sanofi and BMS signed an agreement relating to their alliance following the loss of exclusivity of Plavix® and Avapro®/Avalide® in many major markets.

Under the terms of this agreement, which took effect on January 1, 2013, BMS returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the United States and Puerto Rico, giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS will receive royalty payments on Sanofi's sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in the United States and Puerto Rico) until 2018, and will also receive a payment of \$200 million from Sanofi in December 2018, part of which will be used to buy out the non-controlling interests (see Note D.18.). Rights to Plavix® in the United States and Puerto Rico remain unchanged and continue to be governed by the terms of the original agreement until December 2019.

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/Avalide®) as defined in the new agreement, Sanofi recognizes in its consolidated financial statements the revenue and expenses generated by its own operations. The share of profits reverting to BMS subsidiaries is presented within ***Net income attributable to non-controlling interests*** in the income statement.

In the territory managed by BMS (United States and Puerto Rico for Plavix®), Sanofi recognizes its share of profits and losses within the line item ***Share of profit/(loss) from investments accounted for using the equity method***.

**A.1.8. Impact of Exchange Rates**

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in countries where the euro is not the local currency, our results of operations can be significantly affected by exchange rate movements between the euro and other currencies, primarily the US dollar and, to a lesser extent, the Japanese yen, and currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2017, we earned 33.8% of our net sales in the United States. An



increase in the value of the US dollar against the euro has a positive impact on both our revenues and our operating income. A decrease in the value of the US dollar against the euro has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively affects our operating income. A variation in the value of the US dollar has a particularly significant impact on our operating income, which is higher in the United States than elsewhere, and on the contribution to net income of our collaborations with Regeneron and BMS in the United States (see Financial Presentation of Alliances above).

For a description of arrangements entered into to manage operating foreign exchange risks as well as our hedging policy, see Item 11. Quantitative and Qualitative Disclosures about Market Risk, and Item 3. Key Information D. Risk Factors Risks Related to Financial Markets Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition.

#### **A.1.9. Divestments**

On January 1, 2017, Sanofi and BI finalized the strategic transaction agreed in June 2016, involving the exchange of Sanofi's Animal Health business (Merial) for BI's Consumer Healthcare business. After final enterprise value adjustments, the exchange values of the two businesses effectively transferred during 2017 were determined to be 10,557 million for Sanofi's Animal Health business and 6,239 million for BI's Consumer Healthcare business. The divestment of the Animal Health business generated an after-tax gain of 4,643 million in 2017.

At the end of December 2016, Sanofi Pasteur and MSD ended their European joint venture Sanofi Pasteur MSD (SPMSD). This transaction involves the divestment of Sanofi's share in the joint venture and the acquisition of the vaccines portfolio that reverts to Sanofi. The consideration for the transfer was (i) a fixed sum of 127 million received on January 4, 2017 and (ii) contingent consideration based on a percentage of MSD sales during the 2017-2024 period of specified products previously distributed by SPMSD, and receivable in annual installments over the same period. As of December 31, 2016, the fair value of the contingent consideration was measured at 458 million and recognized in the available-for-sale financial assets category.

There were no material divestments in 2015.

For further details about the divestments mentioned above, see Note D.1. and D.2. to our consolidated financial statements included at Item 18 of this annual report.

#### **A.1.10. Acquisitions**

In 2017, as part of the strategic transaction between Sanofi and BI, we acquired BI's Consumer Healthcare business. The goodwill arising on that acquisition represents (i) the capacity to draw on a specialized structure to refresh the existing product portfolio; (ii) the

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**Table of Contents**

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

competencies of the staff transferred to Sanofi; (iii) the benefits derived from the creation of new growth platforms; and (iv) the expected future synergies and other benefits from combining the CHC operations of BI and Sanofi. The tax-deductible portion of goodwill amounts to 1,876 million out of total goodwill of 2,222 million. This business generated sales of 1,407 million in the year ended December 31, 2017.

On August 25, 2017, Sanofi acquired 100% of Protein Sciences, a biotechnology company headquartered in Meriden, Connecticut (United States). The principal product of Protein Sciences is Flublok<sup>®</sup>, the only recombinant protein-based influenza vaccine approved by the FDA in the United States. The acquisition price includes two contingent purchase consideration elements of 42.3 million each. The impacts of this acquisition on Sanofi's business operating income and consolidated net income for the year ended December 31, 2017 are not material.

Over the past three years Sanofi acquired further shares in the biopharmaceutical company Regeneron, at a cost of 184 million in 2017, 115 million in 2016 and 117 million in 2015. Sanofi's investment in Regeneron had a carrying amount of 2,512 million as of December 31, 2017, compared with 2,548 million as of December 31, 2016 and 2,245 million as of December 31, 2015 (see Note D.6.). This represents an equity interest of 22.2% as of December 31, 2017, compared with 22.1% as of December 31, 2016 and 2015.

In 2016, as part of the dissolution of the Sanofi Pasteur MSD joint venture, we acquired the vaccines portfolio that reverts to us. The purchase price essentially comprised (i) a fixed sum of 154 million paid on January 4, 2017 and (ii) contingent consideration of 354 million based on a percentage of future sales made by Sanofi Pasteur during the 2017-2024 period of specified former SPMSD products, to be paid in installments over that period.

The impact of acquisitions in 2015 on our consolidated financial statements is not material.

For further information about the acquisitions mentioned above, see Notes D.1. and D.2. to our consolidated financial statements included at Item 18 of this annual report.

**A.1.11. Critical accounting and reporting policies**

Our consolidated financial statements are affected by the accounting and reporting policies that we use. Certain of our accounting and reporting policies are critical to an understanding of our results of operations and financial condition, and in some cases the application of these critical policies can be significantly affected by the estimates, judgments

and assumptions made by management during the preparation of our consolidated financial statements. The accounting and reporting policies that we have

identified as fundamental to a full understanding of our results of operations and financial condition are the following:

### *1/ Revenue recognition*

Our policies with respect to revenue recognition are discussed in Note B.13.1. to our consolidated financial statements included at Item 18 of this annual report. Revenue arising from the sale of goods is presented in the income statement within *Net sales*. Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; we no longer have effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to us.

We offer various types of price reductions on our products. In particular, products sold in the United States are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment. The discounts, incentives and rebates described above are estimated on the basis of specific contractual arrangements with our customers or of specific terms of the relevant regulations and/or agreements applicable for transactions with healthcare authorities, and of assumptions about the attainment of sales targets. We also estimate the amount of sales returns, on the basis of contractual sales terms and reliable historical data. Discounts, incentives, rebates and sales returns are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. For additional details regarding the financial impact of discounts, incentives, rebates and sales returns, see Note D.23. to our consolidated financial statements included at Item 18 of this annual report.

Revenues from non-Sanofi products, mainly comprising royalty income from license arrangements and sales of non-Sanofi products by our US-based entity VaxServe, are presented within **Other revenues**.

### *2/ Business combinations*

As discussed in Note B.3. Business combinations and transactions with non-controlling interests to our consolidated financial statements included at Item 18 of this annual report, business

---

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

combinations are accounted for by the acquisition method. The acquiree's identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 (Business Combinations) are measured initially at their fair values as at the acquisition date, except for (i) non-current assets classified as held for sale, which are measured at fair value less costs to sell and (ii) assets and liabilities that fall within the scope of IAS 12 (Income Taxes) and IAS 19 (Employee Benefits). Business combinations completed on or after January 1, 2010 are accounted for in accordance with the revised IFRS 3 and the revised IAS 27, (Consolidated and Individual Financial Statements), now superseded by IFRS 10 (Consolidated Financial Statements). In particular, contingent consideration payable to former owners agreed in a business combination, e.g. in the form of payments upon the achievement of certain R&D milestones, is recognized as a liability at fair value as of the acquisition date irrespective of the probability of payment. If the contingent consideration was originally recognized as a liability, subsequent adjustments to the liability are recognized in profit or loss (see Note D.18. Liabilities related to business combinations and non-controlling interests to our consolidated financial statements included at Item 18 of this annual report).

***3/ Goodwill impairment and intangible assets***

As discussed in Note B.6. Impairment of property, plant and equipment, intangible assets, and investments accounted for using the equity method and in Note D.5. Impairment of intangible assets and property, plant and equipment to our consolidated financial statements included at Item 18 of this annual report, we test our intangible assets for impairment periodically or when there is any internal or external indication of impairment. We test for impairment on the basis of the same objective criteria that were used for the initial valuation. Our initial valuation and ongoing tests are based on the relationship of the value of our projected future cash flows associated with the asset to either the purchase price of the asset (for its initial valuation) or the carrying amount of the asset (for ongoing tests). The determination of the underlying assumptions relating to the recoverability of intangible assets is subjective and requires the exercise of considerable judgment. Key assumptions relating to goodwill impairment and intangible assets are the perpetual growth rate and the post-tax discount rate. Any changes in key assumptions could result in an impairment charge. A sensitivity analysis to the key assumptions is disclosed in Note D.5. Impairment of intangible assets and property, plant and equipment to our consolidated financial statements included at Item 18 of this annual report.

***4/ Contingent consideration receivable***

As described in Note B.8.6. and D.7. to our consolidated financial statements included at Item 18 of this annual report, contingent consideration receivable such as earn-outs on disposals, for example in the form of a percentage of future sales of the acquirer, are recognized as an asset at fair value as of the date of divestment. Subsequent remeasurements of the fair value of the asset are recognized in profit or loss.

***5/ Pensions and post-retirement benefits***

As described in Note B.23. Employee benefit obligations to our consolidated financial statements included at Item 18 of this annual report, we recognize our pension and retirement benefit commitments as liabilities on the basis of an actuarial estimate of the rights vested in employees and retirees at the end of the reporting period, net of the fair value of plan assets held to meet these obligations. We prepare this estimate at least on an annual basis taking into account financial assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

We recognize all actuarial gains and losses (including the impact of a change in discount rate) immediately through equity. A sensitivity analysis to the discount rate is set forth in Note D.19.1. Provisions for pensions and other benefits to our consolidated financial statements included at Item 18 of this annual report.

Depending on the key assumptions used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings. A sensitivity analysis to these key assumptions is set forth in Note D.19.1. Provisions for pensions and other benefits to our consolidated financial statements included at Item 18 of this annual report.

### ***6/ Deferred taxes***

As discussed in Note B.22. Income tax expense to our consolidated financial statements included at Item 18 of this annual report, we recognize deferred income taxes on tax loss carry-forwards and on temporary differences between the tax base and carrying amount of assets and liabilities. We calculate our deferred tax assets and liabilities using enacted tax rates applicable for the years during which we estimate that the temporary differences are expected to reverse. We do not recognize deferred tax assets when it is more likely than not that the deferred tax assets will not be realized. The recognition of deferred tax assets is determined on the basis of profit forecasts for each tax group, and of the tax consequences of the strategic opportunities available to Sanofi.

### ***7/ Provisions for risks***

Sanofi and its subsidiaries and affiliates may be involved in litigation, arbitration or other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights, compliance and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As discussed in Note B.12. Provisions for risks at Item 18 of this annual report, we record a provision where we have a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying

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**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources. For additional details regarding the financial impact of provisions for risks see Notes D.19.3.

Other provisions and D.22. Legal and Arbitral Proceedings to our consolidated financial statements included at Item 18 of this annual report.

***8/ Provisions for restructuring costs***

Provisions for restructuring costs include early retirement benefits, compensation for early termination of contracts, and rationalization costs relating to restructured sites. Refer to Note D.19.2 to our consolidated financial statements included in Item 18 of this annual report.

Provisions are estimated on the basis of events and circumstances related to present obligations at the end of the reporting period and of past experience, and to the best of management's knowledge at

the date of preparation of the financial statements. The assessment of provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Given the inherent uncertainties related to these estimates and assumptions, the actual outflows resulting from the realization of those risks could differ from our estimates.

***9/ Venezuelan Subsidiaries***

As described in Note A.4. to our consolidated financial statements included at Item 18 of this annual report, Sanofi continues to account for subsidiaries based in Venezuela using the full consolidation method, on the basis that the criteria for control as specified in IFRS 10 (Consolidated Financial Statements) are met. In the context of the existence of several exchange rates in Venezuela, Sanofi has decided to use the DICOM rate (established in February 2016) for the translation of transactions carried out by the Venezuelan subsidiaries.

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**A.2. Results of operations year ended December 31, 2017 compared with year ended December 31, 2016**

The consolidated income statements for the years ended December 31, 2017 and December 31, 2016 are presented below:

	as % of		2016 <sup>(a)</sup>	as % of net sales
	2017	net sales		
( million)				
<b>Net sales</b>	<b>35,055</b>	<b>100.0%</b>	<b>33,821</b>	<b>100.0%</b>
Other revenues	1,149	3.3%	887	2.6%
Cost of sales	(11,611)	(33.1%)	(10,702)	(31.6%)
<b>Gross profit</b>	<b>24,593</b>	<b>70.2%</b>	<b>24,006</b>	<b>71.0%</b>
Research and development expenses	(5,472)	(15.6%)	(5,172)	(15.3%)
Selling and general expenses	(10,058)	(28.7%)	(9,486)	(28.0%)
Other operating income	237		355	
Other operating expenses	(233)		(482)	
Amortization of intangible assets	(1,866)		(1,692)	
Impairment of intangible assets	(293)		(192)	
Fair value remeasurement of contingent consideration	(159)		(135)	
Restructuring costs and similar items	(731)		(879)	
Other gains and losses, and litigation	(215)		211	
<b>Operating income</b>	<b>5,803</b>	<b>16.6%</b>	<b>6,534</b>	<b>19.3%</b>
Financial expenses	(420)		(924)	
Financial income	147		68	
<b>Income before tax and investments accounted for using the equity method</b>	<b>5,530</b>	<b>15.8%</b>	<b>5,678</b>	<b>16.8%</b>
Income tax expense	(1,722)		(1,326)	
Share of profit/(loss) from investments accounted for using the equity method	104		134	
<b>Net income excluding the exchanged/held-for-exchange Animal Health business</b>	<b>3,912</b>	<b>11.2%</b>	<b>4,486</b>	<b>13.3%</b>

Net income/(loss) of the exchanged/held-for-exchange Animal Health business	4,643		314	
<b>Net income</b>	<b>8,555</b>	<b>24.4%</b>	<b>4,800</b>	<b>14.2%</b>
Net income attributable to non-controlling interests	121		91	
<b>Net income attributable to equity holders of Sanofi</b>	<b>8,434</b>	<b>24.1%</b>	<b>4,709</b>	<b>13.9%</b>
Average number of shares outstanding (million)	1,256.9		1,286.6	
Average number of shares outstanding after dilution (million)	1,266.8		1,296.0	
Basic earnings per share (in euros)	6.71		3.66	
Basic earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)	3.02		3.42	
Diluted earnings per share (in euros)	6.66		3.63	
Diluted earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)	2.99		3.39	

(a) The results of the Animal Health business (in 2016), and the gain on the divestment of that business (in 2017), are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); see Notes D.1. and D.36 to the consolidated financial statements).



**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**A.2.1. Net Sales**

Net sales for the year ended December 31, 2017 were 35,055 million, 3.6% higher than in 2016. Exchange rate fluctuations had a negative effect of two percentage points overall, mainly as a result of unfavorable trends in the euro against the US

dollar, the Egyptian pound, the Turkish lira, the Japanese yen and the Chinese yuan renminbi. At constant exchange rates (CER), net sales were up 5.6%, reflecting the acquisition of BI's Consumer Healthcare business and the first-time consolidation of Sanofi's European vaccines business. At constant exchange rates and on a constant structure basis (CER/CS), net sales rose by 0.5%.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2017 and December 31, 2016 to our net sales at constant exchange rates and on a constant structure basis:

<i>( million)</i>	<b>2017</b>	<b>2016</b>	<b>Change</b>
<b>Net sales</b>	<b>35,055</b>	<b>33,821</b>	<b>+3.6%</b>
Effect of exchange rates	672		
<b>Net sales at constant exchange rates</b>	<b>35,727</b>	<b>33,821</b>	<b>+5.6%</b>
Impact of changes in structure		1,741	
<b>Net sales at constant exchange rates and on a constant structure basis</b>	<b>35,727</b>	<b>35,562</b>	<b>+0.5%</b>

When we refer to changes in our net sales **at constant exchange rates (CER)**, that means that we have excluded the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for

the previous period.

When we refer to changes in our net sales **on a constant structure basis (CS)**, that means that we eliminate the effect of changes in structure by restating the net sales for the previous period as follows:

by including sales generated by entities or product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we make the acquisition;

similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and

for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

To facilitate analysis and comparisons with prior periods, some figures are given **at constant exchange rates and on a constant structure basis (CER/CS)**.

#### Analysis of impact on net sales of changes in structure

( million)	<b>2016</b>
BI Consumer Healthcare net sales <sup>(a)</sup>	1,484
Net sales effect of first-time consolidation of the European vaccines activity (SPMSD transaction) <sup>(a)</sup>	261
<b>Total impact of BI and SPMSD</b>	<b>1,745</b>
Other	(4)
<b>Total impact on net sales of changes in structure</b>	<b>1,741</b>

*(a) Based on an unaudited sales estimate.*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

***1/ Net Sales by Operating Segment***

Our net sales comprise the net sales generated by our Pharmaceuticals, Consumer Healthcare and Human Vaccines (Vaccines) segments. Following the integration of BI's Consumer Healthcare business, acquired on January 1, 2017, our Consumer Healthcare business represents a separate operating segment of Sanofi in accordance with IFRS 8. Consequently, we present our Consumer Healthcare net sales separately for the year ended December 31, 2017. Comparatives for the year ended December 31, 2016 have been restated accordingly (Consumer Healthcare was previously included within the Pharmaceuticals segment).

( million)	2017	2016	Change
Pharmaceuticals	25,122	25,914	-3.1%
Consumer Healthcare	4,832	3,330	+45.1%
Vaccines	5,101	4,577	+11.4%
<b>Net sales</b>	<b>35,055</b>	<b>33,821</b>	<b>+3.6%</b>

***2/ Net Sales by Global Business Unit (GBU)***

The table below presents net sales for our Global Business Units (GBUs), reflecting our internal organizational structure that aims to streamline our organization, sharpen our focus and concentrate our efforts on growth drivers. Note that Emerging Markets sales of Diabetes & Cardiovascular and Specialty Care products are included in the General Medicines & Emerging Markets GBU.

( million)	2017	2016	Change on a reported basis	Change at constant exchange rates
Sanofi Genzyme GBU <sup>(a)</sup> (Specialty Care) <sup>(b)</sup>	5,674	5,019	+13.1%	+15.1%
Diabetes & Cardiovascular GBU <sup>(a)</sup>	5,400	6,397	-15.6%	-14.3%
General Medicines & Emerging Markets GBU <sup>(c)(d)</sup>	14,048	14,498	-3.1%	-1.0%
<b>Total Pharmaceuticals<sup>(e)</sup></b>	<b>25,122</b>	<b>25,914</b>	<b>-3.1%</b>	<b>-1.2%</b>
Consumer Healthcare GBU <sup>(e)</sup>	4,832	3,330	+45.1%	+46.3%

Sanofi Pasteur (Vaccines) GBU	5,101	4,577	+11.4%	+14.5%
<b>Total</b>	<b>35,055</b>	<b>33,821</b>	<b>+3.6%</b>	<b>+5.6%</b>

(a) Does not include Emerging Markets net sales.

(b) Rare Diseases, Multiple Sclerosis, Oncology and Immunology.

(c) Includes net sales in Emerging Markets of Specialty Care and Diabetes & Cardiovascular products.

(d) Emerging Markets: World excluding United States, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(e) Following the integration of BI's Consumer Healthcare business, acquired on January 1, 2017, our Consumer Healthcare business represents a separate operating segment of Sanofi in accordance with IFRS 8. Consequently, we present our Consumer Healthcare net sales separately for the year ended December 31, 2017. Comparatives for the year ended December 31, 2016 have been restated accordingly (Consumer Healthcare was previously included within the Pharmaceuticals segment).

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**3/ Net Sales by Franchise**

The table below sets forth our 2017 net sales by franchise in order to facilitate comparisons with our peers. For a detailed reconciliation of net sales by franchise and net sales by GBU for our Pharmaceuticals segment, refer to the table later in this report showing Pharmaceuticals segment net sales by geographical region.

( million)	2017	2016	Change on a reported basis	Change at constant exchange rates
Rare Diseases	2,888	2,777	+4.0%	+6.0%
Multiple sclerosis	2,041	1,720	+18.7%	+20.8%
Oncology	1,519	1,453	+4.5%	+6.4%
Immunology	230	-	-	-
<b>Total Specialty Care</b>	<b>6,678</b>	<b>5,950</b>	<b>+12.2%</b>	<b>+14.5%</b>
<i>of which Developed Markets (Sanofi Genzyme GBU)</i>	5,674	5,019	+13.1%	+15.1%
<i>of which Emerging Markets<sup>(a)(b)</sup></i>	1,004	931	+7.8%	+11.3%
Diabetes	6,395	7,341	-12.9%	-11.1%
Cardiovascular	510	458	+11.4%	+13.3%
<b>Total Diabetes &amp; Cardiovascular</b>	<b>6,905</b>	<b>7,799</b>	<b>-11.5%</b>	<b>-9.6%</b>
<i>of which Developed Markets (Diabetes &amp; Cardiovascular GBU)</i>	5,400	6,397	-15.6%	-14.3%
<i>of which Emerging Markets<sup>(a)(b)</sup></i>	1,505	1,402	+7.3%	+11.6%
<b>Established Prescription Products<sup>(a)</sup></b>	<b>9,761</b>	<b>10,311</b>	<b>-5.3%</b>	<b>-3.4%</b>
<b>Generics<sup>(a)</sup></b>	<b>1,778</b>	<b>1,854</b>	<b>-4.1%</b>	<b>-3.3%</b>

<b>Total Pharmaceuticals<sup>(c)</sup></b>	<b>25,122</b>	<b>25,914</b>	<b>-3.1%</b>	<b>-1.2%</b>
<b>Consumer Healthcare (Consumer Healthcare GBU)<sup>(c)</sup></b>	<b>4,832</b>	<b>3,330</b>	<b>+45.1%</b>	<b>+46.3%</b>
<b>Vaccines (Sanofi Pasteur GBU)</b>	<b>5,101</b>	<b>4,577</b>	<b>+11.4%</b>	<b>+14.5%</b>
<b>Total</b>	<b>35,055</b>	<b>33,821</b>	<b>+3.6%</b>	<b>+5.6%</b>

(a) These lines are aggregated to form the net sales of the General Medicines and Emerging Markets GBU.

(b) Emerging Markets: World excluding United States, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(c) Following the integration of BI's Consumer Healthcare business, acquired on January 1, 2017, our Consumer Healthcare business represents a separate operating segment of Sanofi in accordance with IFRS 8. Consequently, we present our Consumer Healthcare net sales separately for the year ended December 31, 2017. Comparatives for the year ended December 31, 2016 have been restated accordingly (Consumer Healthcare was previously included within the Pharmaceuticals segment).

#### **4/ Net Sales Pharmaceuticals Segment**

In 2017, net sales for the Pharmaceuticals segment (excluding Consumer Healthcare) were 25,122 million, down 3.1% on a reported basis and 1.2% at constant exchange rates (CER). The year-on-year decrease of 792 million includes a reduction of 492 million due to unfavorable exchange rate effects, and the following impacts at constant exchange rates:

growth in net sales for the Multiple Sclerosis franchise (up 358 million), the launch of the Immunology franchise (positive effect of 246 million), and positive performances for the Rare Diseases franchise (up 167 million), the Oncology franchise (up 93 million and the Cardiovascular franchise (up 61 million);

offset by lower net sales for the Diabetes franchise (down 813 million), Established Prescription Products (down 351 million), and Generics (down 61 million).

Comments on the performances of major Pharmaceuticals segment products are provided below.

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**Pharmaceuticals segment net sales, 2017 and 2016**

				<b>Change on</b>	<b>Change at</b>
				<b>a</b>	<b>constant</b>
				<b>reported</b>	<b>exchange</b>
( million)	<b>Indication</b>	<b>2017</b>	<b>2016</b>	<b>basis</b>	<b>rates</b>
Cerezyme <sup>®</sup>	Gaucher disease	730	748	-2.4%	+0.4%
Cerdelga <sup>®</sup>	Gaucher disease	126	106	+18.9%	+20.8%
Myozyme <sup>®</sup> /Lumizyme <sup>®</sup>	Pompe disease	789	725	+8.8%	+10.1%
Fabrazyme <sup>®</sup>	Fabry disease	722	674	+7.1%	+9.2%
Aldurazyme <sup>®</sup>	Mucopolysaccharidosis	207	201	+3.0%	+5.5%
Other		314	323	-2.8%	-1.2%
<b>Total Rare Diseases</b>		<b>2,888</b>	<b>2,777</b>	<b>+4.0%</b>	<b>+6.0%</b>
Aubagio <sup>®</sup>	Multiple sclerosis	1,567	1,295	+21.0%	+23.2%
Lemtrada <sup>®</sup>	Multiple sclerosis	474	425	+11.5%	+13.6%
<b>Total Multiple Sclerosis</b>		<b>2,041</b>	<b>1,720</b>	<b>+18.7%</b>	<b>+20.8%</b>
Jevtana <sup>®</sup>	Prostate cancer	386	358	+7.8%	+9.8%
Thymoglobulin <sup>®</sup>	Organ rejection	291	281	+3.6%	+5.3%
Taxotere <sup>®</sup>	Breast, lung, prostate, stomach, and head & neck cancers	173	179	-3.4%	-0.6%
Eloxatin <sup>®</sup>	Colorectal cancer	179	170	+5.3%	+8.2%
Mozobil <sup>®</sup>	Hematologic malignancies	163	152	+7.2%	+9.2%
Zaltrap <sup>®</sup>	Colorectal cancer	75	65	+15.4%	+16.9%
Other		252	248	+1.6%	+2.0%
<b>Total Oncology</b>		<b>1,519</b>	<b>1,453</b>	<b>+4.5%</b>	<b>+6.4%</b>
Dupixent <sup>®</sup>	Atopic dermatitis	219	-	-	-
Kevzara <sup>®</sup>	Rheumatoid arthritis	11	-	-	-
<b>Total Immunology</b>		<b>230</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Total Specialty Care</b>		<b>6,678</b>	<b>5,950</b>	<b>+12.2%</b>	<b>+14.5%</b>

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Lantus®	Diabetes	4,622	5,714	-19.1%	-17.5%
Toujeo®	Diabetes	816	649	+25.7%	+27.0%
Apidra®	Diabetes	377	367	+2.7%	+4.9%
Amaryl®	Diabetes	337	362	-6.9%	-1.4%
Insuman®	Diabetes	107	129	-17.1%	-15.5%
Lyxumia®	Diabetes	26	33	-21.2%	-18.2%
Soliqua®	Diabetes	26	-	-	-
Other	Diabetes	84	87	-3.4%	-2.3%
<b>Total Diabetes</b>		<b>6,395</b>	<b>7,341</b>	<b>-12.9%</b>	<b>-11.1%</b>
Multaq®	Atrial fibrillation	339	353	-4.0%	-2.5%
Praluent®	Hypercholesterolemia	171	105	+62.9%	+66.7%
<b>Total Cardiovascular</b>		<b>510</b>	<b>458</b>	<b>+11.4%</b>	<b>+13.3%</b>
<b>Total Diabetes &amp; Cardiovascular</b>		<b>6,905</b>	<b>7,799</b>	<b>-11.5%</b>	<b>-9.6%</b>



**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

( million)	Indication	2017	2016	Change on a reported basis	Change at constant exchange rates
Lovenox <sup>®</sup>	Thrombosis	1,575	1,636	-3.7%	-2.1%
Plavix <sup>®</sup>	Atherothrombosis	1,471	1,544	-4.7%	-1.2%
Renage <sup>®</sup> /Renvela <sup>®</sup>	Hyperphosphatemia	802	922	-13.0%	-12.3%
Aprovel <sup>®</sup> /Avapro <sup>®</sup>	Hypertension	691	681	+1.5%	+3.7%
Depakine <sup>®</sup>	Epilepsy	443	416	+6.5%	+9.6%
Synvisc <sup>®</sup> /Synvisc-One <sup>®</sup>	Arthritis	387	408	-5.1%	-3.9%
Allegra <sup>®</sup>	Allergic rhinitis, urticaria	158	186	-15.1%	-12.9%
Stilnox <sup>®</sup> /Ambien <sup>®</sup> /Myslee <sup>®</sup>	Sleep disorders	259	304	-14.8%	-13.5%
Tritace <sup>®</sup>	Hypertension	241	245	-1.6%	+1.2%
Targocid <sup>®</sup>	Bacterial infections	130	149	-12.8%	-10.1%
Lasix <sup>®</sup>	Edema, hypertension	137	148	-7.4%	-4.7%
Other		3,467	3,672	-5.6%	-4.1%
<b>Total Established Prescription Products</b>		<b>9,761</b>	<b>10,311</b>	<b>-5.3%</b>	<b>-3.4%</b>
<b>Generics</b>		<b>1,778</b>	<b>1,854</b>	<b>-4.1%</b>	<b>-3.3%</b>
<b>Total Pharmaceuticals</b>		<b>25,122</b>	<b>25,914</b>	<b>-3.1%</b>	<b>-1.2%</b>

## Rare Diseases franchise

Net sales for the **Rare Diseases** franchise reached 2,888 million in 2017, up 4.0% on a reported basis and 6.0% at constant exchange rates (CER). Sales growth was recorded across all geographies: 8.5% CER in Emerging Markets<sup>(1)</sup>, 6.4% CER in the United States, 5.0% CER in Europe<sup>(2)</sup> and 3.9% CER in the Rest of the World region<sup>(3)</sup>.

In Gaucher disease, net sales of **Cerezyme**<sup>®</sup> were stable year-on-year at 730 million. Sales growth in Emerging Markets (+2.1% CER at 229 million) offset a decrease in the Rest of the World region (-8.3% CER at 43 million). **Cerdelga**<sup>®</sup> reported net sales of 126 million (+20.8% CER), of which 95 million were generated in the United States (+14.1% CER). In Europe, net sales of Cerdelga<sup>®</sup> rose by 52.9% CER to 26 million.

Net sales of **Myozyme**<sup>®</sup> / **Lumizyme**<sup>®</sup> in Pompe disease rose by 10.1% CER to 789 million, driven by sales in the United States (+11.3% CER, at 262 million) and Europe (+8.6% CER, at 352 million). Net sales also rose in Emerging Markets (+12.7% CER, at 116 million) and in the Rest of the World region (+8.9% CER, at 59 million). This sales growth was fueled by increased diagnosis and treatment of Pompe disease.

**Fabrazyme**<sup>®</sup> achieved net sales growth of 9.2% CER, to 722 million. Sales are advancing in many countries due to growth

in the number of patients diagnosed with, and treated for, Fabry disease. Net sales of the product were up 9.3% CER in the United States (at 369 million); 5.8% CER in Europe (at 163 million) despite the launch of new rival products; 9.5% CER in the Rest of the World region (at 112 million); and 16.2% CER in Emerging Markets (at 78 million).

### Multiple Sclerosis franchise

Net sales for the **Multiple Sclerosis** franchise reached 2,041 million in 2017, up 18.7% on a reported basis and 20.8% CER, on strong performances by **Aubagio**<sup>®</sup> and **Lemtrada**<sup>®</sup> in the United States and Europe.

**Aubagio**<sup>®</sup> posted net sales of 1,567 million (+23.2% CER), driven by the United States (+22.0% CER, at 1,084 million) and Europe (+26.0% CER, at 387 million). The product accounted for 9.0% of total prescriptions in the United States in the first quarter of 2017, rising to 9.3% in the second quarter (source: IMS NPA TRX Q1 & Q2 2017).

Net sales of **Lemtrada**<sup>®</sup> amounted to 474 million (+13.6% CER), including 246 million in the United States (+7.3% CER) and 174 million in Europe (+18.5% CER).

- (1) World excluding United States, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.
- (2) Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).
- (3) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**Oncology franchise**

The **Oncology** franchise generated net sales of 1,519 million, up 4.5% on a reported basis and 6.4% CER, due largely to public-sector orders for Leukine<sup>®</sup> in the United States, a good performance for the franchise in Emerging Markets, and overall growth in sales of Jevtana<sup>®</sup> and Thymoglobulin<sup>®</sup>.

Net sales of **Jevtana**<sup>®</sup> totaled 386 million in 2017 (+9.8% CER), driven by growth in the United States (+6.6% CER, at 159 million), Europe (+7.2% CER, at 148 million) and Japan (+17.1% CER, at 46 million).

**Thymoglobulin**<sup>®</sup> net sales rose by 5.3% CER to 291 million, largely on a good performance in Emerging Markets (+13.6% CER, at 66 million).

Net sales of **Taxotere**<sup>®</sup> were stable year-on-year at 173 million. This reflects stronger sales in Emerging Markets (+7.7% CER, at 136 million), especially in China (+13.6% CER, at 65 million), which more than offset the effect of competition from generics, especially in Japan (-38.5% CER, at 15 million).

Net sales of **Eloxatin**<sup>®</sup> rose by 8.2% CER to 179 million. This reflects stronger sales in Emerging Markets (+13.4% CER, at 147 million), especially in China (+15.2% CER, at 103 million), which more than offset a fall in Canadian sales due to competition from generics.

**Immunology franchise**

**Dupixent**<sup>®</sup> (dupilumab, developed in collaboration with Regeneron), for adults with moderate to severe atopic dermatitis, was approved by the FDA in March 2017 and made available in the US market. Since then, the product has generated US net sales of 216 million, reflecting substantial unmet medical needs and rapid access to the market. In Europe, Dupixent<sup>®</sup> was approved at the end of September 2017 for the treatment of adults with moderate to severe atopic dermatitis requiring systemic treatment; the product was made available at the end of the year in Germany, where it generated net sales of 2 million.

**Kevzara**<sup>®</sup> (sarilumab, developed in collaboration with Regeneron), a treatment for rheumatoid arthritis, was approved by the FDA on May 22, 2017 and made available in June 2017 in the US market, where it achieved net sales of 10 million. The product has also been approved in Europe, and has been launched in a number of countries (Germany, the Netherlands and the United Kingdom). Since its launch, Kevzara<sup>®</sup> has recorded 1 million of net sales in Europe.

**Diabetes franchise**

Net sales for the Diabetes franchise amounted to 6,395 million in 2017, down 12.9% on a reported basis and 11.1% CER. The main factor was a fall in sales of Lantus<sup>®</sup> in the United States, where Diabetes franchise net sales were

down 22.8% CER at 3,128 million. As previously indicated, the decline in US net sales

for the Diabetes franchise accelerated during 2017, following the consecutive exclusion of a number of diabetes treatments from the reimbursement lists of two of the country's leading healthcare insurance providers: UnitedHealth (from April 1, 2017) and CVS. Outside the United States, Diabetes franchise net sales advanced in Emerging Markets (+11.4% CER, at 1,494 million) but fell in Europe (-2.0% CER, at 1,287 million), where a good performance from Toujeo® partially compensated for weaker sales of Lantus®.

In 2017, net sales of **insulin glargines** (Lantus® and Toujeo®) were down 13.0% CER at 5,438 million.

Net sales of **Lantus®** were down 17.5% CER in 2017, at 4,622 million. In the United States, sales were down 26.6% CER at 2,542 million, due mainly to a lower average net price, the switching of patients to Toujeo®, and the effect of the product's exclusion from reimbursement lists as described above. Net sales in Europe fell by 12.8% CER to 760 million, due largely to the launch of a biosimilar of Lantus® and the switching of patients to Toujeo®. Over the same period, sales of Lantus® in Emerging Markets reached 1,005 million, up 9.2% CER, driven largely by Africa and Middle East (+18.8% CER, at 288 million) and Asia (+10.6% CER, at 424 million), especially China (+15.8% CER, at 319 million). During 2017, Sanofi filed two patent infringement suits relating to Lantus® in the United States District Court for the District of New Jersey (United States): one against Merck (in August) and the other against Mylan (in October). For further information, refer to Item 8 Information on Legal or Arbitration Proceedings.

The new-generation basal insulin **Toujeo®** posted net sales growth of 27.0% CER in 2017, to 816 million. Net sales in the United States decreased by 2.1% CER to 455 million essentially as the result of a decrease in the average net price of the product during the fourth quarter of 2017 (negative net sales impact of 28.4% including VAT relative to the fourth quarter of 2016). However, this was more than offset by sales growth in Europe (+80.8% CER, at 217 million), Emerging Markets (+300.0% CER, at 79 million) and the Rest of the World region (+88.6% CER, at 65 million).

Net sales of **Amaryl®** fell by 1.4% CER in 2017, to 337 million. Sales growth in Emerging Markets (+2.1% CER, at 278 million) did not fully compensate for lower net sales in the Rest of the World region (-10.0% CER, at 36 million) and in Europe (-22.2% CER, at 21 million).

Net sales of **Apidra®** rose by 4.9% CER in 2017, to 377 million. Lower sales in the United States (-10.4% CER, at 102 million) were offset by sales growth in Emerging Markets (+25.9% CER, at 97 million) and in Europe (+7.1% CER, at 136 million).

**Soliqua™ 100/33 / Suliqua** (injectable insulin glargine 100 Units/mL and lixisenatide 33 mcg/mL) were launched at the start of 2017 in the United States, and at the end of 2017 in the Netherlands. Soliqua™ 100/33 has generated 26 million of net sales in the United States since launch.

Following negotiations with US payers, we have secured coverage of Lantus® and Toujeo® in the vast majority of formularies for 2018.

Table of Contents

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Given the improved sales visibility, we have fine-tuned our forecasts for Diabetes net sales for the 2015-2018 period, which we now expect to show an annualized average decrease in the range of 6% to 8% CER (for information about factors that may impact forward-looking statements, see Cautionary Statement Regarding Forward-Looking Statements ).

**Cardiovascular franchise**

In 2017, net sales of **Praluent**<sup>®</sup> (alirocumab, developed in collaboration with Regeneron) reached 171 million, of which 116 million was generated in the United States and 46 million in Europe. The relatively limited rise in sales during the period reflects significant restrictions by US payers and limited access to the European market. In October 2017, the US Court of Appeals for the Federal Circuit ordered a new trial and vacated the permanent injunction in the dispute concerning Amgen's asserted patent claims for antibodies targeting PCSK9. This ruling means that Sanofi and Regeneron will continue marketing, selling and manufacturing Praluent<sup>®</sup> in the US. For further information on litigation relating to Praluent<sup>®</sup>, refer to Note D.22. to our consolidated financial statements (included as Item 18 of this Annual Report on Form 20-F) and Item 8 Information on Legal or Arbitration Proceedings .

Net sales of **Multaq**<sup>®</sup> amounted to 339 million in 2017, down 2.5% CER year-on-year. The bulk of the sales were generated in the United States (-2.7% CER, at 286 million) and Europe (-2.3% CER, at 42 million).

**Established Prescription Products**

Net sales of Established Prescription Products in 2017 were 9,761 million, down 5.3% on a reported basis and 3.4% CER. Growth in Emerging Markets net sales (+4.8% CER, at 3,800 million) failed to offset lower net sales in Europe (-4.4% CER, at 3,473 million), the start of generic competition for Renvelo<sup>®</sup>/Renagel<sup>®</sup> in the United States, and the impact of competition from generics of Plavix<sup>®</sup> in Japan. In the United States and the Rest of the World region, net sales of Established Prescription Products fell by 13.8% CER (to 1,269 million) and 11.7% CER (to 1,219 million), respectively.

Net sales of **Lovenox**<sup>®</sup> were 1,575 million, down 2.1% CER, due largely to increased competition in Europe (-7.1% CER, at 951 million) with the arrival of biosimilars in the United Kingdom and Germany. This decline canceled out a good performance in Emerging Markets (+7.8% CER, at 475 million).

Net sales of **Plavix**<sup>®</sup> in 2017 were 1,471 million (-1.2% CER), reflecting generic competition in Japan (-30.7% CER, at 235 million) and Europe (-7.4% CER, at 150 million). The effect was partly offset by growth in sales of Plavix<sup>®</sup> in Emerging Markets

(+10.4% CER, at 1,026 million), especially in China where the product posted net sales of 758 million (+12.1% CER). Sales of Plavix<sup>®</sup> in the United States and Puerto Rico are handled by BMS under the terms of the Sanofi-BMS alliance (see Note C.2., Alliance Arrangements with Bristol-Myers Squibb (BMS) ), to our consolidated financial statements, included at Item 18 of this Annual Report on Form 20-F).

**Renvela**<sup>®</sup>/**Renagel**<sup>®</sup> posted net sales of 802 million in 2017, down 12.3% CER, mainly on generic competition in the United States (-14.8% CER, at 645 million) where the first generic versions in powder and pill form were approved in June and July 2017, respectively. In October 2017, Sanofi launched an approved generic version of Renvela<sup>®</sup>/**Renagel**<sup>®</sup> in the United States. In Europe, sales of Renvela<sup>®</sup>/**Renagel**<sup>®</sup> fell by 13.4% CER to 71 million, also due to competition from generics.

Net sales of **Aprovel**<sup>®</sup>/**Avapro**<sup>®</sup> for 2017 were 691 million (+3.7% CER), largely on sales growth in Emerging Markets (+8.7% CER, at 433 million), especially China (+14.2% CER, at 264 million), and in the Rest of the World region (+3.1% CER, at 132 million). In Europe, net sales of Aprovel<sup>®</sup>/**Avapro**<sup>®</sup> were down 9.4% CER at 115 million, due to competition from generics.

We have no comments on sales of our other Established Prescription Products.

## Generics

**Generics** net sales for 2017 were 1,778 million, down 4.1% on a reported basis and 3.3% CER.

Emerging Markets generated net sales of 758 million, down 2.9% CER, due mainly to lower sales in Asia (-68.5% CER, at 22 million) following the divestment of a distribution business in China. The decrease in net sales in Asia more than offset increased Generics sales in Latin America (+1.7% CER, at 428 million), Africa and Middle East (+1.6% CER, at 117 million) and Eurasia (+9.3% CER, at 190 million). Generics sales were also lower in Europe (-4.9% CER, at 760 million) and the United States (-12.0% CER, at 150 million), but increased in the Rest of the World region (+23.9% CER, at 110 million).

In line with our Strategic Roadmap 2020, we have been examining all options and have decided to initiate a carve-out process with a view to divesting our European Generics business. We will be looking for a potential purchaser who will leverage the medium-to-long-term sustainable growth opportunities for this business. We have also confirmed our commitment to our Generics business in other parts of the world, and will focus more on Emerging Markets in order to develop the business in those countries. Signing of definitive transaction agreements<sup>(1)</sup> on the divestiture of European Generics is expected in the third quarter of 2018.

*(1) Following completion of the dialogue with employee representatives*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following table breaks down 2017 net sales of our Pharmaceuticals segment products by geographical region:

	Total GBU	Europe <sup>(a)</sup>	Change at CER	United States	Change at CER	Rest of the world <sup>(b)</sup>	Change at CER	Emerging Markets <sup>(c)</sup>	Change at CER	Total Franchise	Change at CER
( million)											
Cerezyme <sup>®</sup>	501	281	+0.7%	177	0.0%	43	-8.3%	229	+2.1%	730	+0.4%
Cerdelga <sup>®</sup>	125	26	+52.9%	95	+14.1%	4	0.0%	1	-	126	+20.8%
Myozyme <sup>®</sup> /Lumizyme <sup>®</sup>	673	352	+8.6%	262	+11.3%	59	+8.9%	116	+12.7%	789	+10.1%
Fabrazyme <sup>®</sup>	644	163	+5.8%	369	+9.3%	112	+9.5%	78	+16.2%	722	+9.2%
Aldurazyme <sup>®</sup>	142	75	+1.3%	42	+2.4%	25	+8.3%	65	+11.7%	207	+5.5%
Other	269	64	-4.5%	113	-5.8%	92	0.0%	45	+15.8%	314	-1.2%
<b>Total Rare Diseases</b>	<b>2,354</b>	<b>961</b>	<b>+5.0%</b>	<b>1,058</b>	<b>+6.4%</b>	<b>335</b>	<b>+3.9%</b>	<b>534</b>	<b>+8.5%</b>	<b>2,888</b>	<b>+6.0%</b>
Aubagio <sup>®</sup>	1,530	387	+26.0%	1,084	+22.0%	59	+31.1%	37	+17.6%	1,567	+23.2%
Lemtrada <sup>®</sup>	450	174	+18.5%	246	+7.3%	30	+26.1%	24	+38.9%	474	+13.6%
<b>Total Multiple Sclerosis</b>	<b>1,980</b>	<b>561</b>	<b>+23.5%</b>	<b>1,330</b>	<b>+19.0%</b>	<b>89</b>	<b>+29.4%</b>	<b>61</b>	<b>+25.0%</b>	<b>2,041</b>	<b>+20.8%</b>
Jevtana <sup>®</sup>	359	148	+7.2%	159	+6.6%	52	+25.0%	27	+17.4%	386	+9.8%
Thymoglobulin <sup>®</sup>	225	39	+2.6%	162	+3.8%	24	0.0%	66	+13.6%	291	+5.3%
Taxotere <sup>®</sup>	37	3	-25.0%	-	-100.0%	34	-14.6%	136	+7.7%	173	-0.6%
Eloxatin <sup>®</sup>	32	4	0.0%	1	-	27	-15.6%	147	+13.4%	179	+8.2%
Mozobil <sup>®</sup>	154	44	+4.8%	96	+3.2%	14	+87.5%	9	+28.6%	163	+9.2%
Zaltrap <sup>®</sup>	67	51	+8.5%	9	-35.7%	7	-	8	+125.0%	75	+16.9%
Other	236	51	+1.9%	162	+3.8%	23	-16.7%	16	+13.3%	252	+2.0%
<b>Total Oncology</b>	<b>1,110</b>	<b>340</b>	<b>+5.2%</b>	<b>589</b>	<b>+2.9%</b>	<b>181</b>	<b>+5.8%</b>	<b>409</b>	<b>+13.2%</b>	<b>1,519</b>	<b>+6.4%</b>
Dupixent <sup>®</sup>	219	2	-	216	-	1	-	-	-	219	-
Kevzara <sup>®</sup>	11	1	-	10	-	-	-	-	-	11	-
<b>Total Immunology</b>	<b>230</b>	<b>3</b>	<b>-</b>	<b>226</b>	<b>-</b>	<b>1</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>230</b>	<b>-</b>
<b>Sanofi Genzyme (Specialty Care)</b>	<b>5,674</b>	<b>1,865</b>	<b>+10.2%</b>	<b>3,203</b>	<b>+19.8%</b>	<b>606</b>	<b>+7.7%</b>	<b>1,004</b>	<b>+11.3%</b>	<b>6,678</b>	<b>+14.5%</b>

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Lantus®	3,617	760	-12.8%	2,542	-26.6%	315	-10.7%	1,005	+9.2%	4,622	-17.5%
Toujeo®	737	217	+80.8%	455	-2.1%	65	+88.6%	79	+300.0%	816	+27.0%
Apidra®	280	136	+7.1%	102	-10.4%	42	0.0%	97	+25.9%	377	+4.9%
Amaryl®	59	21	-22.2%	2	-33.3%	36	-10.0%	278	+2.1%	337	-1.4%
Insuman®	78	76	-7.3%	2	-33.3%	-	-	29	-29.5%	107	-15.5%
Lyxumia®	24	16	-23.8%	-	-	8	0.0%	2	-33.3%	26	-18.2%
Soliqua™	26	-	-	26	-	-	-	-	-	26	-
Other	80	61	-4.7%	-1	-133.3%	20	+23.5%	4	+33.3%	84	-2.3%
<b>Total Diabetes</b>	<b>4,901</b>	<b>1,287</b>	<b>-2.0%</b>	<b>3,128</b>	<b>-22.8%</b>	<b>486</b>	<b>-1.4%</b>	<b>1,494</b>	<b>+11.4%</b>	<b>6,395</b>	<b>-11.1%</b>
Multaq®	332	42	-2.3%	286	-2.7%	4	-25.0%	7	+16.7%	339	-2.5%
Praluent®	167	46	+155.6%	116	+40.0%	5	+500.0%	4	+300.0%	171	+66.7%
<b>Total Cardiovascular</b>	<b>499</b>	<b>88</b>	<b>+43.5%</b>	<b>402</b>	<b>+6.8%</b>	<b>9</b>	<b>+80.0%</b>	<b>11</b>	<b>+57.1%</b>	<b>510</b>	<b>+13.3%</b>
<b>Total Diabetes &amp; Cardiovascular</b>	<b>5,400</b>	<b>1,375</b>	<b>+0.1%</b>	<b>3,530</b>	<b>-20.2%</b>	<b>495</b>	<b>-0.6%</b>	<b>1,505</b>	<b>+11.6%</b>	<b>6,905</b>	<b>-9.6%</b>



**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

( million)	Total GBU	Europe <sup>(a)</sup>	Change at CER	United States	Change at CER	Rest of the world <sup>(b)</sup>		Emerging Markets <sup>(c)</sup>	Change at CER	Total Franchise	Change at CER
						Change at CER	Change at CER				
Lovenox <sup>®</sup>	1,575	951	-7.1%	58	+9.3%	91	-2.2%	475	+7.8%	1,575	-2.1%
Plavix <sup>®</sup>	1,471	150	-7.4%	1	0.0%	294	-26.0%	1,026	+10.4%	1,471	-1.2%
Renagel <sup>®</sup> /Renvela <sup>®</sup>	802	71	-13.4%	645	-14.8%	36	+6.1%	50	+20.9%	802	-12.3%
Aprovel <sup>®</sup> /CoAprovel <sup>®</sup>	691	115	-9.4%	11	-20.0%	132	+3.1%	433	+8.7%	691	+3.7%
Depakine <sup>®</sup>	443	161	+1.2%	-	-	15	0.0%	267	+15.8%	443	+9.6%
Synvisc <sup>®</sup> / Synvisc-One <sup>®</sup>	387	30	-9.1%	292	-5.1%	14	0.0%	51	+6.3%	387	-3.9%
Allegra <sup>®</sup>	158	9	0.0%	-	-	149	-13.6%	-	-	158	-12.9%
Stilnox <sup>®</sup> /Ambien <sup>®</sup> /Myslee <sup>®</sup>	259	40	-9.1%	55	-33.3%	106	-8.3%	58	+1.8%	259	-13.5%
Tritace <sup>®</sup>	241	152	-1.3%	-	-	5	+25.0%	84	+4.6%	241	+1.2%
Targocid <sup>®</sup>	130	59	-18.9%	-	-	6	-14.3%	65	0.0%	130	-10.1%
Lasix <sup>®</sup>	137	72	-4.0%	-	-	11	-36.8%	54	+5.6%	137	-4.7%
Other	3,467	1,663	-1.7%	207	-19.7%	360	-5.5%	1,237	-3.8%	3,467	-4.1%
<b>Total Established Prescription Products</b>	<b>9,761</b>	<b>3,473</b>	<b>-4.4%</b>	<b>1,269</b>	<b>-13.8%</b>	<b>1,219</b>	<b>-11.7%</b>	<b>3,800</b>	<b>+4.8%</b>	<b>9,761</b>	<b>-3.4%</b>
<b>Generics</b>	<b>1,778</b>	<b>760</b>	<b>-4.9%</b>	<b>150</b>	<b>-12.0%</b>	<b>110</b>	<b>+23.9%</b>	<b>758</b>	<b>-2.9%</b>	<b>1,778</b>	<b>-3.3%</b>
<b>Total Emerging Markets Specialty Care</b>	<b>1,004</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>1,004</b>	<b>+11.3%</b>	<b>-</b>	<b>-</b>
<b>Total Emerging Markets Diabetes &amp; Cardiovascular</b>	<b>1,505</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>1,505</b>	<b>+11.6%</b>	<b>-</b>	<b>-</b>
<b>General Medicines &amp; Emerging Markets</b>	<b>14,048</b>	<b>4,233</b>	<b>-4.5%</b>	<b>1,419</b>	<b>-13.6%</b>	<b>1,329</b>	<b>-9.5%</b>	<b>7,067</b>	<b>+6.2%</b>	<b>14,048</b>	<b>+6.2%</b>
<b>Total Pharmaceuticals</b>	<b>25,122</b>	<b>7,473</b>	<b>-0.3%</b>	<b>8,152</b>	<b>-6.7%</b>	<b>2,430</b>	<b>-4.0%</b>	<b>7,067</b>	<b>+6.2%</b>	<b>25,122</b>	<b>-1.2%</b>

*(a) Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).*

*(b) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.*

*(c) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.*

Table of Contents

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

*5/ Net Sales Consumer Healthcare Segment*

During 2017, we gradually integrated the Consumer Healthcare operations of BI into our Consumer Healthcare GBU. Following completion of the integration process and with effect from December 31, 2017, we have identified our Consumer Healthcare business as an operating segment. Consequently, the net sales of our Consumer Healthcare business are presented separately below, for 2017 and comparative periods.

Net sales of **Consumer Healthcare** products reached 4,832 million in 2017, up 45.1% on a reported basis and 46.3% at constant exchange rates, reflecting the acquisition of BI's Consumer Healthcare business. On a constant structure basis and at constant exchange rates, Consumer Healthcare net sales rose by 2.1%, driven by growth in Emerging Markets and Europe.

( million)	2017	2016	Change on a reported basis	Change at constant exchange rates
Allegra®	423	417	+1.4%	+2.4%
Mucosolvan®	125			
Other	678	374	+81.3%	+84.0%
<b>Allergy, Cough and Cold</b>	<b>1,226</b>	<b>791</b>	<b>+55.0%</b>	<b>+56.6%</b>
Doliprane®	323	309	+4.5%	+5.5%
Buscopan®	191			
Other	744	563	+32.1%	+32.5%
<b>Pain Relief</b>	<b>1,258</b>	<b>872</b>	<b>+44.3%</b>	<b>+45.9%</b>
Dulcolax®	211			
Enterogermina®	168	159	+5.7%	+6.9%
Essentiale®	150	145	+3.4%	+0.7%
Zantac®	117			
Other	284	217	+30.9%	+31.8%
<b>Digestive Health</b>	<b>930</b>	<b>521</b>	<b>+78.5%</b>	<b>+79.5%</b>
Pharmaton®	100			

Other	552	450	+22.7%	+22.2%
<b>Food Supplements</b>	<b>652</b>	<b>450</b>	<b>+44.9%</b>	<b>+44.9%</b>
Gold Bond®	201	195	+3.1%	+5.6%
Other	565	501	+12.8%	+13.4%
<b>Other products</b>	<b>766</b>	<b>696</b>	<b>+10.1%</b>	<b>+11.2%</b>
<b>Total Consumer Healthcare</b>	<b>4,832</b>	<b>3,330</b>	<b>+45.1%</b>	<b>+46.3%</b>

In Emerging Markets, Consumer Healthcare net sales rose by 31.3% CER in 2017 to 1,616 million. On a constant structure basis and at constant exchange rates (CER/CS), net sales rose by 3.0%, driven by growth for Pain Relief (+43.9% CER and +5.5% CER/CS, at 454 million), Allergy, Cough and Cold (+33.1 CER and +5.0% CER/CS, at 349 million) and Digestive Health (+22.1% CER and +3.3% CER/CS, at 377 million), though the effect was mitigated by lower sales in Food Supplements (+36.5% CER but -3.6% CER/CS, at 273 million).

In Europe, net sales rose by 62.0% CER to 1,422 million. On a constant structure basis and at constant exchange rates, net sales were up 2.0%, propelled by growth in Pain Relief (+34.8% CER

and +4.3% CER/CS, at 515 million) and in particular higher sales of Dolipran® in France.

In the United States, net sales advanced by 22.5% CER to 1,133 million. On a constant structure basis and at constant exchange rates, net sales rose by 1.3%, driven by strong growth in Allergy, Cough and Cold (+10.8% CER and CER/CS, at 367 million), largely as a result of the launch of Xyzal® Allergy 24HR (net sales 65 million) which was authorized for OTC sale in February 2017. However the effect was offset by lower net sales in Digestive Health (-13.1% CER/CS, at 188 million), especially sales of Zantac®.

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

In the Rest of the World region, Consumer Healthcare net sales for 2017 reached 661 million, up 145.1% CER. On a constant structure basis and at constant exchange rates, net sales rose by 1.5%, driven by Pain Relief (+9.4% CER/CS, at 122 million) and Digestive Health (+13.5% CER/CS, at 58 million). The effect was partly offset by lower sales in Allergy, Cough and Cold (-12.5% CER/CS, at 158 million).

The following table breaks down 2017 net sales of our Consumer Healthcare segment by geographical region:

( million)	Total	Europe <sup>(a)</sup>	Change at CER	United States	Change at CER	Rest of the world <sup>(b)</sup>	Change at CER	Emerging Markets <sup>(c)</sup>	Change at CER
Allegra <sup>®</sup>	423	12	+33.3%	233	-3.3%	47	+17.5%	131	+6.4%
Mucosolvan <sup>®</sup>	125	58	-	-	-	15	-	52	-
Other	678	282	+145.2%	134	+49.4%	96	+284.6%	166	+20.1%
<b>Allergy, Cough and Cold</b>	<b>1,226</b>	<b>352</b>	<b>+183.9%</b>	<b>367</b>	<b>+10.8%</b>	<b>158</b>	<b>+143.9%</b>	<b>349</b>	<b>+33.1%</b>
Doliprane <sup>®</sup>	323	277	+6.5%	-	-	-	-	46	-
Buscopan <sup>®</sup>	191	76	-	-	-	17	-	98	-
Other	744	162	+32.0%	167	+8.3%	105	+692.9%	310	+12.6%
<b>Pain Relief</b>	<b>1,258</b>	<b>515</b>	<b>+34.8%</b>	<b>167</b>	<b>+8.3%</b>	<b>122</b>	<b>+814.3%</b>	<b>454</b>	<b>+43.9%</b>
Dulcolax <sup>®</sup>	211	93	-	61	-	22	-	35	-
Enterogermina <sup>®</sup>	168	64	-3.0%	-	-	-	-	104	+14.0%
Essentiale <sup>®</sup>	150	34	+17.2%	-	-	1	-	115	-3.4%
Zantac <sup>®</sup>	117	-	-	105	-	12	-	-	-
Other	284	116	+34.9%	22	-12.0%	23	+271.4%	123	+23.2%
<b>Digestive Health</b>	<b>930</b>	<b>307</b>	<b>+70.2%</b>	<b>188</b>	<b>+668.0%</b>	<b>58</b>	<b>+742.9%</b>	<b>377</b>	<b>+22.1%</b>
Pharmaton <sup>®</sup>	100	20	-	-	-	-	-	80	-

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Other	552	102	+7.4%	2	-50.0%	255	+67.7%	193	-5.1%
<b>Food Supplements</b>	<b>652</b>	<b>122</b>	<b>+28.7%</b>	<b>2</b>	<b>-50.0%</b>	<b>255</b>	<b>+67.7%</b>	<b>273</b>	<b>+36.5%</b>
Gold Bond®	201	-	-	198	+5.8%	3	-	-	-
Other	565	126	+30.6%	211	-6.1%	65	+113.8%	163	+12.4%
<b>Other products</b>	<b>766</b>	<b>126</b>	<b>+30.6%</b>	<b>409</b>	<b>-0.7%</b>	<b>68</b>	<b>+100.0%</b>	<b>163</b>	<b>+12.4%</b>
<b>Total Consumer Healthcare</b>	<b>4,832</b>	<b>1,422</b>	<b>+62.0%</b>	<b>1,133</b>	<b>+22.5%</b>	<b>661</b>	<b>+145.1%</b>	<b>1,616</b>	<b>+31.3%</b>

(a) Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).

(b) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

(c) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

#### 6/ Net Sales *Human Vaccines (Vaccines) Segment*

In 2017, net sales for our Vaccines segment were 5,101 million, up 11.4% on a reported basis and 14.5% CER, as a result of the dissolution of the SPMSD joint venture in Europe. On a constant structure basis and at constant exchange rates, Vaccines net sales rose by 8.3%, driven mainly by the performance of the Polio/

Pertussis/Hib franchise across all geographies. In the United States, Vaccines net sales increased by 5.6% CER to 2,570 million. Net sales for the Vaccines segment in Emerging Markets were up 7.8% CER at 1,575 million. In Europe, Vaccines net sales reached 630 million (+137.3% CER and +20.7% CER/CS).

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The table below sets forth 2017 and 2016 net sales for our Vaccines segment by product range:

( million)	2017	2016	Change on a reported basis	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines (including Hexaxim <sup>®</sup> /Hexyon <sup>®</sup> , Pentacel <sup>®</sup> , Pentaxim <sup>®</sup> and Imovax <sup>®</sup> )	1,827	1,495	+22.2%	+24.3%
Influenza vaccines (including Vaxigrip <sup>®</sup> , Fluzone HD <sup>®</sup> and Fluzone <sup>®</sup> )	1,589	1,521	+4.5%	+9.5%
Meningitis/Pneumonia Vaccines (including Menactra <sup>®</sup> )	623	633	-1.6%	+0.2%
Travel and Other Endemics Vaccines	493	368	+34.0%	+35.9%
Adult Booster Vaccines (including Adacel <sup>®</sup> )	474	417	+13.7%	+16.5%
Dengvaxia <sup>®</sup>	3	55	-94.5%	-98.2%
Other Vaccines	92	88	+4.5%	+9.1%
<b>Total Vaccines</b>	<b>5,101</b>	<b>4,577</b>	<b>+11.4%</b>	<b>+14.5%</b>

In 2017, **Polio/Pertussis/Hib vaccines** posted net sales of 1,827 million (+24.3% CER). On a constant structure basis and at constant exchange rates, net sales for the franchise rose by 15.3%. In Emerging Markets, sales for this franchise reached 940 million (+14.5% CER), driven by strong growth in Asia (+44.1% CER, at 360 million) on higher sales of Pentaxim<sup>®</sup> in China, although we expect more limited shipments there in the first half of 2018. Net sales of Polio/Pertussis/Hib vaccines also advanced in the United States (+10.1% CER, at 435 million) and in Europe (+37.3% CER/CS, at 300 million), reflecting good performances by Pentacel<sup>®</sup> and Hexaxim<sup>®</sup>, respectively.

Net sales of **Influenza vaccines** rose by 9.5% CER, to 1,589 million. This performance reflected higher sales for the franchise in the United States (+7.3% CER, at 1,128 million), largely as a result of sales to the Biomedical Advanced Research and Development Authority (BARDA) of the US Department of Health and Human Services. Sales of influenza vaccines also rose in Emerging Markets (+7.4% CER, at 297 million) largely on sales growth in Brazil, and in Europe (+12.9% CER/CS, at 113 million) due in particular to the success of VaxigripTetra<sup>®</sup>.

Net sales of **Meningitis/Pneumonia vaccines** were stable year-on-year at 623 million. **Menactra**® posted net sales of 600 million (+4.6% CER), of which 484 million was generated in the United States.

Net sales of **Travel and Other endemics vaccines** increased by 35.9% CER in 2017, to 493 million. On a constant structure basis and at constant exchange rates, net sales rose by 19.0%, reflecting increased supply of rabies and hepatitis A vaccines.

Net sales of **Adult Booster vaccines** in 2017 were 474 million, up 16.5% CER. On a constant structure basis and at constant exchange rates, net sales were virtually unchanged year-on-year (-0.2%). Increased sales in Europe (+6.2% CER/CS, at 119 million) and the Rest of the World region (+12.5% CER, at 26 million) offset lower sales in Emerging Markets (-22.9% CER, at 37 million).

**Dengvaxia**® posted net sales of 3 million in 2017, reflecting repurchases of inventory following discontinuation of the public vaccination program initiated in the Philippines in early 2016. On November 29, 2017 Sanofi announced results of a new analysis of long-term Dengvaxia® data which found differences in vaccine performance depending on whether or not the vaccinated individual had previously been infected with the dengue virus.



**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following table presents the 2017 net sales of our Vaccines segment by geographical region:

( million)					Rest of					
	Total	Europe <sup>(a)</sup>	Change at CER	United States	Change at CER	the world <sup>(b)</sup>	Change at CER	Emerging Markets <sup>(c)</sup>	Change at CER	
Polio/Pertussis/Hib Vaccines (including Hexaxim <sup>®</sup> /Hexyon <sup>®</sup> , Pentacel <sup>®</sup> , Pentaxim <sup>®</sup> and Imovax <sup>®</sup> )	1,827	300	+187.6%	435	+10.1%	152	+2.6%	940	+14.5%	
Influenza Vaccines (including Vaxigrip <sup>®</sup> , Fluzone HD <sup>®</sup> and Fluzone <sup>®</sup> )	1,589	113	+37.3%	1,128	+7.3%	51	+28.2%	297	+7.4%	
Meningitis/Pneumonia Vaccines (including Menactra <sup>®</sup> )	623	1	-80.0%	485	-4.1%	34	+106.3%	103	+9.6%	
Travel and Other Endemics Vaccines	493	90	+253.8%	155	+26.2%	54	+6.0%	194	+18.1%	
Adult Booster Vaccines (including Adacel <sup>®</sup> )	474	119	+172.7%	292	-	-26	+17.4%	37	-22.9%	
Dengvaxia <sup>®</sup>	3	-	-	-	-	-	-	3	-98.2%	
Other Vaccines	92	7	+40.0%	75	+8.3%	9	-	1	-	
<b>Total Vaccines</b>	<b>5,101</b>	<b>630</b>	<b>+137.3%</b>	<b>2,570</b>	<b>+5.6%</b>	<b>326</b>	<b>+13.4%</b>	<b>1,575</b>	<b>+7.8%</b>	

(a) Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).

(b) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

(c) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

**7/ Net Sales by Geographical Region**

The following table presents our net sales by geographical region for the years ended December 31, 2017 and 2016:

( million)	2017	2016	Change on a reported basis	Change at constant exchange rates
<b>United States</b>	11,855	12,391	-4.3%	-2.0%
<b>Emerging Markets<sup>(a)</sup></b>	10,258	9,593	+6.9%	+9.7%
<i>of which Asia (including South Asia<sup>(b)</sup>)</i>	3,732	3,468	+7.6%	+10.3%
<i>of which Latin America</i>	2,837	2,503	+13.3%	+12.8%
<i>of which Africa and Middle East</i>	2,326	2,405	-3.3%	+2.5%
<i>of which Eurasia<sup>(c)</sup></i>	1,242	1,090	+13.9%	+18.3%
<b>Europe<sup>(d)</sup></b>	9,525	8,679	+9.7%	+10.2%
<b>Rest of the world<sup>(e)</sup></b>	3,417	3,158	+8.2%	+10.6%
<i>of which Japan</i>	1,803	1,688	+6.8%	+11.6%
<i>of which South Korea</i>	426	360	+18.3%	+17.8%
<b>Total net sales</b>	<b>35,055</b>	<b>33,821</b>	<b>+3.6%</b>	<b>+5.6%</b>

(a) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(b) India, Bangladesh and Sri Lanka. In 2016, South Asia was included in the Africa, Middle East and South Asia region. The presentation of 2016 net sales has been amended accordingly in the interests of comparability.

(c) Russia, Ukraine, Georgia, Belarus, Armenia and Turkey.

(d) Western Europe and Eastern Europe (excluding Eurasia).

(e) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.



**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Sales in the **United States** totaled 11,855 million in 2017, down 4.3% on a reported basis and 3.5% on a constant structure basis and at constant exchange rates. The main factor was lower sales for two franchises: Diabetes (-22.8% CER at 3,128 million), and Established Prescription Products (-13.8% CER, at 1,269 million) due to competition from generics of Renvela<sup>®</sup>/Renagel<sup>®</sup>. The impact was partly offset by the performance of the Multiple Sclerosis franchise (+19.0% CER, at 1,330 million), the launch of Dupixent<sup>®</sup>, and growth in Vaccines sales (+5.6% CER at 2,570 million).

In **Emerging Markets**, net sales reached 10,258 million, up 6.9% on a reported basis and up 9.7% CER. On a constant structure basis and at constant exchange rates net sales rose by 6.0%, driven by sales growth for Established Prescription Products (+4.8% CER, at 3,800 million) and the Diabetes franchise (+11.4% CER, at 1,494 million), and a good performance from Vaccines (+7.8% CER, at 1,575 million). In **Asia**, net sales were 3,732 million, up 10.3% CER (+8.7% CER/CS), reflecting a solid performance in China (+15.1% CER/CS, at 2,218 million) on a recovery in Vaccines sales and growth for Established Prescription Products and the Diabetes franchise. In **Latin America**, net sales advanced by 12.8% CER (+5.9% CER/CS) to 2,837 million, boosted by good performances in Brazil (+5.7% CER/CS) and Argentina (+21.0% CER/CS, at 311 million). Net sales in Brazil reached 1,133 million, driven by Established Prescription Products and Consumer Healthcare. In the **Africa and Middle East** region, net sales totaled 2,326 million, up 2.5% CER but down 0.5% on a constant structure basis and at constant exchange rates. Solid performances in Egypt (+28.3% CER/CS) and Algeria (+6.8% CER/CS) were offset by lower sales in Morocco (-27.0% CER/CS) following the divestment of the Maphar site, in Saudi Arabia (-7.5% CER/CS), and in South Africa (-7.1% CER/CS). In the **Eurasia** region net sales reached 1,242 million, up 18.3% CER (+12.6% CER/CS) reflecting strong sales growth in Turkey (+18.1% CER/CS) and in Russia (+8.2% CER/CS). Net sales in Russia were 642 million, driven by Consumer Healthcare and by the Diabetes and Rare Diseases franchises.

In **Europe**, net sales were 9,525 million, up 10.2% CER and stable on a constant structure basis and at constant exchange rates. Lower sales of Established Prescription Products (-5.6% CER/CS, at 3,473 million) were offset by growth in sales of Vaccines (+20.7% CER/CS, at 630 million) and the Multiple Sclerosis franchise (+23.5% CER/CS, at 561 million). Net sales in France amounted to 2,330 million, down 2.3% CER/CS, as lower sales of Established Prescription Products and Generics were only partially offset by sales growth for Vaccines, Consumer Healthcare and the Multiple Sclerosis franchise.

In the **Rest of the World** region, net sales rose by 10.6% CER to 3,417 million. However, on a constant structure basis and at

constant exchange rates net sales for the region fell by 1.5%. This reflects a drop in sales for Established Prescription Products (-11.8% CER/CS, at 1,219 million) and the Diabetes franchise (-1.4% CER/CS, at 486 million), partly offset by stronger sales for Vaccines, the Specialty Care franchise, Generics and Consumer Healthcare. In Japan, net sales were up 11.6% CER at 1,803 million. On a constant structure basis, Japanese net sales fell by 7.3% due to the impact of generic competition for Plavix<sup>®</sup> and lower sales of Lantus<sup>®</sup>.

**A.2.2. Other income statement items*****1/ Other revenues***

Other revenues mainly comprise royalties under licensing agreements, and VaxServe sales of non-Sanofi products. Other revenues rose by 29.5% to 1,149 million in 2017, compared with 887 million in 2016. This was mainly due to higher sales at VaxServe ( 859 million, versus 581 million in 2016).

***2/ Gross profit***

Gross profit reached 24,593 million in 2017, versus 24,006 million in 2016, a rise of 2.4%. The gross margin ratio (gross profit as a percentage of net sales) was 70.2% in 2017 compared with 71.0% in 2016. The decrease includes the impact of the fair value remeasurement of inventories acquired in the exchange transaction with BI ( 166 million in 2017).

The gross margin ratio for the Pharmaceuticals segment<sup>(1)</sup> decreased by 0.2 of a percentage point to 72.2%, mainly reflecting the negative effect of lower US sales for the Diabetes franchise, though the effect was partly offset by Emerging Markets (especially China), and the Multiple Sclerosis and Immunology franchises.

The gross margin ratio for the Vaccines segment<sup>(2)</sup> was 0.2 of a percentage point lower at 61.7%.

***3/ Research and development expenses***

Research and development (R&D) expenses amounted to 5,472 million in 2017 (versus 5,172 million in 2016) and represented 15.6% of net sales (versus 15.3% in 2016). The overall year-on-year increase of 300 million (+5.8%) included 217 million for the Pharmaceuticals segment<sup>(1)</sup> (+4.7%) and 83 million for the Vaccines segment<sup>(2)</sup> (+15.0%).

The year-on-year increase in R&D expenses was due partly to the integration of BI Consumer Healthcare products and of Sanofi products that were previously in the SPMSD portfolio, and partly to progress on development projects in immuno-oncology (isatixumab, PD-1) and for sotagliflozin.

*(1) Includes the Consumer Healthcare business and an allocation of global support function costs. For more information see A.2.3. Segment Results below.*

*(2) Includes an allocation of global support function costs. For more information see A.2.3. Segment Results below.*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

***4/ Selling and general expenses***

Selling and general expenses totaled 10,058 million (28.7% of net sales), compared with 9,486 million in 2016 (28.0% of net sales). This represents a year-on-year rise of 572 million (+6.0%).

Selling and general expenses for the Pharmaceuticals<sup>(1)</sup> and Vaccines<sup>(2)</sup> segments rose by 433 million (+5.0%) and 138 million (+18.6%), respectively. This increase mainly reflected the launch costs of Dupixent®, Kevzara® and Xyzal®, plus investment in marketing and sales efforts in key emerging markets and in the European vaccines business.

***5/ Other operating income and expenses***

Overall, this represented net income of 4 million in 2017, compared with a net expense of 127 million in 2016.

( million)	<b>2017</b>	<b>2016</b>	<b>Change 2017/2016</b>
Other operating income	237	355	(118)
Other operating expenses	233	482	(249)
<b>Other operating income/(expenses), net</b>	<b>4</b>	<b>(127)</b>	<b>131</b>

The overall year-on-year improvement of 131 million reflected (i) a reduction in operating foreign exchange losses from 146 million (including 102 million on our Venezuelan operations) in 2016 to 80 million in 2017; and (ii) a decrease in income from our pharmaceutical alliance partners from 191 million in 2016 to 7 million in 2017, mainly relating to Regeneron following the launch of Dupixent® and Kevzara®. This was partly offset by (i) gains on disposals relating to ongoing operations (90 million in 2017, compared with 40 million in 2016) and (ii) impairment losses of 87 million taken against property, plant and equipment associated with the dengue vaccine (see Notes D.25. and D.26. to our consolidated financial statements).

***6/ Amortization of intangible assets***

Amortization charged against intangible assets amounted to 1,866 million in 2017, versus 1,692 million in 2016.

The 174 million year-on-year increase was mainly due to a 245 million rise in amortization expense following the recognition of intangible assets in connection with the exchange transaction with BI finalized on January 1, 2017. The effect was partly offset by a reduction in amortization charged against intangible assets recognized on the acquisition of Aventis (365 million in 2017, versus 482 million in 2016) as some products reached the end of their life cycles.

#### ***7/ Impairment of intangible assets***

In 2017, this line item showed impairment losses of 293 million against intangible assets, compared with 192 million in 2016.

In 2017, this line item included (i) a 190 million impairment loss taken against intangible assets associated with the dengue vaccine; (ii) a 54 million impairment loss relating to *Clostridium difficile* vaccine development projects following our decision to discontinue the related programs; and (iii) impairment losses of 23 million taken against rights relating to a number of marketed products in the Pharmaceuticals segment.

In 2016, this line item included (i) a net impairment loss of 58 million on various R&D projects in the Pharmaceuticals and Vaccines segments; and (ii) impairment losses of 134 million taken against rights relating to a number of marketed products in the Pharmaceuticals segment.

#### ***8/ Fair value remeasurement of contingent consideration***

Fair value remeasurements of contingent consideration liabilities recognized on acquisitions in accordance with the revised IFRS 3 represented a net expense of 159 million in 2017, versus a net expense of 135 million in 2016.

The 2017 remeasurements relate to contingent consideration arising from the dissolution of the SPMSD joint venture (expense of 187 million), and to contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi (gain of 28 million in 2018, versus expense of 78 million in 2016). See Note D.18. to our consolidated financial statements.

#### ***9/ Restructuring costs and similar items***

Restructuring costs and similar items amounted to 731 million in 2017, compared with 879 million in 2016.

In 2017, restructuring costs mainly comprised employee-related expenses arising from headcount adjustment plans in the United States and Europe, and write-downs of industrial assets in France and the United States.

#### ***10/ Other gains and losses, and litigation***

In 2017, the line item ***Other gains and losses, and litigation*** shows an expense of 215 million, due mainly to a provision for a vendor's liability guarantee relating to a past divestment.

At the end of December 2016, Sanofi Pasteur and MSD ended their SPMSD joint venture. The derecognition of Sanofi's investment in SPMSD generated a pre-tax gain on disposal of 211 million in 2016.

- (1) Includes the Consumer Healthcare business and an allocation of global support function costs. For more information see A.2.3 Segment Results below.*
- (2) Includes an allocation of global support function costs. For more information see A.2.3 Segment Results below.*



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**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

***11/ Operating income***

Operating income totaled 5,803 million for 2017, compared with 6,534 million for 2016. The year-on-year decrease of 11.2% was attributable mainly to increases in cost of sales, R&D expenses, selling and general expenses, and amortization and impairment of intangible assets.

***12/ Financial income and expenses***

Net financial expenses for 2017 were 273 million, compared with 856 million for 2016, a decrease of 583 million. This decrease mainly reflected the impairment loss of 457 million taken against our equity investment in Alnylam in 2016, in line with a decline in its market value of as of the reporting date relative to historical cost. Most of that decline occurred when Alnylam decided to discontinue the revusiran development program on October 5, 2016.

Net financial expenses directly related to our debt, net of cash and cash equivalents (see the definition in section 4. Consolidated Balance sheet below) amounted to 221 million in 2017, compared with 218 million in 2016, reflecting an increase in the cost of debt.

The net interest cost relating to employee benefits amounted to 92 million in 2017, compared with 114 million in 2016.

***13/ Income before tax and investments accounted for using the equity method***

Income before tax and investments accounted for using the equity method totaled 5,530 million in 2017, compared with 5,678 million in 2016, a fall of 2.6%.

***14/ Income tax expense***

Income tax expense represented 1,722 million in 2017, versus 1,326 million in 2016, giving an effective tax rate (based on consolidated net income) of 31.1% in 2017, compared with 23.4% in 2016. The increase in the effective tax rate was mainly due to the direct and indirect effects of the US tax reform (the Tax Cuts and Jobs Act of 2017, which came into force on January 1, 2018). The effect was partially offset by the consequences of the French Constitutional Council ruling of October 6, 2017 with respect to the additional 3% levy on dividends paid out in cash. The net effect of those two items was to increase the effective tax rate by 8% (see Note D.30. to our consolidated financial statements).

The effects of the US tax reform are based on a preliminary analysis of the Tax Cuts and Jobs Act of 2017. The final impact may differ and will be adjusted in 2018 to reflect the completion of our analysis and final calculations, and/or further clarifications or guidance issued by the US Congress, the US Internal Revenue Service, the US Securities and

Exchange Commission or other regulators.

Changes in the level of income tax expense are also significantly impacted by the tax effects of the amortization and impairment of intangible assets ( 719 million in 2017, versus 694 million in 2016) and of restructuring costs ( 134 million in 2017, versus 95 million in 2016).

The effective tax rate on our business net income<sup>(1)</sup> is a non-GAAP financial measure. It is calculated on the basis of business operating income, minus net financial expenses and before (i) the share of profit/loss from investments accounted for using the equity method and (ii) net income attributable to non-controlling interests. We believe the presentation of this measure, used by our management, is also useful for investors as it provides a means to analyze the effective tax cost of our current business activities. It should not be seen as a substitute for the effective tax rate based on consolidated net income.

When calculated on business net income<sup>(1)</sup>, our effective tax rate was 23.5% in 2017, compared with 23.3% in 2016. The main impacts on this tax rate are the geographical mix of the profits of Sanofi entities; the tax effects of the elimination of intragroup margin on inventory; favorable settlements of recent proceedings involving the tax authorities in various countries; and changes in tax rates, particularly in France, the Netherlands and Belgium.

The table below reconciles our effective tax rate based on consolidated net income to our effective tax rate based on business net income:

<i>(as a percentage)</i>	<b>2017</b>	<b>2016 (a)</b>
<b>Effective tax rate based on consolidated net income</b>	<b>31.1</b>	<b>23.4</b>
Tax effects:		
Amortization and impairment of intangible assets	3.2	3.7
Restructuring costs and similar items	(0.2)	(1.3)
Impairment loss charged against the investment in Alnylam		(1.5)
Other tax effects <sup>(b)</sup>	(10.6)	(1.0)
<b>Effective tax rate based on business net income</b>	<b>23.5</b>	<b>23.3</b>

*(a) The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); see Notes D.1. and D.36. to our consolidated financial statements.*

*(b) For 2017, this line comprises (i) the direct and indirect effects of the US tax reform (negative impact of 1,193 million) and (ii) the consequences of the French Constitutional Council ruling of October 6, 2017 with respect to the additional 3% levy on dividends paid out in cash (positive impact of 451 million).*

*(1) Non-GAAP financial measure: see definition under A.1.5. Segment information 3/ Business Net Income above.*



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**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

***15/ Share of profit/(loss) from investments accounted for using the equity method***

Investments accounted for using the equity method contributed net income of 104 million in 2017, compared with 134 million in 2016.

This line item mainly comprises our share of the profits and losses of Regeneron, which represented net income of 101 million in 2017 and 126 million in 2016.

***16/ Net income excluding the exchanged/held-for-exchange Animal Health business***

Net income excluding the held-for-exchange Animal Health business amounted to 3,912 million in 2017, versus 4,486 million in 2016.

***17/ Net income/(loss) of the exchanged/held-for-exchange Animal Health business***

In accordance with IFRS 5, the net income or loss of the Animal Health business is presented in a separate line item, ***Net income/(loss) of the held-for-exchange Animal Health business*** (see Notes D.1. and D.36. to our consolidated financial statements). At the start of January 2017, Sanofi and BI confirmed that they had finalized the strategic transaction agreed in June 2016, involving the exchange of Sanofi's Animal Health business (Merial) for BI's Consumer Healthcare business. Consequently, for 2017 this line item shows the net after-tax gain of 4,643 million on the divestment of the Animal Health business.

***18/ Net income***

Net income amounted to 8,555 million in 2017, compared with 4,800 million in 2016.

***19/ Net income attributable to non-controlling interests***

Net income attributable to non-controlling interests was 121 million in 2017, versus 91 million in 2016. This line item mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi (84 million, versus 86 million in 2016). The year-on-year decrease was directly related to competition from generics of clopidogrel (active ingredient of Plavix®) and irbesartan (active ingredient of Aprovel®) in Europe.

**20/ Net income attributable to equity holders of Sanofi**

Net income attributable to equity holders of Sanofi amounted to 8,434 million, versus 4,709 million in 2016.

Basic earnings per share for 2017 was 6.71 (including the net gain on the divestment of the Animal Health business), 83.3% higher than the 2016 figure of 3.66, based on an average number of shares outstanding of 1,256.9 million in 2017 (1,286.6 million in 2016). Diluted earnings per share for 2017 was 6.66, 83.5% higher than the 2016 figure of 3.63, based on an average number of shares outstanding after dilution of 1,266.8 million in 2017 and 1,296.0 million in 2016.

**A.2.3. Segment results**

Business operating income (defined in Note D.35. to our consolidated financial statements) amounted to 9,343 million in 2017 (26.7% of net sales), 0.6% higher than the 2016 figure of 9,285 million (27.5% of net sales).

As indicated in Notes B.26 and D.35. ( Segment Information ) to our consolidated financial statements, Sanofi has three operating segments: Pharmaceuticals, Consumer Healthcare and Human Vaccines (Vaccines).

The table below sets forth our business operating income for the **year ended December 31, 2017**, based on our **new segment reporting model**:

<i>( million)</i>	<b>December 31, 2017</b>	<b>as % of segmental net sales</b>
Pharmaceuticals	9,025	35.9%
Consumer Healthcare	1,543	31.9%
Vaccines	1,804	35.4%
Other	(3,029)	-
<b>Business operating income</b>	<b>9,343</b>	<b>26.7%</b>

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Due to lack of available data and the unduly complex and significant adjustments that would be required (in particular to our reporting tools), the comparative information has not been restated to reflect the changes arising from our new segment reporting model. Consequently, we present segment information for 2017 and comparative periods using our **previous segment reporting model** in the table below:

	December 31,		Change
	2017	2016	
( million)			
Pharmaceuticals <sup>(a)</sup>	7,891	7,824	+0.9%
Vaccines <sup>(b)</sup>	1,521	1,573	-3.3%
Other	(69)	(112)	-38.4%
<b>Business operating income</b>	<b>9,343</b>	<b>9,285</b>	<b>+0.6%</b>

(a) Includes Consumer Healthcare and an allocation of global support function costs.

(b) Includes an allocation of global support function costs.

The table below sets forth our segment results for the **year ended December 31, 2017**, based on our **new segment reporting model**:

	December 31, 2017								
	Pharma- ceuticals	as % of net Consumer sales	Healthcare sales	as % of net sales	Vaccines sales	as % of net sales	Other	Total Sanofi	as % of net sales
( million)									
<b>Net sales</b>	<b>25,122</b>	<b>100.0%</b>	<b>4,832</b>	<b>100.0%</b>	<b>5,101</b>	<b>100.0%</b>	-	<b>35,055</b>	<b>100.0%</b>
Other revenues	287	1.1%	-	-	862	16.9%	-	1,149	3.3%
Cost of sales	(6,728)	(26.8)%	(1,648)	(34.1)%	(2,798)	(54.9)%	(271)	(11,445)	(32.6)%
Research and development expenses	(4,056)	(16.1)%	(123)	(2.5)%	(557)	(10.9)%	(736)	(5,472)	(15.6)%

Selling and general expenses	(5,750)	(22.9)%	(1,605)	(33.2)%	(698)	(13.7)%	(2,005)	(10,058)	(28.7)%
Other operating income and expenses	34		94		(107)		(17)	4	
Share of profit/(loss) from investments accounted for using the equity method	233		1		1			235	
Net income attributable to non-controlling interests	(117)		(8)		-			(125)	
<b>Business operating income</b>	<b>9,025</b>	<b>35.9%</b>	<b>1,543</b>	<b>31.9%</b>	<b>1,804</b>	<b>35.4%</b>	<b>(3,029)</b>	<b>9,343</b>	<b>26.7%</b>

The table below sets forth our segment results for the **year ended December 31, 2017**, based on our **previous segment reporting model**:

( million)	December 31, 2017			Total Sanofi
	Pharmaceuticals <sup>(a)</sup>	Vaccine <sup>(b)</sup>	Other	
<b>Net sales</b>	<b>29,954</b>	<b>5,101</b>	-	<b>35,055</b>
Other revenues	287	862	-	1,149
Cost of sales	(8,628)	(2,817)	-	(11,445)
Research and development expenses	(4,835)	(637)	-	(5,472)
Selling and general expenses	(9,176)	(881)	(1)	(10,058)
Other operating income and expenses	180	(108)	(68)	4
Share of profit/(loss) from investments accounted for using the equity method	234	1	-	235
Net income attributable to non-controlling interests	(125)	-	-	(125)
<b>Business operating income</b>	<b>7,891</b>	<b>1,521</b>	<b>(69)</b>	<b>9,343</b>

(a) Includes Consumer Healthcare and an allocation of global support function costs.

(b) Includes an allocation of global support function costs.

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The table below sets forth our segment results for the year ended December 31, 2016, based on our **previous segment reporting model**:

	<b>December 31, 2016</b>			<b>Total Sanofi</b>
( million)	<b>Pharmaceuticals<sup>(a)</sup></b>	<b>Vaccines<sup>(b)</sup></b>	<b>Other</b>	
<b>Net sales</b>	<b>29,244</b>	<b>4,577</b>	-	<b>33,821</b>
Other revenues	274	613	-	887
Cost of sales	(8,349)	(2,353)	-	(10,702)
Research and development expenses	(4,618)	(554)	-	(5,172)
Selling and general expenses	(8,743)	(743)	-	(9,486)
Other operating income and expenses	(1)	(14)	(112)	(127)
Share of profit/(loss) from investments accounted for using the equity method	129	48	-	177
Net income attributable to non-controlling interests	(112)	(1)	-	(113)
<b>Business operating income</b>	<b>7,824</b>	<b>1,573</b>	<b>(112)</b>	<b>9,285</b>

*(a) Includes Consumer Healthcare and an allocation of global support function costs.*

*(b) Includes an allocation of global support function costs.*

The tables below provide an analysis of business operating income for the Pharmaceuticals and Vaccines segments, based on our **previous segment reporting model**:

**Business operating income: Pharmaceuticals segment <sup>(a)</sup>**



<i>( million)</i>	<b>December 31, 2017</b>	<b>as % of net sales</b>	<b>December 31, 2016</b>	<b>as % of net sales</b>	<b>Change 2017/2016</b>
<b>Net sales</b>	<b>29,954</b>	<b>100.0%</b>	<b>29,244</b>	<b>100.0%</b>	<b>+2.4%</b>
Other revenues	287	1.0%	274	0.9%	+4.7%
Cost of sales	(8,628)	(28.8)%	(8,349)	(28.5)%	+3.3%
<b>Gross profit</b>	<b>21,613</b>	<b>72.2%</b>	<b>21,169</b>	<b>72.4%</b>	<b>+2.1%</b>
Research and development expenses	(4,835)	(16.1)%	(4,618)	(15.8)%	+4.7%
Selling and general expenses	(9,176)	(30.6)%	(8,743)	(29.9)%	+5.0%
Other operating income and expenses	180		(1)		
Share of profit/(loss) from investments accounted for using the equity method	234		129		
Net income attributable to non-controlling interests	(125)		(112)		
<b>Business operating income</b>	<b>7,891</b>	<b>26.3%</b>	<b>7,824</b>	<b>26.8%</b>	<b>+0.9%</b>

*(a) Includes Consumer Healthcare and an allocation of global support function costs.*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**Business operating income: Vaccines segment <sup>(a)</sup>**

( million)	December 31, 2017	as % of net sales	December 31, 2016	as % of net sales	Change 2017/2016
<b>Net sales</b>	<b>5,101</b>	<b>100%</b>	<b>4,577</b>	<b>100.0%</b>	<b>+11.4%</b>
Other revenues	862	16.9%	613	13.3%	+40.6%
Cost of sales	(2,817)	(55.2)%	(2,353)	(51.4)%	+19.7%
<b>Gross profit</b>	<b>3,146</b>	<b>61.7%</b>	<b>2,837</b>	<b>61.9%</b>	<b>+10.9%</b>
Research and development expenses	(637)	(12.5)%	(554)	(12.1)%	+15.0%
Selling and general expenses	(881)	(17.3)%	(743)	(16.2)%	+18.6%
Other operating income and expenses	(108)		(14)		
Share of profit/(loss) from investments accounted for using the equity method	1		48		
Net income attributable to non-controlling interests	-		(1)		
<b>Business operating income</b>	<b>1,521</b>	<b>29.8%</b>	<b>1,573</b>	<b>34.4%</b>	<b>-3.3%</b>

(a) Includes an allocation of global support function costs.

## A.2.4. Business net income

Business net income is a non-GAAP financial measure that we use to evaluate our operational performance. Refer to A.15.3 Business Net Income above for the definition of this measure, and for a reconciliation to **Net income attributable to equity holders of Sanofi**.

Our business net income for 2017 was 6,964 million, 4.7% lower than in 2016 (7,308 million, including 476 million of business net income from Animal Health). Excluding Animal Health, our business

net income was 6,964 million in 2017 (19.9% of net sales) in 2017, compared with 6,832 million (20.2% of net sales) in 2016.

We also report business earnings per share non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding.

Business earnings per share was 5.54 in 2017, 2.5% lower than the 2016 figure of 5.68, based on an average number of shares outstanding of 1,256.9 million in 2017 and 1,286.6 million in 2016.

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**A.3. Results of operations year ended December 31, 2016 compared with year ended December 31, 2015**

The consolidated income statements for the years ended December 31, 2016 and December 31, 2015 are presented below:

<i>( million)</i>	<b>2016<sup>(a)</sup></b>	<b>as % of net sales</b>	<b>2015<sup>(a)(b)</sup></b>	<b>as % of net sales</b>
<b>Net sales</b>	<b>33,821</b>	<b>100.0%</b>	<b>34,060</b>	<b>100.0%</b>
Other revenues	887	2.6%	801	2.4%
Cost of sales	(10,702)	(31.6%)	(10,919)	(32.1%)
<b>Gross profit</b>	<b>24,006</b>	<b>71.0%</b>	<b>23,942</b>	<b>70.3%</b>
Research and development expenses	(5,172)	(15.3%)	(5,082)	(14.9%)
Selling and general expenses	(9,486)	(28.0%)	(9,382)	(27.5%)
Other operating income	355		254	
Other operating expenses	(482)		(462)	
Amortization of intangible assets	(1,692)		(2,137)	
Impairment of intangible assets	(192)		(767)	
Fair value remeasurement of contingent consideration	(135)		53	
Restructuring costs and equivalents	(879)		(795)	
Other gains and losses, and litigation	211		-	
<b>Operating income</b>	<b>6,534</b>	<b>19.3%</b>	<b>5,624</b>	<b>16.5%</b>
Financial expenses	(924)		(559)	
Financial income	68		178	
<b>Income before tax and investments accounted for using the equity method</b>	<b>5,678</b>	<b>16.8%</b>	<b>5,243</b>	<b>15.4%</b>
Income tax expense	(1,326)		(709)	
	134		(22)	

Share of profit/(loss) from investments accounted for using the equity method				
<b>Net income excluding the exchanged/held-for-exchange Animal Health business</b>	<b>4,486</b>	<b>13.3%</b>	<b>4,512</b>	<b>13.2%</b>
Net income/(loss) of the exchanged/held-for-exchange Animal Health business	314		(124)	
<b>Net income</b>	<b>4,800</b>	<b>14.2%</b>	<b>4,388</b>	<b>12.9%</b>
Net income attributable to non-controlling interests	91		101	
<b>Net income attributable to equity holders of Sanofi</b>	<b>4,709</b>	<b>13.9%</b>	<b>4,287</b>	<b>12.6%</b>
Average number of shares outstanding (million)	1,286.6		1,306.2	
Average number of shares outstanding after dilution (million)	1,296.0		1,320.7	
Basic earnings per share (in euros)	3.66		3.28	
Basic earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)	3.42		3.38	
Diluted earnings per share (in euros)	3.63		3.25	
Diluted earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)	3.39		3.34	

(a) *The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.1. and D.36. to our consolidated financial statements.*

(b) *Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in Other revenues from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly; refer to Note B.13. to our consolidated financial statements.*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**A.3.1. Net sales**

Net sales for the year ended December 31, 2016 were 33,821 million, 0.7% lower than in 2015. Exchange rate fluctuations had a negative effect of 1.9 percentage points overall, with adverse trends in the Argentine peso, Chinese yuan renminbi, Mexican peso and pound sterling outweighing the positive effect of the Japanese yen and US dollar. At constant exchange rates (CER), net sales rose by 1.2%.

This performance included the negative effects of a change in the exchange rate applied in translating the results of our Venezuelan

operations into euros. This change reflected reforms to the Venezuelan foreign exchange system in February 2016, and the continued impossibility of converting bolivars to US dollars at the official preferential exchange rate<sup>(1)</sup>. In addition, in the first half of 2015, Sanofi benefited from a significant increase in product demand in Venezuela, due to buying patterns associated with local market conditions. As a result, our net sales in Venezuela amounted to 18 million in 2016, compared with 455 million in 2015. Excluding Venezuela, our net sales increased by 2.6% CER.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2016 and December 31, 2015 to our net sales at constant exchange rates:

( million)	2016 <sup>(a)(b)</sup>	2015 <sup>(a)(b)</sup>	Change
<b>Net sales</b>	<b>33,821</b>	<b>34,060</b>	<b>-0.7%</b>
Effect of exchange rates	(661)		
<b>Net sales at constant exchange rates</b>	<b>34,482</b>	<b>34,060</b>	<b>+1.2%</b>

*(a) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item **Net sales** does not include the net sales of the Animal Health business.*

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

accordingly.

### ***I/ Net Sales by Operating Segment***

Our net sales comprise the net sales generated by our Pharmaceuticals, Consumer Healthcare and Human Vaccines (Vaccines) segments. Following the integration of BI's Consumer Healthcare business, acquired on January 1, 2017, our Consumer Healthcare business represents a separate operating segment of Sanofi in accordance with IFRS 8. Consequently, we present our Consumer Healthcare net sales separately for the year ended December 31, 2017; see section A.2.2. Net sales above. Comparatives for the year ended December 31, 2016 and December 31, 2015 have been restated accordingly (Consumer Healthcare was previously included within the Pharmaceuticals segment).

The following table sets forth our 2016 and 2015 net sales by operating segment:

<i>( million)</i>	<b>2016<sup>(a)</sup></b>	<b>2015<sup>(a)(b)</sup></b>	<b>Change</b>
Pharmaceuticals	25,914	26,307	-1.5%
Consumer Healthcare	3,330	3,492	-4.6%
Vaccines	4,577	4,261	7.4%
<b>Net sales</b>	<b>33,821</b>	<b>34,060</b>	<b>-0.7%</b>

*(a) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item **Net sales** does not include the net sales of the Animal Health business.*

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

*(1) The exchange rate used in 2016 was the DICOM rate of 710 bolivars per US dollar, as opposed to the SICAD administered exchange rate of 13.5 bolivars per US dollar used in 2015.*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**2/ Net Sales by Global Business Unit (GBU)**

The table below presents net sales for our Global Business Units (GBUs) reflecting the new structure intended to streamline our organization, sharpen our focus and concentrate our efforts on growth drivers. Within this new structure, Emerging Markets sales of Diabetes & Cardiovascular and Specialty Care products are included in the General Medicines & Emerging Markets GBU.

<i>Net sales by Global Business Unit (GBU)</i>			<b>Change on</b>	<b>Change at</b>
<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>a reported</b>	<b>constant</b>
			<b>basis</b>	<b>exchange rates</b>
Sanofi Genzyme GBU <sup>(a)</sup> (Specialty Care) <sup>(b)</sup>	5,019	4,275	+17.4%	+17.3%
Diabetes & Cardiovascular GBU <sup>(a)</sup>	6,397	6,517	-1.9%	-2.0%
General Medicines & Emerging Markets GBU <sup>(c)(d)</sup>	14,498	15,515	-6.6%	-3.3%
<b>Total Pharmaceuticals<sup>(e)</sup></b>	<b>25,914</b>	<b>26,307</b>	<b>-1.5%</b>	<b>+0.4%</b>
Consumer Healthcare GBU <sup>(e)</sup>	3,330	3,492	-4.6%	-1.6%
Sanofi Pasteur (Vaccines) GBU <sup>(f)</sup>	4,577	4,261	+7.4%	+8.8%
<b>Total</b>	<b>33,821</b>	<b>34,060</b>	<b>-0.7%</b>	<b>+1.2%</b>

*(a) This line excludes Emerging Markets net sales.*

*(b) Rare Diseases, Multiple Sclerosis, Oncology and Immunology.*

*(c) Includes net sales in Emerging Markets of Specialty Care and Diabetes & Cardiovascular products.*



- (d) *Emerging Markets: World excluding United States, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.*
- (e) *Following the integration of BI's Consumer Healthcare business, acquired on January 1, 2017, our Consumer Healthcare business represents a separate operating segment of Sanofi in accordance with IFRS 8. Consequently, we present our Consumer Healthcare net sales separately for the year ended December 31, 2017. Comparatives for the year ended December 31, 2016, and December 31, 2015 have been restated accordingly (Consumer Healthcare was previously included within the Pharmaceuticals segment).*
- (f) *Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**3/ Net Sales by Franchise**

The table below sets forth our 2016 net sales by franchise in order to facilitate comparisons with our peers. For a detailed reconciliation of net sales by franchise and net sales by GBU for our Pharmaceuticals segment, refer to the table showing Pharmaceuticals segment net sales by geographical region.

<i>Net Sales by Franchise</i>			Change on	
			a reported	Change at constant
( million)	2016	2015	basis	exchange rates
Rare Diseases	2,777	2,550	+8.9%	+11.7%
Multiple Sclerosis	1,720	1,114	+54.4%	+56.1%
Oncology	1,453	1,504	-3.4%	-2.2%
Immunology	-	-	-	-
<b>Total Specialty Care</b>	<b>5,950</b>	<b>5,168</b>	<b>+15.1%</b>	<b>+17.2%</b>
<i>of which Developed Markets (Sanofi Genzyme GBU)</i>	5,019	4,275	+17.4%	+17.3%
<i>of which Emerging Markets<sup>(a)(b)</sup></i>	931	893	+4.3%	+16.7%
Diabetes	7,341	7,580	-3.2%	-1.8%
Cardiovascular	458	350	+30.9%	+31.1%
<b>Total Diabetes &amp; Cardiovascular</b>	<b>7,799</b>	<b>7,930</b>	<b>-1.7%</b>	<b>-0.4%</b>
<i>of which Developed Markets (Diabetes &amp; Cardiovascular GBU)</i>	6,397	6,517	-1.8%	-2.0%
<i>of which Emerging Markets<sup>(a)(b)</sup></i>	1,402	1,413	-0.7%	+7.2%
<b>Established Prescription Products<sup>(a)</sup></b>	<b>10,311</b>	<b>11,292</b>	<b>-8.7%</b>	<b>-6.8%</b>
<b>Generics<sup>(a)</sup></b>	<b>1,854</b>	<b>1,917</b>	<b>-3.3%</b>	<b>+0.7%</b>
<b>Total Pharmaceuticals<sup>(c)</sup></b>	<b>25,914</b>	<b>26,307</b>	<b>-1.5%</b>	<b>+0.4%</b>
<b>Consumer Healthcare (Consumer Healthcare GBU)<sup>(c)</sup></b>	<b>3,330</b>	<b>3,492</b>	<b>-4.6%</b>	<b>-1.6%</b>
<b>Vaccines (Sanofi Pasteur GBU)<sup>(d)</sup></b>	<b>4,577</b>	<b>4,261</b>	<b>+7.4%</b>	<b>+8.8%</b>

<b>Total</b>	<b>33,821</b>	<b>34,060</b>	<b>-0.7%</b>	<b>+1.2%</b>
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(a) These lines are aggregated to form the net sales of the General Medicines and Emerging Markets GBU.

(b) Emerging Markets: World excluding United States, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(c) Following the integration of BI's Consumer Healthcare business, acquired on January 1, 2017, our Consumer Healthcare business represents a separate operating segment of Sanofi in accordance with IFRS 8. Consequently, we present our Consumer Healthcare net sales separately for the year ended December 31, 2017. Comparatives for the year ended December 31, 2016, and December 31, 2015 have been restated accordingly (Consumer Healthcare was previously included within the Pharmaceuticals segment).

(d) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

**Table of Contents**

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

***4/ Net Sales Pharmaceuticals Segment***

In 2016, net sales for the Pharmaceuticals segment were 25,914 million, down 1.5% on a reported basis and up 0.4% at constant exchange rates (CER). The year-on-year decrease of 393 million reflected the negative effect of exchange rates (down 498 million), and the following impacts at CER:

growth in net sales for the Multiple Sclerosis franchise (up 625 million), the Rare Diseases franchise (up 298million), the Cardiovascular franchise (up 109 million) and the Generics (up 13 million); and

lower net sales for Established Prescription Products (down 770 million), the Diabetes franchise (down 137 million) and the Oncology franchise (down 33 million).

Excluding Venezuela, pharmaceuticals net sales rose by 1.7% CER. Comments on the performances of major Pharmaceuticals segment products are provided below.

**Pharmaceuticals segment net sales, 2016 and 2015**

<i>Net sales by product and franchise</i> ( million)	<b>Indication</b>	<b>2016</b>	<b>2015</b>	<b>Change on a reported</b>	<b>Change at constant</b>

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				basis	exchange rates
Cerezyme®	Gaucher disease	748	757	-1.2%	+5.3%
Cerdelga®	Gaucher disease	106	66	+60.6%	+59.1%
Myozyme®/Lumizyme®	Pompe disease	725	650	+11.5%	+13.5%
Fabrazyme®	Fabry disease	674	592	+13.9%	+14.7%
Aldurazyme®	Mucopolysaccharidosis	201	195	+3.1%	+7.7%
Other		323	290	+11.4%	+10.0%
<b>Total Rare Diseases</b>		<b>2,777</b>	<b>2,550</b>	<b>+8.9%</b>	<b>+11.7%</b>
Aubagio®	Multiple sclerosis	1,295	871	+48.7%	+49.7%
Lemtrada®	Multiple sclerosis	425	243	+74.9%	+79.0%
<b>Total Multiple sclerosis</b>		<b>1,720</b>	<b>1,114</b>	<b>+54.4%</b>	<b>+56.1%</b>
Jevtana®	Prostate cancer	358	321	+11.5%	+11.5%
Thymoglobulin®	Organ rejection	281	256	+9.8%	+10.9%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	179	222	-19.4%	-17.1%
Eloxatin®	Colorectal cancer	170	227	-25.1%	-21.6%
Mozobil®	Hematologic malignancies	152	143	+6.3%	+7.0%
Zaltrap®	Colorectal cancer	65	77	-15.6%	-14.3%
Other		248	258	-3.9%	-3.9%
<b>Total Oncology</b>		<b>1,453</b>	<b>1,504</b>	<b>-3.4%</b>	<b>-2.2%</b>
Dupixent®	Atopic dermatitis	-	-	-	-
Kevzara®	Rheumatoid arthritis	-	-	-	-
<b>Total Immunology</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Total Specialty Care</b>		<b>5,950</b>	<b>5,168</b>	<b>+15.1%</b>	<b>+17.2%</b>

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

<i>Net sales by product and franchise</i>				<b>Change on</b>	<b>Change at</b>
<i>( million)</i>	<b>Indication</b>	<b>2016</b>	<b>2015</b>	<b>a reported</b>	<b>constant</b>
				<b>basis</b>	<b>exchange</b>
					<b>rates</b>
Lantus®	Diabetes	5,714	6,390	-10.6%	-9.4%
Toujeo®	Diabetes	649	164	+295.7%	+294.5%
Apidra®	Diabetes	367	376	-2.4%	-1.1%
Amaryl®	Diabetes	362	393	-7.9%	-3.8%
Insuman®	Diabetes	129	141	-8.5%	-3.5%
Lyxumia®	Diabetes	33	38	-13.2%	-13.2%
Soliqua®	Diabetes	-	-	-	-
Other	Diabetes	87	78	11.5%	+9.0%
<b>Total Diabetes</b>		<b>7,341</b>	<b>7,580</b>	<b>-3.2%</b>	<b>-1.8%</b>
Multaq®	Atrial fibrillation	353	341	+3.5%	+3.8%
Praluent®	Hypercholesterolemia	105	9	+1,066.7%	+1,066.7%
<b>Total Cardiovascular</b>		<b>458</b>	<b>350</b>	<b>+30.9%</b>	<b>+31.1%</b>
<b>Total Diabetes &amp; Cardiovascular</b>		<b>7,799</b>	<b>7,930</b>	<b>-1.7%</b>	<b>-0.4%</b>
Lovenox®	Thrombosis	1,636	1,719	-4.8%	-1.7%
Plavix®	Atherothrombosis	1,544	1,929	-20.0%	-18.8%
Renagel®/Renvela®	Hyperphosphatemia	922	935	-1.4%	-1.1%
Aprovel® / Avapro®	Hypertension	681	762	-10.6%	-7.0%
Depakine®	Epilepsy	416	422	-1.4%	+3.3%
Synvisc® / Synvisc-One®	Arthritis	408	413	-1.2%	-0.2%
Allegra®	Allergic rhinitis, urticaria	186	194	-4.1%	-11.9%
Stilnox®/Ambien®/Myslee®	Sleep disorders	304	306	-0.7%	-2.9%
Tritace®	Hypertension	245	274	-10.6%	-7.7%
Targocid®	Bacterial infections	149	160	-6.9%	-3.8%

Lasix®	Edema, hypertension	148	162	-8.6%	-6.2%
Other		3,672	4,016	-8.6%	-6.5%
<b>Total Established Prescription Products</b>		<b>10,311</b>	<b>11,292</b>	<b>-8.7%</b>	<b>-6.8%</b>
<b>Generics</b>		<b>1,854</b>	<b>1,917</b>	<b>-3.3%</b>	<b>+0.7%</b>
<b>TOTAL PHARMACEUTICALS</b>		<b>25,914</b>	<b>26,307</b>	<b>-1.5%</b>	<b>+0.4%</b>

### Rare Diseases franchise

Net sales for the **Rare Diseases** franchise reached 2,777 million in 2016, up 8.9% on a reported basis and 11.7% CER.

In Gaucher disease, net sales of **Cerezyme**® advanced by 5.3% CER to 748 million, as strong growth in Emerging Markets<sup>(1)</sup> (+27.1% CER, at 239 million) more than compensated for lower

sales in the United States (-10% CER, at 181 million) due to the launch of **Cerdelga**®. **Cerdelga**® reported net sales of 106 million, of which 85 million were generated in the United States. In Europe, where **Cerdelga**® became available in a number of countries (including Germany, France, Italy and some Nordic countries), net sales of the product were 17 million.

*(1) World excluding United States, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.*

Table of Contents

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Net sales of **Myozyme**<sup>®</sup> / **Lumizyme**<sup>®</sup> in Pompe disease rose by 13.5% CER to 725 million, driven by sales in the United States (+16.6% CER, at 240 million) and Europe (+8.5% CER, at 327 million). Net sales also rose sharply in Emerging Markets (+20.2% CER, at 102 million) and in the Rest of the World region<sup>(1)</sup> (+20.5% CER, at 56 million). This performance was mainly due to increased worldwide diagnosis.

In Fabry disease, **Fabrazyme**<sup>®</sup> posted net sales growth of 14.7% CER to 674 million. The product reported growth in many countries due to an increase in the number of patients treated, with notable performances in the United States (+12.8% CER, at 345 million), Europe (+13.6% CER, at 156 million), but also in Japan (+14% CER, at 73 million), and in Emerging Markets (+25.4% CER, at 68 million).

**Multiple Sclerosis franchise**

Net sales for the Multiple Sclerosis franchise reached 1,720 million in 2016, up 54.4% on a reported basis and 56.1% CER. This progression was mainly due to net sales of **Aubagio**<sup>®</sup>, which advanced by 49.7% CER to 1,295 million. In the United States, net sales reached 908 million, up 46.6% CER. In Europe, the product continued to extend its geographical reach, and net sales rose by 56.9% CER to 308 million. Aubagio<sup>®</sup> was the fastest-growing oral treatment in the multiple sclerosis market, with a patient market share of 8.8% in the United States (IMS NSP TRX Q4 2016).

Net sales of **Lemtrada**<sup>®</sup> amounted to 425 million (+79% CER), including 233 million in the United States and 151 million in Europe, mainly in Germany and the United Kingdom.

**Oncology franchise**

The Oncology franchise generated net sales of 1,453 million, down 3.4% on a reported basis and 2.2% CER, reflecting lower sales of Taxotere<sup>®</sup>, Eloxatin<sup>®</sup> and Zaltrap<sup>®</sup>, though the effect was partially compensated by increased sales of Jevtana<sup>®</sup>, Thymoglobulin<sup>®</sup> and Mozobil<sup>®</sup>.

Net sales of **Jevtana**<sup>®</sup> totaled 358 million in 2016, up 11.5% CER, driven by a strong performance in the United States (+18.9% CER, at 152 million) and in Japan (+85% CER, at 41 million).

Net sales of **Thymoglobulin**<sup>®</sup> rose by 10.9% CER to 281 million on good performances in Emerging Markets (+23.5% CER, at 59 million), the United States (+10.3% CER, at 160 million) and the Rest of the World region



(+10% CER, at 24 million).

**Taxotere**<sup>®</sup> saw net sales fall by 17.1% CER to 179 million, reflecting competition from generics in Emerging Markets (-3.5% CER, at 130 million) and in Japan (-60% CER, at 26 million),

though the effect was partly offset by stronger sales in China (+26.5% CER, at 59 million).

Net sales of **Eloxatin**<sup>®</sup> were down 21.6% CER at 170 million, hit by a slump in sales in Canada (-86.2% CER, at 8 million) due to competition from generics.

Net sales of **Mozobil**<sup>®</sup> reached 152 million, up 7% CER, mainly on sales growth in the United States (+14.5% CER, at 95 million).

**Zaltrap**<sup>®</sup> (aflibercept, developed in collaboration with Regeneron) reported a decline in net sales of 14.3% CER to 65 million. This reflected lower sales in the United States (-33.3% CER, at 14 million) and also in Europe (-7.8% CER, at 47 million).

### Diabetes franchise

Net sales for the Diabetes franchise amounted to 7,341 million in 2016, down 3.2% on a reported basis and 1.8% CER. The main factor was reduced sales of Lantus<sup>®</sup> in the United States, where net sales for the Diabetes franchise fell by 4.6% CER to 4,127 million. Outside the United States, Diabetes franchise net sales reached 3,214 million, driven by Emerging Markets (+7% CER at 1,395 million, or +10.7% CER excluding Venezuela). In Europe, net sales were 1,319 million, down 0.4% CER, as a strong performance from Toujeo<sup>®</sup> offset lower sales of Lantus<sup>®</sup>.

Net sales of **insulin glargines** (Lantus<sup>®</sup> and Toujeo<sup>®</sup>) fell by 1.8% CER to 6,363 million.

Net sales of **Lantus**<sup>®</sup> were down 9.4% CER in 2016, at 5,714 million. In the United States, sales were down 12.5% CER at 3,528 million, mainly due to a decrease in the average selling price and patients switching to Toujeo<sup>®</sup>. Net sales in Europe fell by 10.3% CER to 878 million, due largely to the launch of a biosimilar of Lantus<sup>®</sup> in July 2015. Over the same period, sales of Lantus<sup>®</sup> in Emerging Markets reached 953 million, up 6.0% CER (+8.5% CER excluding Venezuela), driven largely by Asia (+13.6% CER, at 351 million) and especially China.

**Toujeo**<sup>®</sup>, a new-generation basal insulin which saw its first launches in 2015, posted net sales of 649 million, including 475 million in the United States and 120 million in Europe. Worldwide rollout continued in 2016, and Toujeo<sup>®</sup> became available in more than 40 countries including United States, Germany, Spain, France, the United Kingdom and Japan. In Japan, the two-week prescription limit was lifted in September 2016, resulting in a significant increase in market share (10.8% in December 2016, based on IMS basal insulin market share by value).

Net sales of **Amaryl**<sup>®</sup> fell by 3.8% CER to 362 million, mainly due to a drop in sales in Japan (-30.4% CER, at 36 million) due to competition from generics. This was to some extent compensated

*(1) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

for by sales growth in Europe (+3.8% CER, at 27 million) and the United States (+50% CER, at 3 million). In Emerging Markets, the product's sales held steady at 292 million, although if Venezuela is excluded sales grew by 8.4%.

Net sales of **Apidra**<sup>®</sup> fell by 1.1% CER to 367 million. Sales declined in the United States (-20.7% CER, at 115 million), reflecting a tougher competitive and pricing environment. However, the effect was partly cushioned by increased sales in Emerging Markets (+32.4% CER, at 81 million) and Europe (+2.4% CER, at 127 million).

**Lyxumia**<sup>®</sup> generated 33 million of net sales in 2016, down 13.2% CER.

**Cardiovascular franchise**

Net sales of **Praluent**<sup>®</sup> (alirocumab, developed in collaboration with Regeneron) reached 105 million in 2016, of which 85 million was generated in the United States and 18 million in Europe, where the product became available in a number of countries including Germany, Spain, the Netherlands, the United Kingdom, and some Nordic countries. Praluent<sup>®</sup> was also launched in Japan, Canada and Mexico. Amgen initiated patent infringement proceedings in several countries against Sanofi and Regeneron relating to Praluent<sup>®</sup> in which Amgen has requested injunctive relief (see Note D.22. to the consolidated financial statements included at Item 18 and Item 8 – Updates to Note D.22 of the annual report for more information).

Net sales of **Multaq**<sup>®</sup> were 353 million (+3.8% CER), of which 299 million was generated in the United States (+4.2% CER) and 44 million in Europe (+2.3% CER).

**Established Prescription Products**

Net sales of established prescription products in 2016 amounted to 10,311 million, down 8.7% on a reported basis and 6.8% CER. This mainly reflected the situation in Venezuela (net sales were down 4.9% CER excluding Venezuela), and competition from generics of Plavix<sup>®</sup> in Japan. In Europe and the United States, net sales of established prescription products fell by 4.8% (to 3,642 million) and 2.4% (to 1,490 million), respectively.

Net sales of **Lovenox**<sup>®</sup> were 1,636 million, down 1.7% CER, due largely to competition from generics in the United States (-29.9% CER, at 54 million). In Europe, sales of Lovenox<sup>®</sup> were 1.1% lower CER at 1,027 million, as a result of competition from two

biosimilars containing enoxaparin sodium that received a positive opinion from the CHMP (Committee for Medicinal Products for Human Use) of the EMA (European Medicines Agency) in July 2016. Net sales of the product rose by 1.6% CER in Emerging Markets (to 462 million), or by 3.7% CER if Venezuela is excluded.

Net sales of **Plavix**<sup>®</sup> were 1,544 million (-18.8% CER), reflecting generic competition in Japan (-54% CER, at 355 million) and Europe (-11.4% CER, at 162 million). The effect was partly offset by growth in sales of Plavix<sup>®</sup> in Emerging Markets (+3.4% CER, at 970 million, or 7.9% excluding Venezuela), especially in China where the product posted net sales of 701 million (+12.3% CER). Sales of Plavix<sup>®</sup> in the United States and Puerto Rico are handled by BMS under the terms of the Sanofi-BMS alliance (see Note C.2., Alliance Arrangements with Bristol-Myers Squibb (BMS) , to our consolidated financial statements).

Net sales of **Renvela**<sup>®</sup>/**Renagel**<sup>®</sup> fell by 1.1% CER to 922 million. In the United States, net sales advanced by 5.5% CER to 764 million. Generics of this product began to be sold in some European countries, as a result of which net sales of Renvela<sup>®</sup>/**Renagel**<sup>®</sup> in Europe slipped by 31.4% to 82 million. We expect potential generic competition in the United States in the first half of 2017.

**Aprovel**<sup>®</sup>/**Avapro**<sup>®</sup> reported a drop in net sales of 7.0% CER to 681 million, mainly as a result of competition from generics in Europe (-13.5% CER, at 127 million) and Japan (-10.6% CER, at 82 million). In Emerging Markets (excluding Venezuela), net sales rose by 6.4% CER to 410 million, mainly on a good performance in China (+9.1% CER, at 239 million).

We have no comments on sales of our other prescription products.

## Generics

Net sales of **Generics** amounted to 1,854 million, down 3.3% on a reported basis but up 0.7% CER and 2.5% CER if Venezuela is excluded.

Emerging Markets generated net sales of 785 million (+1.8% CER, or +6.1% CER excluding Venezuela), boosted by Latin America (other than Venezuela), Turkey and China. In Europe, net sales were flat at 802 million. In the United States, net sales increased by 1.8% CER to 175 million. In the Rest of the World region, sales reached 92 million (+1.2% CER), mainly on increased sales of generics in Japan (+1.5% CER, at 74 million).

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following table breaks down 2016 net sales of our Pharmaceuticals segment products by geographical region:

	Total	Change at constant exchange rates	Change at constant exchange rates	Change at constant exchange rates	Change at constant exchange rates	Change at constant exchange rates	Change at constant exchange rates	Change at constant exchange rates	Change at constant exchange rates	Total	Change at constant exchange rates
( million)	GBUs	Europe <sup>(a)</sup>	United States	Rest of the world <sup>(b)</sup>	Emerging markets <sup>(c)</sup>	Franchise					
Cerezyme <sup>®</sup>	509	280	+0.0%	181	-10.0%	48	-2.1%	239	+27.1%	748	+5.3%
Cerdelga <sup>®</sup>	106	17	+183.3%	85	+41.7%	4	-	-	-	106	+59.1%
Myozyme <sup>®</sup> /Lumizyme <sup>®</sup>	623	327	+8.5%	240	+16.6%	56	+20.5%	102	+20.2%	725	+13.5%
Fabrazyme <sup>®</sup>	606	156	+13.6%	345	+12.8%	105	+15.5%	68	+25.4%	674	+14.7%
Aldurazyme <sup>®</sup>	141	75	+2.7%	42	+5.0%	24	+9.1%	60	+15.5%	201	+7.7%
Other	285	67	+30.8%	121	+6.1%	97	+2.2%	38	+11.1%	323	+10.0%
<b>Total Rare Diseases</b>	<b>2,270</b>	<b>922</b>	<b>+8.6%</b>	<b>1,014</b>	<b>+9.4%</b>	<b>334</b>	<b>+9.8%</b>	<b>507</b>	<b>+22.9%</b>	<b>2,777</b>	<b>+11.7%</b>
Aubagio <sup>®</sup>	1,261	308	+56.9%	908	+46.6%	45	+46.9%	34	+75.0%	1,295	+49.7%
Lemtrada <sup>®</sup>	407	151	+73.6%	233	+82.0%	23	+64.3%	18	+110.0%	425	+79.0%
<b>Total Multiple Sclerosis</b>	<b>1,668</b>	<b>459</b>	<b>+62.2%</b>	<b>1,141</b>	<b>+52.7%</b>	<b>68</b>	<b>+52.2%</b>	<b>52</b>	<b>+85.3%</b>	<b>1,720</b>	<b>+56.1%</b>
Jevtana <sup>®</sup>	335	139	+0.0%	152	+18.9%	44	+53.8%	23	-3.7%	358	+11.5%
Thymoglobulin <sup>®</sup>	222	38	-2.5%	160	+10.3%	24	+10.0%	59	+23.5%	281	+10.9%
Taxotere <sup>®</sup>	49	4	-42.9%	4	-500.0%	41	-47.3%	130	-3.5%	179	-17.1%
Eloxatin <sup>®</sup>	36	4	0.0%	-	-100.0%	32	-60.7%	134	+8.5%	170	-21.6%
Mozobil <sup>®</sup>	145	42	+4.9%	95	+14.5%	8	0.0%	7	-33.3%	152	+7.0%
Zaltrap <sup>®</sup>	61	47	-7.8%	14	-33.3%	-	-50.0%	4	+33.3%	65	-14.3%
Other	233	52	-3.6%	157	-3.1%	24	0.0%	15	-15.8%	248	-3.9%

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Total Oncology	1,081	326	-2.4%	582	+6.4%	173	-30.3%	372	+2.9%	1,453	-2.2%
Dupixent®	-	-	-	-	-	-	-	-	-	-	-
Kevzara®	-	-	-	-	-	-	-	-	-	-	-
Total Immunology	-	-	-	-	-	-	-	-	-	-	-
<b>Sanofi Genzyme (Specialty Care)</b>	<b>5,019</b>	<b>1,707</b>	<b>+16.4%</b>	<b>2,737</b>	<b>+23.2%</b>	<b>575</b>	<b>-3.4%</b>	<b>931</b>	<b>+16.7%</b>	<b>5,950</b>	<b>+17.2%</b>
Lantus®	4,761	878	-10.3%	3,528	-12.5%	355	-12.9%	953	+6.0%	5,714	-9.4%
Toujeo®	630	120	+566.7%	475	+246.0%	35	+775.0%	19	+260.0%	649	+294.5%
Apidra®	286	127	+2.4%	115	-20.7%	44	+2.6%	81	+32.4%	367	-1.1%
Amaryl®	70	27	+3.8%	3	+50.0%	40	-32.7%	292	+0.3%	362	-3.8%
Insuman®	85	82	-11.7%	3	+50.0%	-	-100.0%	44	+13.6%	129	-3.5%
Lyxumia®	30	21	-8.3%	-	-	9	-11.1%	3	-40.0%	33	-13.2%
Soliqua®	-	-	-	-	-	-	-	-	-	-	-
Other	84	64	+6.7%	3	-57.1%	17	+66.7%	3	+0.0%	87	+9.0%
<b>Total Diabetes</b>	<b>5,946</b>	<b>1,319</b>	<b>-0.4%</b>	<b>4,127</b>	<b>-4.6%</b>	<b>500</b>	<b>-6.5%</b>	<b>1,395</b>	<b>+7.0%</b>	<b>7,341</b>	<b>-1.8%</b>

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

	Total	Change at constant exchange rates	Change at constant exchange rates	Change at constant exchange rates	Change at constant exchange rates	Total	Change at constant exchange rates
(in million)	GBUs	United States	Rest of the world	Emerging Markets	Franchise	rate of change	rate of change
Ampliq <sup>®</sup>	347	44	299	4	6	353	+3.8%
Alucent <sup>®</sup>	104	18	85	1	1	105	+1,066.7%
Total Cardiovascular	451	62	384	5	7	458	+31.1%
Total Diabetes & Cardiovascular	<b>6,397</b>	<b>1,381</b>	<b>4,511</b>	<b>505</b>	<b>1,402</b>	<b>7,799</b>	<b>-0.4%</b>
Benvenox <sup>®</sup>	1,636	1,027	54	93	462	1,636	-1.7%
Avix <sup>®</sup>	1,544	162	1	411	970	1,544	-18.8%
Canagliflozin <sup>®</sup> /Renvela <sup>®</sup>	922	82	764	33	43	922	-1.1%
Coaprovel <sup>®</sup> /CoAprovel <sup>®</sup>	681	127	15	127	412	681	-7.0%
Empakine <sup>®</sup>	416	161	-	15	240	416	+3.3%
Synvisc <sup>®</sup> / Synvisc-One <sup>®</sup>	408	33	313	14	48	408	-0.2%
Levamisole <sup>®</sup>	186	9	-	177	-	186	-11.9%
Alprazolam <sup>®</sup> /Ambien <sup>®</sup> /Lysle <sup>®</sup>	304	44	84	120	56	304	-2.9%
Clonidine <sup>®</sup>	245	154	-	4	87	245	-7.7%
Argocid <sup>®</sup>	149	74	-	7	68	149	-3.8%
Other	3,820	1,769	259	419	1,373	3,820	-5.9%
Total Established Prescription Products	10,311	3,642	1,490	1,420	3,759	10,311	-6.8%
Generics	1,854	802	175	92	785	1,854	+0.7%
Total Emerging Markets					931		+16.7%
Specialty Care	931				1,402		+7.2%

Global Emerging Markets											
Diabetes & Cardiovascular											
General Medicines & Emerging Markets	14,498	4,444	-4.1%	1,665	-1.9%	1,512	-24.5%	6,817	+2.5%		
<b>TOTAL</b>											
<b>PHARMACEUTICALS</b>	<b>25,914</b>	<b>7,532</b>	<b>+0.9%</b>	<b>8,913</b>	<b>+4.4%</b>	<b>2,592</b>	<b>-17.3%</b>	<b>6,877</b>	<b>+2.5%</b>	<b>25,914</b>	<b>+0.4%</b>

(a) Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).

(b) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

(c) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.



Table of Contents

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

*5/ Net Sales Consumer Healthcare (CHC) Segment*

During 2017, we gradually integrated the Consumer Healthcare operations of BI into our Consumer Healthcare GBU. Following completion of the integration process and with effect from December 31, 2017, we have identified our Consumer Healthcare business as an operating segment. Consequently, the net sales of our Consumer Healthcare business are presented separately below for 2016 and 2015 in the interests of comparability. In 2016, **Consumer Healthcare** products generated net sales of 3,330 million, down 4.6% on a reported basis and 1.6% CER. Excluding Venezuela, net sales of Consumer Healthcare products were up 1.4% CER.

			<b>Change on</b>	<b>Change at</b>
			<b>a reported</b>	<b>constant</b>
( million)	<b>2016</b>	<b>2015</b>	<b>basis</b>	<b>exchange rates</b>
Allegra <sup>®</sup>	417	424	-1.7%	-0.2%
Mucosolvan <sup>®</sup>	-	-	-	-
Other	374	405	-7.7%	-4.0%
<b>Allergy, Cough and Cold</b>	<b>791</b>	<b>829</b>	<b>-4.6%</b>	<b>-2.1%</b>
Doliprane <sup>®</sup>	309	303	+2.0%	+2.6%
Buscopan <sup>®</sup>	-	-	-	-
Other	563	542	+3.9%	+8.7%
<b>Pain Relief</b>	<b>872</b>	<b>845</b>	<b>+3.2%</b>	<b>+6.5%</b>
Dulcolax <sup>®</sup>	-	-	-	-
Enterogermina <sup>®</sup>	159	161	-1.2%	+2.5%
Essentiale <sup>®</sup>	145	196	-26.0%	-20.9%
Zantac <sup>®</sup>	-	-	-	-
Other	217	249	-12.9%	-8.8%

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<b>Digestive Health</b>	<b>521</b>	<b>606</b>	<b>-14.0%</b>	<b>-9.7%</b>
Pharmaton®	-	-	-	-
Other	450	477	-5.7%	-2.5%
<b>Food Supplements</b>	<b>450</b>	<b>477</b>	<b>-5.7%</b>	<b>-2.5%</b>
Gold Bond®	195	171	+14.0%	+13.5%
Other	501	564	-11.2%	-8.2%
<b>Other products</b>	<b>696</b>	<b>735</b>	<b>-5.3%</b>	<b>-3.1%</b>
<b>Total Consumer Healthcare</b>	<b>3,330</b>	<b>3,492</b>	<b>-4.6%</b>	<b>-1.6%</b>

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Net sales in the United States were 938 million, up 3.8% CER, despite lower sales of Allegra<sup>®</sup> OTC (-4.7% CER, at 243 million) and Nasacof<sup>®</sup> (-9.2% CER, at 90 million) due to an increased competitive environment. In Emerging Markets, net sales slipped by 7.9% CER to 1,238 million, reflecting the impact of Venezuela but also lower sales in Russia and China. In Russia, net sales mainly decreased due to the challenging local economic situation. In the Rest of the World region, net sales were up 9.9% at 275 million, driven by sales in Australia (+10.2% CER, at 203 million). In Europe, net sales were stable year-on-year at 879 million.

( million)	Total	Europe <sup>(a)</sup>	Change at constant exchange rates	United States	Change at constant exchange rates	Rest of the world <sup>(b)</sup>	Change at constant exchange rates	Emerging Markets <sup>(c)</sup>	Change at constant exchange rates
Allegra <sup>®</sup>	417	9	+12.5%	243	-4.7%	40	+17.6%	125	+3.1%
Mucosolvan <sup>®</sup>	-	-	-	-	-	-	-	-	-
Other	374	115	-4.9%	89	-8.2%	26	+14.3%	144	+3.0%
<b>Allergy, Cough and Cold</b>	<b>791</b>	<b>124</b>	<b>-3.8%</b>	<b>332</b>	<b>-5.7%</b>	<b>66</b>	<b>+16.4%</b>	<b>269</b>	<b>-0.3%</b>
Doliprane <sup>®</sup>	309	260	+1.6%	-	-	-	-100.0%	49	+10.9%
Buscopan <sup>®</sup>	-	-	-	-	-	-	-	-	-
Other	563	122	+6.0%	157	+18.9%	14	-	270	+5.3%
<b>Pain Relief</b>	<b>872</b>	<b>382</b>	<b>+3.02%</b>	<b>157</b>	<b>+18.9%</b>	<b>14</b>	<b>-7.1%</b>	<b>319</b>	<b>+6.1%</b>
Dulcolax <sup>®</sup>	-	-	-	-	-	-	-	-	-
Enterogermina <sup>®</sup>	159	66	+6.5%	-	-	-	-100.0%	93	+1.0%
Essentiale <sup>®</sup>	145	29	+3.4%	-	-	-	-	116	-25.1%
Zantac <sup>®</sup>	-	-	-	-	-	-	-	-	-
Other	217	86	+4.8%	25	0.0%	7	0.0%	99	-19.3%
<b>Digestive Health</b>	<b>521</b>	<b>181</b>	<b>+5.2%</b>	<b>25</b>	<b>0.0%</b>	<b>7</b>	<b>-14.3%</b>	<b>308</b>	<b>-16.8%</b>
Pharmaton <sup>®</sup>	-	-	-	-	-	-	-	-	-
Other	450	94	-13.8%	4	0.0%	155	+13.8%	197	-7.1%

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<b>Food Supplements</b>	<b>450</b>	<b>94</b>	<b>-13.8%</b>	<b>4</b>	<b>0.0%</b>	<b>155</b>	<b>+13.8%</b>	<b>197</b>	<b>-7.1%</b>
Gold Bond®	195	-	-	191	+14.4%	4	-25.0%	-	-
Other	501	98	0.0%	229	+2.3%	29	0.0%	145	-24.5%
<b>Other products</b>	<b>696</b>	<b>98</b>	<b>0.0%</b>	<b>420</b>	<b>+7.5%</b>	<b>33</b>	<b>-2.6%</b>	<b>145</b>	<b>-24.5%</b>
<b>Total Consumer Healthcare</b>	<b>3 330</b>	<b>879</b>	<b>0.0%</b>	<b>938</b>	<b>+3.8%</b>	<b>275</b>	<b>+9.9%</b>	<b>1238</b>	<b>-7.9%</b>

(a) Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).

(b) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

(c) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**6/ Net Sales Human Vaccines (Vaccines) Segment**

In 2016, net sales for the Vaccines segment were 4,577 million, up 7.4% on a reported basis and 8.8% CER. This rise was driven mainly by sales of influenza vaccines in the United States and Polio/Pertussis/Hib vaccines in Emerging Markets plus sales of Dengvaxia<sup>®</sup>, the world's first dengue vaccine.

The table below sets forth 2016 and 2015 net sales for our Vaccines segment by product range:

( million)	2016	2015	Change on a reported basis	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines (including Pentacel <sup>®</sup> , Pentaxim <sup>®</sup> , Imovax <sup>®</sup> and Hexaxim <sup>®</sup> )	1,495	1,348	+10.9%	+12.7%
Influenza Vaccines (including Vaxigrip <sup>®</sup> and Fluzone <sup>®</sup> )	1,521	1,322	+15.1%	+16.6%
Meningitis/Pneumonia Vaccines (including Menactra <sup>®</sup> )	633	614	+3.1%	+4.1%
Adult Booster Vaccines (including Adacel <sup>®</sup> )	417	496	-15.9%	-15.5%
Travel and Other Endemics Vaccines	368	375	-1.9%	-0.8%
Dengvaxia <sup>®</sup>	55	-	-	-
Other vaccines <sup>(a)</sup>	88	106	-17.0%	-17.0%
<b>Total Vaccines segment<sup>(a)</sup></b>	<b>4,577</b>	<b>4,261</b>	<b>+7.4%</b>	<b>+8.8%</b>

(a)

*Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.*

**Polio/Pertussis/Hib** vaccines posted net sales of 1,495 million (+12.7% CER). In Emerging Markets, sales for this franchise reached 832 million (+18.2% CER) due to sales growth for Hexaxim® in the Middle East and Africa (+238.1% CER, at 205 million). This more than compensated for local disruption in the Chinese market, which hampered sales for the franchise (-59.9% CER, at 112 million). In the United States, net sales amounted to 405 million (+2.5% CER), with an expected decline in sales of Pentacel® (-2.0% CER, at 246 million) more than compensated for by stronger sales of Imovax® (+22.2% CER, at 55 million). During 2016, Sanofi Pasteur experienced delays in production of Pentacel®, which eased during the fourth quarter.

Net sales of **Influenza** vaccines rose by 16.6% CER, to 1,521 million. This performance was mainly driven by higher sales for this franchise in the United States (+24.4% CER, at 1,117 million), supporting Sanofi Pasteur's differentiation strategy in influenza vaccines. Sales of influenza vaccines also rose in Emerging Markets (+3.7% CER, at 282 million) and in the Rest of the World region (+8.3% CER, at 39 million), but fell in Europe (-13.5% CER, at 83 million) mainly due to Sanofi sales to Sanofi Pasteur MSD being deferred to 2017 as a result of inventory repurchases in connection with the termination of Sanofi Pasteur MSD joint venture.

Net sales of **Meningitis/Pneumonia** vaccines reached 633 million (+4.1% CER). **Menactra®** generated net sales of 586 million (+4.8% CER); sales in the United States rose by +4.4% CER to 516 million largely as a result of trends in orders from the Centers for Disease Control and Prevention (CDC), a US federal agency.

Net sales of **Dengvaxia®** amounted to 55 million, reflecting two deliveries for the public dengue vaccination program in the Philippines, the first dose for the public vaccination program in Paraná state (Brazil), and sales to the private sector.

Net sales of **Adult Booster** vaccines fell by 15.5% CER to 417 million, reflecting lower sales in the United States (-16.4% CER, at 302 million) due to increased competition for Adacel®. The franchise also recorded a drop in sales in Europe (-29% CER, at 44 million) mainly driven by supply issues with Repeva® and Emerging Markets (-7.4% CER, at 48 million).

Net sales of **Travel and Other Endemics** vaccines were relatively stable year-on-year at 368 million.

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following table presents the 2016 net sales of our Vaccines segment by geographical region:

( million)	<b>Total</b>	<b>Europe<sup>(a)</sup></b>	<b>Change at constant exchange rates<sup>(a)</sup></b>	<b>United States</b>	<b>Change at constant exchange rates</b>	<b>Rest of the world<sup>(b)</sup></b>	<b>Change at constant exchange rates<sup>(b)</sup></b>	<b>Emerging Markets<sup>(c)</sup></b>	<b>Change at constant exchange rates<sup>(c)</sup></b>
Polio/Pertussis/Hib Vaccines (incl. Pentacel <sup>®</sup> and Pentaxim <sup>®</sup> )	1,495	105	+16.7%	405	+2.5%	153	+9.3%	832	+18.2%
Influenza Vaccines (including Vaxigrip <sup>®</sup> and Fluzone <sup>®</sup> )	1,521	83	-13.5%	1,117	+24.4%	39	+8.3%	282	+3.7%
Meningitis/Pneumonia Vaccines (including Menactra <sup>®</sup> )	633	5	+66.7%	518	+4.6%	16	+88.9%	94	-7.5%
Adult Booster Vaccines (including Adacel <sup>®</sup> )	417	44	-29.0%	302	-16.4%	23	+20.0%	48	-7.4%
Travel and Other Endemics Vaccines	368	26	-13.3%	126	+13.5%	50	-5.7%	166	-6.1%
Dengvaxia <sup>®</sup>	55	-	-	-	-	-	-	55	-
Other vaccines	88	5	+100.0%	72	-16.7%	10	-9.1%	1	-75.0%
<b>Total Vaccines segment</b>	<b>4,577</b>	<b>268</b>	<b>-5.3%</b>	<b>2,540</b>	<b>+8.3%</b>	<b>291</b>	<b>+8.9%</b>	<b>1,478</b>	<b>+12.4%</b>

(a) Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).

(b) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

(c) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

SPMSD, our joint venture with Merck & Co. in Europe, reported net sales (not included in our consolidated net sales) of 940 million in 2016, up 14.1% on a reported basis from 2015. The main drivers were growth in sales of Gardasil<sup>®</sup> (+30.6%, at 214 million), the new hexavalent pediatric vaccine Hexyon<sup>®</sup> (+201% on a reported basis, at 110 million), and the chickenpox vaccine Varivax<sup>®</sup>

(+73.0% on a reported basis, at 54 million). In March 2016, Sanofi Pasteur and Merck announced their intention to end the SPMSD joint venture, in order to pursue their own distinct growth strategies in Europe. Sanofi Pasteur and MSD ended their joint venture at the end of December 2016.

### 7/ Net Sales by Geographical Region

The following table presents our net sales by geographical region for the years ended December 31, 2016 and 2015:

( million)	2016	2015	Change on a reported basis	Change at constant exchange rates
<b>United States</b>	12,391	11,764	+5.3%	+5.1%
<b>Emerging Markets<sup>(a)</sup></b>	9,593	10,072	-4.8%	+2.4%
<i>Of which Asia (including South Asia)</i>	3,468	3,446	+0.6%	+4.8%
<i>Of which Latin America</i>	2,503	3,047	-17.9%	-7.1%
<i>Of which Africa and Middle East</i>	2,405	2,312	+4.0%	+10.2%
<i>Of which Eurasia<sup>(b)</sup></i>	1,090	1,132	-3.7%	+5.2%
<b>Europe<sup>(c)</sup></b>	8,679	8,729	-0.6%	+0.6%
<b>Rest of the world<sup>(d)</sup></b>	3,158	3,495	-9.6%	-13.4%
<i>Of which Japan</i>	1,688	2,034	-17.0%	-24.8%
<b>Total net sales</b>	33,821	34,060	-0.7%	+1.2%

(a) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(b) India, Bangladesh and Sri Lanka. In 2016, South Asia was included in the Africa, Middle East and South Asia region. The presentation of 2016 and 2015 net sales has been amended accordingly in the interests of comparability.

(c) Russia, Ukraine, Georgia, Belarus, Armenia and Turkey.

(d) Western Europe and Eastern Europe (excluding Eurasia).



*(e)Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

In the **United States**, net sales rose by 5.1% CER to 12,391 million. Lower sales for the Diabetes franchise (-4.6% CER, at 4,127 million) and Established Prescription Products (-2.4% CER, at 1,490 million) were more than compensated for by solid performances for the Vaccines segment (+8.3%, at 2,540 million), and for the Multiple Sclerosis (+52.7%, at 1,141 million) and Rare Diseases (+9.4% CER, at 1,014 million) franchises.

In **Emerging Markets**, net sales reached 9,593 million, up 2.4% CER (but +7% CER excluding Venezuela). Growth in Emerging Markets was driven by increased sales for Vaccines (+12.4% CER, at 1,478 million), and the Rare Diseases (+22.9% CER, at 507 million), and Diabetes (+7% CER, at 1,395 million) franchises. In **Asia**, net sales amounted to 3,468 million (including 2,039 million in China), representing a rise of 4.8% CER. In the **Africa and Middle East** region, net sales were up 10.2% at 2,405 million, driven by the Middle East (+8.7% CER, at 1,326 million) and South Africa (+26.2% CER, at 253 million). Net sales in **Latin America** totaled 2,503 million, a fall of 7.1% CER, due mainly to the situation in Venezuela; excluding Venezuela, net sales were up 8.5% CER. The main driver of Latin American sales growth (excluding Venezuela) was the increase in sales in Mexico (+5.8% CER, at 548 million), Argentina (+47.3% CER, at 267 million), and Colombia (+10% CER, at 268 million). In Brazil, net sales were 983 million (+1.7% CER) thanks to the performances of the Rare Diseases franchise, Generics, and the contribution from Dengvaxia®. In the **Eurasia** region net sales were up 5.2% CER at 1,090 million, reflecting strong sales growth in Turkey and Ukraine, which more than compensated for lower sales in Russia (-7.1% CER, at 499 million). Net sales in Russia were adversely affected by a decrease in sales for Consumer Healthcare and the Oncology franchise, partially offset by strong performances from Established Prescription Products, Vaccines, and the Diabetes franchise.

In **Europe**, net sales reached 8,679 million (+0.6% CER). Positive performances from the Multiple Sclerosis franchise (+62.2% CER, at 459 million) and the Rare Diseases franchise (+8.6% CER, at 922 million) offset weaker sales in Established Prescription Products (-4.8% CER, at 3,642 million) and Vaccines (-5.3% CER, at 268 million). Net sales in France were 2,206 million, down 1.9% CER, mainly reflecting lower sales of Lantu®, Plavix® and Aprovel®.

In the Rest of the World region, net sales fell by 13.4% CER to 3,158 million. This reflects negative performances for Established Prescription Products (-25.7% CER, at 1,420 million), and the Diabetes (-6.5% CER, at 500 million) and Oncology (-30.3% CER, at 173 million) franchises, partially offset by positive performances for the Multiple Sclerosis and Rare Diseases

franchises and for Consumer Healthcare. In Japan, net sales were 1,688 million (-24.8% CER) reflecting the negative impact of competition from generics of Plavix® (-54% CER, at 355 million), though the effect was somewhat cushioned by the performances of the Rare Diseases franchise and Consumer Healthcare.

### A.3.2. Other income statement items

#### 1/ Other revenues

Other revenues mainly comprise royalties under licensing agreements contracted in the ordinary course of business. Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

Other revenues rose by 10.7% to 887 million in 2016, compared with 801 million in 2015. This year-on-year increase reflects a higher level of sales of non-Sanofi products by VaxServe.

#### 2/ Gross profit

Gross profit reached 24,006 million in 2016 (71.0% of net sales), versus 23,942 million in 2015 (70.3% of net sales), a rise of 0.3%.

The gross margin ratio for the Pharmaceuticals<sup>(1)</sup> segment was 0.9 of a point higher at 72.4%, mainly due to improved productivity in our industrial facilities. Other factors included a positive impact from the Sanofi Genzyme GBU and the Cardiovascular franchise in the United States, which more than offset weaker sales for the Diabetes franchise in the United States and competition from generics of Plavix®.

The gross margin ratio for the Vaccines<sup>(2)</sup> segment was unchanged year-on-year at 62%.

#### 3/ Research and development expenses

Research and development (R&D) expenses amounted to 5,172 million in 2016 (versus 5,082 million in 2015) and represented 15.3% of net sales (versus 14.9% in 2015). The overall year-on-year rise of 90 million (+1.8%) included 88 million for the Pharmaceuticals<sup>(1)</sup> segment (+1.9%) and 2 million for the Vaccines<sup>(2)</sup> segment (+0.4%).

This slight overall increase reflected cost control measures and reduced spending on Praluent® and dupilumab, more than offset by higher costs linked to the commencement of a number of Phase III studies, in particular on isatuximab.

*(1) Includes the Consumer Healthcare business and an allocation of global support function costs. For more information see A.2.3 Segment Results above.*

*(2) Includes an allocation of global support function costs. For more information see A.2.3 Segment Results above.*

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**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

***4/ Selling and general expenses***

Selling and general expenses totaled 9,486 million (28.0% of net sales), compared with 9,382 million in 2015 (27.5% of net sales). This represents a year-on-year rise of 104 million (+1.1%).

By segment, the year on-year increase was 87 million (+1.0%) for Pharmaceuticals<sup>(1)</sup> and 17 million (+2.3%) for Vaccines<sup>(2)</sup>. The rise in costs was mainly due to preparations for the launches of sarilumab (Kevzara<sup>®</sup>) and dupilumab (Dupixent<sup>®</sup>).

***5/ Other operating income and expenses***

In 2016, other operating income totaled 355 million (versus 254 million in 2015), and other operating expenses 482 million (versus 462 million in 2015). Overall, this represented a net expense of 127 million in 2016, versus a net expense of 208 million in 2015.

These items included gains on disposal amounting to 40 million in 2016; this compares with 146 million in 2015, which mainly related to intangible assets in the United States.

In 2016, they also included 192 million received under an arbitration settlement of a contractual dispute, and a payment of 90 million in settlement of litigation regarding generics of Cipr<sup>®</sup>.

The net overall improvement of 81 million in other operating income and expenses also reflected a reduction in operating foreign exchange losses on our Venezuelan operations, which fell from 240 million in 2015 to 102 million in 2016 (see Note D.26. to our consolidated financial statements).

***6/ Amortization of intangible assets***

Amortization charged against intangible assets amounted to 1,692 million in 2016, versus 2,137 million in 2015.

This year-on-year decrease of 445 million reflected (i) the amortization in full, in December 2015, of a priority review voucher acquired in May 2015 for \$245 million and used for the filing of a new drug application with the FDA for LixiLan; and (ii) a decrease in amortization charged against the intangible assets recognized on the acquisition of Aventis (482 million in 2016, versus 637 million in 2015) as some products reached the end of their life cycles.

### ***7/ Impairment of intangible assets***

In 2016, this line item showed impairment losses of 192 million against intangible assets, compared with 767 million in 2015.

In 2016, this line item included (i) a net impairment loss of 58 million on R&D projects in the Pharmaceuticals and Vaccines segments; and (ii) impairment losses of 134 million taken against rights relating to a number of marketed products in the Pharmaceuticals segment.

In 2015, this line item included (i) a net impairment loss of 340 million on R&D projects in the Pharmaceuticals and Vaccines segments, primarily Synvisc-One® in osteoarthritis of the hip and the rotavirus vaccine project (Shantha); and (ii) impairment losses of 427 million taken against rights relating to a number of marketed products in the Pharmaceuticals segment, mainly Afrezza® in the United States (following termination of the license and collaboration agreement with MannKind Corporation) and Auvi-Q®/Allerject® in the United States and Canada (following the voluntary recall of this product in the fourth quarter of 2015).

### ***8/ Fair value remeasurement of contingent consideration***

Fair value remeasurements of contingent consideration liabilities recognized on acquisitions in accordance with the revised IFRS 3 represented a net expense of 135 million in 2016, compared with a net gain of 53 million in 2015.

These remeasurements mainly related to (i) the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi (expense of 78 million in 2016 and of 104 million in 2015); and (ii) an increase in the market value of the contingent value rights (CVRs) issued by Sanofi in connection with the Genzyme acquisition, which represented a net expense of 58 million in 2016 and a net gain of 143 million in 2015 (see Note D.18. to our consolidated financial statements).

### ***9/ Restructuring costs and similar items***

Restructuring costs and similar items amounted to 879 million in 2016, compared with 795 million in 2015.

The restructuring costs recognized in 2016 related mainly to the implementation of an organizational transformation program in France (457 million) and in the Rest of the World as part of the 2020 strategic roadmap. With effect from January 1, 2016, this line item includes expenses regarded as equivalent to restructuring costs that have arisen from certain transformation programs implemented by Sanofi as part of the transformation strategy announced in November 2015, and more specifically programs intended to deliver a global information systems solution, to standardize and consolidate processes, and to transition towards a worldwide services platform. See Note D.27. to our consolidated financial statements.

### ***10/ Other gains and losses, and litigation***

At the end of December 2016, Sanofi Pasteur and MSD ended their joint venture SPMSD. The derecognition of Sanofi's investment in SPMSD generated pre-tax gain on disposal of 211 million.

*(1) Includes the Consumer Healthcare business and an allocation of global support function costs. For more information see A.2.3 Segment Results above.*

*(2) Includes an allocation of global support function costs. For more information see A.2.3 Segment Results above.*

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**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS*****11/ Operating income***

Operating income totaled 6,534 million for 2016, versus 5,624 million for 2015, an improvement of 16.2%; this was attributable mainly to lower charges for amortization and impairment of intangible assets, and the gain on disposal of the investment in the SPMSD joint venture.

***12/ Financial income and expenses***

Net financial expenses for 2016 were 856 million in 2016, compared with 381 million in 2015, an increase of 475 million. This increase was mainly a result of an impairment loss of 457 million taken against our shares in Alnylam, which reflected a decline in the market value of those shares as of the reporting date relative to their historical cost; most of that decline occurred when Alnylam decided to discontinue the revusiran development program on October 5, 2016.

Financial expenses directly related to our debt, net of cash and cash equivalents (see the definition in Consolidated Balance sheet below) amounted to 218 million in 2016, compared with 274 million in 2015, in line with a reduction in the cost of debt.

Interest expenses relating to post-employment benefit obligations amounted to 114 million in 2016, the same as in 2015.

***13/ Income before tax and investments accounted for using the equity method***

Income before tax and associates and joint ventures totaled 5,678 million in 2016, versus 5,243 million in 2015, a rise of 8.3%.

***14/ Income tax expense***

Income tax expense totaled 1,326 million in 2016, versus 709 million in 2015, giving an effective tax rate (based on consolidated net income) of 23.4% in 2016 compared with 13.5% in 2015 (see Note D.30. to our consolidated financial statements). The year-on-year trend in the effective tax rate was mainly attributable to changes in the geographical mix of our profits and of local tax rates in the territories where we operate, and changes in tax rates

notably in France and Japan (see Note D.30. to our consolidated financial statements).

Changes in the level of income tax expense were significantly impacted by the tax effects of the amortization and impairment of intangible assets ( 694 million in 2016, versus 1,019 million in 2015) and of restructuring costs ( 95 million in 2016, versus 273 million in 2015).

The effective tax rate on our business net income<sup>(1)</sup> is a non-GAAP financial measure. It is calculated on the basis of business

operating income, minus net financial expenses and before the share of profit/loss from investments accounted for using the equity method and net income attributable to non-controlling interests. We believe the presentation of this measure, used by our management, is also useful for investors as it provides a means to analyze the effective tax cost of our current business activities. It should not be seen as a substitute for the effective tax rate on consolidated net income.

Our effective tax rate was 23.3% in 2016, compared with 21.7% in 2015. The main impacts on this tax rate were the geographical mix of the profits of Sanofi entities; the tax effects of the elimination of intragroup margin on inventory; favorable settlements of recent proceedings involving the tax authorities in various countries; and changes in tax rates, particularly in Italy, Japan, Hungary and France. In 2015, there was also a favorable effect as a result of changes in the taxation of dividends in France following a ruling by the Court of Justice of the European Union and the resulting amendments to the 2015 Finance Act.

The table below reconciles our effective tax rate (based on consolidated net income) and the effective tax rate on our business net income:

<i>(as a percentage)</i>	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>
<b>Effective tax rate on consolidated net income</b>	<b>23.4</b>	<b>13.5</b>
Tax effects:		
Amortization and impairment of intangible assets	3.7	6.5
Restructuring costs and similar items	(1.3)	2.9
Impairment loss charged against the investment of Alnylam	(1.5)	0
Other items	(1.0)	(1.2)
<b>Effective tax rate on business net income</b>	<b>23.3</b>	<b>21.7</b>

*(a) The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.1. and D.36. to our consolidated financial statements.*

#### ***15/ Share of profit/(loss) from investments accounted for using the equity method***

Investments accounted for using the equity method contributed net income of 134 million in 2016, compared with a net loss of 22 million in 2015.

This line item mainly comprises our share of the profits and losses of Regeneron, which represented net income of 126 million in 2016 and a net loss of 54 million in 2015.



*(1) See definition under section A.1.5. Segment information 3/ Business Net Income .*

**124**

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

***16/ Net Income excluding the exchanged/held-for-exchange Animal Health business***

Net income excluding the exchanged/held-for-exchange Animal Health business amounted to 4,486 million in 2016, versus 4,512 million in 2015.

***17/ Net income/(loss) of the exchanged/held-for-exchange Animal Health business***

In accordance with IFRS 5, the net income or loss of the Animal Health business is presented in a separate line item, ***Net income/(loss) of the exchanged/held-for-exchange Animal Health business*** (see Notes D.1. and D.36. to our consolidated financial statements). This business reported net income of 314 million in 2016, compared with a net loss of 124 million in 2015. The Animal Health business generated operating income of 678 million in 2016, against 101 million in 2015. The year-on-year increase was mainly due to the discontinuation of depreciation of property, plant and equipment and amortization of intangible assets with effect from the end of 2015, when these non-current assets of the Animal Health business were reclassified as ***Assets held for sale or exchange*** in accordance with IFRS 5. Income tax expense for the year was 359 million, compared with 216 million in 2015.

***18/ Net income***

Net income amounted to 4,800 million in 2016, compared with 4,388 million in 2015.

***19/ Net income attributable to non-controlling Interests***

Net income attributable to non-controlling interests was 91 million in 2016, versus 101 million in 2015. This line item mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi (86 million, versus 94 million in 2015). The year-on-year fall was directly related to competition from generics of clopidogrel (active ingredient of Plavix®) and irbesartan (active ingredient of Aprovel®) in Europe.

***20/ Net income attributable to equity holders of Sanofi***

Net income attributable to equity holders of Sanofi amounted to 4,709 million, versus 4,287 million in 2015.

Basic earnings per share for 2016 was 3.66, 11.6% higher than the 2015 figure of 3.28, based on an average number of shares outstanding of 1,286.6 million in 2016 (1,306.2 million in 2015). Diluted earnings per share for 2016 was 3.63, 11.7% higher than the 2015 figure of 3.25, based on an average number of shares outstanding after dilution of

1,296 million in 2016 and 1,320.7 million in 2015.

### A.3.3. Segment Results

Business operating income (as defined in Note D.35. to our consolidated financial statements) amounted to 9,285 million in 2016 (27.5% of net sales), 0.3% lower than the 2015 amount of 9,313 million (27.3% of net sales).

As indicated in Notes B.26 and D.35. ( Segment Information ) to our consolidated financial statements, Sanofi has three operating segments: Pharmaceuticals, Consumer Healthcare and Human Vaccines (Vaccines).

Due to lack of available data and the unduly complex and significant adjustments that would be required (in particular to our reporting tools), the comparative information has not been restated to reflect the changes arising from our new segment reporting model. Consequently, we present segment information for 2016 and 2015 using our previous segment reporting model in the tables below.

Business operating income by segment for 2016 and 2015 is set forth below:

( million)	December 31, 2016	December 31, 2015	Change
Pharmaceuticals <sup>(a)</sup>	7,824	8,013	-2.4%
Vaccines <sup>(b)(c)</sup>	1,573	1,414	+11.2%
Other	(112)	(114)	-1.8%
<b>Business operating income</b>	<b>9,285</b>	<b>9,313</b>	<b>-0.3%</b>

*(a) Includes Consumer Healthcare and an allocation of global support function costs.*

*(b) Includes an allocation of global support function costs.*

*(c) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following tables set forth our segment results and business operating income for the years ended December 31, 2016 and 2015:

**Year ended December 31, 2016**

( million)	Pharmaceuticals <sup>(a)</sup>	Vaccines <sup>(b)(c)</sup>	Other	Total Sanofi
<b>Net sales</b>	<b>29,244</b>	<b>4,577</b>	-	<b>33,821</b>
Other revenues	274	613	-	887
Cost of sales	(8,349)	(2,353)	-	(10,702)
Research and development expenses	(4,618)	(554)	-	(5,172)
Selling and general expenses	(8,743)	(743)	-	(9,486)
Other operating income and expenses	(1)	(14)	(112)	(127)
Share of profit/(loss) from investments accounted for using the equity method	129	48	-	177
Net income attributable to non-controlling interests	(112)	(1)	-	(113)
<b>Business operating income</b>	<b>7,824</b>	<b>1,573</b>	<b>(112)</b>	<b>9,285</b>

*(a) Includes Consumer Healthcare and an allocation of global support function costs.*

*(b) Includes an allocation of global support function costs.*

*(c) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.*

## Year ended December 31, 2015

( million)	Pharmaceuticals <sup>(a)</sup>	Vaccines <sup>(b)(c)</sup>	Other	Total Sanofi
<b>Net sales</b>	<b>29,799</b>	<b>4,261</b>	-	<b>34,060</b>
Other revenues	288	513	-	801
Cost of sales	(8,788)	(2,131)	-	(10,919)
Research and development expenses	(4,530)	(552)	-	(5,082)
Selling and general expenses	(8,656)	(726)	-	(9,382)
Other operating income and expenses	(121)	27	(114)	(208)
Share of profit/(loss) from investments accounted for using the equity method	146	23	-	169
Net income attributable to non-controlling interests	(125)	(1)	-	(126)
<b>Business operating income</b>	<b>8,013</b>	<b>1,414</b>	<b>(114)</b>	<b>9,313</b>

*(a) Includes Consumer Healthcare and an allocation of global support function costs.*

*(b) Includes an allocation of global support function costs.*

*(c) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.*

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The tables below provide an analysis of business operating income for our Pharmaceuticals and Vaccines segments.

**Business operating income: Pharmaceuticals segment<sup>(a)</sup>**

( million)	December 31, 2016	as % of net sales	December 31, 2015	as % of net sales	Change 2016/2015
<b>Net sales</b>	29,244	100.0%	29,799	100.0%	-1.9%
Other revenues	274	0.9%	288	1.0%	-4.9%
Cost of sales	(8,349)	(28.5)%	(8,788)	(29.5)%	-5.0%
<b>Gross profit</b>	<b>21,169</b>	<b>72.4%</b>	<b>21,299</b>	<b>71.5%</b>	<b>-0.6%</b>
Research and development expenses	(4,618)	(15.8)%	(4,530)	(15.2)%	+1.9%
Selling and general expenses	(8,743)	(29.9)%	(8,656)	(29.0)%	+1.0%
Other operating income and expenses	(1)		(121)		
Share of profit/(loss) from investments accounted for using the equity method	129		146		
Net income attributable to non-controlling interests	(112)		(125)		
<b>Business operating income</b>	<b>7,824</b>	<b>26.8%</b>	<b>8,013</b>	<b>26.9%</b>	<b>-2.4%</b>

(a) Includes Consumer Healthcare and an allocation of global support function costs.

**Business operating income: Vaccines segment<sup>(a)</sup>**

( million)	December 31, 2016 <sup>(b)</sup>	as % of net sales	December 31, 2015 <sup>(b)</sup>	as % of net sales	Change 2016/2015
<b>Net sales</b>	4,577	100%	4,261	100.0%	+7.4%
Other revenues	613	13.4%	513	11.9%	+19.5%

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Cost of sales	(2,353)	(51.4)%	(2,131)	(50.0)%	+10.4%
<b>Gross profit</b>	<b>2,837</b>	<b>62.0%</b>	<b>2,643</b>	<b>62.0%</b>	<b>+7.3%</b>
Research and development expenses	(554)	(12.1)%	(552)	(13.0)%	+0.4%
Selling and general expenses	(743)	(16.2)%	(726)	(17.0)%	+2.3%
Other operating income and expenses	(14)		27		
Share of profit/(loss) from investments accounted for using the equity method	48		23		
Net income attributable to non-controlling interests	(1)		(1)		
<b>Business operating income</b>	<b>1,573</b>	<b>34.4%</b>	<b>1,414</b>	<b>33.2%</b>	<b>+11.2%</b>

(a) Includes an allocation of global support function costs.

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

**Table of Contents**

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**A.3.4. Business Net Income**

Business net income is a non-GAAP financial measure that we use to evaluate our performance. See Business Net Income above for the definition of this measure, and for a reconciliation to *Net income attributable to equity holders of Sanofi*.

Our business net income for 2016 was 7,308 million, 0.9% lower than in 2015 (7,371 million). These figures include the business net income of the Animal Health business (476 million in 2016, 368 million in 2015). Excluding Animal Health, our business net income was 6,832 million in 2016 (20.2% of net sales) and 7,003 million in 2015 (20.6% of net sales).

We also report business earnings per share non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding.

Business earnings per share was 5.68 in 2016, 0.7% higher than the 2015 figure of 5.64, based on an average number of shares outstanding of 1,286.6 million in 2016 and 1,306.2 million in 2015.

**B/ Liquidity and Capital Resources**

Our operations generate significant positive cash flows. We fund our day-to-day investments (with the exception of significant acquisitions) primarily with operating cash flow, and pay regular dividends on our shares.

We define debt, net of cash and cash equivalents as (i) the sum total of short-term debt, long-term debt and interest rate and currency derivatives used to hedge debt, minus (ii) the sum total of cash and cash equivalents and interest rate and currency

derivatives used to hedge cash and cash equivalents. We believe the presentation of this non-GAAP financial indicator reviewed by our management is useful as it provides information to measure overall liquidity and capital resources.



As of December 31, 2017 we had reduced our debt, net of cash and cash equivalents to 5,229 million (versus 8,206 million), due largely to the receipt of a balancing cash payment as part of the transaction with BI. As of December 31, 2016, our debt, net of cash and cash equivalents stood at 8,206 million versus 7,254 million as of December 31, 2015 mainly due to share repurchases made at the end of 2016, carried out in anticipation of the receipt of net proceeds from the transaction with BI finalized in most markets in early 2017. See Note D.17. to our consolidated financial statements.

In order to assess the Company's financing risk, we also use the gearing ratio, a non-GAAP financial measure (see table in section B.2. Consolidated Balance Sheet and Debt below). The gearing ratio is defined as the ratio of debt, net of cash and cash equivalents, to total equity. As of December 31, 2017, our gearing ratio was 9.0% of our net equity versus 14.2% as of December 31, 2016 and 12.5% as of December 31, 2015.

### B.1. Consolidated statement of cash flows

Generally, factors that affect our earnings—for example, pricing, volume, costs and exchange rates—flow through to cash from operations. The most significant source of cash from operations is sales of our branded pharmaceutical products and human vaccines. Receipts of royalty payments also contribute to cash from operations.

#### Summarized consolidated statements of cash flows

( million)	2017	2016	2015
Net cash provided by/(used in) operating activities	7,379	7,838	8,290
Net cash provided by/(used in) investing activities	(2,896)	(2,511)	(3,011)
Net cash inflow from the exchange of the Animal Health business for BI's Consumer Healthcare business	3,535	-	-
Net cash provided by/(used in) financing activities	(7,902)	(4,101)	(3,578)
Impact of exchange rates on cash and cash equivalents	(74)	(101)	(232)
<b>Net change in cash and cash equivalents</b>	<b>42</b>	<b>1,125</b>	<b>1,469</b>

#### B.1.1. Year Ended December 31, 2017 Compared with Year Ended December 31, 2016

**Net cash provided by operating activities** amounted to 7,379 million in 2017, versus 7,838 million in 2016.

Operating cash flow before changes in working capital for 2017 was 7,231 million, versus 7,010 million in 2016. Working capital requirements fell by 148 million in 2017, compared with a

reduction of 828 million in 2016; the main factors in 2017 were an increase in accounts receivable of 529 million and an increase in accounts payable of 577 million.

We run the risk of delayed payments or even non-payment by our customers, who consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies (see Item 3.D Risk Factors 2. Risks Relating to Our Business We are subject to the risk of non payment by our customers ). Over our



**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

business as a whole, the amount of trade receivables overdue by more than 12 months which primarily consists of amounts due from public sector bodies decrease to 93 million as of December 31, 2017 from 198 million as of December 31, 2016 (see Note D.10. to our consolidated financial statements).

**Net cash used in investing activities** amounted to 2,896 million in 2017, compared with 2,511 million in 2016.

Acquisitions of property, plant and equipment and intangible assets totaled 1,956 million, versus 2,083 million in 2016. There were 1,388 million of acquisitions of property, plant and equipment (versus 1,219 million in 2016), most of which were in the Pharmaceuticals segment, primarily in industrial facilities. The Vaccines segment invested 346 million in property, plant and equipment in 2017 (versus 315 million in 2016). Acquisitions of intangible assets ( 568 million, versus 864 million in 2016) mainly comprised contractual payments for intangible rights under license and collaboration agreements.

Acquisitions of investments during 2017 amounted to 1,312 million, net of cash acquired and after including assumed liabilities and commitments, compared with 634 million in 2016. In 2017, these included the acquisition of Protein Sciences ( 594 million), our contribution to the Onduo joint venture ( 50 million), and purchases of additional shares in Regeneron ( 184 million).

After-tax proceeds from disposals ( 535 million) arose mainly from the sale of mutual fund investments previously held to meet commitments under post-employment plans; divestments of Consumer Healthcare brands in the United States; and the divestment of Consumer Healthcare products to Ipsen (for 83 million). After-tax proceeds from disposals in 2016 amounted to 209 million and arose mainly from the divestment of the equity interest in Nichi-Iko Pharmaceutical Co., Inc. and the divestment of product rights relating to Oenobiol.

***Net cash inflow from the exchange of the Animal Health business for BI's Consumer Healthcare business*** comprised the following items for 2017: (i) the receipt by Sanofi of a balancing cash payment of 4,207 million; (ii) reimbursements of intragroup accounts with Merial entities totaling 967 million; (iii) a tax payment of 1,784 million on the gain arising on the divestment; and (iv) the cash held by the BI subsidiaries acquired by Sanofi. After final enterprise value adjustments, the exchange values of the two businesses effectively transferred during 2017 were determined to be 10,557 million for Sanofi's Animal Health business and 6,239 million for BI's Consumer Healthcare business (see Note D.1. to the consolidated financial statements).

**Net cash used in financing activities** amounted to 7,902 million in 2017, compared with 4,101 million in 2016. The 2017 figure includes net external debt finance repaid (i.e. net change in short-term and long-term debt) of

2,297 million; this compares with net external debt financing raised of 2,293 million in 2016. It also includes the effect of changes in share capital (repurchases of

own shares, net of capital increases), amounting to 1,843 million (versus 2,603 million in 2016), and the dividend payout to our shareholders of 3,710 million (versus 3,759 million in 2016).

The **net change in cash and cash equivalents** during 2017 was an increase of 42 million.

### **B.1.2. Year Ended December 31, 2016 Compared with Year Ended December 31, 2015**

**Net cash provided by operating activities excluding the exchanged/held-for-exchange Animal Health business** amounted to 7,838 million in 2016, versus 8,290 million in 2015.

Operating cash flow before changes in working capital (excluding the net income or loss of the held-for-exchange Animal Health business) for 2016 was 7,010 million, versus 7,235 million in 2015. Working capital requirements fell by 828 million in 2016, compared with a reduction of 1,055 million in 2015, mainly reflecting a 447 million increase in accounts payable and a 168 million reduction in accounts receivable.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect *Operating income*, which is discussed in detail above under Results of Operations Year Ended December 31, 2016 Compared with Year Ended December 31, 2015. The principal difference is that operating cash flow before changes in working capital includes our share of the profits and losses from investments accounted for using the equity method, net of dividends and similar income received.

**Net cash used in investing activities excluding the exchanged/held-for-exchange Animal Health business** amounted to 2,511 million in 2016, compared with 3,011 million in 2015.

Acquisitions of property, plant and equipment and intangible assets totaled 2,083 million, compared with 2,772 million in 2015. The main items were investments in industrial and research facilities (1,267 million, versus 1,163 million in 2015) and contractual payments for intangible rights, primarily under license and collaboration agreements (668 million, versus 1,465 million in 2015).

Acquisitions of investments during 2016 amounted to 634 million, net of cash acquired and after including assumed liabilities and commitments, versus 362 million in 2015. In 2016, these acquisitions included our contribution to the Onduo joint venture, and purchase of additional shares in Regeneron.

After-tax proceeds from disposals amounted to 209 million, and arose mainly from the sale of the equity interest in Nichi-Iko Pharmaceutical Co., Inc. and of product rights relating to Oenobiol®. In 2015, after-tax proceeds from disposals totaled 211 million, and related mainly to the divestment of our equity interest in Merrimack Pharmaceuticals and the sale of rights to Sklice® to Arbor Pharmaceuticals LLC in the United States.

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**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**Net cash used in financing activities excluding the exchanged/held-for-exchange Animal Health business** amounted to 4,101 million in 2016, compared with 3,578 million in 2015. The 2016 figure includes net external debt financing raised of 2,293 million ( 1,346 million in 2015); the effect of changes in our share capital (repurchases of own shares, net of capital increases), amounting to 2,603 million ( 1,211 million in 2015); and the dividend payout to our shareholders of 3,759 million ( 3,694 million in 2015).

**The net change in cash and cash equivalents excluding the exchanged/held-for-exchange Animal Health business** was an increase of 1,125 million in 2016, compared with an increase of 1,469 million in 2015.

**Net cash flows for the exchanged/held-for-exchange Animal Health business** represented net cash inflows of 339 million in 2016 and 361 million in 2015. This comprised a net cash inflow from operating activities of 346 million in 2016 ( 630 million in 2015); a net cash outflow from investing activities of 26 million ( 246 million in 2015); and a net cash outflow from financing activities of 111 million ( 23 million in 2015).

**B.2. Consolidated balance sheet and debt**

Total assets were 99,826 million as of December 31, 2017, compared with 104,672 million a year earlier, a decrease of 4,846 million.

Our **debt, net of cash and cash equivalents** was 5,229 million as of December 31, 2017, compared with 8,206 million as of December 31, 2016. We believe the presentation of this non-GAAP financial measure, which is reviewed by our management, provides useful information to measure our overall liquidity and capital resources. We define **debt, net of cash and cash equivalents** as (i) the sum total of short term debt, long term debt, and interest rate derivatives and currency derivatives used to hedge debt, minus (ii) the sum total of cash and cash equivalents and interest rate derivatives and currency derivatives used to hedge cash and cash equivalents.

( million)	2017	2016	2015
Long-term debt	14,326	16,815	13,118
Short-term debt and current portion of long-term debt	1,275	1,764	3,436
Interest rate and currency derivatives used to hedge debt	(57)	(100)	(152)
Cash and cash equivalents	(10,315)	(10,273)	(9,148)
<b>Debt, net of cash and cash equivalents</b>	<b>5,229</b>	<b>8,206</b>	<b>7,254</b>
Total equity	58,258	57,724	58,210
<b>Gearing ratio</b>	<b>9.0%</b>	<b>14.2%</b>	<b>12.5%</b>

To assess our financing risk, we use the gearing ratio, another non-GAAP financial measure. Our gearing ratio (debt, net of cash and cash equivalents as a proportion of total equity) fell from 14.2% in 2016 to 9.0% in 2017. Analyses of debt as of December 31, 2017 and December 31, 2016, by type, maturity, interest rate and currency, are provided in Note D.17. to our consolidated financial statements.

We expect that the future cash flows generated by our operating activities will be sufficient to repay our debt. The financing arrangements in place as of December 31, 2017 at Sanofi parent company level are not subject to covenants regarding financial ratios and do not contain any clauses linking credit spreads or fees to our credit rating.

Other key movements in the balance sheet are described below.

**Total equity** amounted to 58,258 million as of December 31, 2017, versus 57,724 million as of December 31, 2016. The net year-on-year increase in equity was attributable primarily to:

increases: our net income for the year ended December 31, 2017 ( 8,555 million); and

decreases: the dividend payout to our shareholders in respect of the 2016 financial year ( 3,710 million), the net change in currency translation differences ( 3,240 million, mainly on the US dollar), repurchases of our own shares ( 2,159 million), and actuarial losses on pensions and other post-employment benefits ( 117 million).

As of December 31, 2017, we held 0.2 million of our own shares, recorded as a deduction from equity and representing 0.01% of our share capital.

**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**Goodwill** and **Other intangible assets** ( 53,344 million in total) rose by 2,178 million year-on-year, the main factors being:

increases: movements related to the acquisition of BI's Consumer Healthcare business ( 2,222 million of goodwill and 3,771 million of other intangible assets); and

decreases: amortization and impairment charged during the period ( 2,311 million) and movements in currency translation differences ( 3,315 million).

**Investments accounted for using the equity method** ( 2,863 million) decreased by 27 million mainly as a result of currency translation differences on the investment in Regeneron, partly offset by acquisitions of additional Regeneron shares and our share of the net income of Regeneron.

**Other non-current assets** were 544 million higher at 3,364 million. The main movement during the year was an appreciation of 780 million (including currency translation effects) in the market value of our equity investment in Alnylam.

**Non-current provisions and other non-current liabilities** were 320 million higher year-on-year at 9,154 million, mainly as a result of the recognition at December 31, 2017 of the portion of the tax liability arising from the US tax reform that falls due after more than one year.

**Deferred taxes** represented a net asset of 2,685 million, year-on-year increase of 308 million, mainly due to reversals of deferred tax liabilities on the remeasurement of acquired intangible assets ( 1,084 million). The effect was partly offset by a reduction in accrued expenses and provisions that are tax-deductible at the time of payment, and the effects of reduced tax rates in France and the United States.

**Liabilities related to business combinations and to non-controlling interests** decreased by 207 million to 1,369 million. The main movements in this item are fair value remeasurements of contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi (see Note D.18. to our consolidated financial statements).

**B.3. Liquidity**

We expect that our existing cash resources and cash from operations will be sufficient to finance our foreseeable working capital requirements. At year-end 2017, we held cash and cash equivalents amounting to 10,315 million, substantially all of which were held in euros (see Note D.13. to our consolidated financial statements included at Item 18 of this annual report). As at December 31, 2017, our subsidiaries based in Venezuela held cash and cash equivalents in bolivars representing 7 million,

which are subject to foreign exchange controls (see Note A.4. to our consolidated financial statements included at Item 18 of this annual report). As at December 31, 2017, 556 million of our cash and cash equivalents were held by our captive insurance and reinsurance companies in accordance with insurance regulations.

We run the risk of delayed payments or even non-payment by our customers, who consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies (see Item 3.D. Risk Factors 2. Risks Relating to Our Business We are subject to the risk of non-payment by our customers ). Deteriorating credit and economic conditions and other factors in some countries have resulted in, and may continue to result in, an increase in the average length of time taken to collect our accounts receivable in these countries. Should these factors continue, it may require us to re-evaluate the collectability of these receivables in future periods. We carefully monitor sovereign debt issues and economic conditions and evaluate accounts receivable in these countries for potential collection risks. We have been conducting an active recovery policy, adapted to each country and including intense communication with customers, negotiations of payment plans, charging of interest for late payments, and legal action. Over our business as a whole, the amount of trade receivables overdue by more than 12 months (which primarily consists of amounts due from public sector bodies) decreased from 198 million as of December 31, 2016 to 93 million as of December 31, 2017 (see Note D.10. to our consolidated financial statements).

In November 2011, Sanofi obtained the necessary corporate authorizations to purchase any or all of the outstanding Contingent Value Rights ( CVR ) and subsequently purchased CVRs in 2011. In 2012 following a tender offer initiated in September 2012 on the basis of the same corporate authorization, Sanofi purchased an additional 40,025,805 CVRs (for a total consideration of approximately \$70 million), followed by a further 10,928,075 CVRs (for approximately \$9 million) in 2013, 1,879,774 CVRs (for approximately \$1 million) in 2014, and none in 2015, 2016 and 2017. As of December 31, 2017, a total of 236,457,284 CVRs were outstanding out of the 291,313,510 issued at the time of the Genzyme acquisition.

At year-end 2017, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position. Undrawn confirmed credit facilities amounted to a total of 8 billion at December 31, 2017. For a discussion of our treasury policies, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

We expect that cash from our operations will be sufficient to repay our debt. For a discussion of our liquidity risks, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.



**Table of Contents**

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

**C/ Off-Balance Sheet Arrangements / Contractual Obligations and Other Commercial Commitments**

We have various contractual obligations and other commercial commitments arising from our operations. Our contractual obligations and our other commercial commitments as of December 31, 2017 are shown in Notes D.3., D.17., D.18., D.21. and D.36. to our consolidated financial statements included at Item 18 of this annual report. Note D.21. to our consolidated financial statements discloses details of commitments under our principal research and development collaboration agreements. For a description of the principal contingencies arising from certain business divestitures, refer to Note D.22.d) to our 2017 consolidated financial statements.

Sanofi's contractual obligations and other commercial commitments are set forth in the table below:

<i>December 31, 2017</i>	Payments due by period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
( million)					
Future contractual cash flows relating to debt and debt hedging instruments <sup>(a)</sup>	16,631	1,403	4,920	4,275	6,033
Operating lease obligations	1,452	294	407	284	467
Finance lease obligations	39	13	8	8	10
Irrevocable purchase commitments					
given	5,500	3,101	1,021	483	895
received	(181)	(87)	(56)	(10)	(28)
Research & development license agreements					
Commitments related to R&D and other commitments	951	577	342	10	22
Potential milestone payment <sup>(d)</sup>	1,907	84	246	941	636
Obligations related to R&D license agreements reflected in the balance sheet	196	55	61	13	67

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Obligations relating to business combinations <sup>(a)</sup>	4,293	354	2,630	1,069	240
Firm commitment related to the BMS agreement <sup>(b)</sup>	97	97	-	-	-
Estimated benefit payments on unfunded pensions and post employment benefits <sup>(c)</sup>	1,097	56	108	116	817
<b>Total contractual obligations and other commitments</b>	<b>31,982</b>	<b>5,947</b>	<b>9,687</b>	<b>7,189</b>	<b>9,159</b>
<b>Undrawn general-purpose credit facilities</b>	<b>8,010</b>	<b>7</b>	<b>8,003</b>		<b>-</b>

(a) See Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

(b) See Note D.3. to our consolidated financial statements included at Item 18 of this annual report.

(c) These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down-payments (see Note D.3.) to our consolidated financial statements included at Item 18 of this annual report) and (ii) goods and services.

(d) This line includes all potential milestone payments on projects regarded as reasonably possible, i.e. on projects in the development phase.

(e) See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

(f) See Note C.2. to our consolidated financial statements included at Item 18 of this annual report.

(g) See Note D.19.1. to our consolidated financial statements included at Item 18 of this annual report. The table above does not include the ongoing annual employer's contributions to plan assets, estimated at 136 million in 2017.

**Table of Contents**

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

We may have payments due to our current or former research and development partners under collaborative agreements. These agreements typically cover multiple products, and give us the option to participate in development on a product-by-product basis. When we exercise our option with respect to a product, we pay our collaboration partner a fee and receive intellectual property rights to the product in exchange. We are also generally required to fund some or all of the development costs for the products that we select, and to make payments to our partners when those products reach development milestones.

We have entered into collaboration agreements under which we have rights to acquire products or technology from third parties through the acquisition of shares, loans, license agreements, joint development, co-marketing and other contractual arrangements. In addition to upfront payments on signature of the agreement, our contracts frequently require us to make payments contingent upon the completion of development milestones by our alliance partner or upon the granting of approvals or licenses.

Because of the uncertain nature of development work, it is impossible to predict (i) whether Sanofi will exercise further options for products, or (ii) whether the expected milestones will be achieved, or (iii) the number of compounds that will reach the relevant milestones. It is therefore impossible to estimate the maximum aggregate amount that Sanofi will actually pay in the future under existing collaboration agreements.

Given the nature of its business, it is highly unlikely that Sanofi will exercise all options for all products or that all milestones will be achieved.

The main collaboration agreements relating to development projects are described in Note D.21.1. to our consolidated financial statements included at Item 18 of this annual report. Milestone payments relating to development projects under these agreements included in the table above exclude projects still in the research phase ( 7.2 billion in 2017, 6.2 billion in 2016) and payments contingent upon the attainment of sales targets once a product is on the market ( 10.1 billion in 2017, 8.2 billion in 2016).

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

Item 6. Directors, Senior Management and Employees

**A. Directors and Senior Management**

Since January 1, 2007, Sanofi has separated the offices of Chairman and Chief Executive Officer. Successive annual evaluations conducted since that date have indicated that this governance structure is appropriate to Sanofi's current configuration. This arrangement was maintained with the appointment of Serge Weinberg to the office of Chairman firstly on May 17, 2010, then on May 6, 2011 and again on May 4, 2015. The Board of Directors regards this governance structure as appropriate to the current context.

The **Chairman** organizes and directs the work of the Board, and is responsible for ensuring the proper functioning of the corporate decision-making bodies in compliance with good governance principles. The Chairman coordinates the work of the Board of Directors with that of its Committees. He ensures that the Company's management bodies function properly, and in particular that the directors are able to fulfil their duties. The Chairman is accountable to the Shareholders' General Meeting, which he chairs.

In addition to these roles conferred by law, the Chairman:

in coordination with the Chief Executive Officer, liaises between the Board of Directors and the shareholders of the Company;

is kept regularly informed by the Chief Executive Officer of significant events and situations affecting the affairs of the Company, and may request from the Chief Executive Officer any information useful to the Board of Directors;

may, in close collaboration with the Chief Executive Officer, represent the Company in high-level dealings with governmental bodies and with key partners of the Company and/or of its subsidiaries, both nationally and internationally;

seeks to prevent any conflict of interest and manages any situation that might give rise to a conflict of interest. He also gives rulings, in the name of the Board, on requests to take up external directorships of which he may become aware or that may be submitted to him or her by a director;

may interview the statutory auditors in preparation for the work of the Board of Directors and the Audit Committee; and

strives to promote in all circumstances the values and image of the Company.

The Chairman is also required to develop and maintain a proper relationship of trust between the Board and the Chief Executive Officer, so as to ensure that the latter consistently and continuously implements the orientations determined by the Board.

In fulfilling his remit, the Chairman may meet with any individual, including senior executives of the Company, while avoiding any

involvement in directing the Company or managing its operations, which are exclusively the responsibility of the Chief Executive Officer.

Finally, the Chairman reports to the Board on the fulfilment of his remit.

An internal rule applied within Sanofi stipulates that a director cannot be appointed or reappointed once he or she has reached the age of 70. A resolution to incorporate that rule into our Articles of Association, bringing the situation of the Chairman of the Board into line with that of the other directors, will be submitted to the approval of the Annual General Meeting of May 2, 2018.

The **Chief Executive Officer** manages the Company, and represents it in dealings with third parties within the limit of the corporate purpose. The Chief Executive Officer has the broadest powers to act in all circumstances in the name of the Company, subject to the powers that are attributed by law to the Board of Directors and to the Shareholders General Meeting and within the limits set by the Board of Directors.

The Chief Executive Officer must be less than 65 years old.

### **Limitations on the powers of the Chief Executive Officer set by the Board**

With effect from March 6, 2018, the limitations on the powers of the Chief Executive Officer are specified in the Board Charter. Without prejudice to legal provisions regarding authorizations that must be granted by the Board (regulated agreements, guarantees, divestments of equity holdings or real estate, etc.), prior approval from the Board of Directors is required for transactions or decisions resulting in an investment or divestment, or an expenditure or guarantee commitment, made by the Company and its subsidiaries, in excess of:

a cap of 500 million (per transaction) for transactions, decisions or commitments pertaining to a previously approved strategy; and

a cap of 150 million (per transaction) for transactions, decisions or commitments not pertaining to a previously approved strategy.

When such transactions, decisions or commitments give rise to installment payments to the contracting third party (or parties) that are contingent upon future results or objectives, such as the registration of one or more products, attainment of the caps is calculated by aggregating the various payments due from signature of the contract until (and including) filing of the first application for marketing authorization in the United States or in Europe.

Attainment of the above caps is also assessed after taking into account all commitments to make payments on exercise of a firm

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

or conditional option with immediate or deferred effect, and all guarantees or collateral to be provided to third parties over the duration of such commitments.

The prior approval procedure does not apply to transactions and decisions that result in the signature of agreements that solely involve subsidiaries and the Company itself.

**Board of Directors**

Each year, the Board of Directors conducts a review to ensure that there is an appropriate balance in its composition and in the composition of its Committees. In particular, the Board seeks to ensure gender balance, a broad diversity of competencies and countries of origin, and international experiences, reflecting our status as a diversified global business. The Board investigates and evaluates not only potential candidates, but also whether existing directors should seek reappointment. Above all, the Board seeks directors who show independence of mind and are competent, dedicated and committed, with compatible and complementary personalities.

As of December 31, 2017 the Board of Directors had 16 members, including two directors representing employees. 44% of the directors were women and 38% were non-French nationals.

Subject to the powers expressly attributed to the Shareholders' General Meeting and within the scope of the Company's corporate purpose, the Board of Directors' remit covers all issues relating to the proper management of the Company, and through its decisions the Board determines matters falling within its authority.

The rules and operating procedures of our Board of Directors are defined by law, by our Articles of Association, and by our Board charter (an English language version of which is reproduced in full as Exhibit 1.2 to this Annual Report on Form 20-F).

**Term of office**

The term of office of directors is four years. Directors are required to seek reappointment by rotation, such that members of the Board are required to seek reappointment on a regular basis in the most equal proportions possible. Exceptionally, the Shareholders' Ordinary General Meeting may appoint a director to serve for a term of one, two or three years, in order to ensure adequate rotation of Board members. Each director standing down is eligible for reappointment. Should one or more directorships fall vacant as a result of death or resignation, the Board of Directors may make provisional appointments in the period between two Shareholders' General Meetings, in accordance with applicable laws.

Directors may be removed from office at any time by a Shareholders' General Meeting.

## Independence of Board Members

Under the terms of the AFEP-MEDEF corporate governance code (the AFEP-MEDEF Code), a director is independent when he or she has no relationship of any kind whatsoever with the Company, its group or its senior management that may color his or her judgment. More specifically, a director can only be regarded as independent if he or she:

is not (and has not been during the past five years):

an employee or executive officer of the Company;

an employee, executive officer or director of an entity consolidated by the Company; or

an employee, executive officer or director of the Company's parent, or of an entity consolidated by that parent (criterion 1);

is not an executive officer of an entity in which (i) the Company directly or indirectly holds a directorship or (ii) an employee of the Company is designated as a director or (iii) an executive officer of the Company (currently, or who has held office within the past five years) holds a directorship (criterion 2);

is not a customer, supplier, investment banker or corporate banker that is material to the Company or its group, or for whom the Company or its group represents a significant proportion of its business (criterion 3);

has no close family ties with a corporate officer of the Company (criterion 4);

has not acted as auditor for the Company over the course of the past five years (criterion 5);

does not represent a shareholder that has a significant or controlling interest in the Company (criterion 6); or

does not receive variable compensation in cash or in the form of shares or any compensation linked to the performance of the Company or its group (criterion 7).

The influence of other factors such as length of service on the Board, the ability to understand challenges and risks, and the courage to express ideas and form a judgment, is also evaluated before it is decided whether a director can be regarded as independent.

In compliance with our Board Charter and pursuant to the AFEP-MEDEF Code, the Board of Directors' meeting of March 6, 2018 discussed the independence of the current directors. Of the sixteen directors, eleven were deemed to be independent directors by reference to the independence criteria used by the Board of Directors pursuant to the AFEP-MEDEF Code: Serge Weinberg, Robert Castaigne, Bernard Charlès, Claudie Haigneré, Patrick Kron, Fabienne Lecorvaisier, Melanie Lee, Suet-Fern Lee, Carole Piwnica, Diane Souza and Thomas C. Südhof.





**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

Consequently, the proportion of independent directors is 79%. This compares with the AFEP-MEDEF recommendation of 50% in companies with dispersed ownership and no controlling shareholder (which is the case for Sanofi). In accordance with the recommendations of the AFEP-MEDEF Code, directors representing employees are excluded when calculating the proportion of independent directors.

	<b>Criterion 1</b>	<b>Criterion 2</b>	<b>Criterion 3<sup>(1)</sup></b>	<b>Criterion 4</b>	<b>Criterion 5</b>	<b>Criterion 6</b>	<b>Criterion 7</b>	<b>Less than 12 years on the Board</b>	<b>Status</b>
<b>Serge Weinberg</b>	No <sup>(2)</sup>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Robert Castaigne</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No <sup>(3)</sup>	Independent
<b>Bernard Charlès</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Claudie Haigneré</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Patrick Kron</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Fabienne Lecorvaisier</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Melanie Lee</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Suet-Fern Lee</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Carole Piwnica</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Diane Souza</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Thomas C. Südhof</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent

Failure to fulfil one of the criteria does not automatically disqualify a director from being independent.

The Board's conclusions on specific cases are set out below.

(1) Business Relationships Review

In its examination of the independence of each director, the Board of Directors took into account the various relationships between directors and Sanofi and concluded that no relationships were of a kind that might undermine their independence. The Board of Directors noted that the Company and its subsidiaries had, in the normal course of business, over the past three years, sold products and provided services to, and/or purchased products and received services from, companies in which certain of the Company's directors who are classified as independent (or their close family members) were senior executives or employees during 2017. In each case, the amounts paid to or received from such companies over the past three years were determined on an arm's length basis and did not represent amounts that the Board regarded as undermining the independence of the directors in question.

(2) Serge Weinberg

When the offices of Chairman of the Board and Chief Executive Officer were temporarily combined on October 29, 2014, the Board of Directors determined that Serge Weinberg – given his role as Chief Executive Officer – could no longer be regarded as independent. When the two offices were separated again in April 2015, the Board of Directors determined that Serge Weinberg could be regarded as independent and could therefore resume the chairmanship of the Appointments and Governance Committee.

Under Article 8.6 of the amended AFEP-MEDEF Code issued in November 2016, a non-executive officer cannot be regarded as independent if he or she receives variable compensation in cash or shares or any compensation linked to the performance of the

Company or group. This is consistent with recommendations made by the AMF in its 2017 report on corporate governance, executive compensation, internal control and risk management. Serge Weinberg complies with this criterion, in that he receives fixed compensation only, with no entitlement to variable compensation in either cash or shares.

(3) Robert Castaigne

The Board of Directors considers that the situation of Robert Castaigne has changed since his first appointment to the Board. Prior to 2012, Robert Castaigne had not been regarded as an independent director due to his past relationship with Total. Since April 2008, when the independence criteria of the AFEP-MEDEF Code were adopted, his situation has changed in two ways:

Robert Castaigne retired from Total more than four years ago;

Total passed below the 5% threshold of our voting rights (as per the notification of February 16, 2012). Later in 2012, Total ceased to have any equity interest in Sanofi.

Consequently, the Board of Directors took the view that Robert Castaigne's historical links with Total no longer created a presumption of non-independence.

Moreover, the Board of Directors does not believe that belonging to the Board for more than 12 years of itself disqualifies a director from being independent. The length of Board service criterion is intended to address the concern that the passage of time may deprive a director of his ability to challenge senior management. This is a legitimate concern, which Sanofi takes very seriously.

This is why the Board of Directors applies this criterion pragmatically in light of the specific circumstances of each case. In the case of Robert Castaigne, the Board considers that he has demonstrated great independence of mind, which is fundamentally what the AFEP-MEDEF criteria are seeking to ensure. For more

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

information see C. Board Practices – Application of the AFEP-MEDEF Code , below.

Finally, there was no other factor calling into question Robert Castaigne’s independence.

Consequently, the Board determined on that basis, at its meeting of May 4, 2012 and upon the recommendation of its Appointments and Governance Committee, that Robert Castaigne qualified as an independent director. That position was reiterated at the Board meeting of March 6, 2018.

This decision has no effect on compliance with the independence rules of the AFEP-MEDEF Code, which is the main objective of the Code. The fact that the proportion of independent directors on the Board is 79% demonstrates that the Board in no way underestimates the importance of having a majority of independent directors in its governance.

Robert Castaigne’s term of office expires at the Annual General Meeting of May 2, 2018, and he will not be proposed for reappointment. That decision has been taken pursuant to an internal rule whereby a director cannot be appointed or reappointed once he or she has reached the age of 70. That rule was previously applied on the expiry of the terms of office of other Sanofi directors, namely Klaus Pohle, Igor Landau, Jean-René Fourtou and Uwe Bicker. In the interests of clarity and transparency, a resolution to amend our Articles of Association to incorporate that rule will be submitted to the Annual General Meeting of May 2, 2018 for approval.

**Board evaluation**

Under the terms of the Board Charter, a discussion of the Board’s operating procedures must be included on the agenda of one Board meeting every year. The Charter also requires a formal evaluation to be performed every three years under the direction of the Appointments and Governance Committee, with assistance from an independent consultant if deemed necessary.

In 2016, the evaluation was conducted using a questionnaire, supplemented by subsequent meetings between some directors and the Secretary to the Board. The results were presented at the Board meeting of March 2, 2017, with the directors welcoming the progress made since the previous evaluation.

The 2017 Board evaluation was again based on a questionnaire, containing more than one hundred questions. Each director was allowed a few weeks to complete the questionnaire using a secure digital platform. The responses were then analyzed by the Secretary to the Board, and supplemented by one-on-one interviews. The results were presented to, and discussed by, the Appointments and Governance Committee. A detailed report prepared at that meeting was

presented at the Board meeting of March 6, 2018.

Once again, directors welcomed the improvements in how the Board and its Committees operate since the previous evaluation: meetings were well prepared, the time spent on meetings has been

better used, discussions were lively and decisions taken by the Board rigorously followed up. The Board also appreciated the addition of further high-level scientific and pharmaceutical expertise to the Board, coupled with further progress on increasing the proportions of non-French and female directors.

Finally, the directors judged the current governance structure (separation of the office of Chairman of the Board from that of Chief Executive Officer) to be appropriate to the Company's needs and to be working effectively.

The issues most frequently raised in the evaluation were the diversity and complementarity of the Board following the appointment of the new directors, the role of the Committees, executive sessions, an update on the implementation of the Company's digital strategy, and implementation of the external growth strategy.

The areas for progress and vigilance identified by the Board in the latest evaluation were:

continuing to work on succession planning for the Chief Executive Officer and key executive posts;

closer monitoring of the principal risks facing Sanofi;

deeper understanding of changes in the industry environment (markets and competition), and the potential implications for Sanofi;

deeper strategic thinking;

ex post assessment of the impact of strategic decisions, especially acquisitions;

preparation of more detailed reports by the Appointments and Governance Committee;

increase in the number of executive sessions.

With the terms of office of some directors coming up for renewal in 2018, their contribution to the work of the Board and its Committees was assessed and in each case was judged to have met the Group's needs and to have been in line with its expectations. More generally, the Board found that directors had once again demonstrated strong commitment and were working well together. The diversity of their competencies, expertise and profiles contributed significantly to the quality of the work done by the Board and its Committees.

### Succession planning

The remit of the Appointments and Governance Committee includes preparing for the future of the Company's executive bodies, in particular through the establishment of a succession plan for executive officers.

This plan, which is regularly reviewed, addresses three scenarios:

unplanned vacancy due to prohibition, resignation or death;

forced vacancy due to poor performance, mismanagement or misconduct; and

planned vacancy due to retirement or expiration of term of office.

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

Through its work and discussions, the Committee seeks to devise a succession plan that is adaptable to situations arising in the short, medium or long term.

Although aware that separating the offices of Chairman and Chief Executive Officer provides continuity of power, the Committee nonetheless assesses the situation of the Chairman as well as that of the executive team.

To fulfill its remit, the Appointments and Governance Committee:

provides the Board with progress reports, in particular at executive sessions, so as to ensure that the Committee's work is consistent with the Company's strategic ambitions;

co-ordinates with the Compensation Committee. In that regard, having directors that sit on both Committees is a great advantage;

works closely with the Chief Executive Officer to (i) ensure the plan is consistent with the Company's own practices and market practices, (ii) ensure high-potential internal prospects receive appropriate support and training, and (iii) check there is adequate monitoring of key posts likely to fall vacant;

meet with key executives as needed; and

involve the Chief Executive Officer insofar as he has a key role in planning for his own successor, though without him directing the process.

In fulfilling their remit, Committee members are acutely conscious of confidentiality issues.

**Composition of the Board of Directors as of December 31, 2017**



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As of December 31, 2017, our Board of Directors comprised:

Director	Age	Gender	Nationality	First appointed	Term expires	Years of Board service	AC	AGC	CC	SC
Serge Weinberg, Chairman of the Board <sup>(a)</sup>	66	M	French	2009	2019 AGM	8		C		C
Olivier Brandicourt, Chief Executive Officer	61	M	French	2015	2018 AGM	2				
Laurent Attal	59	M	French	2012	2020 AGM	5				
Robert Castaigne <sup>(a)</sup>	71	M	French	2000	2018 AGM	17	C			
Bernard Charlès <sup>(a)</sup>	60	M	French	2017	2021 AGM	1				
Claudie Haigneré <sup>(a)</sup>	60	F	French	2008	2020 AGM	9				
Patrick Kron <sup>(a)</sup>	64	M	French	2014	2018 AGM	3			C	
Fabienne Lecorvaisier <sup>(a)</sup>	55	F	French	2013	2021 AGM	4				
Melanie Lee <sup>(a)</sup>	59	F	British	2017	2021 AGM	1				
Suet-Fern Lee <sup>(a)</sup>	59	F	Singaporean	2011	2019 AGM	6				
Christian Mulliez	57	M	French	2004	2018 AGM	13				
Marion Palme <sup>(b)</sup>	35	F	German	2017	2021 AGM	1				
Carole Piwnica <sup>(a)</sup>	59	F	Belgian	2010	2020 AGM	7				
Christian Senectaire <sup>(b)</sup>	53	M	French	2017	2021 AGM	1				
Diane Souza <sup>(a)</sup>	65	F	American	2016	2020 AGM	2				
Thomas C. Südhof <sup>(a)</sup>	62	M	German/American	2016	2020 AGM	2				

**Independent directors**  
79%

**Female directors**  
44%

**Non-French directors**  
38%

*AC: Audit Committee*

*AGC: Appointments and Governance Committee*

*CC: Compensation Committee*

*SC: Strategy Committee*

*C: Chairman*

*(a) Independent director*

*(b) Director representing employees*

**138**

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Competencies of Board members**

The Board of Directors, in liaison with the Appointments and Governance Committee, must ensure that the composition of the Board is balanced, diverse and fit for purpose.

In assessing its composition, the Board takes account of the corporate strategy, and of the new challenges facing the Company, and determines whether the qualities of serving directors are sufficient for the Board to deliver on its remit.

Over the past two years, the Board has altered its composition in line with its roadmap by:

bringing additional scientific expertise onto the Board;

further raising the proportion of non-French directors;

increasing the proportion of women on the Board; and

developing its competencies in digital.

The Board has completed an overview of the key competencies currently represented. The matrix below shows a comprehensive, balanced spread of the types of competencies required, both in general terms and by reference to our strategic ambitions (the matrix shows the number of directors possessing each of those competencies)<sup>(1)</sup>:

The Annual General Meeting of May 2, 2018 will be asked to reappoint Olivier Brandicourt, Patrick Kron, and Christian Mulliez as directors. To maintain the level of Board expertise in accounting and financial matters, and given that Robert Castaigne's term of office will not be renewed, the shareholders will also be asked to approve the appointment of Emmanuel Babeau as a new director.

The following pages provide key information about each director individually:

directorships and appointments held during 2017 (directorships in listed companies are indicated by an asterisk, and each director's principal position is indicated in bold);

other directorships held during the last five years; and

education, training and professional experience.

*(1) The information shown excludes directors representing employees.*

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Serge Weinberg**

Date of birth:	February 10, 1951
Nationality:	French
First appointed:	December 2009
Last reappointment:	May 2015
Term expires:	2019
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Serge Weinberg****Within the Sanofi Group****Outside the Sanofi Group****Current directorships In French companies and appointments**

Chairman of the Board of Directors of Sanofi\*

**Chairman of Weinberg Capital Partners**

Chairman of the Strategy Committee of Sanofi

Chairman of Financière Piasa, Piasa Holding and Maremma  
Manager of Alret

Chairman of the Appointments and Governance Committee of Sanofi

Director of Madrigall

**In foreign companies**

None

None

**Past directorships****In French companies**

None

Director of Alliance Automotive Participations SAS (until 2014) and Schneider Electric\* (until 2014)

**expiring within the last five years**

Member of the Supervisory Board of Financière BFSA (until 2013), and Schneider Electric\* (until 2013)  
Weinberg Capital Partners permanent representative on the Board of Sasa Industrie (until 2013)  
Vice Chairman and Director of Financière Sasa (until 2016)  
Chairman of the Supervisory Board of Financière Climater SAS  
Chairman of the Supervisory Board of Tess SAS

**In foreign companies**

None

Chairman of Corum (Switzerland, until 2013)

**Education and business experience**

Graduate in law, degree from the *Institut d Etudes Politiques*

Graduate of ENA (*Ecole Nationale d Administration*)

Since 2005

**Chairman of Weinberg Capital Partners**

1976-1982

*Sous-préfet* and then Chief of Staff of the French Budget Minister (1981)

1982-1987

Deputy General Manager of FR3 (French television channel) and then Chief Executive Officer of Havas Tourisme

1987-1990

Chief Executive Officer of Pallas Finance

1990-2005

Various positions at PPR\* group including Chairman of the Management Board for 10 years

2006-2009

Chairman of the Board of Accor\*

2005-2010

Vice Chairman of the Supervisory Board of Schneider Electric\*

**Number of shares held**

1,636 shares

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Olivier Brandicourt**

Date of birth:	February 13, 1956
Nationality:	French
First appointed:	April 2015
Term expires:	2018
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Olivier Brandicourt**

<b>Within the Sanofi Group</b>	<b>Outside the Sanofi Group</b>
--------------------------------	---------------------------------

**Current directorships In French companies and appointments**

**Chief Executive Officer of None Sanofi\***

Chairman of the Executive Committee of Sanofi  
Member of the Strategy Committee of Sanofi

President of Sanofi Biotechnology SAS

**In foreign companies**

None

Member of the Board of Management of the Pharmaceutical Research and Manufacturers of America (PhRMA, United States)

Member of the Council of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA, Switzerland)

Member and Vice-President of the European Federation of Pharmaceutical

Industries and Associations (EFPIA, Brussels)  
 Member of the National Committee on US-China Relations (United States)  
 Honorary Member of the Royal College of Physicians (United Kingdom)

**Past directorships expiring within the last five years**

**In French companies**

None

None

**In foreign companies**

None

Bayer Group (Germany):  
 Chief Executive Officer and Chairman of the Executive Committee of Bayer HealthCare AG (until 2015)  
 Member of the Executive Council of Bayer AG\* (until 2015)  
 Member and Vice-Chair of the Board of Trustees of the Children's Aid Society of New York (United States)

**Education and business experience**

Degree in Medical Mycology, Pasteur Institute, France

Masters in Human Biology, Paris XII University, France

Medical Degree with subspecialty in Infectious Diseases and Tropical Medicine, Paris V University, France

1979-1981	National Service with the <i>Office de la recherche scientifique et technique outre-mer</i> (ORSTOM) (Republic of Congo)
1981-1987	Research Fellow and Hospital & University Assistant in the Department of Parasitology, Tropical Medicine and Public Health at the Pitié-Salpêtrière Hospital (France)
1987-2000	Various operational and commercial positions at Warner-Lambert/Parke-Davis, including Vice-President and General Manager (1998-2000)
2000-2013	Various operational and managerial positions at Pfizer Inc.*, including member of the Executive Leadership Team (2010-2013) and President & General Manager Emerging Markets & Established Business Unit (2012-2013)
2013-2015	Chief Executive Officer and Chairman of the Executive Committee of Bayer HealthCare AG and Member of the Executive Council of Bayer AG*

**Number of shares held**

1,000 shares



**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Laurent Attal**

Date of birth:	February 11, 1958
Nationality:	French
First appointed:	May 2012
Last reappointment:	May 2016
Term expires:	2020
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Laurent Attal**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships and appointments**

Director of Sanofi\*  
Member of the Strategy Committee of Sanofi

Director of *Fondation d'Entreprise L'Oréal*

**In foreign companies**

None

None

**Past directorships expiring with the last five years**

**In French companies**

None

None

**In foreign companies**

None

None

**Education and business experience**

Doctor of medicine, dermatologist

MBA from INSEAD (*Institut Européen d'Administration des Affaires*)

Since 1986

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Various positions within the L'Oréal\* Group, including posts within the active cosmetics division and as President and Chief Executive Officer of L'Oréal USA (United States)

Since 2002  
Since 2010

Member of the Executive Committee of L'Oréal\*

**Vice-President General Manager Research and Innovation at L'Oréal\***

**Number of shares held**

1,000 shares

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Robert Castaigne**

Date of birth:	April 27, 1946
Nationality:	French
First appointed:	February 2000
Last reappointment:	May 2014
Term expires:	2018
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Robert Castaigne**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships In French companies and appointments**

Independent director of Sanofi*	Société Générale*:
---------------------------------	--------------------

Chairman of the Audit Committee of Sanofi

Director

Member of the Audit and Internal Control Committee

Member of the Nomination Committee

Vinci\* :

Director

Member of the Audit Committee

Chairman of the Remuneration Committee

**In foreign companies**

None	Novatek* (Russia):
	Director
	Member of the Audit Committee
	Member of the Remuneration and Nomination Committee

**Past directorships  
expiring within the  
last five years**

<b>In French companies</b>
None
<b>In foreign companies</b>
None

None
None

**Education and business experience**

	Degree from <i>École Centrale de Lille</i> and <i>École Nationale Supérieure du Pétrole et des Moteurs</i>
	Doctorate in economics
1972-2008	Various positions at the Total* group, including Chief Financial Officer and member of the Executive Committee (1994-2008)
2007-2011	Director and member of the Audit Committee of <i>Compagnie Nationale à Portefeuille</i> (Belgium)

**Number of shares held**

1,000 shares

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Bernard Charlès**

Date of birth:	March 30, 1957
Nationality:	French
First elected:	May 2017
Term expires:	2021
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Bernard Charlès**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships and appointments In French companies**

Independent director of Sanofi\*

**Vice-Chairman of the Board of Directors and Chief Executive Officer of Dassault Systèmes SE\***

**In foreign companies**

None

Dassault Systèmes group:

Chairman of the Board of Directors of Dassault Systemes Corp., Dassault Systemes SolidWorks Corp., Dassault Systemes Simulia Corp. and Dassault Systemes Biovia Corp. (United States)

Chairman of the Advisory Board of Dassault Systemes 3DExcite GmbH (Germany)

**Past directorships  
expiring within the  
last five years**

**In French companies**

None

None

**In foreign companies**

Dassault Systèmes group:

Chairman of the Board of Directors of Dassault Systemes Delmia Corp., Dassault Systemes Enovia Corp. (Germany) and Dassault Systemes Canada Software Inc. (Canada)

None

Chairman of the Supervisory Board of RealTime Technology AG (Germany)

**Education and business experience**

Graduate of *École Normale Supérieure* engineering school, Cachan (France)

*Agrégé* and Ph.D. in mechanical engineering majoring in automation engineering and information science

Since 1995

Chief Executive Officer of Dassault Systèmes SE\* (France)

Since 2016

**Vice-Chairman of the Board of Directors and Chief Executive Officer of Dassault Systèmes SE\* (France)**

1983-1984

National Service as Scientific Advisor in the ministry of Defense (France)

1986-1988

Founder of the New Technology, Research and Strategy division at Dassault Systèmes SE\* (France)

1988-1994

Président Dassault Systèmes Research and Development (France)

2005

Knight of the *Légion d honneur* (France)

2009

Member of *Académie des Technologies* (France)

2012

Officer of the *Légion d honneur* (France)

2017

Member of the National Academy of Engineering United States of America (United States)

**Number of shares held**

0<sup>(a)</sup>

*(a) Under the Board Charter, each director must be a shareholder in a personal capacity and hold at least 1,000 Sanofi shares in their own name. However, directors are allowed a period of two years in which to acquire these shares.*

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Claudie Haigneré**

Date of birth:	May 13, 1957
Nationality:	French
First appointed:	May 2008
Last reappointment:	May 2016
Term expires:	2020
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Claudie Haigneré****Within the Sanofi Group****Outside the Sanofi Group****Current directorships and appointments In French companies**

Independent director of Sanofi\*

Director of *Fondation de l'Université de Lyon, Fondation C-Génial, Fondation d'Entreprise L'Oréal* and *Fondation*

Member of the Appointments and Governance Committee of Sanofi

*Lucoste*

Member of the Compensation Committee of Sanofi

Member of *Académie des Technologies, Académie des Sports, Académie Nationale de l'Air et de l'Espace* and *Académie des Sciences de l'Outre-Mer*

**In foreign companies**

None

None

**Past directorships expiring within the last five years****In French companies**

None

Director and member of the Innovation and Technology Committee of Orange\* (until 2016)

Chairwoman of Universcience (*Cité des Sciences et de l'Industrie et Palais de la Découverte*) (until 2015)

Director of *Fondation de France* (until 2015), *École Normale Supérieure* (until 2015), *Campus Condorcet* (until 2015), *Pôle de Recherche et d'Enseignement Supérieur Hautes-Études-Sorbonne-Arts-et-Métiers* (until 2015), and *Fondation Lacoste* (until 2016)

Chairwoman of the Board of Directors of *La Géode* (until 2015)

**In foreign companies**

None

None

**Education and business experience**

Rheumatologist, doctorate in sciences majoring in neurosciences  
 Selected in 1985 by the CNES (French National Space Center) as an astronaut candidate  
 1984-1992 Rheumatologist, Cochin Hospital (Paris)  
 1996 Scientific space mission to the MIR space station (Cassiopee, Franco-Russian mission)  
 2001 Scientific and technical space mission to the International Space Station (Andromède mission)  
 2002-2004 Deputy Minister for Research and New Technologies in the French government  
 2004-2005 Deputy Minister for European Affairs in the French government  
 2005-2009 Adviser to the Director General of the European Space Agency  
 2007-2011 Vice-Chairwoman (Finance) of the IAA (International Academy of Astronautics)  
 2010-2011 Director of *Aéro Club de France*  
 2010-2015 Chairwoman of Universcience (French public-sector body)  
 2015 Special Adviser to the Director General of the European Space Agency

**Number of shares held**

1,000 shares



**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Patrick Kron**

Date of birth:	September 26, 1953
Nationality:	French
First appointed:	May 2014
Term expires:	2018
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Patrick Kron**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships and appointments in French companies**

Independent director of Sanofi\*

Chairman of the Compensation Committee of Sanofi

Member of the Appointments and Governance Committee of Sanofi

Member of the Strategy Committee of Sanofi

**In foreign companies**

None

Director of Bouygues\*

Director of Lafarge-Holcim\*

Director of Halcor Metal Works\*

**Chairman of Truffle Capital SAS**

Chairman of PKC&I SAS

Permanent representative of PKC&I on the

Supervisory Board of Segula Technologies

Vice-President of the *Les Arts Florissants* choral group association

None

**Past directorships expiring within the**

**In French companies**

None

Alstom\*:

**last five years**

Chairman and Chief Executive Officer  
(until 2016)

Chairman of Alstom Resources  
Management (until 2015)  
Director of *Association Française des  
Entreprises Privées* (AFEP) (until 2015)

**In foreign companies**

None

Alstom\*:  
Director of Alstom UK Holdings Ltd.  
(United Kingdom, until 2012)

Director and Managing Director of Alstom  
Asia Pte. Ltd. (Singapore, until 2014)

**Education and business experience**

Degree from <i>École Polytechnique</i> and <i>École Nationale Supérieure des Mines de Paris</i>	
1979-1984	Various positions at the French Ministry of Industry, including as project officer at the <i>Direction régionale de l' Industrie, de la Recherche et de l' Environnement</i> (DRIRE) and in the Ministry's general directorate
1984-1988	Operational responsibilities in one of the Pechiney Group's biggest factories in Greece, then manager of the Greek subsidiary
1988-1993	Various senior operational and financial positions within the Pechiney Group
1993	Member of the Executive Committee of the Pechiney Group
1993-1997	Chairman and Chief Executive Officer of Carbone Lorraine
1995-1997	Manager of the Food and Health Care Packaging Sector at Pechiney, and Chief Operating Officer of American National Can Company in Chicago (United States)
1998-2002	Chief Executive Officer of Imerys
2003-2016	Chief Executive Officer, then Chairman and Chief Executive Officer, of Alstom*
Since 2016	<b>Chairman of Truffle Capital CAS</b>
Since 2016	Chairman of PKC&I SAS

**Number of shares held**

1,000 shares

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Fabienne Lecorvaisier**

Date of birth:	August 27, 1962
Nationality:	French
First appointed:	May 2013
Last reappointment:	May 2017
Term expires:	2021
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Fabienne Lecorvaisier**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships In French companies and appointments**

Independent director of Sanofi\*

Air Liquide Group\*:

Member of the Audit Committee

Director of Air Liquide International

Chairwoman and Chief Executive Officer of Air Liquide Finance

Director of Air Liquide Eastern Europe

**In foreign companies**

None

Air Liquide Group\*:

Executive Vice President of Air Liquide International Corporation

Director of American Air Liquide Holdings, Inc. and SOAEO

Manager of Air Liquide US LLC

**Past directorships  
expiring within the  
last five years**

**In French companies**

None

Air Liquide Group\*:

Director of Orkyn until May 2012

Director of Air Liquide France Industries until May 4,  
2016

Director of Aqualung International until October 2017

Director of Air Liquide Welding SA until October 2017

**In foreign companies**

None

Air Liquide Group\*:

Director of Air Liquide Japon (Japan, until 2013)

**Education and business experience**

Civil engineer, graduate of *Ecole Nationale des Ponts et Chaussées*

Since July 2017

**Executive Vice President, Chief Financial Officer and Executive Committee member of  
Air Liquide\***

Since 2008

Chief Financial Officer and Executive Committee member of Air Liquide\*

1985-1989

Member of the Corporate Finance Department, then Mergers and Acquisitions Department of  
Société Générale\*

1989-1990

Senior Banking Executive in charge of the LBO Department (Paris)/Corporate Finance  
Department (Paris and London) at Barclays

1990-1993

Assistant General Manager of Banque du Louvre, Taittinger Group

1993-2007

Various positions within Essilor\* including Group Chief Financial Officer (2001-2007) and  
Chief Strategy and Acquisitions Officer (2007-2008)

**Number of shares held**

1,000 shares

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Melanie Lee**

Date of birth:	July 29, 1958
Nationality:	British
First elected:	May 2017
Term expires:	2021
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Melanie Lee**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships and appointments**

**In French companies**  
Independent director of Sanofi\*

None

**In foreign companies**

None

Director of Think10 (United Kingdom)

**Past directorships expiring within the last five years**

**In French companies**

None

None

**In foreign companies**

None

Director of Syntaxin Ltd\* (United Kingdom, until 2013)  
Director of BTG plc\* (United Kingdom, until 2014)  
Non-executive director of Lundbeck A/S (Denmark, until 2015)

Director of NightstaRx Ltd. (United Kingdom, until 2016)

### Education and business experience

	Degree in Biology, University of York
	Ph.D. from the National Institute for Medical Research, London
Since 2013	Director and Consultant, Think10 (United Kingdom)
Since 2014	<b>Chief Scientific Officer, BTG plc* (United Kingdom)</b>
1988-1998	Senior Biologist and subsequently Research Unit Head, Receptor Systems at Glaxo/GlaxoWellcome (United Kingdom)
2004-2007	Chairwoman of the Board of Directors of Cancer Research Technology Ltd. (United Kingdom)
1998-2009	Executive Director of Research at Celltech plc., and subsequently Executive Vice President, Research and President New Medicines at UCB Celltech (United Kingdom)
2003-2011	Deputy Chairwoman of Cancer Research U.K. (United Kingdom)
2009-2013	Chief Executive Officer and Director of Syntaxin Ltd.* (United Kingdom)
2014	Founder of NightstaRx Ltd. (United Kingdom)
2011-2015	Non-executive director of Lundbeck A/S (Denmark)

### Number of shares held

0<sup>(a)</sup>

*(a) Under the Board Charter, each director must be a shareholder in a personal capacity and hold at least 1,000 Sanofi shares in their own name. However, directors are allowed a period of two years in which to acquire these shares.*

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Suet-Fern Lee**

Date of birth:	May 16, 1958
Nationality:	Singaporean
First appointed:	May 2011
Last reappointment:	May 2015
Term expires:	2019
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Suet-Fern Lee**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships In French companies and appointments**

Independent director of Sanofi\* Axa\*:

Director

Member of the Finance Committee  
Member of the Supervisory Board,  
Rothschild & Co\*

**In foreign companies**

None

Director of Stamford Corporate Services Pte Ltd (Singapore) and the World Justice Project (United States), Caldecott Inc. (Cayman Islands) and Morgan Lewis & Bockius LLP (United States)

**Past directorships expiring within the last five years**

**In French companies**

None

None

**In foreign companies**

None	<p>Director of Macquarie International Infrastructure Fund Ltd* (Bermuda, until 2015) and of the National Heritage Board (Singapore, until 2015)</p> <p>Chairwoman of the Board of Directors of the Asian Civilisations Museum (Singapore, until 2015)</p> <p>Director of Rickmers Trust Management Pte Ltd* (Singapore, until 2017)</p>
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### Education and business experience

	<p>Law degree from Cambridge University (1980)</p> <p>Admitted to the Bar in London (1981) and Singapore (1982)</p> <p><b>Director of Morgan Lewis &amp; Bockius Stamford LLP (formerly Morgan Lewis Stamford LLP, Singapore)</b></p> <p>Partner of Morgan Lewis &amp; Bockius LLP (United States)</p> <p>Chairwoman of the International Leadership Team, Morgan Lewis &amp; Bockius</p>
Since 2006	<p>Member of the Board of Trustees of Nanyang Technological University (Singapore)</p> <p>Member of the Accounting Advisory Board of National University of Singapore Business School (Singapore)</p>
Since 2007	<p>Member of the Advisory Committee of Singapore Management University School of Law (Singapore)</p>
Since 2014	<p>Member of the Senate and the Executive Committee of the Singapore Academy of Law where she also chairs the Committee on Legal Education and Studies (Singapore)</p> <p>Chairwoman of the Expert Panel of the Centre of Cross-Border Commercial Law in Asia of the Singapore Management University School of Law (Singapore)</p>
2010-2011	<p>President of the Inter-Pacific Bar Association</p>

### Number of shares held

1,000 shares



**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Christian Mulliez**

Date of birth:	November 10, 1960
Nationality:	French
First appointed:	June 2004
Last reappointment:	May 2014
Term expires:	2018
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Christian Mulliez**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships and appointments**

Director of Sanofi\*  
Member of the Audit Committee of Sanofi  
Member of the Compensation Committee of Sanofi

Chairman of the Board of Directors of Regefi  
Director of DG 17 Invest

**In foreign companies**

None

Director of L Oréal USA Inc. (United States) and The Body Shop International (United Kingdom)

**Past directorships expiring within the last five years**

**In French companies**

None

None

**In foreign companies**

None

Director of Galderma Pharma  
(Switzerland, until 2014)

**Education and business experience**

Degree from ESSEC (*École Supérieure des Sciences Économiques et Commerciales*)

Since 2003

**Executive Vice President, Chief Financial Officer of L'Oréal\***

1984-2002

Various positions at Synthélabo and then Sanofi-Synthélabo, including Vice President Finance

**Number of shares held**

1,525 shares

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Carole Piwnica**

Date of birth:	February 12, 1958
Nationality:	Belgian
First appointed:	December 2010
Last reappointment:	May 2016
Term expires:	2020
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Carole Piwnica**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships In French companies and appointments**

Independent director of Sanofi\*

Eutelsat Communications\*:

Member of the Audit Committee of Sanofi

Independent director

Chairwoman of the Nomination and Governance Committee

Rothschild & Co\*:

Independent member of the Supervisory Board

Member of the Audit Committee and the Strategy Committee

**In foreign companies**

None

**Director of Naxos UK Ltd (United Kingdom)**

Director of Big Red (United States),  
Elevance (United States) and i2O  
(United Kingdom)  
Director of Amyris Inc\* (United States)

**Past directorships  
expiring within the  
last five years**

**In French companies**

None

None

**In foreign companies**

None

Director of Louis Delhaize\* (Belgium,  
until 2013) and RecyCoal Ltd. (United  
Kingdom, until 2015)

**Education and business experience**

Degree in law, *Université Libre de Bruxelles*

Master of Laws, New York University

Admitted to the Bar in Paris and New York

Since 2006

**Founder Director of Naxos UK Ltd (United Kingdom)**

1985-1991

Attorney at Proskauer, Rose (New York) and Shearman & Sterling (Paris)  
with practice in mergers and acquisitions

1991-1994

General Counsel of Gardini & Associés

1994-2000

Chief Executive Officer of Amylum France, then Chairwoman of Amylum  
Group

1998-2004

Director of Spadel (Belgium)

1996-2006

Director of Tate & Lyle Plc (United Kingdom)

2000-2006

Director and Vice-Chairwoman of Tate & Lyle Plc for Governmental  
Affairs (United Kingdom)

1996-2006

Chairwoman of the Liaison Committee and director of the *Confédération  
Européenne des Industries Agro-Alimentaires* (CIAA)

2000-2006

Chairwoman of the Export Commission and director of the *Association  
Nationale des Industries Alimentaires* (ANIA)

2006-2009

Member of the Ethical Committee of Monsanto\* (United States)

1996-2010

Director of Toepfer GmbH (Germany)

2007-2010

Director of Dairy Crest Plc\* (United Kingdom)

2003-2011

Director, Chairwoman of the Corporate Responsibility Committee and  
member of the Compensation Committee of Aviva Plc\* (United Kingdom)

**Number of shares held**

1,000 shares

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Diane Souza**

Date of birth:	July 3, 1952
Nationality:	American
First elected:	May 2016
Term expires:	2020
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Diane Souza**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships and appointments In French companies**

Independent director of Sanofi\*

None

Member of the Compensation Committee of Sanofi

**In foreign companies**

None

Member of the Board of Directors of Farm Credit East (United States)

**Past directorships expiring within the last five years**

**In French companies**

None

None

**In foreign companies**

None

UnitedHealth Group:  
Member of the Board of Directors of Unimerica Insurance Company, Unimerica Life Insurance Company of New York, National Pacific Dental, Inc., Nevada

Pacific Dental, DBP Services of New York, IPA, Dental Benefits Providers of California, Inc., Dental Benefit Providers of Illinois, Inc., Dental Benefit Providers, Inc., Spectera, Inc. and Spectera of New York, IPA, Inc. (United States)

### Education and business experience

Degree in Accounting from University of Massachusetts  
Honorary doctorate in Business Studies from University of Massachusetts Dartmouth  
Certified Public Accountant  
Diploma in Dental Hygiene from Northeastern University, Forsyth School for Dental Hygienists

1979	Audit Staff Accountant at Price Waterhouse (United States)
1980-1988	Various positions at Deloitte Haskins & Sells, from Audit Staff Accountant to Senior Tax Manager-in-Charge (United States)
1988-1994	Various positions at Price Waterhouse from Audit Staff Accountant to Head of the Northeast Insurance Tax Region (United States)
1994-2006	Various positions at Aetna Inc. including Deputy Vice President Federal and State Taxes; Vice President and Chief Financial Officer, Large Case Pensions; Vice President and Head of Global Internal Audit Services; Vice President, National Customer Operations; and finally Vice President, Strategic Systems & Processes (United States)
2007-2008	Principal consultant at Strategic Business Solutions, LLC (United States)
2008-2014	Chief Operating Officer of OptumHealth Specialty Benefits (2008), then Chief Executive Officer of UnitedHealthcare Specialty Benefits (United States)

### Number of shares held

2,054 American Depository Receipts,  
equivalent to 1,027 shares

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Thomas C. Südhof**

Date of birth:	December 22, 1955
Nationality:	German and American
First elected:	May 2016
Term expires:	2020
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Thomas C. Südhof****Within the Sanofi Group****Outside the Sanofi Group****Current directorships In French companies**

<b>and appointments</b>	Independent director of Sanofi*	None
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**In foreign companies**

None	None
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**Past directorships In French companies**

<b>expiring within the last five years</b>	None	None
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**In foreign companies**

None	None
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**Education and business experience**

Degree in medicine from the Faculty of Medicine of the University of Göttingen (Germany)

Since 2008 **Avram Goldstein Professor of Molecular & Cellular Physiology, Neurosurgery, Psychiatry, and Neurology in the School of Medicine at Stanford University** (United States)

Since 1986 Investigator at the Howard Hughes Medical Institute (United States)

Since 2002 Co-founder and member of the Scientific Advisory Board of REATA Pharmaceuticals (United States)

Since 2011 Co-founder and member of the Scientific Advisory Board of Circuit Therapeutics, Inc. (United States)

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Since 2013	Member of the Review Board of Genentech Neuroscience (United States)
Since 2013	Member of the Scientific Advisory Board of the Shemyakin-Ovchinnikov Institute of Bio-Organic Chemistry (Russia)
Since 2014	Co-founder and member of the Scientific Advisory Board of Bluenobel, Inc. (China)
Since 2014	Member of the Scientific Advisory Board of Elysium, Inc. (United States)
Since 2014	Member of the Scientific Advisory Board of the Singapore National Research Foundation (Singapore)
Since 2014	Member of the Scientific Advisory Board of the Chinese Academy Institute of Biophysics (China)
Since 2014	Member of the Scientific Advisory Committee of the Institute of Cellular and Molecular Biology of A*Star (China)
Since 2016	Member of the Scientific Advisory Board of Simcere, Inc. (China)
Since 2017	Member of the Scientific Advisory Board of Abide (USA)
Since 2017	Member of the Scientific Advisory Board of C-Bridge (China)
Since 2017	Member of the Scientific Advisory Board of Cytodel, Inc. (USA)
Since 2017	Co-founder and member of the Scientific Advisory Board of Neucyte, Inc. (United States)
1978-1981	Research assistant at the Max Planck Institute for Biophysical Chemistry (Germany)
1979	Student on exchange clerkship program at Harvard Medical School (United States)
1981-1982	Intern at the University Hospital of Göttingen (Germany)
1983-1986	Postdoctoral Fellow, Dept. of Molecular Genetics, UT Southwestern Medical School (USA)
1986-2008	Professor and subsequently Chair of the Neuroscience Department at the University of Texas Southwestern Medical School (United States)
2008	Bernard Katz Prize of the Biophysical Society, jointly with Reinhard Jahn
2013	Nobel Prize for Physiology or Medicine, jointly with James Rothman and Randy Shekman
2013	Albert Lasker Prize for Basic Medical Research, jointly with Richard Sheller

### Number of shares held

1,024 American Depositary Receipts, equivalent to 512 shares<sup>(a)</sup>

*(a) Under the Board Charter, each director must be a shareholder in a personal capacity and hold at least 1,000 Sanofi shares in their own name. However, directors are allowed a period of two years in which to acquire these shares.*



**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Marion Palme**

Date of birth:	December 22, 1982
Nationality:	German
First elected:	May 2017
Term expires:	2021
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Marion Palme****Within the Sanofi Group****Outside the Sanofi Group****Current directorships and appointments**

Director representing employees of Sanofi

None

**In foreign companies**

None

Member of the German Industrial Union Mining, Chemistry, Energy (IG BCE) (Germany))

**Past directorships expiring within the last five years****In French companies**

Member of the European Works Council

None

**In foreign companies**

None

None

**Education and business experience**

Bachelor of Science in Chemical Engineering from Provdadis School of International Management and Technology (2011)

Since 2005

**Laboratory Technician at the Frankfurt site (Germany)**

2002-2005

Apprenticeship as a laboratory technician at the Frankfurt site (Germany)

**Number of shares held**

89(a)

*(a) In accordance with Article L.225-25 of the French Commercial Code, directors representing employees are exempt from the obligation to hold shares.*

**154**

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Christian Senectaire**

Date of birth:	October 9, 1964
Nationality:	French
First elected:	May 2017
Term expires:	2021
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Christian Senectaire**

	<b>Within the Sanofi Group</b>	<b>Outside the Sanofi Group</b>
<b>Current directorships and appointments</b>	<p><b>In French companies</b></p> <p>Director representing employees of Sanofi</p> <p>Member of the Supervisory Board of the Sanofi Group Savings Scheme (PEG)</p> <p>Member of the Supervisory Board of the Sanofi Group Collective Retirement Savings Plan (PERCO)</p> <p><b>In foreign companies</b></p> <p>None</p>	<p>SAS Laboratoires Pichot: Member of the Compensation and Disclosure Committee</p>
<b>Past directorships expiring within the last five years</b>	<p><b>In French companies</b></p> <p>Alternate member of the Works Council at the Vertolaye site and of the Sanofi Chimie Works Council</p> <p>Titular member and Secretary of the Sanofi Group Works Council</p>	<p>None</p>

Central Delegate for the CFDT  
union, Sanofi Chimie

Deputy Group Delegate for the  
CFDT union, Sanofi France

**In foreign companies**

None

None

**Education and business experience**

Since 1987

Staff representative on the CFDT ticket (France)

Since 2009

Senior production technician at the Vertolaye site (France)

1985-2009

Chemical industry machine operator at the Neuville site and then the  
Vertolaye site (France)

**Number of shares held**

118<sup>(a)</sup>

*(a) In accordance with Article L.225-25 of the French Commercial Code, directors representing employees are exempt from the obligation to hold shares.*

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Changes in the composition of the Board of Directors in 2017**

The composition of the Board of Directors changed during 2017 with the appointment of four new directors to the Board including two directors representing employees to the Board, by early application of the French Social Dialogue and Employment Act of August 17, 2015.

The table below shows changes in the composition of the Board of Directors during 2017, and the changes that will be submitted for approval at the Annual General Meeting of May 2, 2018:

	<b>Annual General Meeting of May 10, 2017</b>	<b>Annual General Meeting of May 2, 2018</b>
<b>Expiry of term of office</b>	None	Robert Castaigne (independent director)
<b>Renewal of term of office</b>	Fabienne Lecorvaisier (independent director)	Olivier Brandicourt Christian Mulliez
<b>Proposed new appointments</b>	Bernard Charlès (independent director) Melanie Lee (independent director)	Patrick Kron (independent director) Emmanuel Babeau (independent director)
<b>Other changes</b>	Marion Palme (director representing employees) <sup>(a)</sup> Christian Senectaire (director representing employees) <sup>(b)</sup>	None

*(a) Designated by the European Works Council.*

*(b)*

*Designated by the trade union body which is the most representative, within the meaning of the applicable legislation, in the Company and those of its direct or indirect subsidiaries that have their registered office in French territory.*

If the terms of office mentioned above are renewed and Emmanuel Babeau is appointed to the Board, there would be no change in the number of Board members (16). The proportion of independent directors (79%) and female directors (44%), calculated using currently applicable rules, would not change either.

As of December 31, 2017, the members of our Board of Directors collectively held (directly, or via the employee share ownership fund associated with the Group savings scheme) 12,907 of our shares, representing 0.0010% of our share capital.

As of December 31, 2017, no corporate officer has been the subject of any conviction or court order, or been associated with any bankruptcy or winding-up order. As of this day, there is no potential conflict of interest between any corporate officer and Sanofi.

Under current French legislation, and given that employees own less than 3% of our share capital, the Board does not include a director representing employee shareholders.

### **Executive Committee**

The Executive Committee is chaired by the Chief Executive Officer. The Committee meets at least twice a month. During 2017, Peter Guenter and David P. Meeker left the Executive Committee and Stefan Oelrich, Executive Vice President, Diabetes and Cardiovascular, and Bill Sibold, Executive Vice President, Sanofi Genzyme, became member of it.

As of December 31, 2017, the Executive Committee had 14 members.

The list below shows all 15 permanent members of our Executive Committee as of the date of publication of this Annual Report on Form 20-F.

**Olivier Brandicourt**, Chief Executive Officer;

**Dominique Carouge**, Executive Vice President, Business Transformation;

**Olivier Charmeil**, Executive Vice President and General Manager, General Medicines and Emerging Markets;

**Jérôme Contamine**, Executive Vice President, Chief Financial Officer;

**Karen Linehan**, Executive Vice President, Legal Affairs and General Counsel;

**David Loew**, Executive Vice President, Sanofi Pasteur;

**Philippe Luscan**, Executive Vice President, Global Industrial Affairs;

**Alan Main**, Executive Vice President, Consumer HealthCare;

**Muzammil Mansuri**, Executive Vice President, Strategy and Business Development;

**Ameet Nathwani**, Executive Vice President, Medical Affairs;

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Stefan Oelrich**, Executive Vice President and General Manager, Diabetes & Cardiovascular;

**Roberto Pucci**, Executive Vice President, Human Resources;

**Bill Sibold**, Executive Vice President, Sanofi Genzyme;

**Kathleen Tregoning**, Executive Vice President, External Affairs;

**Elias Zerhouni**, President, Global Research and Development.

The name, business address, present principal occupation or employment and material occupations, positions, offices or employment for the past five years of each of the executive officers of Sanofi are set forth below. The business address and phone number of each such executive officer is c/o Sanofi, 54 rue La Boétie, 75008 Paris, France, +33 1 53 77 40 00.

**Olivier Brandicourt**

*Chief Executive Officer*

Date of birth: February 13, 1956

Olivier Brandicourt was appointed Chief Executive Officer on April 2, 2015, and is also a member of our Strategy Committee.

For additional information regarding his professional education and business experience see Competencies of Board members above.

**Dominique Carouge**

*Executive Vice President, Business Transformation*



Date of birth: March 17, 1961

Dominique Carouge is a graduate of *Ecole Supérieure de Commerce de Reims*. He also holds an *expertise comptable* (CPA) qualification in France, as well as a Corporate Governance and Board management certificate from Sciences Po (*Certificat d Administrateur de Sociétés*).

Dominique Carouge started his career in 1985 as an external auditor at Ernst & Young (EY) both in France (Paris) and in the US (Philadelphia). He joined Sanofi in 1991. Since then and for the past 27 years, he has held various finance positions of increasing responsibility and leadership across Australia, New Zealand, Germany and France. In 1991, he joined Roussel Uclaf where he held a positions of increasing seniority in finance. In 1996, he was appointed Chief Financial Officer for Hoechst Marion Roussel in Australia. From 1999 to 2002, he was in charge of Business Planning and Reporting at Aventis Pharma in Frankfurt, Germany. In 2003, he was appointed Operations Controller for the Aventis Group.

In 2005, Dominique Carouge became Chief Financial Officer for the Vaccines division.

From 2009 to 2011, he held the role of VP, Chief Strategy and Finance Officer for Sanofi Pasteur, and then Vice-President, Administration & Management for Global R&D from 2011 to 2016.

On January 1, 2016, he was appointed Deputy CFO and Head of Finance Operations and Group Controlling.

He was appointed to his present position in January 2018 with an effective date of February 15, 2018.

Dominique Carouge is a citizen of France.

### **Olivier Charmeil**

#### ***Executive Vice President, General Medicines and Emerging Markets***

Date of birth: February 19, 1963

Olivier Charmeil is a graduate of HEC (*Ecole des Hautes Etudes Commerciales*) and of the *Institut d Etudes Politiques* in Paris. From 1989 to 1994, he worked in the Mergers & Acquisitions department of Banque de l Union Européenne. He joined Sanofi Pharma in 1994 as head of Business Development. Subsequently, he held various positions within the Group, including Chief Financial Officer (Asia) of Sanofi-Synthélabo in 1999 and Attaché to the Chairman, Jean-François Dehecq, in 2000, before being appointed as Vice President, Development within the Sanofi-Synthélabo International Operations Directorate, where he was responsible for China and support functions. In 2003, Olivier Charmeil was appointed Chairman and Chief Executive Officer of Sanofi-Synthélabo France, before taking the position of Senior Vice President, Business Management and Support within the Pharmaceutical Operations Directorate. In this role, he piloted the operational integration of Sanofi-Synthélabo and Aventis. He was appointed Senior Vice President Asia/Pacific, Pharmaceutical Operations in February 2006; Operations Japan reported to him from January 1, 2008, as did Asia/Pacific and Japan Vaccines from February 2009. On January 1, 2011, Olivier Charmeil was appointed Executive Vice President Vaccines, and joined our Executive Committee.

In May, 2015, Olivier Charmeil and André Syrota were appointed as Co-Leaders of *Medicine of the Future*, an initiative developed by the French Minister for Economy, Industry and Digital Affairs, the French Minister for Social Affairs, Health and Women's Rights and the French Minister for National and Higher Education and Research. They have been tasked with assembling a group of industrialists and academics, with the objective of imagining how French industry can accelerate the launch and export of innovative industrial products, with an emphasis on new biotechnologies.

On June 1, 2016, Olivier Charmeil was appointed Executive Vice President and General Manager of our General Medicines and Emerging Markets Global Business Unit.

Olivier Charmeil is a citizen of France.

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Jérôme Contamine**

***Executive Vice President, Chief Financial Officer***

Date of birth: November 23, 1957

Jérôme Contamine is a Graduate of *École Polytechnique (X)*, ENSAE (*École Nationale de la Statistique et de l'Administration Économique*), and ENA (*Ecole Nationale d'Administration*). After four years at the *Cour des Comptes* as a Senior State General Auditor, he joined Elf Aquitaine in 1988 as advisor to the Chief Financial Officer, and became Group Finance and Treasury Director in 1991. He became the General Manager of Elf Petroleum Norway in 1995, after being named Deputy Vice President of Elf Upstream Division for Europe and the US. In 1999, he was appointed as a member of the taskforce for integration with Total, in charge of the reorganization of the merged entity, TotalFinaElf, and in 2000 became Vice President Europe and Central Asia, Upstream Division of Total. The same year, he joined Veolia Environnement as CFO and Deputy General Manager. In 2003, he was appointed Vice-President Senior Executive, Deputy Chief Executive Officer, Financial Director of Veolia Environnement. Since 2006 he has been a director of Valeo. Jérôme Contamine joined Sanofi as Executive Vice President, Chief Financial Officer (CFO) in March 2009.

Jérôme Contamine is a citizen of France.

**Karen Linehan**

***Executive Vice President, Legal Affairs and General Counsel***

Date of birth: *January 21, 1959*

Karen Linehan graduated from Georgetown University with Bachelor of Arts and Juris Doctorate degrees. Prior to practicing law, Ms. Linehan served on the congressional staff of the Speaker of the US House of Representatives from September 1977 to August 1986. Until December 1990, she was an Associate in a mid-size law firm in New York. In January 1991, she joined Sanofi as Assistant General Counsel of its US subsidiary. In July 1996, Ms. Linehan moved to Paris to work on international legal matters within Sanofi and she has held a number of positions within the Legal Department, most recently as Vice President Deputy Head of Legal Operations. She was appointed to her current

position in March 2007.

Karen Linehan is a citizen of the United States of America and Ireland.

### **David Loew**

*Executive Vice President, Sanofi Pasteur*

Date of birth: March 20, 1967

David Loew has a degree in Finance and Marketing and an MBA from the University of St. Gallen in Switzerland.

He started his career in the United States at Coopers & Lybrand and Hewlett Packard in 1990, before joining Roche in 1992. Over the next 21 years, David held a variety of positions with Roche including Global Oncology Head, General Manager Switzerland, Global Chief Marketing Officer & Head of Global Product Strategy, and Region Head Eastern Europe, Middle East and Africa for the Pharma Division of Roche.

David joined Sanofi in July 2013 as Senior Vice President Commercial Operations Europe and became Head of Global Commercial Operations at Sanofi Pasteur in January 2016. He was the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) representative on the Board of the Global Alliance for Vaccines and Immunization (GAVI). He also chaired the Steering Committee of IFPMA, comprising the CEOs of the member companies (GSK, Merck, Johnson & Johnson, Pfizer, Takeda, Novartis and Daiichi Sankyo), until July 2017.

He was appointed to his current position on June 1, 2016.

David Loew is a citizen of Switzerland.

### **Philippe Luscan**

*Executive Vice President, Global Industrial Affairs*

Date of birth: April 3, 1962

Philippe Luscan is a graduate of the *École Polytechnique (X)* and the *École Nationale Supérieure des Mines de Paris* in Biotechnology. He began his career in 1987 as a Production Manager at Danone. In 1990, he joined Sanofi as Director of the Sanofi Chimie plant at Sisteron, France, and subsequently served as Industrial Director of Sanofi in the United States, as Vice President Supply Chain and as Vice President Chemistry from September 2006. He was appointed to his present position in September 2008. From January 2015 to September 2017, he was also Chairman of Sanofi in France.

Philippe Luscan is a citizen of France.

### **Alan Main**

*Executive Vice President, Consumer Healthcare*

Date of birth: July 3, 1963

Alan Main has a BA (Hons) in International Marketing from Thames Polytechnic in London, and has completed various executive and leadership development programs at London, Harvard and Columbia Business Schools, as well as INSEAD (Asia).

Alan has more than 30 years of marketing and general management experience in the Consumer Health and Medical Device fields, initially with Stafford Miller/Block Drug (now part of GSK). He then moved to Merrell Dow (now part of Sanofi) and London Rubber Company. In 1992, he joined Roche Consumer Health where he took on positions of increasing responsibility in the

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

United Kingdom, South Africa and the Asia-Pacific region. Following the acquisition of Roche Consumer Health by Bayer in 2004, Alan continued to occupy key management roles, including Region Head for Asia Pacific and Europe. In 2010 Alan transferred to the medical device business of Bayer as Global President for Bayer Medical Care.

He was appointed to his present position in October 2016.

Alan Main is a citizen of the United Kingdom.

**Muzammil Mansuri**

***Executive Vice President, Strategy and Business Development***

Date of birth: *January 20, 1954*

Muzammil Mansuri holds a Bachelor of Science degree in Chemistry and a Ph.D. in Organic Chemistry from University College London. He held post-doctoral positions at the University of California, Los Angeles (UCLA) and Columbia University. He started his career in 1981 with Shell Research Limited where he began as a research scientist. After Shell, he spent several years with Bristol-Myers Company in various R&D roles with increasing responsibility. From 2007 to 2010, he was Chairman and CEO at CGI Pharmaceuticals. Before joining Sanofi, Muzammil's most recent position was Senior Vice President, Research & Development Strategy and Corporate Development at Gilead Sciences. He was appointed to his current position in February 2016.

Muzammil Mansuri is a citizen of the United States of America and the United Kingdom.

**Ameet Nathwani**

***Executive Vice President, Medical Affairs***

Date of birth: October 5, 1963

Dr. Nathwani was born in Uganda and studied in the United Kingdom. He qualified in medicine in 1987 in London, and acquired his specialization in Cardiology at a number of University Hospitals in London. He also has a diploma in Pharmaceutical Medicine and an executive Masters in Business Administration.

Dr. Nathwani has more than twenty years' experience in the pharmaceutical industry, beginning in 1994 when he joined Glaxo Group Research. Between 1994 and 2004 he held increasingly senior functional and franchise leadership roles in research and development in Glaxo, SmithKline Beecham and GlaxoSmithKline, in Europe and the US. He joined Novartis in 2004 as Senior Vice President and Global Development Head of the Cardiovascular and Metabolic Franchise, and over an 11-year period held a number of senior development and commercial positions including Global Head of the Critical Care Franchise. In June 2014 he was appointed Global Head of Medical Affairs at Novartis Pharma AG

and became a member of the Pharma Executive Committee, where he led the establishment of a Real World Evidence Center of Excellence and piloted the Digital Medicine strategy.

He was appointed to his present position in May 2016.

Ameet Nathwani is a citizen of the United Kingdom.

### **Stefan Oelrich**

#### ***Executive Vice President and General Manager, Diabetes & Cardiovascular***

Date of birth: June 1, 1968

Stefan Oelrich holds a Master's degree in Business Administration from the Business School of the Cologne Chamber of Commerce. He began his career in Bayer AG in Germany in 1992 where he held positions of increasing responsibility and leadership across Latin America, Europe and the US including General Manager for Bayer Healthcare in Belgium and France. He served as Vice-President of Marketing at Bayer's US Pharmaceuticals Division, followed by a promotion to Senior Vice-President & General Manager US Women's Healthcare. At Sanofi, Stefan Oelrich served as head of Sanofi's global diabetes franchise from June 2016. Prior to that, he held the role of Diabetes & Cardiovascular (DCV) Europe Region Head & Sanofi Europe Coordinator, where he was heavily involved in establishing the DCV global business unit from mid-2015 onwards. Between 2011 and 2015 he served as General Manager for Germany, Switzerland and Austria.

He was appointed to his current position in October 2017.

Stefan Oelrich is a citizen of Germany.

### **Roberto Pucci**

#### ***Executive Vice President, Human Resources***

Date of birth: December 19, 1963

Roberto Pucci has a law degree from the University of Lausanne, Switzerland. He started his career in 1985 at Coopers & Lybrand in Geneva, Switzerland as an external auditor. He then joined Hewlett-Packard (HP) in 1987, where he held various positions in Human Resources in Switzerland and Italy including HR Manager for the European Headquarters and Human Resources Director in Italy. In 1999, he became Director, Compensation & Benefits for Agilent Technologies, a spin off from HP, and was appointed Vice President Human Resources Europe in 2003. In 2005 he moved to the United States to join Case New Holland, a subsidiary of the Fiat Group, as Senior Vice President, Human Resources, and in 2007 was appointed Executive Vice President, Human Resources for the Fiat Group in Turin, Italy. Roberto Pucci joined Sanofi as Executive Vice President Human Resources in October 2009.

Roberto Pucci is a citizen of Italy and Switzerland.





**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Bill Sibold**

*Executive Vice President, Sanofi Genzyme*

Date of birth: October 29, 1966

Bill Sibold holds an MBA from Harvard Business School and a BA in Molecular Biophysics and Biochemistry from Yale University. He has more than twenty-five years of experience in the biopharmaceutical industry. Bill Sibold began his career with Eli Lilly and then held a number of leadership positions within Biogen, including driving their US commercial operations in neurology, oncology and rheumatology. He also worked for Biogen in Australia and the Asia-Pacific region, and served as Chief Commercial Officer at Avanir Pharmaceuticals. Bill Sibold joined Sanofi in late 2011 as head of the MS franchise where he oversaw the successful launches of Aubagio® and Lemtrada®. From January 2016, he served as head of Sanofi Genzyme's Global Multiple Sclerosis, Oncology and Immunology organization, where he led preparation for the global launches of dupilumab and sarilumab.

Bill Sibold has headed up Sanofi Genzyme, our specialty care global business unit, since July 1, 2017.

Bill Sibold is a citizen of Canada and of the United States of America.

**Kathleen Tregoning**

*Executive Vice President, External Affairs*

Date of birth: January 20, 1971

Kathleen Tregoning received her Bachelor's degree in International Relations from Stanford University and her master's degree in Public Policy from the Kennedy School of Government at Harvard University.

She has more than 20 years of professional experience in policy, advocacy, stakeholder outreach and external engagement. She began her career in 1993 with Andersen Consulting in San Francisco and later served as a Policy Advisor and then Assistant Deputy Mayor in the Office of the Mayor for the City of Los Angeles.

In 2001, Kathleen moved to Washington DC where she served as a professional staff member in the US Congress, working for the chairmen of the House of Representatives Ways & Means Committee, the House Energy & Commerce Committee, and the Senate Budget Committee. In these positions she was a key resource for members of Congress on a wide range of health care issues including Medicare, Medicaid, prescription drugs, disease management, health care information technology, and post-acute care.

Kathleen joined Biogen in 2006 as Vice President, Public Policy & Government Affairs. Over the next nine years, she built the company's first global government affairs team to advance policies

that enable the delivery of innovative biopharmaceutical products to patients. In 2015, Kathleen was appointed Senior Vice President, Corporate Affairs at Biogen, overseeing the company's policy and advocacy engagement, corporate and employee communications, media relations, product communications and philanthropy/community outreach on a global basis.

She was appointed to her current position in February 2017.

Kathleen Tregoning is a citizen of the United States of America.

## **Elias Zerhouni**

### ***President, Global Research and Development***

Date of birth: April 12, 1951

Born in Algeria where he completed his initial medical training, Dr. Zerhouni continued his academic career at the Johns Hopkins University and Hospital (United States) in 1975 where he rose to the rank of professor of Radiology and Biomedical Engineering. He served as Chair of the Russell H. Morgan Department of Radiology and Radiological Sciences, Vice Dean for Research and Executive Vice Dean of the School of Medicine from 1996 to 2002 before his appointment as Director of the National Institutes of Health of the United States of America from 2002 to 2008. Dr. Zerhouni was received as member of the US National Academy of Sciences Institute of Medicine in 2000. He was appointed as Chair of Innovation at the *Collège de France* and elected a member of the French Academy of Medicine in 2010, and received the Transatlantic Innovation Leadership award in December 2011. He is the author of over 200 scientific publications and has filed eight patents. In February 2009, Sanofi named Dr. Zerhouni Scientific Advisor to the Chief Executive Officer and to the Senior Vice-President Research & Development. He was appointed President Global Research & Development Medicines and Vaccines and became a member of our Executive Committee in January 2011. In 2013, he was appointed as a member of the US National Academy of Engineering. He is also a member of the Board of Directors of Danaher.

Dr. Zerhouni is a citizen of the United States of America.

## **B. Compensation**

### **Compensation and arrangements for corporate officers**

#### **Compensation policy for executive officers**

This section describes the compensation policy for executive officers, as established pursuant to Article L. 225-37-2 of the French Commercial Code. It sets forth the principles and criteria used in determining, allocating and awarding the fixed, variable and exceptional components that collectively comprise the total compensation and benefits of whatever kind awarded to our executive officers in respect of the office they hold.



**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The payment and award in a given year of any variable and exceptional components of compensation as described below that may arise in respect of the previous year are contingent on approval by the shareholders in an Ordinary General Meeting of the compensation package of the executive officer in question, on the terms stipulated in Article L. 225-100 of the French Commercial Code.

That condition which affects the Chief Executive Officer only, given that the compensation of the Chairman of the Board of Directors (when the two offices are separated) consists solely of fixed compensation and benefits in kind applies in this case to the following components of compensation:

annual variable compensation (established on the basis partly of quantitative criteria, and partly of qualitative criteria);

equity-based compensation (subject to fulfillment of performance conditions).

The compensation policy for executive officers is established by the Board of Directors, acting on the recommendation of the Compensation Committee. The members of that Committee, the majority of whom are independent directors, were chosen for their technical competencies and their good understanding of current standards, future developments and Sanofi's practices.

To fulfill their remit, the Committee regularly invites the Head of Human Resources and the Head of Compensation and Employee Benefits to attend their meetings, although they absent themselves when the Committee deliberates. Committee members also work with the Secretary to the Board, who has contacts with our principal shareholders ahead of the Annual General Meeting.

In addition, the Chairman of the Committee:

discusses the financial, accounting and tax impacts of the proposed compensation policy with the Chairman of the Audit Committee;

plays an active role at meetings of the Appointments and Governance Committee and the Strategy Committee (to both of which he belongs), thereby gaining assurance that the proposed criteria are consistent and appropriate in light of Sanofi's strategic ambitions.

The Committee obtains assurance at the start of each year as to the level of attainment of the performance criteria for the past financial year.

The Board of Directors applies the AFEP-MEDEF Code when determining the compensation and benefits awarded to our corporate officers and executive officers.

### **Compensation policy for the Chairman of the Board of Directors**

The compensation policy for the Chairman of the Board of Directors is identical to that approved by the Annual General Meeting of Sanofi shareholders on May 10, 2017.

The compensation of the Chairman of the Board of Directors (where the office of Chairman is separate from that of Chief Executive Officer, as is currently the case) consists solely of fixed compensation and benefits in kind and excludes any variable or exceptional compensation, any awards of stock options or performance shares, and any directors' attendance fees.

Where the office of Chairman is separate from that of Chief Executive Officer, as is currently the case, the Chairman of the Board is not entitled to the Sanofi top-up defined-benefit pension plan.

Nor is he entitled to a termination benefit or a non-compete indemnity.

Executive officers do not receive attendance fees in their capacity as directors. The Chairman of the Board does not receive attendance fees in his capacity as Chairman of the Board, Chairman of the Appointments and Governance Committee or Chairman of the Strategy Committee.

### **Compensation policy for the Chief Executive Officer**

The compensation policy for the Chief Executive Officer is identical to that approved by the Annual General Meeting of Sanofi shareholders on May 10, 2017. Clarifications were nevertheless given on:

the composition of the benchmark panel used as a basis for comparison for the compensation of the Chief Executive Officer, which has been aligned on that used for TSR in our equity-based compensation plans;

the performance conditions applicable to the pension entitlement of the Chief Executive Officer.

The compensation policy of the Chief Executive Officer is based on the same structures and principles as the general Sanofi compensation policy.

#### General principles

The Sanofi compensation policy seeks to be consistent with market and industry practice in order to provide competitive levels of compensation, create a strong link between company and individual performance, and maintain a balance between short-term performance and medium-/long-term performance.



**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The compensation of the Chief Executive Officer is set by the Board of Directors acting on the recommendation of the Compensation Committee, with reference to compensation paid to the chief executive officers of the following ten leading global pharmaceutical companies: AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., Johnson & Johnson Inc., GlaxoSmithKline plc, Merck Inc., Novartis AG, Pfizer Inc., and Roche Holding Ltd.

This panel comprises companies that are comparable to Sanofi.

Consistency with market practice is fundamental in order to attract and retain the talents necessary to our success. We also review the practices of the principal CAC 40 companies in order to reach a fair balance and to take into account our corporate interest, market practices, the performance of the Chief Executive Officer, and our other stakeholders.

Equity-based compensation is a critical tool for our worldwide attractiveness as an employer, and aims to align employee and shareholder interests and reinforce employees' ties to Sanofi.

Acting on the recommendation of the Compensation Committee, the Board of Directors determines the performance conditions attached to equity-based compensation for all beneficiaries at Sanofi and its subsidiaries worldwide, favoring the attainment of objectives based on our consolidated results and balance sheet. Our equity-based compensation plan rules are made available to our shareholders on the governance page of our website ([www.sanofi.com](http://www.sanofi.com)) in the same form as that distributed to our employees.

Since 2011, the Board of Directors has substantially reworked our equity-based compensation policy to reinforce the link with long-term performance for all beneficiaries and to reduce potential dilution. As a result of very positive and encouraging shareholder feedback collected through corporate governance roadshows, contacts with governance professionals and the results of votes at Annual General Meetings, the Board decided to maintain this policy.

The current policy can generally be characterized by reduced dilution; diversified, multi-year performance conditions; increased transparency; and specific additional requirements for the Chief Executive Officer.

The policy requires that grants be primarily based on performance shares with only a limited number of high-level executives continuing to receive stock options.

Greater reliance on performance shares makes it possible to maintain a comparable level of employee incentivization while reducing the dilutive effect of equity-based compensation plans for existing shareholders. However, the Board of Directors continues to believe that due to their ratchet effect, options remain an appropriate component of the compensation of high level executives.

The Board of Directors makes any grant of stock options or performance shares contingent on several distinct performance criteria in order to ensure that our equity-based compensation plans incentivize overall performance and do not encourage excessive risk taking. Failure to achieve these criteria over the entire performance measurement period results in a reduction or loss of the initial grant.

Grants are also contingent on the beneficiary's continued employment in the Sanofi group during the lock-up period (4 years for options, 3 years for performance shares, followed by further stringent lock-up obligations in the case of the Chief Executive Officer).

The exercise price of stock options is set by the Board, never incorporates a discount, and must be at least equal to the average of the quoted market prices on the 20 trading sessions preceding the date of grant by the Board.

The Board is not allowed to reset the terms of prior grants, for instance with easier performance conditions or a lower exercise price.

#### On taking up office

When the Chief Executive Officer is an outside appointment, the Board of Directors may decide, acting on a recommendation from the Compensation Committee, to compensate the appointee for some or all of the benefits he may have forfeited on leaving his previous employer. In such a case, the terms on which the Chief Executive Officer is hired aim to replicate the diversity of what was forfeited, with a comparable level of risk (variable portion, medium-term equity-based or cash compensation)

#### During the term of office

##### Compensation structure

Our policy aims at achieving a balance in the compensation structure between fixed compensation, benefits in kind, short-term variable cash compensation, and medium-term variable equity-based compensation. The proportions of annual fixed and variable compensation are not subject to annual review. Compensation adjustments based on performance and market practice are effected primarily through equity-based compensation, which is medium-term and aims at aligning the interests of the Chief Executive Officer with those of our shareholders and stakeholders.

Our overall compensation policy is designed to motivate and reward performance by ensuring that a significant portion of compensation is contingent on the attainment of financial, operational and social criteria aligned with the corporate interest and with the creation of shareholder value. Variable cash compensation and equity-based compensation are the two principal levers for action.



**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

*Annual variable compensation*

Annual variable compensation is in a range between 0% and 250% of fixed compensation, with a target of 150%. It is determined by reference to quantitative and qualitative criteria. The percentage of variable compensation linked to the attainment of quantitative criteria may be scaled down regardless of actual performance, in order to give greater weight to the attainment of qualitative criteria. This flexibility can only operate to reduce the amount of variable compensation, and cannot compensate for underperformance on quantitative criteria.

In accordance with Article L. 225-100 of the French Commercial Code, payment of annual variable compensation in a given year in respect of the previous year is contingent on a favorable shareholder vote at the Annual General Meeting.

*Equity-based compensation*

The Chief Executive Officer's equity-based compensation may not exceed 250% of his target short-term compensation (fixed plus variable). The valuation of stock options is calculated at the date of grant using the Black & Scholes method. The valuation of performance shares is also calculated at the date of grant, and represents the difference between the quoted market price of the share on the date of grant and the aggregate present value of the dividends to be received over the next three years. The parameters used to calculate the valuations are market parameters available in the financial press. The Chief Executive Officer's equity-based compensation is contingent upon attainment of the performance conditions.

In 2017, on the basis of the information published as of the date of this annual report on Form 20-F, the median fixed compensation of the chief executive officers of the aforementioned ten leading global pharmaceutical companies was in the region of 1,300,000, the median of the annual variable compensation was in the region of 2,200,000 and the median of the long-term compensation granted (whether in shares or in cash) represented around 800% of the fixed compensation.

Each grant to our Chief Executive Officer takes into account previous grants and his overall compensation.

In any event, the maximum number of exercisable options or shares to be delivered may not be more than the number of options initially granted or performance shares initially awarded.

Any award of equity-based compensation in a given year is contingent on a favorable shareholder vote at the Annual General Meeting.

#### *Attendance fees*

Executive officers do not receive attendance fees in their capacity as directors. Consequently, the Chief Executive Officer does not

receive attendance fees in his capacity as a director or as a member of the Strategy Committee.

#### *Exceptional compensation*

No exceptional compensation can be awarded to the Chief Executive Officer.

#### On leaving office

The Chief Executive Officer is entitled to a top-up defined-benefit pension plan, a termination benefit, and a non-compete indemnity. Each of those benefits is taken into account by the Board of Directors when fixing the overall compensation of the Chief Executive Officer.

#### *Pension arrangements*

The Chief Executive Officer is covered by a top-up defined-benefit pension plan falling within the scope of Article L. 137-11 of the French Social Security Code. The plan is offered to all employees of Sanofi and its French subsidiaries who meet the eligibility criteria specified in the plan rules. The plan, which remains open, was set up on October 1, 2008 as the final stage in the process of harmonizing the status of personnel across the French subsidiaries.

This top-up defined-benefit pension plan is offered to executives (as defined by AGIRC, a confederation of executive pension funds) of Sanofi and its French subsidiaries who meet the eligibility criteria specified in the plan rules; the benefit is contingent upon the plan member ending his or her career within the Sanofi group. The plan is reserved for executives with at least ten years of service whose annual base compensation has for ten calendar years (not necessarily consecutive) exceeded four times the French social security ceiling, and is wholly funded by the Company and outsourced to an insurance company.

The top-up pension, which may not exceed 37.50% (1.5% per year of service, capped at 25 years) of the reference compensation, is in the form of a life annuity, and is transferable as a survivor's pension. The annuity is based on the arithmetical average of the three highest years' average annual gross compensation paid during any three of the five years (not necessarily consecutive) preceding final cessation of employment. This reference compensation is capped at 60 times the French social security ceiling applicable in the year in which the pension is taken. In addition, vesting of new rights for the Chief Executive Officer has been subject to a performance condition since January 1, 2017. The performance condition is applied on the following basis:

if the level of attainment for variable compensation is equal to or greater than the target (i.e. 150% of fixed compensation), 100% of the contingent top-up pension rights will vest, corresponding to an uplift of 1.5% in the annual reference compensation used to calculate the annuity payable under the plan;



**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

if the level of attainment for variable compensation is less than 100% of fixed compensation, no top-up pension rights will vest for the year in question; and

between those two limits, vested rights are calculated on a prorata basis. Consequently, the annual uplift in contingent rights is capped at 1.5% of the annual reference compensation used to calculate the annuity payable under the plan, which is below the upper limit of 3% of annual reference compensation stipulated in Article L. 225-42-1 of the French Commercial Code.

The annuity supplements any other schemes for which the plan member may be eligible in France or abroad, subject to a cap on the total pension from all sources set at 52% of the reference compensation. If the total amount of the annuities paid under all such schemes were to exceed the 52% cap, the amount of the Sanofi top-up defined-benefit pension annuity would be reduced accordingly in order to respect that cap.

This retirement plan is subject to various charges and contributions within France: CSG, CRDS, CSAM, CASA, contributions of 7% and 14% on the annuity, and of 24% on the external funding.

*Termination arrangements*

The termination benefit only becomes payable if the departure of the Chief Executive Officer is forced, i.e. in the event of removal from office or resignation linked to a change in strategy or control of the Company. Compensation for non-renewal of the term of office is irrelevant in the case of the Chief Executive Officer, because this office is held for an indefinite term.

In addition, no termination benefit is payable in the following circumstances:

in the event of removal from office for gross or serious misconduct (*faute grave ou lourde*);

if the Chief Executive Officer elects to leave the Company to take up another position;

if the Chief Executive Officer is assigned to another position within Sanofi;

if the Chief Executive Officer takes his pension.

The amount of the termination benefit is capped at 24 months of the Chief Executive Officer's most recent total compensation on the basis of (i) the fixed compensation effective on the date of leaving office and (ii) the last variable compensation received prior to that date, subject to fulfilment of the performance criteria for the three financial years preceding the date of leaving office.

The amount of the termination benefit is reduced by any amount received as consideration for the non-compete undertaking, such that the aggregate amount of those two benefits may never exceed two years of total fixed and variable compensation.

#### *Non-compete undertaking*

In the event of his departure from the Company, the Chief Executive Officer undertakes, during the 12-month period following his departure, not to join a competitor of the Company as an employee or corporate officer, or to provide services to or cooperate with such a competitor.

In return for this undertaking, he receives an indemnity corresponding to one year's total compensation effective on the day he ceases to hold office and the last individual variable compensation received prior to that date. This indemnity is payable in 12 monthly installments.

However, the Board of Directors reserves the right to release the Chief Executive Officer from the undertaking for some or all of that 12-month period. In such cases, the non-compete indemnity would not be due for the period of time waived by the Company.

#### Consequences of the Chief Executive Officer's departure for equity-based compensation

If the Chief Executive Officer leaves the Company for reasons other than resignation or removal from office for gross or serious misconduct (in which case any award of equity-based compensation is forfeited), the overall allocation percentage will be prorated to reflect the amount of time the Chief Executive Officer remained with Sanofi during the vesting period.

If at any time prior to the expiration of (i) the period of validity of the options or (ii) the vesting period of the performance shares the Chief Executive Officer joins a competitor of Sanofi as an employee or corporate officer, or provides services to or cooperates with such a competitor, he irrevocably loses those options and performance shares regardless of any full or partial waiver by the Board of Directors of the non-compete undertaking relating to his office as Chief Executive Officer.

If the Chief Executive Officer retires at statutory retirement age prior to the expiration of (i) the period of validity of the options or (ii) the vesting period of the performance shares, he will retain entitlement to the options and performance shares initially awarded but will continue to be bound by the other terms of the plan, including performance conditions.

There is no acceleration clause in the event of a change of control.



**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

*Summary of benefits awarded to the Chief Executive Officer on leaving office*

The table below presents a summary of the benefits (as described above) that could be claimed by the Chief Executive Officer on leaving office depending on the terms of his departure. The information provided in this summary is without prejudice to any decisions that may be made by the Board of Directors.

	<b>Voluntary departure / Removal from office for gross or serious misconduct</b>	<b>Forced departure</b> 24 months of fixed compensation as of the date of leaving office	<b>Retirement</b>
<b>Termination benefit<sup>(a)</sup></b>		+	
		24 months of most recent individual variable compensation received <sup>(d)</sup>	
<b>Non-compete indemnity<sup>(b)</sup></b>	12 months of fixed compensation as of the date of leaving office	Amounts received as non-compete indemnity 12 months of fixed compensation as of the date of leaving office	/
	+	+	/
	12 months of most recent individual variable		

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	compensation received prior to leaving office	12 months of most recent individual variable compensation received prior to leaving office	(Years of service x 1.5% <sup>(e)</sup> )
<b>Top-up pension<sup>(c)</sup></b>			X
			60 x the French social security ceiling effective as of the retirement date
<b>Stock option and performance shares not yet vested</b>	Forfeited in full	/ Rights retained in prorata to period of employment	Rights retained <sup>(f)</sup>
		within Sanofi <sup>(f)</sup>	

- (a) *The amount of the termination benefit is reduced by any amount received as consideration for the non-compete undertaking, such that the aggregate amount of those two benefits may never exceed two years of total fixed and variable compensation.*
- (b) *The Board of Directors may decide to release the Chief Executive Officer from the non-compete undertaking for some or all of the 12-month period. In that case, the non-compete indemnity would not be due, or would be scaled down proportionately.*
- (c) *In accordance with the Sanofi top-up defined-benefit pension plan rules dated October 1, 2008, amended on January 1, 2012, the top-up pension cannot exceed 37.50% (1.5% per year of service, capped at 25 years) of the reference compensation and supplements any other pension schemes for which the Chief Executive Officer may be eligible, subject to a cap on the total pension from all sources set at 52% of the reference compensation.*
- (d) *Subject to fulfillment of the performance conditions, assessed over the three financial years preceding the departure from office as described in Item 6 Arrangements for executive officers 2. Termination arrangements.*
- (e) *Subject to fulfillment of the performance condition, assessed for each year.*
- (f) *In this case, the Chief Executive Officer remains subject to the terms of the plans, including the performance conditions.*



**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Compensation of the Chairman of the Board, Serge Weinberg**

Serge Weinberg has held the office of Chairman of the Board of Directors since May 17, 2010. He has never had, and does not currently have, a contract of employment with Sanofi.

The Chairman of the Board also chairs the Appointments and Governance Committee and the Strategy Committee.

The remits of the Chairman of the Board are specified in the Board Charter, which is reproduced in its entirety in Exhibit 1.2.

During the course of 2017, Chairman's activities included:

chairing all the meetings of the Board of Directors (nine in 2017) and of the Committees of which he is a member (three meetings of the Appointments and Governance Committee, ten meetings of the Strategy Committee), and participating in Committee meetings to which he was invited (Audit Committee and Compensation Committee);

close monitoring of the proper implementation of the decisions taken by the Board;

meetings with directors, including (i) on the appointments of Bernard Charlès, Melanie Lee, Marion Palme and Christian Senectaire, to explain to them how the Board operates and to answer their questions, (ii) in connection with the annual evaluation of the Board's operating procedures and (iii) on matters relating to the projects presented to the Board;

regular meetings with members of the senior management team;

interviews with the media;

on-site visits to group locations in France or abroad, and meeting the employees;

meetings with biotechs and medtechs in France and abroad; and

representing Sanofi at events or official meetings with representatives of the public authorities and other stakeholders, in line with his remit as defined by the Board Charter.

The Chairman also has a role in explaining positions taken by the Board within its sphere of competence, especially in terms of strategy, governance and executive compensation. In furtherance of this role, Serge Weinberg drew on his experience of corporate communication in:

answering letters from investors and shareholders;

holding meetings with certain shareholders and proxy advisors; and

attending a meeting of the Individual Shareholders Committee at Sanofi headquarters in March 2017, answering questions about the Company's latest news, future prospects and dividend policy.

Those tasks were carried out after coordination with the Chief Executive Officer, and in close collaboration with our Investor Relations department.

### **Compensation in respect of 2017**

On March 2, 2017, acting on a recommendation from the Compensation Committee, the Board of Directors set the terms of Serge Weinberg's compensation for the 2017 financial year.

For the 2017 financial year, his annual fixed compensation was maintained at 700,000.

In line with our compensation policy for the Chairman of the Board, as approved by our shareholders at the Annual General Meeting of May 10, 2017, he did not receive any variable compensation and was not awarded any stock options or performance shares. Nor did he receive any attendance fees in his capacity as a Director.

The amount reported for benefits in kind relates mainly to a company car with a chauffeur.

Serge Weinberg is not covered by the Sanofi top-up defined-benefit pension plan.

### **Compensation in respect of 2018**

On March 6, 2018, acting on a recommendation from the Compensation Committee, the Board of Directors set the terms of Serge Weinberg's compensation. For the 2018 financial year, his annual fixed compensation was maintained at 700,000. Consequently, Serge Weinberg's compensation has remained unchanged since his arrival in 2010. In line with AMF recommendations, he will not receive any variable compensation, stock options or performance shares. Nor will he receive any attendance fees.

### **Compensation, options and shares awarded to Serge Weinberg (table no.1 of the AFEP-MEDEF Code)**

	2017	2016
( ) Compensation due for the year (details provided in the table below)	708,353	708,353
Valuation of stock options awarded during the year	N/A	N/A
Valuation of performance shares awarded during the year	N/A	N/A
Valuation of other long-term compensation plans	N/A	N/A
<b>Total</b>	<b>708,353</b>	<b>708,353</b>

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Compensation awarded to Serge Weinberg (table no. 2 of the AFEP-MEDEF Code)**

	2017		2016	
	Amounts due	Amounts paid	Amounts due	Amounts paid
( ) Fixed compensation <sup>(a)</sup>	700,000	700,000	700,000	700,000
Annual variable compensation	N/A	N/A	N/A	N/A
Exceptional compensation	N/A	N/A	N/A	N/A
Attendance fees	N/A	N/A	N/A	N/A
Benefits in kind	8,353	8,353	8,353	8,353
<b>Total</b>	<b>708,353</b>	<b>708,353</b>	<b>708,353</b>	<b>708,353</b>

*The amounts reported are gross amounts before taxes.*

*(a) Fixed compensation due in respect of a given year is paid during that year.*

**Compensation of the Chief Executive Officer, Olivier Brandicourt**

Olivier Brandicourt has served as Chief Executive Officer since April 2, 2015. He has never had, and does not currently have, a contract of employment with Sanofi.

**Compensation, options and shares awarded to Olivier Brandicourt (table no.1 of the AFEP-MEDEF Code)**

	2017	2016
( ) Compensation due for the year (details provided in the table below)	2,993,118	5,155,113
Valuation of stock options awarded during the year <sup>(a)</sup>	2,686,200	1,452,000
Valuation of performance shares awarded during the year <sup>(b)</sup>	4,075,000	3,053,000
Valuation of other long-term compensation plans	N/A	N/A
<b>Total</b>	<b>9,754,318</b>	<b>9,660,113</b>

- (a) Valuation at the date of grant using the Black & Scholes method assuming fulfillment of the performance conditions.*
- (b) Valuation at the date of grant assuming fulfillment of the performance conditions. This represents the difference between the quoted market price of the share on the date of grant and the present value of the dividends to be received over the next three years.*

The parameters used to calculate the valuations are market parameters available in the financial press.

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Fixed and variable compensation awarded to Olivier Brandicourt (table no. 2 of the AFEP-MEDEF Code)**

	2017		2016	
	Amounts due	Amounts paid	Amounts due	Amounts paid
( ) Exceptional compensation awarded in consideration for benefits forfeited <sup>(a)</sup>	0	0	2,000,000	2,000,000
<i>Sub-total: exceptional compensation</i>	<i>0</i>	<i>0</i>	<i>2,000,000</i>	<i>2,000,000</i>
Fixed compensation <sup>(b)</sup>	1,200,000	1,200,000	1,200,000	1,200,000
Annual variable compensation <sup>(c)</sup>	1,792,800	1,954,800	1,954,800	1,491,300
Directors' attendance fees	N/A	N/A	N/A	N/A
Benefits in kind	318	318	313	313
<i>Sub-total: annual compensation</i>	<i>2,993,118</i>	<i>3,155,188</i>	<i>3,155,113</i>	<i>2,691,613</i>
<b>Total</b>	<b>2,993,118</b>	<b>3,155,188</b>	<b>5,155,113</b>	<b>4,691,613</b>

The amounts reported are gross amounts before taxes.

(a) The amount due and paid to Olivier Brandicourt on taking up office, to compensate him for the significant benefits that he forfeited upon his departure from his previous employer relates to the 2016 financial year only.

(b) Fixed compensation due in respect of a given year is paid during that year.

(c) Variable compensation in respect of a given year is determined at the start of the following year and paid after the Annual General Meeting in that year, subject to shareholder approval.

**Compensation in respect of 2017**

On March 2, 2017, acting on a recommendation from the Compensation Committee, the Board of Directors set the terms of Olivier Brandicourt's compensation for the 2017 financial year.

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In line with our compensation policy for the Chief Executive Officer, as approved by our shareholders at the Annual General Meeting of May 10, 2017 his annual compensation for 2017 comprised (i) fixed

annual gross compensation of 1,200,000 (unchanged since he took office) and (ii) variable annual compensation in a range from 0% to 250% of his fixed annual compensation, with a target of 150%, and subject to both quantitative and qualitative criteria.

These objectives were 40% based on financial indicators (sales growth one-third, business net income<sup>(1)</sup> two-thirds), and 60% based on specific individual objectives.

The Board of Directors, acting on recommendations from the Compensation Committee, adjusts the individual performance criteria annually, while always seeking to maintain continuity and consistency from one year to the next.

### Individual objectives for 2016

new product launches (10%);

research and development (15%);

ongoing transformation of Sanofi (25%);

organization and staff relations (10%);

### Individual objectives for 2017

excellence of product launches (10%);

external growth (14%);

operational transformation (12%);

organization and staff relations (12%);

the new product pipeline (12%).

*(1) For a definition, see Item 5 Operating and Financial Review and Prospects Business Net Income .*

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

Qualitative criteria account for 24% of the overall variable compensation objectives for 2017 (versus 35% for 2016), and hence represent a relatively limited proportion of the total.

In addition, acting on the recommendation of the Compensation Committee and in light of experience, the Board of Directors decided that the percentage of variable compensation linked to the attainment of quantitative criteria could be scaled down regardless of actual performance, in order to give greater weight to the attainment of qualitative criteria. This flexibility can only operate to reduce the amount of variable compensation, and cannot compensate for underperformance on quantitative criteria.

In general, the performance criteria applied to variable compensation and to the vesting of stock options and performance shares are exacting, and consistent with our corporate objectives.

For confidentiality reasons, neither the level of attainment required (target) for the quantitative criteria nor the details of the qualitative criteria can be disclosed; however, they were pre-determined on a precise basis. In evaluating those criteria, the performance of major global pharmaceutical companies is always taken into account.

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 6, 2018 reviewed the attainment of each criterion and sub-criterion. The Board's conclusions are summarized in the table below.

	CRITERION	TYPE	WEIGHT	TARGET/ MAXIMUM	ASSESSMENT	COMMENTS	LEVEL OF ATTAINMENT
<b>FINANCIAL OBJECTIVES</b>	Sales	Quantitative	13.3%	19.95% /	Slightly below target	Confidential target	103.4%



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<b>(40%)</b>	Business net income <sup>(a)</sup>	Quantitative	26.7%	33.25% 40.05% /	Slightly above target		
	Excellence of product launches	Quantitative	10%	15% /	Below target	Confidential target	
	External growth	Quantitative	14%	25% 21% / 35%	Above target	Acquisitions of Protein Sciences, Bioverativ and Ablynx, identified, initiated and partially realized in 2017	
<b>INDIVIDUAL OBJECTIVES</b> <b>(60%)</b>	New product pipeline	Quantitative	12%	18% / 30%	Above target	Registrations and submissions within the timeframe. Strengthening of early stage pipeline	97%
	Operational transformation	Qualitative	12%	18% / 30%	On target	Implementation of the digital strategy. Cost reduction programme in line with the target	
	Organization and staff relations	Qualitative	12%	18% / 30%	On target	Strengthening of the talent pool. Positive results of the survey made among employees	
<b>TOTAL</b>			<b>100%</b>	<b>150% / 250%</b>			<b>99.6%</b>

(a) For a definition, see Item 5 Operating and Financial Review and Prospects Business Net Income .

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 6, 2018 set Olivier Brandicourt's variable compensation for 2017 at 1,792,800, equivalent to 149.4% of his fixed compensation.

Payment of his variable compensation in respect of the 2017 financial year is contingent on approval of his compensation package by the shareholders in an Ordinary General Meeting, on the terms stipulated in Article L. 225-100 of the French Commercial Code.

Olivier Brandicourt is subject to, benefits from and contributes to the same health cover, and death and disability plans as are applicable to other employees of Sanofi based in France.

He received a benefit in kind in 2017 representing social contribution payments of 318 made by Sanofi on his behalf. Sanofi's policy is to make these payments (which arise on the employer's pension contributions and are normally payable by the employee) on behalf of all of its employees in France, including Olivier Brandicourt.

In line with our compensation policy for the Chief Executive Officer as approved by our shareholders at the Annual General Meeting of May 10, 2017, and acting on the recommendations of the Compensation Committee, the Board of Directors meeting of May 10, 2017 decided to award Olivier Brandicourt 220,000 stock subscription options and 50,000 performance shares in respect of the 2017 financial year. Using the Black & Scholes model, the valuation of those awards, as of May 10, 2017, was equivalent to 5.6 times his fixed compensation for 2017.

In compliance with the AFEP-MEDEF Code, the entire amount of these awards is contingent upon both internal criteria based upon business net income<sup>(1)</sup> and return on assets (ROA), and an external criterion based on total shareholder return (TSR) relative to a benchmark panel of ten of the leading global pharmaceutical companies. The panel is the same as that used to determine the overall compensation of the Chief Executive Officer: AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., Johnson & Johnson Inc., GlaxoSmithKline plc, Merck Inc., Novartis AG, Pfizer Inc. and Roche Holding Ltd.

Those criteria were selected because they align medium-term equity-based compensation with the strategy adopted by Sanofi.

The arrangements relating to these awards are as follows:

The performance criterion based on business net income accounts for 50% of the award. This criterion corresponds to the ratio, at constant exchange rates, of actual business net income to budgeted business net income. It represents the average actual-to-budget ratio for business net income attained over the entire period. Budgeted business net income is derived from the budget as approved by the Board of Directors at the beginning of each financial year. The business net income objective may not be lower than the bottom end of the full-year guidance range publicly announced by Sanofi at the beginning of each year. If the ratio is less than 95%, the corresponding options or performance shares are forfeited.

<b>Actual-to-budget attainment ratio ( R )</b>	<b>Business net income allocation</b>
If R is less than 95%	0%
If R is 95%	50%
If R is > 95% but < 98%	$(50 + [(R - 95) \times 16])\%$
If R is <sup>3</sup> 98% but £ 105%	R%
If R is > 105% but < 110%	$(105 + [(R - 105) \times 3])\%$
If R is <sup>3</sup> 110%	120%

The ROA criterion accounts for 30% of the award. The award is based on a target ROA, below which some or all of the options or performance shares are forfeited.

<b>Average ROA ( P )</b>	<b>ROA allocation</b>
If P is £ the minimum target (M)	0%
If P is between the minimum (M) and intermediate (I) performance	$[30 \times (P-M)/(I-M)]\%$
If P is equal to the intermediate performance (I)	30%
If P is between the intermediate performance (I) and the target ROA (T)	$[70 \times (P-T)/(T-I) + 100]\%$
If P is <sup>3</sup> the target ROA	100%

(1) For a definition, see *Item 5 Operating and Financial Review and Prospects Business Net Income*.

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**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The TSR criterion accounts for 20% of the award. Total shareholder return (TSR) reflects both the appreciation in the value of our shares (the increase in the share price) and the value distributed to our shareholders (dividends), i.e. the two sources of return on investment in Sanofi shares. Our TSR is compared with the benchmark panel of ten companies listed above. The number of options exercisable and performance shares vesting depends upon our position relative to the TSR for the other companies in the panel. Below the median, the corresponding options or performance shares are forfeited.

The median is the performance of the company ranked sixth. The upper bound is the arithmetical average of the performances of the panel companies ranked first and second. The intermediate level is equal to:  $\text{median} + [(\text{upper bound} - \text{median}) \div 2]$ .

if Sanofi's TSR is below the median, the TSR allocation will be 0%;

if Sanofi's TSR is equal to the median, the TSR allocation will be 50%;

if Sanofi's TSR is equal to the intermediate level, the TSR allocation will be 100%;

if Sanofi's TSR is the upper bound, the TSR allocation will be 150%;

if Sanofi's TSR is above the median but below the upper bound, the TSR allocation will be calculated using linear interpolation.

In addition to the three criteria described above, in the case of stock options there is an implicit condition in the form of the exercise price, and a condition of continuing employment within Sanofi.

In order to align equity-based compensation with medium-term performance, performance is measured over three financial years.

Vesting is subject to a non-compete clause.

In the event that Olivier Brandicourt leaves the Company for reasons other than resignation or removal from office for gross or serious misconduct, the overall allocation percentage will be prorated to reflect the amount of time he remained with Sanofi during the vesting period.

Until he ceases to hold office, the Chief Executive Officer is required to retain a quantity of Sanofi shares equivalent to (i) 50% of any gain (net of taxes and social contributions) arising on the exercise of stock options and (ii) 50% of any gain (net of taxes and social contributions) arising on the vesting of performance shares, calculated as of the date on which those shares vest. Those shares must be retained in registered form until he ceases to hold office.

In accordance with the AFEP-MEDEF Code, the Chief Executive Officer is bound by insider trading rules (contained in the Board Charter) which stipulate periods during which he must refrain from trading in Sanofi shares.

In compliance with the AFEP-MEDEF Code and our Board Charter, Olivier Brandicourt has undertaken to refrain from entering into speculative or hedging transactions, and so far as the Company is aware no such instruments have been contracted.

The Board regards these performance conditions as good indicators of the development of shareholder value in terms of: the quality of investment decisions in a period where external growth plays a greater role than in the past (ROA condition); a commitment to delivering challenging bottom-line results in a tough business environment (business net income condition); and matching or bettering our peer group in terms of shareholder returns (TSR condition).

For confidentiality reasons, the amount of the quantitative measures for the internal criteria cannot be disclosed. However, they were determined on a precise basis, and the level of attainment for the internal criteria will be disclosed at the end of the performance measurement period.

In line with our commitment to transparency, we publish in our annual report the attainment level determined by the Board of Directors for performance conditions (and the corresponding allocation rate) applicable to equity-based compensation plans awarded to the Chief Executive Officer and other members of the Executive Committee. The Board believes that disclosing the attainment level allows our shareholders to better understand the demanding nature of the performance conditions.

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The attainment levels and allocation rates for equity-based compensation plans that have expired since 2011 are as follows:

	Attainment level			Allocation rate
	Business net income	ROA	TSR	
March 9, 2011 plan (stock options only) <sup>(a)</sup>	2011-2012: 106% percentage points above target	2011-2012: 1.7 (5th of 12)	2011-2012: 100% > 100%	2011-2012:  2013-2014: 94.8%
	2013-2014: 97.7%	2013-2014: 0.2 (8th of 11) a percentage point above target	2013-2014: 78.6%	i.e. 97.4% for 2011-2014  i.e. 292,200 stock options
March 5, 2012 plans (stock options only) <sup>(a)</sup>	2012-2014: 84.4%	2012-2014: 0.5 of a percentage point above target	2012-2014: 57.6% (9th of 11)	2012-2014: 85.3%
March 5, 2013 plans (stock options only) <sup>(a)</sup>	2013-2015: 83.2%	2013-2015: 0.2 of a percentage point above target	2013-2015: 0% (9th of 11)	i.e. 204,720 stock options 2013-2015: 73.3%
March 5, 2014 plans <sup>(a)</sup>	2014-2016 101.5%	2014-2016: 0.7 of a percentage point above target	2014-2016: 0% (11th of 11)	i.e. 175,920 stock options 2014-2016: 80.6%

				i.e. 193,440 stock options and 36,270 performance shares
June 24, 2015 plans	2015-2017 102.2%	2015-2017: 2.1 percentage points above target	2015-2017: 0% (8th of 11)	2015-2017: 81.12%
				i.e. 178,464 stock options and 36,504 performance shares

**Ratio of business net income to net sales**

	<b>Business net income</b>	<b>Net sales</b>	<b>Ratio (target: &gt; 18 %)</b>	<b>Allocation rate</b>
June 24, 2015 plan <sup>(b)</sup>	2015: 7,371m	2015: 37,057m	2015: 19.9%	2015-2017: 100%
	2016: 7,308m	2016: 36,529m	2016: 20%	i.e. 66,000 performance shares
	2017: 6,964m	2017: 35,055m	2017: 19.9%	

(a) The attainment level and allocation rates shown relate to the equity-based compensation plans awarded to the predecessor of the current Chief Executive Officer.

(b) This plan relates to the award by the Board of Directors, acting on a recommendation from the Compensation Committee, of 66,000 performance shares to Olivier Brandicourt on his taking up office, as partial consideration for benefits forfeited on leaving his previous employer.

(c) Net sales including the Animal Health business in 2015 and 2016, as well as Vaxserve activity in 2015. Reported net sales for 2015 and 2016 respectively amount to 34,542 million and 33,821 million, excluding the Animal Health business in line with IFRS 5. On that basis, the ratio of business net income to net sales is 21.3% in 2015 and 21.6% in 2016.

**Stock options awarded to Olivier Brandicourt in 2017 (table no. 4 of the AFEP-MEDEF Code)**

<b>Source</b>	<b>Date of plan</b>	<b>Type of option</b>	<b>Valuation of options ( )</b>	<b>Number of options granted during the period</b>	<b>Exercise price ( )</b>	<b>Exercise period</b>
Sanofi	05/10/2017	Subscription options	2,686,200	220,000	88.97	05/10/2021 05/10/2027





**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

Using the Black & Scholes model, each option awarded on May 10, 2017 was valued at 12.21, valuing the total benefit at 2,686,200.

The Board of Directors had previously decided to limit the number of options that could be awarded to executive officers to 15% of the total limit approved by the Shareholders Annual General Meeting of May 4, 2016 (0.5% of the share capital). The number of options awarded to the Chief Executive Officer in 2017 represents 3.49%

of the total limit approved by that Meeting and 58.19% of the total amount awarded to all beneficiaries on May 10, 2017.

It is important to note that since 2015, stock options have been restricted to members of the Executive Committee residing outside France and to beneficiaries in countries where shares cannot be awarded; they are no longer awarded to all beneficiaries of equity-based compensation plans. This explains why the proportion of options granted to the Chief Executive Officer is higher than in the past.

**Stock options exercised by Olivier Brandicourt in 2017 (table no. 5 of the AFEP-MEDEF Code)**

No stock options are currently exercisable.

**Summary of stock options held by Olivier Brandicourt**

Source	Date of plan	Type of option	Valuation of options ( )	Number of options granted	Exercise price ( )	Exercise period
Sanofi	06/24/2015	Subscription options	3,546,400	220,000	89.38	06/25/2019 06/24/2025
Sanofi	05/04/2016	Subscription options	1,452,000	220,000	75.90	05/05/2020 05/04/2026
Sanofi	05/10/2017		2,686,200	220,000	88.97	05/10/2021

Subscription  
options

05/10/2027

As of the date of publication of the present report, the total number of unexercised options held by Olivier Brandicourt represented 0.05% of the share capital as at December 31, 2017.

**Performance shares awarded to Olivier Brandicourt in 2017 (table no. 6 of the AFEP-MEDEF Code)**

<b>Source</b>	<b>Date of plan</b>	<b>Valuation of performance shares ( )</b>	<b>Number of performance shares awarded during the period</b>	<b>Expiry date</b>	<b>Availability date</b>
Sanofi	05/10/2017	4,075,000	50,000	05/10/2020	05/11/2020

Each performance share awarded on May 10, 2017, was valued at 81.50, valuing the total benefit at 4,075,000.

The Board of Directors had previously decided to limit the number of performance shares that could be awarded to executive officers to 5% of the total limit approved by the Shareholders Annual

General Meeting of May 4, 2016 (1.5% of the share capital). The number of shares awarded to Olivier Brandicourt in 2017 represents 0.26% of the total limit approved by that Meeting and 1.39% of the total awarded to all beneficiaries on May 10, 2017.

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Performance shares awarded to Olivier Brandicourt which became available in 2017 (table no. 7 of the AFEP-MEDEF Code)**

No performance shares became available.

**Summary of performance shares awarded to Olivier Brandicourt**

<b>Source</b>	<b>Date of plan</b>	<b>performance shares ( )</b>	<b>Number of performance shares awarded</b>	<b>Vesting date</b>	<b>Availability date</b>
Sanofi	06/24/2015	5,248,320	66,000	06/25/2019	06/26/2019
Sanofi	06/24/2015	3,578,400	45,000	06/25/2019	06/26/2019
Sanofi	05/04/2016	3,053,000	50,000	05/04/2019	05/05/2019
Sanofi	05/10/2017	4,075,000	50,000	05/10/2020	05/11/2020

As of the date of publication of the present report, the total number of performance shares awarded to Olivier Brandicourt represented 0.02% of the share capital as of December 31, 2017.

**Compensation in respect of 2018**

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 6, 2018 decided to maintain Olivier Brandicourt's fixed annual compensation for 2018 at the same level as for 2016 and 2017 ( 1,200,000), and also to retain the same variable annual compensation structure whereby 40% is based on financial indicators (sales growth one-third, business net income two-thirds) and 60% on specific individual objectives.

Those individual objectives comprise:

business transformation (20%);

pipeline of products (12%);

organization and people (12%);

new products (10%); and

mergers and acquisitions (6%).

For 2018, the variable compensation of Olivier Brandicourt will remain in a range between 0% and 250% of his fixed compensation, with a target of 150%.

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 6, 2018 proposed to award Olivier Brandicourt 220,000 stock subscription options and 50,000 performance shares in respect of the 2018 financial year. The award of these stock subscription options and performance shares to Olivier Brandicourt in respect of the 2018 financial year is contingent on approval of his compensation package by the shareholders at the Ordinary General Meeting, on the terms stipulated in Article L. 225-100 of the French Commercial Code.

## Arrangements for executive officers

### 1. Pension arrangements

Olivier Brandicourt is covered by the Sanofi top-up defined-benefit pension plan, which falls within the scope of Article L. 137-11 of the French Social Security Code. For a fuller description of the plan, refer to Compensation policy for executive officers above.

Based on the assumptions used in the actuarial valuation of the plan, 532 executives were eligible for this plan (50 retirees, 108 early retirees and 374 active employees) as of December 31, 2017.

Because Olivier Brandicourt has pursued his career in different countries and in different groups, he has not continuously paid into the French compulsory industry schemes. Consequently, he was awarded a deemed ten years of service on taking up office at Sanofi.

The Shareholders Annual General Meeting of May 4, 2015 approved the section on the pension benefit contained in the auditors special report on related-party agreements.

Under the terms of Article 229 II of the law on growth, the economy and equality of opportunity (the Macron Law ), Olivier Brandicourt top-up pension arrangements fall outside the scope of that law in terms of the requirement for pension arrangements to be contingent on performance conditions.

Nonetheless our Board of Directors, acting on a recommendation from the Compensation Committee, decided at its meeting of February 7, 2017 to voluntarily apply a performance condition to the vesting of new contingent rights

arising under Olivier Brandicourt top-up pension plan with effect from January 1, 2017.

This alteration in pension arrangements was approved at the Shareholders Annual General Meeting of May 10, 2017. The terms of this performance condition are described in B. Compensation Compensation and arrangements for corporate officers .

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**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

At a meeting on March 6, 2018, our Board of Directors ascertained whether the performance condition had been met, noting that the level of attainment for the Chief Executive Officer's variable compensation for the 2017 financial year was 99.6%, i.e. 149.4% of his fixed compensation. Consequently, 99.6% of his contingent top-up pension rights vest, corresponding to an uplift of 1.49% in the annual reference compensation used to calculate the annuity payable under the plan.

Taking into account the award of a deemed ten years of service, he has therefore accumulated 12.75 years of service as of December 31, 2017. His reference compensation being limited to 60 times the French social security ceiling (i.e. 2,353,680 in 2017, based on a ceiling of 39,228), the theoretical maximum of his top-up pension is currently 19.115% of that amount, i.e. 449,906.

On leaving Sanofi, Olivier Brandicourt may not benefit from our top-up pension plan unless he is entitled to benefit fully from compulsory industry schemes; this requires him to have reached statutory retirement age (which he did in February 2018) and to have accumulated the required number of three-month periods of qualifying employment. We do not have sufficient information to determine whether retirement in 2018 is a realistic scenario in terms of his period of qualifying employment, since most of his career has been spent outside France.

If Olivier Brandicourt were to retire in 2018, as mentioned above he would have accumulated 12.75 years of service, entitling him to an annuity equal to 19.115% of his reference compensation. That annuity would supplement any other schemes for which he may be eligible in France or abroad, subject to a cap on the total pension from all sources set at 52% of the reference compensation. If the total amount of the annuities paid under all such schemes were to exceed the 52% cap, the amount of the Sanofi top-up defined-benefit pension annuity would be reduced accordingly in order to respect this cap.

## **2. Termination arrangements**

The termination benefit only becomes payable if the departure of the Chief Executive Officer is forced, i.e. in the event of removal

from office linked to a change in strategy or control of the Company; for a fuller description of the benefit, refer to Compensation policy for executive officers above.

In accordance with article L. 225-42-1 of the French Commercial Code and with the AFEP-MEDEF Code, payment of the termination benefit is contingent upon fulfillment of two performance criteria, assessed over the three financial

years preceding his ceasing to hold office. The two criteria are:

the average of the ratios of business net income<sup>(1)</sup> to net sales for each financial year must be at least 15%;

the average of the ratios of operating cash flow before changes in working capital to net sales for each financial year must be at least 18%.

The Shareholders' Annual General Meeting of May 4, 2015 approved the section on the termination benefit contained in the auditors' special report on related-party agreements.

### 3. Non-compete undertaking

This undertaking stipulates that in the event of his departure from the Company, Olivier Brandicourt will not join a competitor of the Company as an employee or corporate officer, or provide services to or cooperate with such a competitor, during the 12-month period following his departure.

In return for this undertaking, he may receive an indemnity corresponding to one year's total compensation on the basis of his fixed compensation payable in 12 monthly installments, it being specified that the Board of Directors reserves the right to release him from that undertaking for some or all of the period covered by the undertaking. In that case, the non-compete indemnity would not be due for the period of time waived by the Company. For a fuller description of the benefit, refer to Compensation policy for executive officers above.

The Shareholders' General Meeting of May 4, 2015 approved the section on the non-compete undertaking contained in the auditors' special report on related party agreements.

### Arrangements in favor of executive officers in office as of December 31, 2017 (table no. 11 of the AFEP-MEDEF Code)

Executive officer	Contract of employment	Top-up pension plan	Compensation or benefits payable or potentially payable on cessation of office	Indemnity payable under non-compete clause
Serge Weinberg	No	No	No	No
Olivier Brandicourt	No	Yes	Yes	Yes

(1) For a definition, see Item 5 Operating and Financial Review and Prospects Business Net Income .





**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Share ownership and lock-up obligation of the Chief Executive Officer for shares obtained on exercise of stock options or performance shares**

The Chief Executive Officer is bound by the same obligations regarding share ownership specified in our Articles of Association and Board Charter as the other corporate officers.

In addition, until he ceases to hold office the Chief Executive Officer is required to retain a quantity of Sanofi shares equivalent to:

50% of any gain (net of taxes and social contributions) arising on the exercise of stock options;

50% of any gain (net of taxes and social contributions) arising on the vesting of performance shares, calculated as of the date on which those shares vest.

Those shares must be retained in registered form until he ceases to hold office.

In compliance with the AFEP-MEDEF Code and our Board Charter, Olivier Brandicourt has undertaken to refrain from entering into speculative or hedging transactions, and so far as the Company is aware no such instruments have been contracted.

**Compensation and pension payments for Directors other than the Chief Executive Officer and the Chairman of the Board of Directors**

**Attendance fees (table no. 3 of the AFEP-MEDEF Code)**

Attendance fees in respect of 2016, the amount of which was approved at the Board meeting of March 2, 2017, were partially paid in July 2016. The balance was paid in 2017.

Attendance fees in respect of 2017, the amount of which was approved at the Board meeting of March 6, 2018, were partially paid in July 2017. The balance will be paid in 2018.

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For 2017 and 2018, the basic annual attendance fee was maintained at 30,000, apportioned on a time basis for directors who assumed or left office during the year.

The variable portion was determined on the basis of actual attendance by directors at meetings in accordance with the principles specified in our Board Charter, and in the proportions described below:

	<b>Amount of the attendance fee per meeting</b>		
	<b>Directors resident in France</b>	<b>Directors resident outside France but within Europe</b>	<b>Directors resident outside Europe</b>
Board of Directors	5,000	7,000	10,000
Audit Committee	7,500 ( 10,000 for the Chairman)	7,500 ( 10,000 for the Chairman)	7,500 ( 10,000 for the Chairman)
Compensation Committee	5,000 ( 7,500 for the Chairman)	7,500	10,000
Appointments and Governance Committee	5,000	7,500	7,500
Strategy Committee	5,000	7,500	10,000

Hence, in accordance with the AFEP-MEDEF Code, attendance fees are allocated predominantly on a variable basis.

The attendance fee payable to a director who participates by conference call or by video-conference is equivalent to half of the attendance fee received by a director resident in France who attends in person.

As an exception, in certain cases two meetings held on the same day give entitlement to a single attendance fee:

if on the day of a Shareholders' General Meeting, the Board of Directors meets both before and after the Meeting, only one attendance fee is paid for the two Board meetings;

if on the same day a Director participates in one meeting of the Compensation Committee and in one meeting of the

Appointments and Governance Committee, only the highest one is paid for both meetings.

The introduction of a separate attendance fee scale depending on whether or not the director is a European resident is intended to take into account the significantly longer travel time required to attend meetings in person.

The Shareholders' Annual General Meeting of May 10, 2017 approved a proposal to increase the maximum overall amount of annual attendance fees to 1,750,000, largely to take account of an increase in the size of the Board. The overall amount of annual attendance fees had previously remained unchanged since the Annual General Meeting of May 6, 2011.

Neither the Chairman nor the Chief Executive Officer receives attendance fees.



**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The table below shows amounts paid in respect of 2016 and 2017 to each member of the Sanofi Board of Directors, including those whose term of office ended during those years.

Name	2017				2016			
	Attendance fees for 2017		Pensions	Total gross compensation	Attendance fees for 2016		Pensions	Total gross compensation
	Fixed portion	Variable portion	paid in 2017		Fixed portion	Variable portion	paid in 2016	
Laurent Attal	30,000	82,500		112,500	30,000	90,000		120,000
Bonnie Bassler <sup>(a)(b)</sup>					22,500	67,500		90,000
Uwe Bicker <sup>(c)(d)</sup>					12,500	43,500		56,000
Robert Castaigne	30,000	117,500		147,500	30,000	137,500		167,500
Bernard Charlès <sup>(e)</sup>	20,000	27,500		47,500				
Jean-René Fourtou <sup>(c)(f)</sup>					12,500	35,000	573,610	621,110
Claudie Haigneré	30,000	57,500		87,500	30,000	92,500		122,500
Patrick Kron	30,000	105,000		135,000	30,000	122,500		152,500
Fabienne Lecorvaisier	30,000	75,000		105,000	30,000	102,500		132,500
Melanie Lee <sup>(d)(e)</sup>	20,000	38,000		58,000				
Suet-Fern Lee <sup>(a)</sup>	30,000	90,000		120,000	30,000	85,000		115,000
Christian Mulliez	30,000	115,000		145,000	30,000	97,500		127,500
Marion Palme <sup>(d)(g)</sup>	15,000	28,500		43,500				
Carole Piwnica <sup>(h)</sup>	30,000	88,750		118,750	30,000	93,750		123,750
Klaus Pohle <sup>(c)(d)</sup>					12,500	50,500		63,000
Christian Senectaire <sup>(g)(i)</sup>	15,000	22,500		37,500				

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Diane Souza <sup>(a)(i)</sup>	30,000	115,000	145,000	20,000	77,500		97,500
Thomas Südhof <sup>(a)(j)</sup>	30,000	82,500	112,500	20,000	52,500		72,500
<b>Total</b>	<b>370,000</b>	<b>1,045,250</b>	<b>1,415,250</b>	<b>340,000</b>	<b>1,147,750</b>	<b>573,610</b>	<b>2,061,360</b>
<b>Total attendance fees (theoretical)</b>		<b>1,415,250</b>				<b>1,487,750</b>	

*The amounts reported are gross amounts before taxes.*

*(a) Resident outside Europe.*

*(b) Left office September 6, 2016.*

*(c) Left office May 4, 2016.*

*(d) Resident outside France but within Europe.*

*(e) Assumed office May 10, 2017.*

*(f) Pension prorated to reflect the period during which he held office.*

*(g) Director representing employees; assumed office in June 2017.*

*(h) Foreign director resident in France for tax purposes.*

*(i) Attendance fees due to Christian Senectaire will be paid directly to Fédération Chimie Energie CFDT*

*(j) Assumed office May 4, 2016.*

The two directors representing employees both have a contract of employment with a Sanofi subsidiary, under which they receive compensation unrelated to their office as director. Consequently, that remuneration is not disclosed.

## Pensions

The amount recognized in the 2017 consolidated income statement in respect of corporate pension plans for corporate officers with

current or past executive responsibilities at Sanofi (or companies whose obligations have been assumed by Sanofi) was 1.3 million.

## Compensation of Senior Management

The compensation of Executive Committee members other than the Chief Executive Officer is established upon the recommendation of the Compensation Committee, taking into consideration the practices of the leading global pharmaceutical companies.

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

In addition to fixed compensation, they receive variable compensation. Their target variable compensation depends on their position, and can represent up to 100% of their fixed compensation. The target amount of individual variable compensation is determined in line with market practice. It rewards the individual contribution of each Executive Committee member both to Sanofi's performance and to the performance of the operations or functions for which he or she has responsibility.

For 2017, the variable component consisted of two elements:

attainment of quantitative objectives (accounting for 50%) which are measured (i) at consolidated level (sales growth 30%, business net income 50%, research and development outcomes 20%, plus an upward/downward adjustment mechanism of up to 5% linked to cash flow optimization and an upward/downward adjustment mechanism of up to 5% linked to new product launches) and (ii) at the level of the operations or functions for which the Executive Committee member has responsibility; and

attainment of quantitative and qualitative objectives both individually (30%) and collectively (20%) within the Executive Committee (together accounting for 50%).

The indicators used are intended to measure growth (in terms of net sales, business net income, research and development outcomes, sales of new products, and cash flow optimization); talent and critical skills management (including hirings in critical areas for the Group); talent retention; increase in the proportion of women in senior management positions; and promotion of high potential individuals.

In addition to this cash compensation, Executive Committee members may be awarded stock options and/or performance shares (see E. Share Ownership below for details of the related plans).

For 2017, the total gross compensation paid and accrued in respect of members of the Executive Committee (excluding Olivier Brandicourt) amounted to 19.3 million, including 8.4 million in fixed compensation.

On May 10, 2017, 145,240 stock subscription options and 233,207 performance shares, (excluding options and performance shares awarded to Olivier Brandicourt) were awarded to members of the Executive Committee.

In compliance with the AFEF-MEDEF Code, these entire awards are contingent upon two internal criteria, based on business net income<sup>(1)</sup> and return on assets (ROA). These criteria were selected because they align medium-term equity-based compensation with the strategy adopted by Sanofi.

The arrangements relating to these awards are as follows:

The performance criterion based on business net income accounts for 60% of the award. This criterion corresponds to the ratio, at constant exchange rates, of actual business net income to budgeted business net income. It represents the average actual-to-budget ratio attained over the entire period. Budgeted business net income is derived from the budget as approved by the Board of Directors at the beginning of each financial year. The business net income objective may not be lower than the bottom end of the full-year guidance range publicly announced by Sanofi at the beginning of each year. If the ratio is less than 95%, the corresponding options or performance shares are forfeited.

<b>Actual-to-budget attainment ratio ( R )</b>	<b>Business net income allocation</b>
If R is less than 95%	0%
If R is 95%	50%
If R is > 95% but < 98%	$(50 + [(R - 95) \times 16])\%$
If R is <sup>3</sup> 98% but £ 105%	R%
If R is > 105% but < 110%	$(105 + [(R - 105) \times 3])\%$
If R is <sup>3</sup> 110%	120%

(1) For a definition, see *Item 5 Operating and Financial Review and Prospects Business Net Income* .

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The ROA criterion accounts for 40% of the award. The award is based on a target ROA, below which some or all of the options or performance shares are forfeited.

<b>Average ROA ( P )</b>	<b>ROA allocation</b>
If P is £ the minimum target (M)	0%
If P is between the minimum (M) and intermediate (I) performance	$[30 \times (P-M)/(I-M)]\%$
If P is equal to the intermediate performance (I)	30%
If P is between the intermediate performance (I) and the target ROA (T)	$[70 \times (P-T)/(T-I) + 100]\%$
If P is <sup>3</sup> the target ROA	100%

In addition to the two criteria described above, in the case of stock options there is an implicit condition in the form of the exercise price, and a condition of continuing employment within Sanofi.

In order to align equity-based compensation with medium-term performance, performance is measured over three financial years.

Vesting is subject to a non-compete clause.

The entire award is forfeited in the event of resignation, or dismissal for gross or serious misconduct.

In the event of individual dismissal other than for gross or serious misconduct or retirement before the age of 60, or if the beneficiary's employer ceases to be part of the Sanofi group, the overall allocation percentage is prorated to reflect the amount of time the person remained with the Sanofi group during the vesting period.



if any of the following events occur, full rights to the award are retained: (i) dismissal as part of a collective redundancy plan, or of an equivalent plan negotiated and approved by the Chief Executive Officer; (ii) retirement on or after reaching the statutory retirement age, or early retirement under a statutory or contractual early retirement plan implemented by the relevant Sanofi entity and duly approved by the Chief Executive Officer of Sanofi; (iii) disability classified in the second or third categories stipulated in Article L. 314-4 of the French Social Security Code; and (iv) death of the beneficiary.

The Board regards these performance conditions as good indicators of the development of shareholder value in terms of (i) the quality of investment decisions in a period where external growth plays a more critical role than in the past (ROA condition) and (ii) the commitment to delivering challenging bottom-line results in a tough business environment (business net income condition).

For confidentiality reasons, the amount of the quantitative measures for the internal criteria cannot be disclosed. However, they were determined on a precise basis, and the level of attainment for the internal criteria will be disclosed at the end of the performance measurement period.

In line with our commitment to transparency, we publish in our annual report the level of attainment determined by the Board of Directors for performance conditions applicable to equity-based compensation plans awarded to the Chief Executive Officer and other members of the Executive Committee. The Board believes that disclosing the level of attainment allows our shareholders to better understand the demanding nature of the performance conditions.

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The levels of attainment for equity-based compensation plans that have expired since 2011 are as follows:

	<b>Attainment level</b>		<b>Allocation rate</b>
	<b>Business net income</b>	<b>ROA</b>	
March 9, 2011 plan (stock options only)	2011-2012: 106%	2011-2012: 1.7 percentage points above target	2011-2012: > 100%
	2013-2014: 97.7%		2013-2014: 98.9%
		2013-2014: 0.2 of a percentage point above target	i.e. 99.5% for 2011-2014
March 5, 2012 plans (stock options only)	2012-2014: 84.4%	2012-2014: 0.5 of a percentage point above target	2012-2014: 92.2%
March 5, 2013 plans (stock options only)	2013-2015: 83.2%	2013-2015: 0.2 of a percentage point above target	2013-2015: 91.6%
March 5, 2014 plans	2014-2016: 101.5%	2014-2016: 0.7 of a percentage point above target	2014-2016: 100.75% <sup>(a)</sup>
June 24, 2015 plans	2015-2017: 102.2%	2015-2017: 2.1 percentage points above target	2015-2017: 100.3% <sup>(a)</sup>

*(a) i.e. 100%, the maximum number of exercisable options or shares to be delivered cannot be more than the number of options initially granted or performance shares initially awarded.*

During 2017, 179,398 stock options were exercised by individuals who were members of the Executive Committee when they exercised.

One of the plans involved pre-dated the creation of the Executive Committee (sanofi-aventis plan of December 14, 2006, exercise price 66.91), while the other four post-dated the creation of the Executive Committee (sanofi-aventis plan of December 13, 2007, exercise price 62.33; sanofi-aventis plan of March 3, 2009, exercise price 45.09; sanofi-aventis plan of March 9, 2011, exercise price 50.48; and sanofi-aventis plan of March 5, 2012, exercise price 56.44).

Under French law, Directors may not receive options or performance shares solely as compensation for service on our Board, and consequently our Company may grant options only to those Directors who are also our officers.

Because some of our non-executive Directors were formerly officers or executive officers of our Company or its predecessor companies, some of our non-executive Directors hold Sanofi stock options.

We do not have separate profit-sharing plans for key executives. As employees, they are able to participate in our voluntary and statutory profit-sharing schemes on the same terms as our other employees. These plans are described below under Employees Profit-sharing schemes.

The total amount accrued as of December 31, 2017 in respect of corporate pension plans for corporate officers with current or past executive responsibilities at Sanofi (or at companies whose obligations have been assumed by Sanofi) and for members of the Sanofi Executive Committee was 68 million, of which 6 million was recognized in the income statement for the year then ended.

### **C. Board Practices**

Neither we nor our subsidiaries have entered into service contracts with members of our Board of Directors or corporate officers providing for benefits upon termination of employment. With respect to Olivier Brandicourt see also B. Compensation Compensation and arrangements for corporate officers above.

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Application of the AFEP-MEDEF Code**

The AFEP-MEDEF Code requires us to specifically report on the application of its recommendations and, if applicable, explain why any of them have not been applied. Currently our departures from this Code are as follows:

<b>Paragraph of the AFEP-MEDEF Code</b>	<b>Recommendation of the AFEP-MEDEF code</b>	<b>Application by Sanofi</b>
8.5.6 Independent Directors	The criteria to be reviewed by the committee and the Board in order to qualify as independent and to prevent risks of conflicts of interest between the director and the management, the corporation, or its group, are the following:	Our Board of Directors does not strictly follow the recommendation according to which being a Board member for more than 12 consecutive years is of itself sufficient to automatically disqualify a director from being regarded as independent.
	<p style="padding-left: 40px;">not to have been a director of the corporation for more than twelve years.</p> <p style="padding-left: 40px;">[ ]</p>	<p>The influence of the passage of time on the relationship between a director and the Company and its management must therefore be evaluated on a case by case basis, and not mechanically. It is only after reviewing all the factors that a director can be determined as being independent or non-independent.</p> <p>While length of service may in certain circumstances be associated with a loss of independence, in other circumstances it may enhance the capacity of a director to question senior management and give</p>

greater independence of mind.

In response to a question asked in 2014 by the *Haut Comité de Gouvernement d'Entreprise* (the body in charge of overseeing the implementation of the AFEF-MEDEF Code), our Board explained that it considers its Appointments and Governance Committee to be best placed to assess the behavior and hence the true independence of a director.

The Board of Directors takes the view that it is in no way favoring competence over independence but rather checking a director's willingness and ability to form his or her own opinion, ask for further information and question the decisions of Senior Management. Consequently, our Board of Directors provides explanations for the specific cases it reviews (see A. Directors and Senior Management Independence of Board Members below).

Nevertheless, the Board would point out that the term of office of the director who has been on the Board for more than 12 years expires at the Annual General Meeting of May 2, 2018, and he will not be proposed for reappointment.

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

<b>Paragraph of the AFEP-MEDEF Code</b>	<b>Recommendation of the AFEP-MEDEF code</b>	<b>Application by Sanofi</b>
9.3. Evaluation of the Board of Directors	<p>The evaluation has three objectives:</p> <p>[ . . .];</p> <p>measure the actual contribution of each director to the Board's work.</p>	<p>Director independence is assessed every year.</p> <p>The issue of competence and individual contribution to the work of the Board and its Committees is addressed on a continuous basis, with a specific review when a director is up for reappointment as a Board or Committee member.</p> <p>Annual evaluations involve each director responding to a detailed questionnaire using a dedicated IT platform. The questionnaire deals specifically with the operating procedures of the Board and gives directors an opportunity to express freely their assessment of the individual contributions of other directors. These evaluations are followed by individual meetings with the Secretary to the Board, at which the responses to the questionnaire are analyzed and discussed.</p> <p>For the formal evaluation conducted every three years, the Board may retain an external consultant. In 2015, when a specialist consultancy firm conducted the</p>

evaluation, directors expressed positive opinions about the collegiate nature of the way the Board and its Committees operate, which is only possible through serious contributions from individual directors and high attendance rates. This also reflects a good mix of profiles and a diversity of competencies, experience and geographical origins among Board members.

17.1. Membership of the Compensation Committee	It is recommended that one of its members be an employee director.	The Board intends to appoint a director representing employees to the Compensation Committee after an induction period of twelve months from the date of his or her initial appointment to the Board in June 2017. This will give the new director time to adapt to how the Company operates, understand its specific characteristics, familiarize himself or herself with the challenges and broad outlines of the Board's remit, and undertake any necessary training.
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Furthermore, until now, the limitations on the powers of the Chief Executive Officer have not been contained in our Board Charter (the equivalent document to the internal rules of the Board as referred to in the AFEP-MEDEF Code), contrary to recommendation 3.2 of the AFEP-MEDEF Code, but rather in a Board decision of July 28, 2009. Those limitations were nonetheless disclosed every year in our annual report and on our corporate website. Because there was no difference in terms of transparency or decision making process, this departure was technical and had no practical repercussions.

However, because we are committed to following best practice in corporate governance, we have incorporated the limitations on the Chief Executive Officer's powers into our Board Charter with effect from March 6, 2018, the date of its most recent update. An English version of the full text of our Board Charter is included as Exhibit 1.2 to our Annual Report on Form 20-F, and on our corporate website.

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Activities of the Board of Directors in 2017**

During 2017, the Board of Directors met nine times, with an overall attendance rate among Board members of over 95%. This attendance rate includes participation by conference call, though only a limited number of Directors participated in this way. Individual attendance rates varied between 75% and 100%.

The following persons attended meetings of the Board of Directors:

the directors;

the Secretary to the Board;

frequently: members of the Executive Committee; and

occasionally: managers of our global functions.

Pursuant to the agreement of February 24, 2005 setting up a European Works Council, and prior to the appointment of two directors representing employees in June 2017, five employee representatives attended Board meetings in a consultative capacity.

The agenda for each meeting of the Board is prepared by the Secretary after consultation with the Chairman, taking account of the agendas for the meetings of the specialist Committees and the suggestions of the directors.

Approximately one week prior to each meeting of the Board of Directors, the directors each receive a file containing the agenda, the minutes of the previous meeting, and documentation relating to the agenda.

The minutes of each meeting are expressly approved at the next meeting of the Board of Directors.

In compliance with our Board Charter, certain issues are examined in advance by the various Committees according to their areas of competence to enable them to make a recommendation; these issues are then submitted for a decision by



the Board of Directors.

At the end of 2015, acting on a recommendation from the Appointments and Governance Committee, the Board decided to raise the number of executive sessions (i.e. Board meetings held without the Chief Executive Officer present) to at least two per year. The primary purpose of such sessions is to assess the performance of the Chief Executive Officer and to discuss succession planning. Three executive sessions have taken place during the 2017 financial year.

In 2017, the main activities of the Board of Directors related to the following issues:

financial statements and financial matters:

review of the individual company and consolidated financial statements for the 2016 financial year and for the first half of 2017, review of the consolidated financial statements for the first three quarters of 2017, review of the draft press releases and presentations to analysts with respect to the publication of such financial statements, examination of documents relating to management forecasts;

delegation of authority to the Chief Executive Officer to issue bonds and guarantees, and renewal of the share repurchase program;

recording the amount of share capital, reducing the share capital through cancellation of treasury shares, and amending the Articles of Association accordingly;

presentation of the 2017 budget and financial forecasts 2017-2019.

compensation matters:

determination of the 2016 variable compensation of the Chief Executive Officer, the 2017 fixed and variable compensation of the Chief Executive Officer and the 2017 fixed compensation of the Chairman of the Board, plus an update on fixed and variable compensation of members of the Executive Committee for 2016 and 2017. During the presentation of the report of the Compensation Committee on the compensation of corporate officers, the Board of Directors deliberates in executive session in their absence: the Board of Directors first discusses the compensation of the Chairman of the Board in his absence, and then the compensation of the Chief Executive Officer with the Chairman present but the Chief Executive Officer still absent;

allocation of Directors' attendance fees for 2016, principles of allocation for 2017 and allocation of attendance fees for the first half of 2017, and expenses of corporate officers;

adoption of equity-based compensation plans, consisting of stock subscription option plans and performance share plans in respect of 2017, and determination of the fulfillment of performance conditions of previous equity-based compensation plans.

appointments and governance matters:

composition of the Board, proposed reappointment of directors and appointment of a new director at the 2017 Annual General Meeting, and director independence;

review of succession planning;

reviews of the Board of Directors' Management Report, the Chairman's Report and the reports of the statutory auditors;

the notice of meeting for the Annual General Meetings of Shareholders and of Holders of Participating Shares (Series issued in 1983, 1984 and 1987 and Series A participating shares issued in 1989), adoption of (i) the draft resolutions (ii) the report of the Board of Directors on the resolutions and (iii) the special reports on the awards of stock subscription options and performance shares, and examination of questions submitted in writing;

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

evaluation of the activities of the Board and its Committees;

review of the Board Charter; and

review of previously-approved related party agreements.

presentation on the Vaccines business;

update on the cost reduction program;

update on the Diabetes business;

update on the anti-infectives;

update on Dupixent®;

update on Depakine®;

review of significant proposed alliances and acquisitions, and strategic opportunities;

Company policy on equal pay and opportunities; and

approval in principle of a share issue reserved for employees.

### Activities of the Board Committees in 2017

Since 1999, our Board of Directors has been assisted in its deliberations and decisions by specialist Committees (see our

Board Charter, provided as Exhibit 1.2 to this Annual Report on Form 20-F). Chairmen and members of these Committees are chosen by the Board from among its members, based on their experience.

The Committees are responsible for the preparation of certain items on the agenda of the Board of Directors. Decisions of the Committees are adopted by a simple majority with the chairman of the Committee having a casting vote. Minutes are drafted, and approved by the Committee members.

The chairman of each Committee reports to the Board on the work of that Committee, so that the Board is fully informed whenever it takes a decision.

Because the Board of Directors has decided to allow an average period of one year to elapse between the date on which a Director is first appointed to serve on the Board and the appointment of that Director to a Committee, the composition of the Committees did not change in 2017.

	<b>Audit Committee</b>		<b>Compensation Committee</b>
<b>Chairman</b>	Robert Castaigne (independent director)		Patrick Kron (independent director)
<b>Members</b>	Fabienne Lecorvaisier (independent director)		Claudie Haigneré (independent director)
	Christian Mulliez		Christian Mulliez
	Carole Piwnica (independent director)		Diane Souza (independent director)
	<b>Proportion of independent directors: 75% (3/4)</b>		<b>Proportion of independent directors: 75% (3/4)</b>
	<b>Appointments and Governance Committee</b>		<b>Strategy Committee</b>
<b>Chairman</b>	Serge Weinberg (independent director)		Serge Weinberg (independent director)
<b>Members</b>	Claudie Haigneré (independent director)		Olivier Brandicourt
	Patrick Kron (independent director)		Laurent Attal
	<b>Proportion of independent directors: 100% (3/3)</b>		Patrick Kron (independent director)
			<b>Proportion of independent directors: 50% (2/4)</b>

## Audit Committee

Three members of the Audit Committee are classified as independent pursuant to the criteria adopted by the Board of Directors: Robert Castaigne, Fabienne Lecorvaisier, and Carole Piwnica.

All four members of the Committee have financial or accounting expertise as a consequence of their education and professional

experience as reflected in their biographies. Furthermore, Robert Castaigne, Fabienne Lecorvaisier, and Christian Mulliez are deemed to be financial experts pursuant to the definition in the Sarbanes-Oxley Act and the definition in Article L. 823-19 of the French Commercial Code. See Item 16A. Audit Committee Financial Expert .

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The Audit Committee met seven times in 2017, including prior to the meetings of the Board of Directors during which the financial statements were approved. In addition to the statutory auditors, the principal financial officers, the Senior Vice President Group Internal Audit and other members of the senior management team attended meetings of the Audit Committee, in particular when risk exposure and off-balance-sheet commitments were discussed.

The Committee members had a very good attendance record, with an overall attendance rate of over 93%. Individual attendance rates varied between 71% and 100%.

The statutory auditors attend all meetings of the Audit Committee; they presented their opinions on the annual and half-year financial statements at the Committee meetings of February 7, 2017 and July 28, 2017, respectively.

In 2017, the main activities of the Audit Committee related to:

preliminary review of the individual company and consolidated financial statements for the 2017 financial year, review of the individual company and consolidated financial statements for the first half of 2017, review of the consolidated financial statements for the first three quarters of 2017, review of the draft press releases and analyst presentations relating to the publication of such financial statements;

Sanofi's financial position, indebtedness and liquidity;

review of the work of the Internal Control function and evaluation of that work for 2016 as certified by the statutory auditors pursuant to Section 404 of the Sarbanes-Oxley Act, and examination of the 2016 Annual Report on Form 20-F;

reporting on guarantees;

review of the draft financial resolutions for the May 10, 2017 Shareholders' Annual General Meeting;

the principal risks facing Sanofi including an update on insurance cover, a report of the Risk Committee, an update on impairment testing of goodwill, a review of whistleblowing and material compliance investigations, a review of tax risks and deferred tax assets, a review of material litigation, and an update on pension funds and actuarial assumptions;

conclusions of Sanofi senior management on internal control procedures, the Board of Directors' Management Report, the 2016 Report under the French Financial Security Act, and the 2016 Chairman's Report, including the description of risk factors contained in the French-language *Document de Référence*;

update on the implementation of IFRS 15 (revenues) and IFRS 9 (financial instruments) accounting standards;

general update on the overall situation regarding information systems and information systems security, and the annual internal audit report;  
coordination of the work between internal audit and internal control;

the audit program, allocation of work and fees between the statutory auditors, and the budget for audit-related services and non-audit services.

The Committee did not use external consultants in 2017.

### Compensation Committee

Of the four members of the Compensation Committee, three are deemed to be independent: Patrick Kron, Claudie Haigneré, and Diane Souza.

The Compensation Committee met three times in 2017.

The Committee members have a good attendance record, with an overall attendance rate of 100%.

When the Committee discusses the compensation policy for members of senior management who are not corporate officers, i.e. the members of the Executive Committee, the Committee invites the Chief Executive Officer to attend.

In 2017, the main activities of the Compensation Committee related to:

fixed and variable compensation of executive officers (Chief Executive Officer and Chairman of the Board);

the 2016 and 2017 fixed and variable compensation of the members of the Executive Committee;

setting the amount of directors' attendance fees for 2016, reviewing the expenses of corporate officers for 2016, and principles for allocating directors' attendance fees for 2017;

review of the governance chapter of the 2016 French-language *Document de Référence*, which contains disclosures about compensation;

implementation of the equity-based compensation policy, including both stock options and performance shares, which was discussed at more than one meeting largely because of the need to review termination clauses;

review of draft say on pay resolutions to be submitted to the shareholders in 2017, and renewal of the delegations of authority to the Board to award stock options and performance shares; and

launch of an employee share ownership plan in June 2017, follow-up report on implementation of the plan, and consideration of the next plan;

update on changes in say on pay requirements in light of the Sapin 2 law; and

the top-up defined-benefit pension plan of the Chief Executive Officer.



**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The Committee did not use external consultants in 2017.

**Appointments and Governance Committee**

All three members of the Appointments and Governance Committee are deemed to be independent: Serge Weinberg and Patrick Kron.

The Appointments and Governance Committee met three times in 2017.

The Committee members have a good attendance record, with an overall attendance rate of 100%.

In 2017, the main activities of the Appointments and Governance Committee related to:

succession planning;

summary of the results of the evaluation of the Board and its Committees;

review of the Board of Directors Management Report, Chairman's Report, and the governance chapter of the French-language *Document de Référence*;

changes in the composition of the Board and its Committees, director independence, proposed reappointments of directors, proposed appointments of new directors, update on the recruitment of a director;

The Committee did not use external consultants in 2017.

**Strategy Committee**

Two of the four members of the Strategy Committee are deemed to be independent.

In 2017, the Strategy Committee met ten times, including twice in expanded sessions that included other directors.

The Committee members have a good attendance record, with an overall attendance rate of 100%.

In 2017, the main activities of the Strategy Committee related to:

review of external growth opportunities, including Bioverativ and Ablynx;

partnership opportunities;

review of the strategy, with a focus on digital;

global environment (healthcare trends, competitive landscape, access to drugs);

research and development (pipeline, Regeneron, research platforms);  
long range financials; and

Sanofi's international presence.

The Committee did not use external consultants in 2017.

### Scientific Committee

In line with Sanofi's strategic roadmap, the Board decided, on March 6, 2018, to set up a fifth permanent Committee to address scientific and R&D issues.

The main roles of this Committee are:

to assist the Board in scrutinizing the strategic orientation and investments proposed by the Chief Executive Officer in those areas;

to identify and discuss emerging trends and new challenges, and ensure that Sanofi is well prepared for them; and

to ensure that processes are in place to enable optimal decision-making on investments in R&D, consistent with the strategy determined by the Board.

The Board Charter will be amended so that the remit, composition and operating procedures of the new Committee are precisely defined. However, it will not be necessary to increase the overall amount allocated to directors' attendance fees, since the amount approved by the Annual General Meeting of May 10, 2017 will be sufficient to cover the extra fees that will be due.

### **Attendance rate of Board members**

In 2017, the average attendance rate of directors at Board and Committee meetings was 96% (95% for Board meetings, 98% for Committee meetings).

Directors who were absent from some meetings provided clear and substantiated explanations for their absence, which related mainly to personal matters or to unscheduled meetings called at short notice (especially where sudden developments on an ongoing project necessitated a Board meeting). The Board pays particular attention to the availability of directors, and makes sure that their other professional commitments do not prevent them from fully discharging their remit with respect to the Company.

### **D. Employees**

#### **Number of Employees**

In 2017, Sanofi employed 106,566 people worldwide, 293 less than in 2016. The tables below give a breakdown of employees by geographic area and function for the years ended December 31, 2017, 2016 and 2015.

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

**Employees by geographic area**

	2017		2016		As of December 31, 2015	
		%		%		%
Europe	48,358	45.4%	46,924	43.9%	47,326	43.4%
Emerging Markets	38,401	36.0%	39,308	36.8%	40,407	37.0%
United States	13,810	13.0%	15,181	14.2%	15,533	14.2%
Rest of the World	5,997	5.6%	5,446	5.1%	5,823	5.3%
<b>Total<sup>(a)</sup></b>	<b>106,566</b>	<b>100.0%</b>	<b>106,859</b>	<b>100.0%</b>	<b>109,089</b>	<b>100.0%</b>

*(a) Excludes workforce for the Animal Health business of 4 employees in 2017, 6,957 in 2016 and 6,542 in 2015.*

**Employees by function**

	2017		2016		As of December 31, 2015	
		%		%		%
Sales Force	30,284	28.4%	30,815	28.8%	32,771	30.0%
Research and Development	14,764	13.9%	15,148	14.2%	15,384	14.1%
Production	40,417	37.9%	41,867	39.2%	42,754	39.2%
Marketing and Support Functions	21,101	19.8%	19,029	17.8%	18,180	16.7%
<b>Total<sup>(a)</sup></b>	<b>106,566</b>	<b>100.0%</b>	<b>106,859</b>	<b>100.0%</b>	<b>109,089</b>	<b>100.0%</b>

*(a) Excludes workforce for the Animal Health business of 4 employees in 2017, 6,957 in 2016 and 6,542 in 2015.*

**Industrial Relations**

In all countries where we operate, we seek to strike a balance between our economic interests and those of our employees, which we regard as inseparable.

Our responsibility towards our employees is based on the basic principles of our Social Charter, which outlines the rights and duties of all Sanofi employees. The Social Charter addresses our key commitments towards our workforce: equal opportunity for all people without discrimination, the right to health and safety, respect for privacy, the right to information and professional training, social protection for employees and their families, freedom of association and the right to collective bargaining, and respect for the principles contained in the Global Compact on labor relations and ILO treaties governing the physical and emotional well-being and safety of children.

Our labor relations are based on respect and dialogue. In this spirit, management and employee representatives meet regularly to exchange views, negotiate, sign agreements and ensure that agreements are being implemented.

Employee dialogue takes place in different ways from country to country, as dictated by specific local circumstances. Depending on the circumstances, employee dialogue relating to information, consultation and negotiation processes may take place at national, regional or company level. It may be organized on an interprofessional or sectorial basis, or both. Employee dialogue

may be informal or implemented through a specific formal body, or a combination of both methods. Whatever the situation, Sanofi encourages employees to voice their opinions, help create a stimulating work environment and take part in decisions aiming to improve the way we work. These efforts reflect one of the principles of the Social Charter, whereby improving working conditions and the necessary adaptation to our business environment go hand-in-hand.

## **Profit-sharing Schemes, Employee Savings Schemes and Employee Share Ownership**

### **Profit-sharing Schemes**

All employees of our French companies belong to voluntary and statutory profit-sharing schemes.

#### **Voluntary Scheme (*Intéressement des salariés*)**

These are collective schemes that are optional for the employer and contingent upon performance. The aim is to give employees an interest in the growth of the business and improvements in its performance.

The amount distributed by our French companies during 2017 in respect of voluntary profit-sharing for the year ended December 31, 2016 represented 1.33% of total payroll.

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

In June 2017, we entered into a new fixed-term statutory profit-sharing agreement for the 2017, 2018 and 2019 financial years. That agreement applies to all employees of our French companies. Under the agreement, Sanofi pays collective variable compensation determined on the basis of the more favorable of (i) growth in consolidated net sales (at constant exchange rates and on a constant structure basis) or (ii) the level of business net income. For each of those criteria, a matrix determines what percentage of total payroll is to be allocated to the scheme. This overall allocation is then reduced by the amount required by law to be transferred to a special profit-sharing reserve. The balance is then distributed between the employees unless the transfer to the reserve exceeds the maximum amount determined under the specified criteria, in which case no profit share is paid to the employees.

**Statutory Scheme (*Participation des salariés aux résultats de l'entreprise*)**

This scheme is a French legal obligation for companies with more than 50 employees that made a profit in the previous financial year.

In November 2007, we entered into a new statutory profit-sharing agreement for an indefinite period, covering all the employees of our French companies.

An amendment to this agreement was signed in April 2009, primarily to align the agreement on a change in French legislation (Law no. 2008-1258 of December 3, 2008) intended to protect against erosion in purchasing power, under which each qualifying employee can elect to receive some or all of his or her profit-sharing bonus immediately without observing the normal mandatory lock-up period.

The amount distributed by our French companies during 2017 in respect of the statutory scheme for the year ended December 31, 2016 represented 8.08% of total payroll.

**Distribution Formula**

In order to favor lower-paid employees, the voluntary and statutory profit-sharing agreements entered into since 2005 split the benefit between those entitled as follows:

60% prorated on the basis of time spent in the Company's employment in the year; and

40% prorated on the basis of gross annual salary during the year, subject to a lower limit equal to the social security ceiling and an upper limit of three times the social security ceiling.

### **Employee Savings Schemes and Collective Retirement Savings Plan**

The employee savings arrangements operated by Sanofi are based on a collective savings scheme (*Plan d'Épargne Groupe*) and a collective retirement savings scheme (*Plan d'Épargne pour la*

*Retraite Collectif*). Those schemes reinvest the sums derived from the statutory and voluntary profit-sharing schemes, plus voluntary contributions from employees.

In June 2017, more than 91% of the employees who benefited from the profit-sharing schemes opted to invest in the collective savings scheme, and nearly 79% opted to invest in the collective retirement savings scheme.

Sanofi supplements the amount invested by employees in these schemes by making a top-up contribution.

In 2017, 130.1 million and 56.9 million were invested in the collective savings scheme and the collective retirement savings scheme respectively through the voluntary and statutory schemes for 2016, and through top-up contributions.

In December 2017, we entered into a new agreement for an indefinite period, setting out revised terms for the top-up contribution to the collective savings scheme and covering all the employees of our French companies.

### **Employee Share Ownership**

As of December 31, 2017, shares held under the collective savings scheme by employees of Sanofi, employees of related companies and former employees amounted to 1.54% of our share capital. For more information about our most recent employee share ownership plan, refer to Item 10. Additional Information Changes in Share Capital Increases in Share Capital .

### **E. Share Ownership**

#### **Senior Management**

Members of the Executive Committee hold shares of our Company amounting in the aggregate to less than 1% of our share capital.

During 2017, 179,398 stock options were exercised by individuals who were members of the Executive Committee when they exercised.

One of the plans involved pre-dated the creation of the Executive Committee (sanofi-aventis plan of December 14, 2006, exercise price 66.91), while the other four post-dated the creation of the Executive Committee (sanofi-aventis plan of December 13, 2007, exercise price 62.33; sanofi-aventis plan of March 3, 2009, exercise price 45.09; sanofi-aventis plan of March 9, 2011, exercise price 50.48; and sanofi-aventis plan of March 5, 2012, exercise price 56.44).

#### **Existing Option Plans as of December 31, 2017**

As of December 31, 2017, a total of 7,889,020 options were outstanding: 104,701 stock purchase options and 7,784,319 stock subscription options. As of that same date, 5,812,165 options were immediately exercisable: 104,701

stock purchase options and 5,707,464 stock subscription options.



**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

Equity-based compensation, consisting of share subscription option plans and performance share plans, aims to align our employees' objectives with those of our shareholders and to reinforce the link between our employees and Sanofi. Under French law, awarding such plans falls within the powers of the Board of Directors. Stock options are awarded to employees and executive officers by our Board of Directors on the basis of recommendations from the Compensation Committee.

Granting options is a way of recognizing the grantee's performance and contribution to the development of Sanofi, and also of securing his or her future commitment.

For each plan, the Compensation Committee and the Board of Directors assess whether it should take the form of options to subscribe for shares or options to purchase shares, based on criteria that are primarily financial.

A list of grantees is proposed by the Chief Executive Officer to the Compensation Committee, which reviews the list and then submits it to the Board of Directors, which takes the decision to grant the options. The Board of Directors also sets the terms for the exercise of the options (including the exercise price) and the lock-up period. The exercise price never incorporates a discount, and is at least equal to the average of the quoted market prices on the 20 trading days preceding the date of grant. Stock option plans invariably specify a lock-up period of four years and a total duration of ten years.

In 2011, the Board of Directors made substantial changes to our equity-based compensation policy. To limit the dilutive effect on our shareholders, the Board of Directors decided to primarily award

performance shares, except for a limited number of high-level executives who may continue to receive options. Regardless of the identity of the grantee, any award of options or performance shares is fully contingent upon performance targets being achieved over three financial years.

At its meeting of May 10, 2017 the Board of Directors (in addition to the 220,000 options awarded to Olivier Brandicourt) awarded 14 grantees a total of 158,040 stock options, each of which gives entitlement to subscribe for one of our shares.

The 2017 awards represent a dilution of approximately 0.03% of our undiluted share capital as of December 31, 2017.

The entire award is contingent upon the same criteria, based on business net income<sup>(1)</sup> and return on assets (ROA), as the award made to members of the Executive Committee. The attainment levels are also the same as for the award made to members of the Executive Committee. Vesting is also subject to a non-compete clause.

The number of options awarded to the Chief Executive Officer in 2017 represents 3.49% of the total limit approved by the Shareholders Annual General Meeting of May 4, 2016 (0.5% of our share capital) and 58.19% of the total award to all beneficiaries made on May 10, 2017.

Not all of our employees were awarded stock options, but a new voluntary profit-sharing agreement was signed in June 2017 which gives all of our employees an interest in Sanofi's performance (for more details refer to Profit-Sharing Schemes, Employee Savings Schemes and Employee Share Ownership, above).

### Share Purchase Option Plans

Source authorization	Date of shareholder authorization	Date of grant	Number of options initially granted	- to the		Start date of exercise period	Expiry date	Exercise price	Number of		Number of options outstanding
				employees awarded the most options <sup>(b)</sup>	10				shares as of 12/31/2017	options as of 12/31/2017	
Synthélabo	06/23/98	03/30/99	716,040	0	176,800	03/31/04	03/30/19	38.08	605,619	5,720	104,701

(a) Comprises the Chairman & Chief Executive Officer, the Chief Executive Officer, and any Deputy Chief Executive Officers in office at the date of grant.

(b) In post at the date of grant.

(1) For a definition, see Item 5. Operating and Financial Review and Prospects A.1.5. Segment Information 3/ Business Net Income.

**Table of Contents**

## ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

## Share Subscription Option Plans

Entity	Date of shareholder authorization	Date of grant	Number of options initially granted	- to the 10 employees of the corporation		Start date of exercise period	Expiry date	Exercise price ( )	Number of shares subscribed as of 12/31/2017	Number of options canceled as of 12/31/2017 <sup>(c)</sup>	Number of options outstanding
				to employees	to employees						
Sanofi-aventis	05/31/07	12/13/07	11,988,975	325,000	625,000	12/14/11	12/13/17	62.33	10,278,983	1,713,292	
Sanofi-aventis	05/31/07	03/02/09	7,736,480	250,000	655,000	03/04/13	03/01/19	45.09	5,423,130	635,330	1,679,000
Sanofi-aventis	04/17/09	03/01/10	7,316,355	0	665,000	03/03/14	02/28/20	54.12	4,046,285	677,585	2,596,000
Sanofi-aventis	04/17/09	03/01/10	805,000	275,000	805,000	03/03/14	02/28/20	54.12	625,000	50,000	130,000
Sanofi-aventis	04/17/09	03/09/11	574,500	0	395,000	03/10/15	03/09/21	50.48	296,468	35,454	242,000
Sanofi-aventis	04/17/09	03/09/11	300,000	300,000	0	03/10/15	03/09/21	50.48	292,200	7,800	
Sanofi	05/06/11	03/05/12	574,050	0	274,500	03/06/16	03/05/22	56.44	155,748	95,021	323,000
Sanofi	05/06/11	03/05/12	240,000	240,000	0	03/06/16	03/05/22	56.44	0	35,280	204,000
Sanofi	05/06/11	03/05/13	548,725	0	261,000	03/06/17	03/05/23	72.19	87,181	105,859	355,000
Sanofi	05/06/11	03/05/13	240,000	240,000	0	03/06/17	03/05/23	72.19	0	64,080	175,000
Sanofi	05/03/13	03/05/14	769,250	0	364,500	03/06/18	03/05/24	73.48	0	98,875	670,000
Sanofi	05/03/13	03/05/14	240,000	240,000	0	03/06/18	03/05/24	73.48	0	46,560	193,000
Sanofi	05/03/13	06/24/15	12,500	0	12,500	06/25/19	06/24/25	89.38	0	1,500	11,000
Sanofi	05/03/13	06/24/15	202,500	0	202,500	06/25/19	06/24/25	89.38	0	0	202,500
Sanofi	05/03/13	06/24/15	220,000	220,000	0	06/25/19	06/24/25	89.38	0	0	220,000
Sanofi	05/04/16	05/04/16	17,750	0	17,750	05/05/20	05/04/26	75.90	0	1,250	16,500
Sanofi	05/04/16	05/04/16	165,000	0	165,000	05/05/20	05/04/26	75.90	0	0	165,000

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fi	05/04/16	05/04/16	220,000	220,000	0	05/05/20	05/04/26	75.90	0	0	220
fi	05/10/17	05/10/17	158,040	0	157,140	05/11/21	05/10/27	88.97	0	0	158
fi	05/10/17	05/10/17	220,000	220,000	0	05/11/21	05/10/27	88.97	0	0	220

*(a) Comprises the Chairman & Chief Executive Officer, the Chief Executive Officer, and any Deputy Chief Executive Officers in office at the date of grant.*

*(b) In post at the date of grant.*

*(c) Includes 183,640 options canceled due to partial non-fulfilment of performance conditions.*

The main characteristics of our stock options are also described in Note D.15.8. to our consolidated financial statements, included in Item 18 of this annual report.

During the year ended December 31, 2017, the ten employees (other than corporate officers) granted the most options were collectively awarded a total of 157,140 options.

During the same period, a total of 261,898 shares were purchased or subscribed for by the ten employees (other than corporate officers) who exercised the most options during the period, at a weighted average exercise price of approximately 59.86 per share.

### Existing Restricted Share Plans as of December 31, 2017

Since 2009, the Board of Directors has awarded shares to certain employees in order to give them a direct stake in our future and performances via trends in the share price, as a partial substitute for the granting of stock options.

Shares are awarded to employees on the basis of a list submitted to the Compensation Committee. This Committee then submits the list to the Board of Directors, which decides whether to award the

shares. The Board of Directors sets the continuing employment conditions to which vesting is subject, and any lock-up conditions for the shares.

In 2011, the Board of Directors made substantial changes to our equity-based compensation policy. To limit the dilutive effect on our shareholders, the Board of Directors decided to primarily award performance shares, except for a limited number of high-level executives who could continue to receive options. Under this revised policy, any award of options or performance shares is fully contingent upon performance targets being achieved over three financial years, regardless of the identity of the grantee.

Our share plans have a three-year vesting period, with no lock-up period.

At its meeting of May 10, 2017, the Board of Directors awarded two plans, in addition to the plan awarded to the Chief Executive Officer:

- a France plan, under which 2,289 beneficiaries were awarded a total of 1,174,270 shares; and

an International plan, under which 5,278 beneficiaries were awarded a total of 2,363,195 shares.

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The 2017 awards represent a dilution of approximately 0.29% of our undiluted share capital as of December 31, 2017.

The entire award is contingent upon the same criteria, based on business net income<sup>(1)</sup> and return on assets (ROA), as the award made to members of the Executive Committee. The attainment levels are also the same as for the awards made to members of the Executive Committee. Vesting is subject to a non-compete clause.

The number of performance shares awarded to the Chief Executive Officer in 2017 represents 0.26% of the total limit approved by the

Shareholders Annual General Meeting of May 4, 2016 (1.5% of the share capital) and 1.39% of the total amount awarded to all beneficiaries on May 10, 2017.

Not all of our employees were awarded performance shares, but a new voluntary profit-sharing agreement was signed in June 2017 which gives all of our employees an interest in Sanofi's performance (for more details refer to Profit-Sharing Schemes, Employee Savings Schemes and Employee Share Ownership , above).

**Restricted Share Plans**

	Date of shareholder authorization	Date of grant	Number of shares initially awarded to officers	- to the employees awarded the most shares <sup>(b)</sup>	- to the 10 employees awarded the most shares <sup>(b)</sup>	Start date of vesting period <sup>(c)</sup>	Vesting date	End of lock-up period	Number of shares vested as of 12/31/2017	Number of rights canceled as of 12/31/2017 <sup>(d)</sup>	Number of shares not yet vested
Sanofi	05/04/12	03/05/13	1,400,260	0	97,300	03/05/13	03/06/16	03/06/18	1,248,635	152,041	0

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Sanofi	05/04/12	03/05/13	11,650	0	1,550	03/05/13	03/06/17	03/06/17	10,675	975	0
Sanofi	05/04/12	03/05/13	2,838,795	0	85,100	03/05/13	03/06/17	03/06/17	2,140,606	708,271	0
Sanofi	05/04/12	03/05/13	45,000	45,000	0	03/05/13	03/06/16	03/06/18	32,985	12,015	0
Sanofi	05/04/12	03/05/14	1,236,720	0	28,060	03/05/14	03/06/17	03/06/19	1,200,470	36,250	0
Sanofi	05/04/12	03/05/14	2,605,515	0	35,400	03/05/14	03/06/18	03/06/18	8,400	456,815	2,145,550
Sanofi	05/04/12	03/05/14	20,900	0	11,300	03/05/14	03/06/18	03/06/18	0	4,000	16,900
Sanofi	05/04/12	03/05/14	45,000	45,000	0	03/05/14	03/06/17	03/06/19	36,270	8,730	0
Sanofi	05/04/15	06/24/15	1,127,120	0	63,000	06/24/15	06/25/18	06/25/20	300	32,150	1,095,520
Sanofi	05/04/15	06/24/15	129,000	0	129,000	06/24/15	06/25/18	06/25/20	0	25,000	104,000
Sanofi	05/04/15	06/24/15	30,300	0	14,950	06/24/15	06/25/19	06/25/19	0	7,200	23,100
Sanofi	05/04/15	06/24/15	2,307,120	0	84,500	06/24/15	06/25/19	06/25/19	5,950	324,120	1,980,300
Sanofi	05/04/15	06/24/15	124,500	0	124,500	06/24/15	06/25/19	06/25/19	0	0	124,500
Sanofi	05/04/15	06/24/15	66,000	66,000	0	06/24/15	06/25/19	06/25/19	0	0	66,000
Sanofi	05/04/15	06/24/15	45,000	45,000	0	06/24/15	06/25/19	06/25/19	0	0	45,000
Sanofi	05/04/16	05/04/16	1,289,825	0	74,400	05/04/16	05/05/19	05/05/19	300	32,600	1,257,925
Sanofi	05/04/16	05/04/16	2,533,100	0	113,750	05/04/16	05/05/19	05/05/19	3,400	239,852	2,290,148
Sanofi	05/04/16	05/04/16	132,000	0	132,000	05/04/16	05/05/19	05/05/19	0	25,000	107,000
Sanofi	05/04/16	05/04/16	93,000	0	93,000	05/04/16	05/05/19	05/05/19	0	0	93,000
Sanofi	05/04/16	05/04/16	50,000	50,000	0	05/04/16	05/05/19	05/05/19	0	0	50,000
Sanofi	05/10/17	05/10/17	1,174,270	0	150,363	05/10/17	05/11/20	05/11/20	225	33,851	1,140,194
Sanofi	05/10/17	05/10/17	2,363,195	0	155,203	05/10/17	05/11/20	05/11/20	584	84,229	2,278,382
Sanofi	05/10/17	05/10/17	50,000	50,000	0	05/10/17	05/11/20	05/11/20	0	0	50,000

(a) Comprises the Chairman & Chief Executive Officer, the Chief Executive Officer, and any Deputy Chief Executive Officers in office at the date of grant.

(b) In post at the date of grant.

(c) Subject to the conditions set.

(d) Includes 684,672 rights canceled due to partial non-fulfilment of performance conditions.

**Table of Contents**

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

As of December 31, 2017, 12,867,519 shares had not yet vested pending fulfilment of performance conditions.

During the year ended December 31, 2017, the ten employees (other than corporate officers) awarded the most shares were collectively awarded a total of 195,011 shares.

**Shares Owned by Members of the Board of Directors**

As of December 31, 2017, members of our Board of Directors held in the aggregate 12,907 shares, or under 1% of the share capital and of the voting rights, excluding the beneficial ownership of 118,227,307 shares held by L. Oréal as of such date which may be attributed to Laurent Attal or Christian Mulliez (who disclaim beneficial ownership of such shares).

**Transactions in Shares by Members of the Board of Directors and equivalent persons in 2017**

As far as Sanofi is aware, transactions in our securities by (i) Board members, (ii) executives with the power to make management decisions affecting our future development and corporate strategy<sup>(1)</sup> and (iii) persons with close personal ties to such individuals (as per Article L. 621-18-2 of the French Monetary and Financial Code) during the year ended December 31, 2017 were as follows:

On February 15, 2017, Jérôme Contamine, Executive Vice President Chief Financial Officer, exercised 15,000 stock purchase options at an exercise price of 56.44 per share, and sold the resulting 15,000 shares at a price of 78.24 per share.

*(1) The list of these persons is regularly updated and filed by our Company with the AMF.*





**Table of Contents**

## ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

## Item 7. Major Shareholders and Related Party Transactions

**A. Major Shareholders**

The table below shows the ownership of our shares as of January 31, 2018, indicating the beneficial owners of our shares. To the best of our knowledge and on the basis of the notifications received as disclosed below, except for L Oréal and BlackRock, Inc., no other shareholder currently holds more than 5% of our share capital or voting rights.

	Total number of issued shares		Number of actual voting rights (excluding treasury shares) <sup>(d)</sup>		Theoretical number of voting rights (including treasury shares) <sup>(e)</sup>	
	Number	%	Number	%	Number	%
<b>L Oréal</b>	118,227,307	9.43	236,454,614	16.95	236,454,614	16.88
<b>BlackRock<sup>(a)</sup></b>	71,240,867	5.68	71,240,867	5.11	71,240,867	5.09
<b>Employees<sup>(b)</sup></b>	19,283,604	1.54	35,310,455	2.53	35,310,455	2.52
<b>Public</b>	1,039,609,706	82.90	1,052,031,833	75.41	1,052,031,833	75.11
<b>Treasury shares<sup>(c)</sup></b>	5,678,098	0.45	-	-	5,678,098	0.41
<b>Total</b>	<b>1,254,039,582</b>	<b>100</b>	<b>1,395,037,769</b>	<b>100</b>	<b>1,400,715,867</b>	<b>100</b>

(a) Based on BlackRock's declaration as of August 18, 2017.

(b) Shares held via the Sanofi Group Employee Savings Plan.

(c) Includes net position of share repurchases under the Group's liquidity contract which amounted to 60,500 shares as of January 31, 2018. Amounts held under this contract vary over time.

(d) Based on the total number of voting rights as of January 31, 2018.

(e) Based on the total number of voting rights as of January 31, 2018 as published in accordance with article 223-11 and seq. of the General Regulations of the Autorité des marchés financiers (i.e. including treasury shares, the

*voting rights of which are suspended).*

Our Articles of Association provide for double voting rights for shares held in registered form for at least two years. All of our shareholders may benefit from double voting rights if these conditions are met, and no shareholder benefits from specific voting rights. For more information relating to our shares, see Item 10. Additional Information B. Memorandum and Articles of Association.

Neither L. Oréal nor BlackRock holds different voting rights from those of our other shareholders.

To the best of our knowledge, no other shareholder currently holds, directly or indirectly and acting alone or in concert, more than 5% of our share capital or voting rights. Furthermore, we believe that we are not directly or indirectly owned or controlled by another corporation or government, or by any other natural or legal persons. To our knowledge, there are no arrangements that may result in a change of control.

During the year ended December 31, 2017 we received a number of share ownership declarations informing us that a legal threshold had been passed, as required under Article L. 233-7 of the French Commercial Code.

Following purchases of our shares in the market, BlackRock, Inc., acting on its own behalf and on behalf of its affiliates, declared that it had passed first below and then above the threshold of 5% of our

voting rights, and that at the time of the most recent declaration held 5.68% of our share capital and 5.09% of our voting rights (declaration of August 18, 2017).

In addition to the statutory requirement to inform the Company and the *Autorité des marchés financiers* (AMF, the French financial markets regulator) that they hold a number of shares (or of securities equivalent to shares or of voting rights pursuant to Article L. 233-9 of the French Commercial Code) representing more than one twentieth (5%), one tenth (10%), three twentieths (15%), one fifth (20%), one quarter (25%), three tenths (30%), one third (1/3), one half (50%), two thirds (2/3), nine tenths (90%) or nineteen twentieths (95%) of the share capital or theoretical voting rights within four trading days after crossing any such ownership threshold (Article L. 233-7 of the French Commercial Code), any natural or legal person who directly or indirectly comes to hold a percentage of the share capital, voting rights or securities giving future access to the Company's capital that is equal to or greater than 1% or any multiple of that percentage, is obliged to inform the Company thereof by registered mail, return receipt requested, indicating the number of securities held, within the five trading days following the date on which each of the thresholds was crossed.

If such declaration is not made, the shares in excess of the fraction that should have been declared will be stripped of voting rights at shareholders' meetings if on the occasion of such meeting the

**Table of Contents**

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

failure to declare has been formally noted and one or more shareholders collectively holding at least 5% of the Company's share capital or voting rights so request at that meeting.

Any natural or legal person is also required to inform the Company, in the forms and within the time limits stipulated above for passing above a threshold, if their direct or indirect holding passes below any of the aforementioned thresholds.

Since January 1, 2018 we have not received any share ownership declaration.

As of December 31, 2017, individual shareholders (including employees of Sanofi and its subsidiaries, as well as retired employees holding shares via the Sanofi Group Employee Savings Plan) held approximately 7.41% of our share capital. Institutional shareholders (excluding L'Oréal) held approximately 76.63% of our share capital. Such shareholders are primarily American (29.08%), French (14.46%) and British (14.56%). German institutions held 3.31% of our share capital, Swiss institutions held 2.22%, institutions from other European countries held 6.6% and Canadian institutions held 1.58% of our share capital. Other international institutional investors (excluding those from Europe

and North America) held approximately 4.82% of our share capital. In France, our home country, we have 24,855 identified shareholders of record. In the United States, our host country, we have 49 identified shareholders of record and 17,529 identified ADS holders of record.

(Source: a survey conducted by Euroclear France as of December 31, 2017, and internal information).

**Shareholders' Agreement**

We are unaware of any shareholders' agreement currently in force.

**B. Related Party Transactions**

See Note D.33. to our consolidated financial statements included at Item 18 of this annual report.

**C. Interests of Experts and Counsel**

N/A

**Table of Contents**

## ITEM 8. FINANCIAL INFORMATION

## Item 8. Financial Information

**A. Consolidated Financial Statements and Other Financial Information**

Our consolidated financial statements as of and for the years ended December 31, 2017, 2016 and 2015 are included in this annual report at Item 18. Financial Statements.

**DIVIDENDS ON ORDINARY SHARES**

We paid annual dividends for the years ended December 31, 2013, 2014, 2015 and 2016 and our shareholders will be asked to approve the payment of an annual dividend of 3.03 per share for the 2017 fiscal year at our next annual shareholders' meeting. If approved, this dividend will be paid on May 15, 2018.

We expect that we will continue to pay regular dividends based on our financial condition and results of operations. The proposed 2017 dividend equates to a distribution of 54.7% of our business earnings per share. For information on the non-GAAP financial measure business earnings per share see Item 5. Operating and Financial Review and Prospects Business Net Income.

The following table sets forth information with respect to the dividends paid by our Company in respect of the 2013, 2014, 2015 and 2016 fiscal years and the dividend that will be proposed for approval by our shareholders in respect of the 2017 fiscal year at our May 2, 2018 shareholders' meeting.

	<b>2017<sup>(a)</sup></b>	<b>2016</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>
Dividend per Share (in )	3.03	2.96	2.93	2.85	2.80

Dividend per Share (in \$) <sup>(b)</sup>	3.63	3.12	3.19	3.46	3.86
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*(a) Proposal, subject to shareholder approval.*

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

The declaration, amount and payment of any future dividends will be determined by majority vote of the holders of our shares at an ordinary general meeting, following the recommendation of our Board of Directors. Any declaration will depend on our results of operations, financial condition, cash requirements, future prospects and other factors deemed relevant by our shareholders. Accordingly, we cannot assure you that we will pay dividends in the future on a continuous and regular basis. Under French law, we are required to pay dividends approved by an ordinary general meeting of shareholders within nine months following the meeting at which they are approved.

#### **DISCLOSURE PURSUANT TO SECTION 13(R) OF THE UNITED STATES EXCHANGE ACT OF 1934**

Sanofi conducts limited business relating to human and animal health products with Iran contributing well under 1% of Sanofi's consolidated net sales in 2017. These activities, which are not financially material to Sanofi, are being disclosed pursuant to Section 13(r) of the United States Exchange Act of 1934, as amended. Sales consisted of bulk and branded pharmaceuticals, and vaccines. US affiliates of Sanofi, or foreign affiliates controlled by US affiliates of Sanofi, are either not involved in these activities or operate under humanitarian licenses issued by the US Treasury Department's Office of Foreign Assets Control. Limited business amounting to approximately 0.9 million in gross revenues has been conducted by non-US subsidiaries of Sanofi not requiring an OFAC license with entities such as public hospitals or distributors tied to the Ministry of Health. It is estimated that this activity

contributed no more than 0.5 million to net profits. A representative office in Tehran incurs incidental expenses from state-owned utilities.

In January 2016, Sanofi and the Iran Food and Drug Administration, affiliated with the Ministry of Health and Medical Education of the Islamic Republic of Iran, signed a Memorandum of Cooperation (MoC) regarding (i) potential future projects to reinforce current partnerships with reputable Iranian manufacturers (in particular to enhance industrial quality standards), (ii) collaborating with the Ministry of Health on programs for the prevention and control of certain chronic and non-communicable diseases (in particular diabetes) and (iii) potential future collaboration on epidemiological studies.

Following the MOC, Sanofi and the Iranian company Barkat Pharmed Co. entered into a non-binding letter of intent on June 16, 2017 to evaluate the possibility of a transaction involving the creation of a joint venture, or other possible forms of transaction, the business purpose of which would be the manufacturing and distribution of pharmaceutical products in Iran. The MoC and the letter of intent did not generate any revenue, nor any net profit.

Sanofi has determined that its activities are compliant with applicable law. In light of the nature of the activities concerned, Sanofi and its affiliates intend to continue their activities in Iran.

#### **INFORMATION ON LEGAL OR ARBITRATION PROCEEDINGS**

This Item 8 incorporates by reference the disclosures found in Note D.22. to the consolidated financial statements at Item 18 of





**Table of Contents**

## ITEM 8. FINANCIAL INFORMATION

this annual report; material updates thereto as of the date of this annual report are found below under the heading **B. Significant Changes** – Updates to Note D.22 .

Sanofi and its subsidiaries are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to limit the patent protection of Sanofi products), competition law and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As a result, we may become subject to substantial liabilities that may not be covered by insurance and could affect our business and reputation. While we do not currently believe that any of these legal proceedings will have a material adverse effect on our financial position, litigation is inherently unpredictable. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on results of operations, cash flows and/or our reputation.

**Patents****Co-Aprovel<sup>®</sup> Patent Infringement Actions (Europe)**

Sanofi has been involved since early 2012 in a number of legal proceedings involving generic companies that attempted to launch or launched generic versions of Sanofi Co-Aprovel<sup>®</sup> in several European countries including the United Kingdom, Belgium, France, Germany, the Netherlands, Italy and Norway. Sanofi filed for and was granted preliminary injunctions (PI) against several generic companies based on Sanofi's Supplemental Protection Certificate (SPC) covering Co-Aprovel<sup>®</sup> until October 15, 2013. The UK Court referred the question on the validity of the Co-Aprovel<sup>®</sup> SPC to the Court of Justice of the European Union (CJEU) in October 2012.

Following the CJEU decision of December 12, 2013 that declared the Co-Aprovel<sup>®</sup> SPC invalid, generic companies (whose products were withdrawn from the market due to national preliminary injunctions or cross-undertakings) have filed damages claims against Sanofi in several countries.

**Lantus<sup>®</sup> Merck Patent Litigation (United States)**

On September 16, 2016, several Sanofi entities filed a patent infringement suit against Merck Sharp & Dohme Corp. ( Merck ) in the United States District Court for the District of Delaware. In its suit, Sanofi alleges infringement of several patents. The suit was triggered by a notification received from Merck in early August 2016, in which Merck stated that it had filed an NDA (505(b)(2) New Drug Application) with FDA for an insulin glargine drug pen product. Merck also stated that its NDA included a paragraph IV certification challenging all of the Sanofi patents then listed in the FDA Orange Book for Sanofi s Lantu<sup>®</sup> and Lantus<sup>®</sup>

SoloStar<sup>®</sup> products. This suit resulted in a stay during which the FDA cannot approve Merck s NDA. The 30 month stay is expected to expire on the earlier of (i) February 8, 2019 or (ii) a court decision in favor of Merck. The Court has scheduled a bench trial to begin on May 29, 2018, a claim construction hearing took place on November 6, 2017, and briefing on summary judgment motions on certain issues pertaining to some of the patents-in-suit is complete.

On August 8, 2017, several Sanofi entities filed a patent infringement suit against Merck in the United States District Court for the District of New Jersey. In its suit, Sanofi alleges infringement of two patents. The suit was triggered by a notification received from Merck in late June 2017, in which Merck stated that it had filed an NDA with the FDA for an insulin glargine drug vial product. Merck also stated that its NDA included a paragraph IV certification challenging all of the Sanofi patents then listed in the FDA Orange Book for Sanofi s Lantu<sup>®</sup> and Lantus<sup>®</sup> SoloStar<sup>®</sup> products. This suit resulted in a stay during which the FDA cannot approve Merck s NDA. The 30 month stay is expected to expire on the earlier of (i) December 30, 2019 or (ii) a court decision in favor of Merck. The parties are currently proceeding with discovery and claim construction.

#### **Lantus<sup>®</sup> Mylan Patent Litigation (United States)**

In June 2017, Mylan Pharmaceuticals, Inc. filed petitions for *Inter Partes* Review (IPR) for US Patent 7,476,652 and 7,713,930 regarding Lantus<sup>®</sup> with the United States Patent Office Patent Trial and Appeal Board (PTAB). In these petitions, Mylan attacks the validity of all claims of these patents. On December 13, 2017, the PTAB decided to move forward with Mylan s IPRs for these two patents. The PTAB s final written decisions concerning the validity of the claims are due on or before December 13, 2018.

On October 24 and 26, 2017, several Sanofi entities filed a patent infringement suit against Mylan N.V., Mylan GmbH, Mylan Inc., and Mylan Pharmaceuticals Inc. (collectively, Mylan ) in the United States District Courts for the District of New Jersey and Northern District of West Virginia. In its suits, Sanofi alleges infringement of several patents. The suits were triggered by a notification received from Mylan in mid-September 2017, in which Mylan stated that it had filed an NDA with the FDA for an insulin glargine drug pen and vial products. Mylan also stated that its NDA included a paragraph IV certification challenging all of the Sanofi patents then listed in the FDA Orange Book for Sanofi s Lantu<sup>®</sup> and Lantus<sup>®</sup> SoloStar<sup>®</sup> products. These suits resulted in a stay during which the FDA cannot approve Mylan s NDA. The 30 month stay is expected to expire on the earlier of (i) March 18, 2020 or (ii) a court decision in favor of Mylan. On February 21, 2018, the West Virginia case was dismissed and the parties are now proceeding only with the New Jersey lawsuit. The parties are currently proceeding with discovery and claim construction.

#### **Multaq<sup>®</sup> Patent Litigation (United States)**

From January 2014 to November 2014, several generic manufacturers notified Sanofi that they had filed Abbreviated

**Table of Contents**

## ITEM 8. FINANCIAL INFORMATION

New Drug Applications (ANDAs) seeking FDA approval to market generic versions of Multaq® (dronedarone hydrochloride) in the US. In April 2015, Sanofi received a tenth notice directed to Multaq® from Lupin. The notices challenged some, but not all, of the patents listed by Sanofi in the FDA's Orange Book in connection with Multaq®. None of the ANDA filers challenged the patent directed to the active ingredient in Multaq®, US Patent 5,223,510 (the 510 patent).

Sanofi brought suit against all of the ANDA filers in the United States District Court for the District of Delaware for patent infringement. Depending on the contents of the particular Paragraph IV Certification, Sanofi has brought suit for infringement of at least three and sometimes four of its Orange Book listed patents. Having settled with all but two generic manufacturers, Sanofi went to trial against Sandoz and Watson in early June 2016 alleging infringement of US patents 8,318,800 (formulation) and 8,410,167 (method of use). In August 2016, the Court ruled in Sanofi's favor finding the 800 patent infringed and the 167 patent valid and infringed by both Sandoz and Watson. In September 2016, Sandoz and Watson filed a Notice of Appeal to the Court of Appeals for the Federal Circuit (CAFC). In November 2017, the CAFC affirmed the lower court decision with respect to both patents finding that the 800 patent was infringed and that the 167 patent was valid and infringed. The defendants did not file a petition for writ of certiorari to the Supreme Court. This litigation is now over.

On October 13, 2015, Sanofi amended its complaint against Lupin to include US Patent 9,107,900 which was listed in the Orange Book in September 2015. In December 2015, Sanofi filed separate patent infringement actions against six of the other defendants based on this patent. Having settled with all but two generic manufacturers, Sanofi went to trial on the 900 patent in April 2017 against Sandoz and Watson. In October 2017, the District Court of Delaware ruled in Sanofi's favor and found that Claims 1, 7, 9 and 14 of the 900 patent were valid and infringed while it found claims 6 and 8 were not infringed. The defendants filed a notice of appeal to the Court of Appeals for the Federal Circuit in December 2017. On January 23, 2018, Sandoz voluntarily dismissed its appeal to the Federal Circuit. Sanofi and Watson settled their litigation on February 13, 2018. This litigation is over.

**Genzyme Aubagio® Patent Litigation (United States)**

Aubagio® is covered by three Orange Book listed patents: US 6,794,410, US 8,802,735, and US 9,186,346. In November/December 2016, a number of generic manufacturers separately notified Sanofi Genzyme that they had filed ANDA applications for Aubagio® with Paragraph IV certifications challenging the 410, 735 and 346 patents. Sanofi Genzyme filed suit against each ANDA filer within 45 days of receipt of each notification in the US District Court for the District of Delaware. In 2017, Sanofi reached settlement with all 20 generic Aubagio® ANDA first filers granting each a royalty-free license to enter the United States market on March 12, 2023.

## Government Investigations and Related Litigation

From time to time, subsidiaries of Sanofi are subject to governmental investigations and information requests from regulatory authorities inquiring as to the practices of Sanofi with respect to the sales, marketing, and promotion of its products.

In December 2013, Genzyme entered into a settlement agreement to resolve civil claims arising out of the investigation into promotional practices of Septrafilm<sup>®</sup> and paid in that respect approximately \$23 million. As part of this settlement, and as part of the settlement entered into by Sanofi US in December 2012 relating to civil claims arising out of an investigation into sampling of its former product Hyalgan<sup>®</sup> for which Sanofi US paid \$109 million, the companies entered into a Corporate Integrity Agreement ( CIA ) with the Office of the Inspector General of the United States Department of Health and Human Services in September 2015. Also in September 2015, Genzyme entered into a Deferred Prosecution Agreement ( DPA ) with the US Department of Justice and paid in that respect approximately \$33 million to resolve the Septrafilm<sup>®</sup> matter completely. The DPA expired in September 2017 and the CIA is currently in effect.

In February 2016, Sanofi US received a civil investigative demand from the US Attorney's Office for the Northern District of Texas requesting documents and information relating to contracts with specialty pharmacies concerning the renal products Renvela<sup>®</sup> and Renagel<sup>®</sup> from January 1, 2006 through February 2, 2016. Sanofi US is cooperating with this investigation.

In March 2016, Sanofi US received a civil investigative demand from the US Attorney's Office for the Southern District of New York requesting documents and information relating to contracts with, services performed by and payments to pharmacy benefit managers regarding Lantus<sup>®</sup> and Apidra<sup>®</sup> from January 1, 2006 forward. Sanofi US is cooperating with this investigation.

In June 2016, the United States declined to intervene in a False Claims Act action filed in Federal Court in New Jersey regarding the sale and marketing of and variability of response to Plavix<sup>®</sup>. Sanofi US is defending this action as well as four State Attorney General actions (Hawaii, Mississippi, New Mexico and West Virginia) concerning the sale and marketing of Plavix<sup>®</sup>.

In December 2016 and January 2017, two putative class actions were filed against Sanofi US and Sanofi GmbH in Federal Court in Massachusetts on behalf of direct-purchasers of Lantus<sup>®</sup> alleging certain antitrust violations. On January 10, 2018, the District Court of Massachusetts dismissed Plaintiffs' complaint against Sanofi. The dismissal of Plaintiffs' entire case was without prejudice.

In January 2017, the Minnesota State Attorney General's office issued a civil investigative demand calling for the production of documents and information relating to pricing and trade practices for Lantus<sup>®</sup> and Toujeo<sup>®</sup>, from January 1, 2008 through present. Sanofi US is cooperating with this investigation.

In March 2017, the Washington State Attorney General's office issued a civil investigative demand calling for the production of

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**Table of Contents**

## ITEM 8. FINANCIAL INFORMATION

documents and information relating to pricing and trade practices for Sanofi's injectable insulin products, from January 1, 2005 through present. Sanofi US is cooperating with this investigation.

In August 2017, Sanofi US received a civil investigative demand from the US Attorney's Office for the Southern District of New York requesting documents and information relating to Sanofi US's certified diabetes educator program during the period from 2007 to the present. Sanofi US is cooperating with this investigation.

In January 2018, Sanofi US received a subpoena from the US Attorney's Office for the District of Massachusetts requesting documents and information relating to Sanofi US's relationship with non-profit organizations that provide assistance to patients taking Sanofi drugs and Sanofi US's patient assistance programs as well as documents and information relating to the sale and marketing of Aubagio® and Lemtrada®. Sanofi US is cooperating with this investigation.

In early 2017, four actions were filed against Sanofi US in Federal Court in New Jersey on behalf of a putative class of diabetes patients alleging violations of the Racketeer Influenced and Corrupt Organizations Act and various state unfair/deceptive trade practices statutes in connection with the pricing of Lantus®, Apidra®, and Toujeo®. On December 26, 2017, Plaintiffs filed a consolidated amended complaint, consolidating these four separate actions. A fifth case (*MSP Recovery Claims, Series LLC*) was filed on February 15, 2018 in New Jersey Federal Court. This matter will be coordinated (not consolidated) with the case above.

In France, in the claim concerning allegations that Sanofi's communication and promotional practices inhibited the entry on the market of generics of clopidogrel (the active ingredient of Plavix®), the French Antitrust Authority issued its decision on May 14, 2013, imposing on Sanofi a fine of 40.6 million. In December 2014, the Paris Court of Appeals rejected Sanofi's appeal and confirmed in totality the decision. Sanofi filed a *pourvoi* with the French Supreme Court (*Cour de cassation*) in January 2015. As a consequence of the May 2013 ruling, claims were filed by Sandoz and by Teva in 2014 before the Commercial Court of Paris for compensation of their alleged damages: loss of margin and other ancillary damages (legal fees to external counsel, image and reputation). In June and November 2016 respectively, settlement agreements were entered into with Sandoz and Teva. Consequently, they subsequently withdrew their civil claims, jointly and severally. On October 18, 2016, the Supreme Court confirmed the Court of Appeals' decision. Therefore, the Court of Appeals' decision became definitive. In September 2017, Sanofi and Sanofi Aventis France received a summons before the Paris Commercial Court from the French *Caisse Nationale d'Assurance Maladie* (French Social Security) claiming 115.8 million for their alleged damages.

Sanofi has been engaged in discussions with the US Department of Justice ( DOJ ) and the US Securities and Exchange Commission regarding allegations that certain subsidiaries outside the United States made improper payments in connection with the

sale of pharmaceutical products and whether those payments, if made, fall within the US Foreign Corrupt Practices Act. Sanofi has voluntarily provided information to the DOJ and the SEC and proactively cooperated in both agencies review of the allegations. In February 2018, the DOJ notified Sanofi that it had decided to close its inquiry into the allegations. Sanofi is still cooperating with the SEC s review of the allegations.

## **B. Significant Changes**

### **Updates to Note D.22**

#### *Praluent® (alirocumab)-related Amgen Patent Litigation in the US*

On February 23, 2018, the Federal Circuit denied Amgen s request for rehearing en banc by the full Federal Circuit. We are currently proceeding in the Delaware District Court.

#### *Dupilixent® (dupilumab)-related Amgen Inter Partes Review Petition and Patent Litigation in the US*

On February 15, 2018, the US Patent and Trademark Office (USPTO) granted Sanofi and Regeneron s second and third IPR petitions and instituted *inter partes* reviews of all challenged claims in the 487 Patent.

### **Other Changes**

Sanofi announced that on February 7, 2018 it commenced a tender offer to acquire all of the outstanding shares of common stock of Bioverativ, Inc. for \$105 per share in cash, without interest thereon and net of any required tax withholding.

As a result of the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, on February 23, 2018, the condition to the Offer relating to antitrust approvals has been satisfied. The consummation of the Offer remains subject to various conditions, including the tender of at least a majority of the Shares outstanding immediately prior to the expiration of the Offer, redelivery of a tax opinion delivered at signing, and other customary conditions described in the Offer to Purchase filed by Sanofi with the Securities and Exchange Commission (SEC) on February 7, 2018. The Offer is scheduled to expire one minute past 11:59 p.m., New York City time, on Wednesday, March 7, 2018, unless the Offer is extended in accordance with the Merger Agreement and the applicable rules and regulations of the SEC.

On March 1, 2018, Sanofi announced that the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 had expired. Sanofi also received clearance from the Federal Cartel Office of Germany (the FCO ) in accordance with the Act Against Restraints of Competition, applicable to Sanofi s proposed acquisition of Ablynx NV. The consummation of the Offers remains subject to other conditions, including the tender of shares representing at least 75% of the outstanding shares of Ablynx at the end of the initial acceptance period. The Offers are still expected to be launched by the beginning of the second quarter 2018.



**Table of Contents**

ITEM 8. FINANCIAL INFORMATION

On March 2, 2018, Sanofi announced that the FDA accepted for review the supplemental Biologics License Application of Dupixent® (dupilumab) as an add-on maintenance treatment in certain adults and adolescents (12 years of age and older) with moderate-to-severe asthma.

At its meeting held on March 6, 2018, Sanofi's Board of Directors proposed to submit the appointment of Emmanuel Babeau as a new independent director, as well as the reappointment of Olivier Brandicourt, Patrick Kron and Christian Mulliez as directors, to a shareholder vote during the Annual General Meeting on May 2, 2018. Robert Castaigne, board member since 2000 and current Chair of the Audit Committee, will not seek a new term. Fabienne

Lecorvaisier will succeed him as Chair of the Audit Committee. The Board has also created a new Scientific Committee, which will be chaired by Thomas Südhof.

Emmanuel Babeau is Deputy Chief Executive Officer and Chief Financial Officer of Schneider Electric Group, a position he has held since April 2013. He joined Schneider Electric in 2009 as Chief Financial Officer. Before joining Schneider Electric Group, he was Group Chief Financial Officer of Pernod Ricard SA from 2003 to 2009. Emmanuel Babeau graduated from the *Ecole supérieure de commerce de Paris* in 1989, and also holds a post-graduate diploma in accounting and finance.



**Table of Contents**

ITEM 9. THE OFFER AND LISTING

Item 9. The Offer and Listing

**A. Offer and Listing Details**

We have one class of shares. Each American Depositary Share, or ADS, represents one-half of one share. The ADSs are evidenced by American Depositary Receipts, or ADRs, which are issued by JPMorgan Chase Bank, N.A.

Our shares trade on Compartment A of the regulated market of Euronext Paris, and our ADSs trade on the New York Stock Exchange, or NYSE.

In 2011, in connection with our acquisition of Genzyme, we issued contingent value rights ( CVRs ) under a CVR agreement entered into by and between us and the American Stock Transfer & Trust

Company, LLC ( AST ), as trustee (see Item 10.C. Material Contracts The Contingent Value Rights Agreement). Our CVRs trade on the NASDAQ Global Market.

As of June 30, 2016, UMB Bank, National Association replaced AST and is the successor trustee under the CVR agreement.

**Trading History**

The table below sets forth, for the periods indicated, the reported high and low market prices of our shares on Euronext Paris and our ADSs on the NYSE (source: Bloomberg).

**Shares, as traded  
on Euronext Paris**

**ADSs, as traded on  
the NYSE**

<i>Calendar period</i>	<b>High</b>	<b>Low</b>	<b>High</b>	<b>Low</b>
	<b>(price per share in )</b>		<b>(price per ADS in \$)</b>	
<b>Monthly</b>				
February 2018	71.71	63.09	44.09	38.14
January 2018	75.23	69.79	45.86	42.69
December 2017	76.47	71.85	44.90	42.80
November 2017	81.99	75.26	47.15	44.32
October 2017	86.39	80.58	50.64	47.14
September 2017	85.00	80.68	50.65	48.38
<b>2017</b>				
First quarter	84.93	73.39	45.95	39.42
Second quarter	92.97	82.06	50.24	43.97
Third quarter	86.47	79.20	50.65	46.79
Fourth quarter	86.39	71.85	50.64	42.80
Full Year	92.97	71.85	50.65	39.42
<b>2016</b>				
First quarter	79.13	66.44	42.34	37.63
Second quarter	79.07	62.50	44.50	37.41
Third quarter	77.30	66.72	42.75	37.67
Fourth quarter	78.68	67.22	42.42	36.81
Full Year	79.13	62.50	44.50	36.81
<b>2015</b>				
Full Year	101.10	72.94	54.98	41.13
<b>2014</b>				
Full Year	89.95	68.29	57.42	44.24
<b>2013</b>				
Full Year	87.03	65.91	55.94	44.50

**Table of Contents**

ITEM 9. THE OFFER AND LISTING

Fluctuations in the exchange rate between the euro and the U.S. dollar will affect any comparisons of euro share prices and U.S. ADS prices.

**B. Plan of Distribution**

N/A

**C. Markets**

**Shares and ADSs**

Our shares are listed on Euronext Paris under the symbol `SAN` and our ADSs are listed on the NYSE under the symbol `SNY`.

As of the date of this annual report, our shares are included in a large number of indices, including the CAC 40 Index, the principal French index published by Euronext Paris. This index contains 40 stocks selected among the top 100 companies based on free-float capitalization and the most active stocks listed on the Euronext Paris market. The CAC 40 Index indicates trends in the French stock market as a whole and is one of the most widely followed stock price indices in France. Our shares are also included in the S&P Global 100 Index, the Dow Jones Euro STOXX 50, the Dow Jones STOXX 50, the FTS Eurofirst 100, the FTS Eurofirst 80 and the MSCI Pan-Euro Index, among other indices.

**CVRs**

Our CVRs trade on the NASDAQ Global Market under the symbol `GCVRZ`.

**Trading by Sanofi in our own Shares**

Under French law, a company may not issue shares to itself, but it may purchase its own shares in the limited cases described at Item 10. Additional Information B. Memorandum and Articles of Association Trading in Our Own Shares.

**D. Selling Shareholders**

N/A

**E. Dilution**

N/A

**F. Expenses of the Issue**

N/A

**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

Item 10. Additional Information

**A. Share Capital**

N/A

**B. Memorandum and Articles of Association**

**GENERAL**

Our Company is a *société anonyme*, a form of limited liability company, organized under the laws of France.

In this section, we summarize material information concerning our share capital, together with material provisions of applicable French law and our Articles of Association (*statuts*), an English translation of which has been filed as an exhibit to this annual report. For a description of certain provisions of our Articles of Association relating to our Board of Directors and statutory auditors, see Item 6. Directors, Senior Management and Employees. You may obtain copies of our Articles of Association in French from the *greffe* (Clerk) of the *Registre du Commerce et des Sociétés de Paris* (Registry of Commerce and Companies of Paris, France, registration number: 395 030 844). Please refer to that full document for additional details.

Our Articles of Association specify that our corporate affairs are governed by:

applicable laws and regulations (in particular, Title II of the French Commercial Code); and

the Articles of Association themselves.

Article 3 of our Articles of Association specifies that the Company's corporate purpose, in France and abroad, is:

acquiring interests and holdings, in any form whatsoever, in any company or enterprise, in existence or to be created, connected directly or indirectly with the health and fine chemistry sectors, human and animal therapeutics, nutrition and bio-industry;  
in the following areas:

purchase and sale of all raw materials and products necessary for these activities;

research, study and development of new products, techniques and processes;

manufacture and sale of all chemical, biological, dietary and hygienic products;

obtaining or acquiring all intellectual property rights related to results obtained and, in particular, filing all patents, trademarks and models, processes or inventions;  
operating directly or indirectly, purchasing, and transferring for free or for consideration pledging or securing all intellectual property rights, particularly all patents, trademarks and models, processes or inventions;

obtaining, operating, holding and granting all licenses;

within the framework of a group-wide policy and subject to compliance with the relevant legislation, participating in treasury management transactions, whether as lead company or otherwise, in the form of centralized currency risk management or intra-group netting, or any other form permitted under the relevant laws and regulations;  
and, more generally:

all commercial, industrial, real or personal property, financial or other transactions, connected directly or indirectly, totally or partially, with the activities described above and with all similar or related activities and even with any other purposes likely to encourage or develop the Company's activities.

## **DIRECTORS**

### **Transactions in Which Directors Are Materially Interested**

Under French law, any agreement entered into (directly or through an intermediary) between our Company and any one of the members of the Board of Directors that is not entered into (i) in the ordinary course of our business and (ii) under normal conditions is subject to the prior authorization of the disinterested members of the Board of Directors. The same provision applies to agreements between our Company and another company if one of the members of the Board of Directors is the owner, general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the members of the Board of Directors has an indirect interest.

The Board of Directors must also authorize any undertaking taken by our Company for the benefit of our Chairman, Chief Executive Officer (*directeur général*) or his delegates (*directeurs généraux délégués*) pursuant to which such persons will or may be granted compensation, benefits or any other advantages as a result of the termination of or a change in their offices or following such termination or change.

In addition, except with respect to any non-compete indemnity or certain pension benefits, any such termination package: (i) must be authorized by our shareholders through the adoption of a separate general shareholders meeting resolution for each such beneficiary, which authorization must be renewed at each renewal of such beneficiary's mandate, and (ii) cannot be paid to such beneficiary unless (a) the Board of Directors decides that such beneficiary has

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**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

satisfied certain conditions, linked to such beneficiary's performance measured by our Company's performance, that must have been defined by the Board of Directors when granting such package, and (b) such decision is publicly disclosed.

**Directors Compensation**

The aggregate amount of attendance fees (*jetons de présence*) of the Board of Directors is determined at the Shareholders' Ordinary General Meeting. The Board of Directors then divides this aggregate amount among its members by a simple majority vote. In addition, the Board of Directors may grant exceptional compensation (*rémunérations exceptionnelles*) to individual directors on a case-by-case basis for special assignments following the procedures described above at Transactions in Which Directors Are Materially Interested. The Board of Directors may also authorize the reimbursement of travel and accommodation expenses, as well as other expenses incurred by Directors in the corporate interest. See also Item 6. Directors, Senior Management and Employees.

**Board of Directors Borrowing Powers**

All loans or borrowings on behalf of the Company may be decided by the Board of Directors within the limits, if any, imposed by the Shareholders' General Meeting. There are currently no limits imposed on the amounts of loans or borrowings that the Board of Directors may approve.

**Directors Age Limits**

For a description of the provisions of our Articles of Association relating to age limits applicable to our Directors, see Item 6. Directors, Senior Management and Employees.

**Directors Share Ownership Requirements**

Pursuant to the Board Charter, our Directors are required to hold at least 1,000 shares during the term of their appointment.

**SHARE CAPITAL**

As of December 31, 2017, our share capital amounted to 2,508,039,808, divided into 1,254,019,904 outstanding shares with a par value of 2 per share. All of our outstanding shares are of the same class and are fully paid. Of these



shares, we or entities controlled by us held 173,726 shares (or 0.014% of our outstanding share capital), as treasury shares as of such date. As of December 31, 2017, the carrying amount of such shares was 9 million.

At an extraordinary general meeting held on May 10, 2017, our shareholders authorized our Board of Directors to increase our share capital, through the issuance of shares or other securities giving access to the share capital with or without preemptive rights,

by an aggregate maximum nominal amount of 1.289 billion. See Changes in Share Capital Increases in Share Capital, below.

The maximum total number of authorized but unissued shares as of December 31, 2017 was 141 million, reflecting the unused part of the May 4, 2016 and May 10, 2017 shareholder authorizations to issue shares without preemptive rights, outstanding options to subscribe for shares, and awards of shares.

## STOCK OPTIONS

### Types of Stock Options

We have two types of stock options outstanding: options to subscribe for shares (*options de souscription d'actions*) and options to purchase shares (*options d'achat d'actions*). Upon exercise of an option to subscribe for shares, we issue new shares, whereas upon exercise of an option to purchase shares, the option holder receives existing shares. We purchase our shares on the market prior to the vesting of the options to purchase in order to provide the option holder with shares upon exercise.

Because the exercise of options to purchase shares will be satisfied with existing shares repurchased on the market or held in treasury, the exercise of options to purchase shares has no impact on the amount of our share capital.

### Stock Option Plans

Our combined general meeting held on May 4, 2016 authorized our Board of Directors for a period of 38 months to grant, on one or more occasions, options to subscribe for shares and options to purchase shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or groupings of economic interest of the Group in accordance with Article L. 225-180 of the French Commercial Code.

The aggregate number of options to subscribe for shares and options to purchase shares that may be granted under this authorization may not give entitlement to a total number of shares exceeding 0.5% of the share capital as of the date of the decision by the Board of Directors to grant such options.

The Board of Directors sets the exercise price of options to subscribe for shares and options to purchase shares. However, the exercise price never incorporates a discount and must be at least equal to the average of the quoted market prices on the 20 trading sessions preceding the date of grant by the Board of Directors.

Stock option plans generally provide for a lock-up period of four years and have a duration of ten years.

Under such authorization the shareholders expressly waive, in favor of the grantees of options to subscribe for shares, their preemptive rights in respect of shares that are to be issued as and when options are exercised.



**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

The Board of Directors is granted full power to implement this authorization and to set the terms and conditions on which options are granted and the arrangements with respect to the dividend entitlement of the shares.

See Item 6. Directors, Senior Management and Employees – E. Share Ownership for a description of our option plans currently in force.

**AWARDS OF SHARES**

Our combined general meeting held on May 4, 2016 authorized our Board of Directors for a period of 38 months to allot, on one or more occasions, existing or new restricted shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or economic interest groupings of the Group in accordance with Articles L. 225-197-1 *et seq.* of the French Commercial Code.

The existing or new shares allotted under this authorization may not represent more than 1.5% of our share capital as of the date of the decision by the Board of Directors to allot such shares.

The authorization provides that allotment of shares to the allottees will become irrevocable at the end of a minimum vesting period of three years.

In the case of newly issued shares, the authorization entails the express waiver by the shareholders, in favor of the allottees of restricted shares, of their preemptive rights in respect of shares that are to be issued as and when restricted shares vest.

The Board of Directors sets the terms on which restricted shares are granted and the arrangements with respect to the dividend entitlement of the shares.

See Item 6. Directors, Senior Management and Employees – E. Share Ownership for a description of our restricted shares plans currently in force.

**CHANGES IN SHARE CAPITAL IN 2017**

See Note D.15.1. to our consolidated financial statements included at Item 18 of this annual report.

## VOTING RIGHTS

In general, each shareholder is entitled to one vote per share at any shareholders' general meeting. Our Articles of Association do not provide for cumulative voting rights. However, our Articles of Association provide that any fully paid-up shares that have been held in registered form under the name of the same shareholder for at least two years acquire double voting rights. The double voting rights cease automatically for any share converted into bearer form or transferred from one owner to another, subject to certain exceptions permitted by law.

As of December 31, 2017, there were 146,706,132 shares that were entitled to double voting rights, representing 11.69% of our total share capital, and approximately 20.95% of the voting rights which can be cast at our shareholders' general meeting as of that date.

Double voting rights are not taken into account in determining whether a quorum exists.

Under the French Commercial Code, treasury shares or shares held by entities controlled by that company are not entitled to voting rights and do not count for quorum purposes.

Our Articles of Association allow us to obtain from Euroclear France the name, nationality, address and number of shares held by holders of our securities that have, or may in the future have, voting rights. If we have reason to believe that a person on any list provided by Euroclear France holds securities on behalf of another person, our Articles of Association allow us to request information regarding beneficial ownership directly from such person. See [B. Memorandum and Articles of Association – Form, Holding and Transfer of Shares](#), below.

Our Articles of Association provide that Board members are elected on a rolling basis for a maximum tenure of four years.

## SHAREHOLDERS' AGREEMENT

We are not aware of any shareholders' agreement currently in force concerning our shares.

## SHAREHOLDERS' MEETINGS

### General

In accordance with the provisions of the French Commercial Code, there are three types of shareholders' meetings: ordinary, extraordinary and special.

Ordinary general meetings of shareholders are required for matters such as:

electing, replacing and removing Directors;

appointing independent auditors;

approving the annual financial statements;

declaring dividends or authorizing dividends to be paid in shares, provided the Articles of Association contain a provision to that effect; and

approving share repurchase programs.

Extraordinary general meetings of shareholders are required for approval of matters such as amendments to our Articles of Association, including any amendment required in connection with extraordinary corporate actions. Extraordinary corporate actions include:

changing our Company's name or corporate purpose;

**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

increasing or decreasing our share capital;

creating a new class of equity securities;

authorizing the issuance of:

shares giving access to our share capital or giving the right to receive debt instruments, or

other securities giving access to our share capital;

establishing any other rights to equity securities;

selling or transferring substantially all of our assets; and

the voluntary liquidation of our Company.

Special meetings of shareholders of a certain category of shares or shares with certain specific rights (such as shares with double voting rights) are required for any modification of the rights derived from that category of shares. The resolutions of the shareholders' general meeting affecting these rights are effective only after approval by the relevant special meeting.

**Annual Ordinary Meetings**

The French Commercial Code requires the Board of Directors to convene an annual ordinary general shareholders meeting to approve the annual financial statements. This meeting must be held within six months of the end of each fiscal year. This period may be extended by an order of the President of the Commercial Court. The Board of Directors may also convene an ordinary or extraordinary general shareholders' meeting upon proper notice at any time during the year. If the Board of Directors fails to convene a shareholders' meeting, our independent auditors may call

the meeting. In case of bankruptcy, the liquidator or court-appointed agent may also call a shareholders' meeting in some instances. In addition, any of the following may request the court to appoint an agent for the purpose of calling a shareholders' meeting:

one or several shareholders holding at least 5% of our share capital;

duly qualified associations of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights;

the works council in cases of urgency; or

any interested party in cases of urgency.

### Notice of Shareholders' Meetings

All prior notice periods provided for below are minimum periods required by French law and cannot be shortened, except in case of a public tender offer for our shares.

We must announce general meetings at least thirty-five days in advance by means of a preliminary notice (*avis de réunion*), which

is published in the *Bulletin des Annonces Légales Obligatoires*, or *BALO*. The preliminary notice must first be sent to the French Financial markets authority (*Autorité des marchés financiers*, the AMF), with an indication of the date on which it will be published in the *BALO*. It must be published on our website at least twenty-one days prior to the general meeting. The preliminary notice must contain, among other things, the agenda, a draft of the resolutions to be submitted to the shareholders for consideration at the general meeting and a detailed description of the voting procedures (proxy voting, electronic voting or voting by mail), the procedures permitting shareholders to submit additional resolutions or items to the agenda and to ask written questions to the Board of Directors. The AMF also recommends that, prior to or simultaneously with the publication of the preliminary notice, we publish a summary of the notice indicating the date, time and place of the meeting in a newspaper of national circulation in France and on our website.

At least fifteen days prior to the date set for a first convening, and at least ten days prior to any second convening, we must send a final notice (*avis de convocation*) containing the final agenda, the date, time and place of the meeting and other information related to the meeting. Such final notice must be sent by mail to all registered shareholders who have held shares in registered form for more than one month prior to the date of the final notice and by registered mail, if shareholders have asked for it and paid the corresponding charges. The final notice must also be published in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*, with prior notice having been given to the AMF for informational purposes. Even if there are no proposals for new resolutions or items to be submitted to the shareholders at the meeting, we must publish a final notice in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*.

### Other issues

In general, shareholders can only take action at shareholders' meetings on matters listed on the agenda. As an exception to this rule, shareholders may take action with respect to the appointment and dismissal of directors even if

this action has not been included on the agenda.

Additional resolutions to be submitted for approval by the shareholders at the shareholders meeting may be proposed to the Board of Directors, for recommendation to the shareholders at any time from the publication of the preliminary notice in the *BALO* until twenty-five days prior to the general meeting and in any case no later than twenty days following the publication of the preliminary notice in the *BALO* by:

one or several shareholders together holding a specified percentage of shares;



**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

a duly qualified association of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights; or

the works council.

Within the same period, the shareholders may also propose additional items (*points*) to be submitted and discussed during the shareholders' meeting, without a shareholders' vote. The shareholders must substantiate the reasons for their proposals of additional items.

The resolutions and the list of items added to the agenda of the shareholders' meeting must be promptly published on our website.

The Board of Directors must submit the resolutions to a vote of the shareholders after having made a recommendation thereon. The Board of Directors may also comment on the items that are submitted to the shareholders' meeting.

Following the date on which documents must be made available to the shareholders (including documents to be submitted to the shareholders' meeting and resolutions proposed by the Board of Directors, which must be published on our website at least twenty-one days prior to the general meeting), shareholders may submit written questions to the Board of Directors relating to the agenda for the meeting until the fourth business day prior to the general meeting. The Board of Directors must respond to these questions during the meeting or may refer to a Q&A section located on our website in which the question submitted by a shareholder has already been answered.

**ATTENDANCE AT SHAREHOLDERS' MEETINGS; PROXIES AND VOTES BY MAIL**

In general, all shareholders may participate in general meetings either in person or by proxy. Shareholders may vote in person, by proxy or by mail.

The right of shareholders to participate in general meetings is subject to the recording (*inscription en compte*) of their shares on the second business day, zero hour (Paris time), preceding the general meeting:

for holders of registered shares: in the registered shareholder account held by the Company or on its behalf by an agent appointed by it; and

for holders of bearer shares: in the bearer shareholder account held by the accredited financial intermediary with whom such holders have deposited their shares; such financial intermediaries shall deliver to holders of bearer shares a shareholding certificate (*attestation de participation*) enabling them to participate in the general meeting.

### Attendance in Person

Any shareholder may attend ordinary general meetings and extraordinary general meetings and exercise its voting rights subject to the conditions specified in the French Commercial Code and our Articles of Association.

### Proxies and Votes by Mail

Proxies are sent to any shareholder upon a request received between the publication of the final notice of meeting and six days before the general meeting and must be made available on our website at least twenty-one days before the general meeting. In order to be counted, such proxies must be received at our registered office, or at any other address indicated on the notice of the meeting or by any electronic mail indicated on the notice of the meeting, prior to the date of the meeting (in practice, we request that shareholders return proxies at least three business days prior to the meeting; electronic proxies must be returned before 3 p.m. Paris time, on the day prior to the general meeting). A shareholder may grant proxies to any natural person or legal entity. The agent may be required to disclose certain information to the shareholder or to the public.

Alternatively, the shareholder may send us a blank proxy without nominating any representative. In this case, the chairman of the meeting will vote the blank proxies in favor of all resolutions proposed or approved by the Board of Directors and against all others.

With respect to votes by mail, we must send shareholders a voting form upon request or must make available a voting form on our website at least twenty-one days before the general meeting. The completed form must be returned to us at least three days prior to the date of the shareholders' meeting. For holders of registered shares, in addition to traditional voting by mail, instructions may also be given via the internet.

### QUORUM

The French Commercial Code requires that shareholders holding in the aggregate at least 20% of the shares entitled to vote must be present in person, or vote by mail or by proxy, in order to fulfill the quorum requirement for:

an ordinary general meeting; and

an extraordinary general meeting where the only resolutions pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code).

For any other extraordinary general meeting the quorum requirement is at least 25% of the shares entitled to vote, held by shareholders present in person, voting by mail or by proxy.



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**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

For a special meeting of holders of a certain category of shares, the quorum requirement is one third of the shares entitled to vote in that category, held by shareholders present in person, voting by mail or by proxy.

If a quorum is not present at a meeting, the meeting is adjourned. However, only questions that were on the agenda of the adjourned meeting may be discussed and voted upon once the meeting resumes.

When an adjourned meeting is resumed, there is no quorum requirement for meetings cited in the first paragraph of this *Quorum* section. In the case of any other reconvened extraordinary general meeting or special meeting, the quorum requirement is 20% of the shares entitled to vote (or voting shares belonging to the relevant category for special meetings of holders of shares of such specific category), held by shareholders present in person or voting by mail or by proxy. If a quorum is not met, the reconvened meeting may be adjourned for a maximum of two months with the same quorum requirement. No deliberation or action by the shareholders may take place without a quorum.

**VOTES REQUIRED FOR SHAREHOLDER ACTION**

The affirmative vote of a simple majority of the votes cast may pass a resolution at either an ordinary general meeting or an extraordinary general meeting where the only resolution(s) pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code). At any other extraordinary general shareholders meeting and at any special meeting of holders of a specific category of shares, the affirmative vote of two-thirds of the votes cast is required.

Abstention from voting by those present or those represented by proxy or voting by mail is counted as a vote against the resolution submitted to a shareholder vote.

**CHANGES TO SHAREHOLDERS RIGHTS**

Under French law, the affirmative vote of two-thirds of the votes cast at an extraordinary shareholders meeting is required to change our Articles of Association, which set out the rights attached to our shares, except for capital increases through incorporation of reserves, profits or share premium, or through the issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code).

The rights of a class of shareholders can be amended only after a special meeting of the class of shareholders affected has taken place. The voting requirements applicable to this type of special meeting are the same as those applicable to

an extraordinary general shareholders meeting. The quorum requirements for a special meeting are one-third of the voting shares, or 20% upon resumption of an adjourned meeting.

A unanimous shareholders vote is required to increase the liabilities of shareholders.

## **FINANCIAL STATEMENTS AND OTHER COMMUNICATIONS WITH SHAREHOLDERS**

In connection with any shareholders meeting, we must provide a set of documents which includes our annual report.

We must also provide on our website at least twenty-one days before a shareholders meeting certain information and a set of documents that includes the preliminary notice, the proxies and voting forms, the resolutions proposed by the Board of Directors, and the documents to be submitted to the shareholders meeting pursuant to articles L225-115 and R. 225-83 of the French Commercial Code, etc. The resolutions and the list of items added to the agenda of the shareholders meeting must be promptly published on our website.

## **DIVIDENDS**

We may only distribute dividends out of our distributable profits, plus any amounts held in our reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law or our Articles of Association. Distributable profits consist of our unconsolidated net profit in each fiscal year, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to law or our Articles of Association.

### **Legal Reserve**

The French Commercial Code requires us to allocate 5% of our unconsolidated net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital. This restriction on the payment of dividends also applies to each of our French subsidiaries on an unconsolidated basis. At December 31, 2017, our legal reserve amounted to 282,280,863, representing 11.26% of the aggregate par value of our issued and outstanding share capital as of that date. The legal reserve of any company subject to this requirement may serve to allocate losses that may not be allocated to other reserves, or may be distributed to shareholders upon liquidation of the company.

### **Approval of Dividends**

According to the French Commercial Code, our Board of Directors may propose a dividend for approval by shareholders at the annual general shareholders meeting. If we have earned distributable

**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

profits since the end of the preceding fiscal year, as reflected in an interim income statement certified by our independent auditors, our Board of Directors may distribute interim dividends to the extent of the distributable profits for the period covered by the interim income statement. Our Board of Directors exercises this authority subject to French law and regulations and may do so without obtaining shareholder approval.

**Distribution of Dividends**

Dividends are distributed to shareholders *pro rata* according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by our Board of Directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders' meeting or by our Board of Directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Dividends may be paid in cash or, if the shareholders' meeting so decides, in kind, provided that all shareholders receive a whole number of assets of the same nature paid in lieu of cash. Our Articles of Association provide that, subject to a decision of the shareholders' meeting taken by ordinary resolution, each shareholder may be given the choice to receive his dividend in cash or in shares.

**Timing of Payment**

According to the French Commercial Code, we must pay any existing dividends within nine months of the end of our fiscal year, unless otherwise authorized by court order. Dividends on shares that are not claimed within five years of the date of declared payment revert to the French State.

**CHANGES IN SHARE CAPITAL**

**Increases in Share Capital**

As provided for by the French Commercial Code, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our Board of Directors. The shareholders may delegate to our Board of Directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital. Our Board of Directors may further delegate this

power to our Chief Executive Officer or, subject to our Chief Executive Officer's approval, to his delegates (*directeurs généraux délégués*).

Increases in our share capital may be effected by:

issuing additional shares;  
increasing the par value of existing shares;

creating a new class of equity securities; or

exercising the rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

in consideration for cash;

in consideration for assets contributed in kind;

through an exchange offer;

by conversion of previously issued debt instruments;

by capitalization of profits, reserves or share premium; or

subject to various conditions, in satisfaction of debt incurred by our Company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium or through the issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code) require shareholders' approval at an extraordinary general shareholders' meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders' approval at an extraordinary general shareholders' meeting acting under the regular quorum and majority requirements for such meetings. See "Quorum and Votes Required for Shareholder Action" above.

On May 10, 2017, our shareholders approved various resolutions delegating to the Board of Directors the authority to increase our share capital through the issuance of shares or securities giving access to the share capital, subject to an overall cap set at 1.289 billion. This cap applies to all the resolutions whereby the extraordinary shareholders' meeting delegated to the Board of Directors the authority to increase the share capital, it being also specified that:

the maximum aggregate par value of capital increases that may be carried out with preemptive rights maintained was set at 1.289 billion;

the maximum aggregate par value of capital increases that may be carried out by public offering without preemptive rights was set at 240 million;

the maximum aggregate par value of capital increases that may be carried out by private placement without preemptive rights was set at 240 million;



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**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

capital increases resulting in the issuance of securities to members of employee savings plans are limited to 1% of the share capital as computed on the date of the Board of Directors' decision to issue such securities, and such issuances may be made at a discount of 20% (or 30%) if certain French law restrictions on resales were to apply, i.e. a lock up period of five years (or 10 years).

At its meeting of March 2, 2017, our Board of Directors decided to delegate to the Chief Executive Officer the powers necessary to carry out a capital increase reserved for members of the Group savings program. Every employee subscribing for at least five shares received one additional new share as an employer \$op-up contribution, and every employee subscribing for an additional fifteen shares (i.e. twenty shares in total) received four additional shares as an employer \$op-up contribution for the first ten shares. Beyond the first twenty shares there was no entitlement to any further shares by way of employer \$op-up contribution. The subscription period was open during June 2017.

25,760 employees from approximately 80 countries subscribed for a total of 1,528,982 shares. Of these, 727,943 shares were subscribed via FCPE Actions Sanofi, the dedicated employee share ownership fund for employees of our French subsidiaries; 342,670 shares via FCPE Sanofi Shares, the dedicated employee share ownership fund for employees of our foreign subsidiaries; and 458,369 shares directly by employees who were eligible for the employee share ownership plan but were in countries where local regulations did not allow the use of a dedicated employee share ownership fund.

A total of 92,116 shares were issued by way of employer \$op-up contribution. Of these, 40,209 were issued to FCPE Actions Sanofi; 25,484 to FCPE Sanofi Shares; and 26,423 directly to employees who were eligible for the employee share ownership plan but were in countries where local regulations did not allow the use of a dedicated employee share ownership fund.

Voting rights attached to shares held by FCPE Actions Sanofi are exercised individually by the employees who hold units in the fund; fractional rights are exercised by the fund's supervisory board.

Voting rights attached to shares held by FCPE Sanofi Shares are also exercised individually by the employees who hold units in the fund; any rights not exercised by them are exercised by the fund's supervisory board.

In each case, the supervisory board includes an equal number of representatives of employees and of Sanofi management.

On May 4, 2016, our shareholders approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting options to our employees and/or corporate officers, subject to the overall cap mentioned

above and under the following terms and conditions:

the authorization is valid for a period of 38 months, and any options granted may not give entitlement to a total number of

shares exceeding 0.5% of the share capital as computed on the date of the decision of the Board of Directors to grant such options; see [Stock Options](#) above;

On May 4, 2016, our shareholders also approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting existing or new restricted shares to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

the authorization is valid for a period of 38 months, and is subject to a limit of 1.5% of the share capital as computed on the date of the decision of the Board of Directors to allot such shares; see [Awards of Shares](#) above.

See also [Item 6. Directors, Senior Management and Employees](#) [E. Share Ownership](#) .

## Decreases in Share Capital

In accordance with the provisions of the French Commercial Code, any decrease in our share capital requires approval by the shareholders entitled to vote at an extraordinary general meeting. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced either by an exchange of shares or by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

In addition, specific rules exist to permit the cancellation of treasury shares, by which the shareholders' meeting may authorize the cancellation of up to a maximum of 10% of a company's share capital within an 24-month period. On May 10, 2017, our shareholders delegated to our Board of Directors for 26 months the right to reduce our share capital by canceling our own shares.

## PREEMPTIVE RIGHTS

According to the French Commercial Code, if we issue additional securities to be paid in cash, current shareholders will have preemptive rights to these securities on a *pro rata* basis. These preemptive rights require us to give priority treatment to current shareholders. The rights entitle the individual or entity that holds them to subscribe to the issuance of any securities that may increase the share capital of our Company by means of a cash payment or a set-off of cash debts. Preemptive rights are transferable during the subscription period relating to a particular offering. These rights may also be listed on Euronext Paris Stock Exchange.

Preemptive rights with respect to any particular offering may be waived by the affirmative vote of shareholders holding two-thirds of the shares entitled to vote at an extraordinary general meeting. Our Board of Directors and our independent auditors are required by French law to present reports that specifically address any proposal to waive preemptive rights. In the event of a waiver, the

**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

issuance of securities must be completed within the period prescribed by law. Shareholders may also notify us that they wish to waive their own preemptive rights with respect to any particular offering if they so choose.

The shareholders may decide at extraordinary general meetings to give the existing shareholders a non-transferable priority right to subscribe to the new securities, for a limited period of time.

In the event of a capital increase without preemptive rights to existing shareholders, French law requires that the capital increase be made at a price equal to or exceeding the weighted average market prices of the shares for the last three trading days on Euronext Paris Stock Exchange prior to the determination of the subscription price of the capital increase less 5%.

**FORM, HOLDING AND TRANSFER OF SHARES**

**Form of Shares**

Our Articles of Association provide that the shares may be held in either bearer form or registered form at the option of the holder.

**Holding of Shares**

In accordance with French law relating to the dematerialization of securities, shareholders' ownership rights are represented by book entries instead of share certificates. We maintain a share account with Euroclear France (a French clearing system, which holds securities for its participants) for all shares in registered form, which is administered by BNP Paribas Securities Services. In addition, we maintain separate accounts in the name of each shareholder either directly or, at a shareholder's request, through the shareholder's accredited intermediary. Each shareholder account shows the name of the holder and the number of shares held. BNP Paribas Securities Services issues confirmations (*attestations d'inscription en compte*) to each registered shareholder as to shares registered in the shareholder's account, but these confirmations are not documents of title.

Shares of a listed company may also be issued in bearer form. Shares held in bearer form are held and registered on the shareholder's behalf in an account maintained by an accredited financial intermediary and are credited to an account at Euroclear France maintained by such intermediary. Each accredited financial intermediary maintains a

record of shares held through it and provides the account holder with a securities account statement. Transfers of shares held in bearer form may only be made through accredited financial intermediaries and Euroclear France.

Shares held by persons who are not domiciled in France may be registered in the name of intermediaries who act on behalf of one or more investors. When shares are so held, we are entitled to request from such intermediaries the names of the investors. Also, we may request any legal entity (*personne morale*) which holds more than 2.5% of our shares or voting rights to disclose the name of any person who owns, directly or indirectly, more than one-third

of its share capital or of its voting rights. A person not providing the complete requested information in time, or who provides incomplete or false information, will be deprived of its voting rights at shareholders' meetings and will have its payment of dividends withheld until it has provided the requested information in strict compliance with French law. If such person acted willfully, the person may be deprived by a French court of either its voting rights or its dividends or both for a period of up to five years.

### **Transfer of Shares**

Our Articles of Association do not contain any restrictions relating to the transfer of shares.

Registered shares must be converted into bearer form before being transferred on the Euronext Paris Stock Exchange on the shareholders' behalf and, accordingly, must be registered in an account maintained by an accredited financial intermediary on the shareholders' behalf. A shareholder may initiate a transfer by giving instructions to the relevant accredited financial intermediary.

A fee or commission is payable to the broker involved in the transaction, regardless of whether the transaction occurs within or outside France. Registration duty is currently payable in France if a written deed of sale and purchase (*acte*) is executed in France or outside France with respect to the shares of the Company.

### **REDEMPTION OF SHARES**

Under French law, our Board of Directors is entitled to redeem a set number of shares as authorized by the extraordinary shareholders' meeting. In the case of such an authorization, the shares redeemed must be cancelled within one month after the end of the offer to purchase such shares from shareholders. However, shares redeemed on the open market do not need to be cancelled if the company redeeming the shares grants options on or awards those shares to its employees within one year following the acquisition. See also [Trading in Our Own Shares](#) below.

### **SINKING FUND PROVISIONS**

Our Articles of Association do not provide for any sinking fund provisions.

### **LIABILITY TO FURTHER CAPITAL CALLS**

Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

### **LIQUIDATION RIGHTS**

If we are liquidated, any assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will first be distributed to repay in full the par value of our shares. Any



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**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

surplus will be distributed *pro rata* among shareholders in proportion to the par value of their shareholdings.

**REQUIREMENTS FOR HOLDINGS EXCEEDING CERTAIN PERCENTAGES**

The French Commercial Code provides that any individual or entity, acting alone or in concert with others, that becomes the owner, directly or indirectly, of more than 5%, 10%, 15%, 20%, 25%, 30%, 33 $\frac{1}{3}$ %, 50%, 66 $\frac{2}{3}$ %, 90% or 95% of the outstanding shares or voting rights of a listed company in France, such as our Company, or that increases or decreases its shareholding or voting rights above or below any of those percentages, must notify the company, before the end of the fourth trading day following the date it crosses the threshold, of the number of shares it holds and their voting rights. The individual or entity must also notify the AMF before the end of the fourth trading day following the date it crosses any such threshold. The AMF makes the notice public.

Pursuant to the French Commercial Code and the AMF General Regulation, the participation thresholds shall be calculated on the basis of the shares and voting rights owned, and shall take into account the shares and voting rights which are deemed to be shares and voting rights owned, even if the individual or entity does not itself hold shares or voting rights. In accordance with this deemed ownership principle, the individual or entity must take into account specific situations where shares and voting rights are deemed to be shares and voting rights owned when calculating the number of shares owned to be disclosed in the notifications to the Company and to the AMF. It includes among others situations where an individual or entity is entitled to acquire issued shares at its own initiative, immediately or at the end of a maturity period, under an agreement or a financial instrument, without set-off against the number of shares that this individual or entity is entitled to sell under another agreement or financial instrument. The individual or entity required to make such notification shall also take into account issued shares covered by an agreement or cash-settled financial instrument and having an economic effect for said individual or entity that is equivalent to owning such shares. In the cases of deemed ownership described above, the notification shall mention the type of deemed ownership and include a description of the main characteristics of the financial instrument or agreement with specific details required by the AMF General Regulation.

The AMF General Regulation provides that shares and voting rights subject to multiple cases of deemed ownership shall only be counted once.

When an individual or entity modifies the allocation between the shares it owns and its financial instruments or agreements deemed to be owned shares, it must disclose that change in a new notification. However, the change must only be disclosed if the acquisition of owned shares due to the settlement of the financial instruments or agreements causes the investor to cross a threshold.

Subject to certain limited exceptions, French law and AMF regulations impose additional reporting requirements on persons who acquire more than 10%, 15%, 20%, or 25% of the outstanding shares or voting rights of a company listed in France. These persons must file a report with the company and the AMF before the end of the fifth trading day following the date they cross any such threshold.

In the report, the acquirer will have to specify its intentions for the following six months including:

whether it acts alone or in concert with others;

the means of financing of the acquisition (the notifier shall indicate in particular whether the acquisition is being financed with equity or debt, the main features of that debt, and, where applicable, the main guarantees given or received by the notifier. The notifier shall also indicate what portion of its holding, if any, it obtained through securities loans);

whether or not it intends to continue its purchases;

whether or not it intends to acquire control of the company in question;

the strategy it contemplates *vis-à-vis* the issuer;

the way it intends to implement its strategy, including: (i) any plans for a merger, reorganization, liquidation, or partial transfer of a substantial part of the assets of the issuer or of any other entity it controls within the meaning of article L. 233-3 of the French Commercial Code, (ii) any plans to modify the business of the issuer, (iii) any plans to modify articles of association of the issuer, (iv) any plans to delist a category of the issuer's financial instruments, and (v) any plans to issue the issuer's financial instruments;

any agreement for the temporary transfer of shares or voting rights of the issuer;

the way it intends to settle its agreements or instruments on the shares or voting rights of the issuer mentioned in Article L. 233-9, 4° and 4° bis of the French Commercial Code; and

whether it seeks representation on the Board of Directors.

The AMF makes the report public. Upon any change of intention within the six-month period following the filing of the report, it will have to file a new report for the following six-month period.

In order to enable shareholders to give the required notice, we must each month publish on our website and send the AMF a written notice setting forth the total number of our shares and voting rights (including treasury shares) whenever they vary from the figures previously published.

If any shareholder fails to comply with an applicable legal notification requirement, the shares in excess of the relevant threshold will be deprived of voting rights for all shareholders' meetings until the end of a two-year period

following the date on

**211**



**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

which the owner complies with the notification requirements. In addition, any shareholder who fails to comply with these requirements may have all or part of its voting rights suspended for up to five years by the Commercial Court at the request of our Chairman, any shareholder or the AMF, and may be subject to criminal fines.

Under AMF regulations, and subject to limited exemptions granted by the AMF, any person or entity, acting alone or in concert, that crosses the threshold of 30% of the share capital or voting rights of a French listed company must initiate a public tender offer for the balance of the shares and securities giving access to the share capital or voting rights of such company. Cash-settled derivative instruments or agreements mentioned in Article L. 233-9, 4° bis of the French Commercial Code are not included in the calculation of the number of shares related to the mandatory public tender offer.

In addition, our Articles of Association provide that any person or entity, acting alone or in concert with others, who becomes the owner of 1%, or any multiple of 1% of our share capital or our voting rights, even beyond the minimum declaration limits permitted by the legal and regulatory provisions, must notify us by certified mail, return receipt requested, within five trading days, of the total number of shares and securities giving access to our share capital and voting rights that such person then owns. The same provisions of our Articles of Association apply whenever such owner increases or decreases its ownership of our share capital or our voting rights to such extent that it goes above or below one of the thresholds described in the preceding sentence. Any person or entity that fails to comply with such notification requirement will, upon the request of one or more shareholders holding at least 5% of our share capital or of our voting rights made at the general shareholders' meeting, be deprived of voting rights with respect to the shares in excess of the relevant threshold for all shareholders' meetings until the end of a two-year period following the date on which such person or entity complies with the notification requirements.

**CHANGE IN CONTROL/ANTI-TAKEOVER**

There are no provisions in our Articles of Association that would have the effect of delaying, deferring or preventing a change in control of our Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving our Company or any of our subsidiaries. Further, there are no provisions in our Articles of Association that allow the issuance of preferred stock upon the occurrence of a takeover attempt or the addition of other anti-takeover measures without a shareholder vote.

Our Articles of Association do not include any provisions discriminating against any existing or prospective holder of our securities as a result of such shareholder owning a substantial number of shares.

## TRADING IN OUR OWN SHARES

Under French law, Sanofi may not issue shares to itself. However, we may, either directly or through a financial intermediary acting on our behalf, acquire up to 10% of our issued share capital within a maximum period of 18 months, provided our shares are listed on a regulated market. Prior to acquiring our shares, we must publish a description of the share repurchase program (*descriptif du programme de rachat d'actions*).

We may not cancel more than 10% of our issued share capital over any 24-month period. Our repurchase of shares must not result in our Company holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. We must hold any shares that we repurchase in registered form. These shares must be fully paid up. Shares repurchased by us continue to be deemed issued under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

The shareholders, at an extraordinary general shareholders meeting, may decide not to take these shares into account in determining the preemptive rights attached to the other shares. However, if the shareholders decide to take them into account, we must either sell the rights attached to the shares we hold on the market before the end of the subscription period or distribute them to the other shareholders on a *pro rata* basis.

On May 10, 2017, our shareholders approved a resolution authorizing us to repurchase up to 10% of our shares over an 18-month period. Under this authorization, the purchase price for each Sanofi ordinary share may not be greater than 120.00 and the maximum amount that Sanofi may pay for the repurchases is 15,504,267,840. This authorization was granted for a period of 18 months from May 10, 2017 and cancelled and replaced the authorization granted to the Board of Directors by the combined general meeting held on May 4, 2016. A description of this share repurchase program as adopted by the combined general meeting held on May 10, 2017 (*descriptif du programme de rachat d'actions*) was published on March 3, 2017.

### Purposes of Share Repurchase Programs

Under the European regulation 596/2014, dated April 16, 2014 on market abuse and its delegated regulation 2016/1052 on repurchase programs and stabilization measures, dated March 8, 2016 (which we refer to in this section as the Regulation ), an issuer will benefit from a safe harbor for share transactions that comply with certain conditions relating in particular to the pricing, volume and timing of transactions (see below) and that are made in connection with a share repurchase program the purpose of which is:

to reduce the share capital through the cancellation of treasury shares;

**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

to meet obligations arising from debt financial instruments that are exchangeable into equity instruments; and/or

to meet obligations arising from share option programs or other allocations of shares to employees or to members of the administrative, management or supervisory bodies of the issuer or of an associate company.

Safe harbor transactions will by definition not be considered market abuses under the Regulation. Transactions that are carried out for other purposes than those mentioned above do not qualify for the safe harbor.

However, as permitted by the Regulation, which provides for a presumption of legitimacy for existing market practices that do not constitute market manipulation and that conform with certain criteria, the AMF has established as a French accepted market practice, which therefore benefits from a presumption of legitimacy, the use of liquidity agreements for share purchases that are entered into with a financial services intermediary and that comply with the code of conduct (*charte de déontologie*) approved by the AMF.

The AMF confirmed that all transactions directed at maintaining the liquidity of an issuer's shares must be conducted pursuant to a liquidity agreement with a financial services intermediary acting independently.

As of July 3, 2016, the purchase of shares that are subsequently used as acquisition currency in a business combination transaction, which the AMF previously permitted as an accepted market practice, is no longer considered as such, although such practice, while not benefiting from the presumption of legitimacy, is not prohibited under the Regulation.

**Pricing, Volume and Other Restrictions**

In order to qualify for the safe harbor described above, the issuer must generally comply with the following pricing and volume restrictions:

a share purchase must not be made at a price higher than the higher of the price of the last independent trade and the highest current independent bid on the trading venues where the purchase is carried out; and

subject to certain exceptions for illiquid securities, the issuer must not purchase on any trading day more than 25% of the average daily volume of the shares on the regulated market on which the purchase is carried out. The average daily volume figure must be based on the average daily volume traded in the month preceding the month of public disclosure of the share repurchase program and fixed on that basis for the authorized period of that program. If the program does not make reference to this volume, the average daily volume figure must be based on the average daily volume traded in the 20 trading days preceding the date of purchase.

In addition, unless the issuer has in place a time-scheduled repurchase program or the repurchase program is lead-managed by an investment firm or a credit institution which makes its trading decisions concerning the timing of the purchase of the issuer's shares independently of the issuer, the issuer must not, for the duration of the repurchase program, engage in the following activities:

selling its own shares;

effecting any transaction during a closed period imposed by the applicable law of the Member State in which the transaction occurs (i.e. under French law, during the period between the date on which the company has knowledge of insider information and the date on which such information is made public and during the 30 calendar day period before the announcement of an interim financial report or a year-end report which the issuer is obliged to make public); or

effecting any transaction in securities with respect to which the issuer has decided to delay the public disclosure of inside information, in accordance with applicable rules.

### **Use of Share Repurchase Programs**

Pursuant to the AMF rules, issuers must immediately allocate the repurchased shares to one of the purposes provided for in the Regulation and must not subsequently use the shares for a different purpose. As an exception to the foregoing, shares repurchased with a view to covering stock option plans may, if no longer needed for this purpose, be re-allocated for cancellation or sold in compliance with AMF requirements relating in particular to blackout periods. Shares repurchased in connection with one of the market practices authorized by the AMF (see above) may also be re-allocated to one of the purposes contemplated by the Regulation or sold in compliance with AMF requirements. Shares repurchased with a view to their cancellation must be cancelled within 24 months following their acquisition.

During the year ended December 31, 2017, we used the authority delegated by our shareholders to repurchase our shares on the stock market.

Pursuant to our share repurchase programs authorized by our shareholders on May 4, 2016 and on May 10, 2017, we repurchased 26,855,536 of our shares for a weighted average price of 80.04, i.e. a total cost of 2,149 million (including 20,000 shares purchased with a view to covering restricted share plans). Brokerage fees and financial transaction taxes (net of income taxes) amounted to 6.2 million. Our Company did not resort to derivatives to repurchase our own shares.

On April 27, 2017, the Board of Directors cancelled 36,380,198 treasury shares repurchased between November 2016 and the end of March 2017 pursuant to the share repurchase program of the Company.



**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

On December 14, 2017, the Board of Directors cancelled 10,402,540 treasury shares repurchased between April and September 2017 pursuant to the share repurchase program of the Company.

During 2017, pursuant to the liquidity contract, Rothschild & Cie:

purchased 1,012,115 of our shares at an average weighted price of 82.82 for a total amount of 83,822,744; and

sold 962,365 of our shares at an average weighted price of 83.13 for a total amount of 80,000,590.

In 2017, of the 136,843 shares allocated to stock purchase option plans outstanding at December 31, 2016, 32,142 shares were transferred to grantees of options. In 2017, of the 20,000 shares allocated to restricted share plans outstanding at December 31, 2016, 725 shares were transferred to beneficiaries of performance shares.

As a result, as of December 31, 2017, out of the 173,726 treasury shares, representing 0.014% of our share capital, 123,976 were allocated to outstanding stock purchase option plans and restricted share plans and 49,750 were allocated to the liquidity account. At the same date, none of the shares was allocated to the purpose of cancellation.

As of December 31, 2017, we directly owned 173,726 Sanofi shares with a par value of 2 representing around 0.014% of our share capital and with an estimated value of 9 million, based on the share price at the time of purchase.

**Reporting Obligations**

Pursuant to the Regulation, the AMF Regulation and the French Commercial Code, issuers trading in their own shares are subject to the following reporting obligations:

issuers must report all transactions in their own shares to the competent authority of each trading venue on which the shares are admitted to trading or are traded within seven trading days of the transaction in a prescribed format, unless such transactions are carried out pursuant to a liquidity agreement that complies with the ethical code

approved by the AMF;

issuers must declare to the AMF on a monthly basis all transactions completed under the share repurchase program unless they provide the same information on a weekly basis; and

post on its website the transactions disclosed and keep that information available to the public for at least a 5-year period from the date of public disclosure.

#### **OWNERSHIP OF SHARES BY NON-FRENCH PERSONS**

The French Commercial Code and our Articles of Association currently do not limit the right of non-residents of France or non-French persons to own or, where applicable, to vote our securities. However, non-residents of France must file an

administrative notice with the French authorities in connection with certain direct and indirect investments in us, including the acquisition of a controlling interest in our Company. Under existing administrative rulings, ownership of 33 $\frac{1}{3}$ % or more of our share capital or voting rights is regarded as a controlling interest, but a lower percentage might be held to be a controlling interest in certain circumstances depending upon factors such as:

the acquiring party's intentions;

the acquiring party's ability to elect directors; or

financial reliance by the company on the acquiring party.

Moreover, certain foreign investments in companies incorporated under French laws are subject to prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.

#### **ENFORCEABILITY OF CIVIL LIABILITIES**

We are a limited liability company (*société anonyme*) organized under the laws of France, and most of our officers and directors reside outside the United States. In addition, a substantial portion of our assets is located in France.

As a result, investors may find it difficult or be unable to effect service of process within the United States upon or obtain jurisdiction over our Company or our officers and directors in US courts in actions predicated on the civil liability provisions of US securities law. It may also be difficult to enforce against them, either inside or outside the United States, judgments obtained against them in US courts, or to enforce in US courts, judgments obtained against them in courts in jurisdictions outside the United States, in any action based on civil liabilities under US federal securities laws. There is doubt as to the enforceability against such persons in France, whether in original actions or in actions to enforce judgments of US courts, of liabilities based solely on US federal securities laws. In addition, actions in the United States under US federal securities laws could be affected under certain circumstances by French law No. 68-678 of July 26, 1968 as amended by French Law No. 80-538 of July 16, 1980, which may preclude or restrict the obtaining of evidence in France or from French persons in connection with those actions. Additionally, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France.

**C. Material Contracts**

**THE CONTINGENT VALUE RIGHTS AGREEMENT**

In connection with its acquisition of Genzyme Corporation, now a wholly-owned subsidiary of Sanofi, Sanofi issued one CVR per Genzyme share. On March 30, 2011, Sanofi and American Stock Transfer & Trust Company, LLC ( AST ), as trustee, entered into a Contingent Value Rights Agreement (the CVR Agreement )



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**Table of Contents**

## ITEM 10. ADDITIONAL INFORMATION

governing the terms of the CVRs. On May 13, 2016, AST tendered its resignation as trustee under the CVR Agreement to Sanofi. As of June 30, 2016, UMB Bank, National Association replaced AST and is the successor trustee under the CVR Agreement.

Pursuant to the terms of the CVR Agreement, a holder of a CVR is entitled to cash payments upon the achievement of contractually defined milestones. The first three milestones (related, respectively, to (i) manufacturing of Cerezyme<sup>®</sup> and Fabrazyme<sup>®</sup> (ii) US regulatory approval on or before March 31, 2014 of Lemtrada<sup>®</sup> for the treatment of MS (the Approval Milestone ) and (iii) Product Sales Milestone #1, pursuant to which a holder of a CVR would have been entitled to receive \$2 per CVR if Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) post launch equaled or exceeded a total of \$400 million within certain specified periods and territories) were not met. The remaining milestone payments under the CVR Agreement are summarized below:

*Product Sales Milestone #2 Payment.* \$3 per CVR upon the first instance in which Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) for a four calendar quarter period are equal to or in excess of \$1.8 billion. Given that the Approval Milestone was not achieved, an additional \$1 per CVR will be paid should Product Sales Milestone #2 be achieved, totaling \$4 per CVR.

*Product Sales Milestone #3 Payment.* \$4 per CVR upon the first instance in which Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) for a four calendar quarter period are equal to or in excess of \$2.3 billion (however, no quarter in which Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) were used to determine the achievement of Product Sales Milestone #1 or #2 shall be included in the calculation of sales for determining whether Product Sales Milestone #3 has been achieved).

*Product Sales Milestone #4 Payment.* \$3 per CVR upon the first instance in which Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) for a four calendar quarter period are equal to or in excess of \$2.8 billion (however, no quarter in which Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) were used to determine the achievement of Product Sales Milestone #1, #2 or #3 shall be included in the calculation of sales for determining whether Product Sales Milestone #4 has been achieved).

On February 7, 2018, Sanofi disclosed that, based upon actual sales trends to date, it does not expect that product sales milestones #2 to #4 will be met.

The CVR Agreement will terminate on the earlier of (a) December 31, 2020 and (b) the date that Product Sales Milestone #4 is paid (the Termination Date ), provided that if any milestone has been achieved prior to the Termination

Date, but the associated CVR payment has not been paid on or prior to the Termination Date, the CVR Agreement shall not terminate until such payment has been paid in full in accordance with the terms of the CVR Agreement.

Sanofi has agreed to use diligent efforts (as defined in the CVR Agreement), until the CVR Agreement is terminated, to achieve

each of the remaining milestones. However, we are not required to take all possible actions to achieve these goals. Sanofi has also agreed to use its commercially reasonable efforts to maintain a listing for trading of the CVRs on the NASDAQ market.

For more information on Lemtrada® see [Item 4.B Business Overview](#) [Pharmaceutical Products](#) [Multiple Sclerosis](#) .

The CVR Agreement does not prohibit Sanofi or any of its subsidiaries or affiliates (as defined in the CVR Agreement) from acquiring the CVRs, whether in open market transactions, private transactions or otherwise. Sanofi has certain disclosure obligations in connection with such acquisitions under the CVR Agreement. Sanofi may also, subject to certain terms and conditions as set forth in the CVR Agreement, optionally purchase and cancel all (but not less than all) of the outstanding CVRs at a cash price as set forth in the CVR Agreement if (i) the volume-weighted average price paid per CVR for all CVRs traded over the forty-five trading days prior to such date is less than fifty cents and (ii) Lemtrada® sales (as defined in the CVR Agreement) in the four calendar quarters ended immediately prior to such date are less than \$1 billion in the aggregate.

A copy of the form of CVR Agreement is on file with the SEC as Annex B to Amendment No. 2 to the Registration Statement on Form F-4 filed with the Securities and Exchange Commission on March 24, 2011. Reference is made to such exhibit for a more complete description of the terms and conditions of the CVR Agreement, and the foregoing summary of such terms and conditions is qualified in its entirety by such exhibit.

#### **D. Exchange Controls**

French exchange control regulations currently do not limit the amount of payments that we may remit to non-residents of France. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary.

#### **E. Taxation**

##### **GENERAL**

The following generally summarizes the material French and US federal income tax consequences to US holders (as defined below) of purchasing, owning and disposing of our ADSs and ordinary shares (collectively the Securities ). This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of our Securities. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

*This summary does not constitute a legal opinion or tax advice. Holders are urged to consult their own tax advisers regarding the*



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**Table of Contents**

## ITEM 10. ADDITIONAL INFORMATION

*tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including the effect of any US federal, state, local or other national tax laws.*

A set of tax rules is applicable to French assets that are held by or in foreign trusts. These rules provide *inter alia* for the inclusion of trust assets in the settlor's net assets for purpose of applying the French real estate wealth tax, for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the French real estate wealth tax and for a number of French tax reporting and disclosure obligations. The following discussion does not address the French tax consequences applicable to Securities held in trusts. *If Securities are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

The description of the French and US federal income tax consequences set forth below is based on the laws (including, for US federal income tax purposes, the Internal Revenue Code of 1986, as amended (the Code), final, temporary and proposed US Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof) in force as of the date of this annual report, the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994 (the Treaty), which entered into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax regulations issued by the French tax authorities within the *Bulletin Officiel des Finances Publiques-Impôts* (the Regulations) in force as of the date of this report. *US holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits, especially with regard to the Limitations on Benefits provision, in light of their own particular circumstances.*

For the purposes of this discussion, a US holder is a beneficial owner of Securities that is (i) an individual who is a US citizen or resident for US federal income tax purposes, (ii) a US domestic corporation or certain other entities created or organized in or under the laws of the United States or any state thereof, including the District of Columbia, or (iii) otherwise subject to US federal income taxation on a net income basis in respect of Securities. A non-US holder is a person other than a US holder.

If a partnership holds Securities, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. *If a US holder is a partner in a partnership that holds Securities, the holder is urged*

*to consult its own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

This discussion is intended only as a general summary and does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of the Securities

to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. The discussion applies only to investors that hold our Securities as capital assets that have the US dollar as their functional currency, that are entitled to Treaty benefits under the Limitation on Benefits provision contained in the Treaty, and whose ownership of the Securities is not effectively connected to a permanent establishment or a fixed base in France. Certain holders (including, but not limited to, US expatriates, partnerships or other entities classified as partnerships for US federal income tax purposes, banks, insurance companies, regulated investment companies, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, persons who acquired the Securities pursuant to the exercise of employee stock options or otherwise as compensation, persons that own (directly, indirectly or by attribution) 5% or more of our voting stock or 5% or more of our outstanding share capital, dealers in securities or currencies, persons that elect to mark their securities to market for US federal income tax purposes, persons that acquire ADSs in pre-release transactions (i.e. prior to deposit of the relevant ordinary shares) and persons holding Securities as a position in a synthetic security, straddle or conversion transaction) may be subject to special rules not discussed below.  *Holders of Securities are advised to consult their own tax advisers with regard to the application of French tax law and US federal income tax law to their particular situations, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction.*

## **French Taxes**

### **Estate and Gift Taxes and Transfer Taxes**

In general, a transfer of Securities by gift or by reason of death of a US holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978, unless the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or the Securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Pursuant to Article 235 ter ZD of the French General Tax Code, purchases of Securities are subject to a 0.3% French tax on financial transactions (the FTFF ) provided that Sanofi s market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year. A list of companies whose market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year used to be published annually by the French Ministry of Economy. It is now published by the French tax authorities, and could be amended at any time. Pursuant to Regulations BOI-ANX-000467-20171221 issued on December 21,

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**Table of Contents**

## ITEM 10. ADDITIONAL INFORMATION

2017, purchases of Sanofi's Securities in 2018 should be subject to the FTFF as the market capitalization of Sanofi exceeded 1 billion euros as of December 1, 2017. In accordance with Article 726-II of the French General Tax Code, purchases which are subject to the FTFF should however not be subject to transfer taxes (*droits d'enregistrement*) in France.

**Wealth Tax**

The French wealth tax (*impôt de solidarité sur la fortune*) has been replaced with a French real estate wealth tax (*impôt sur la fortune immobilière*) with effect from January 1, 2018. French real estate wealth tax applies only to individuals and does not generally apply to the Securities if the holder is a US resident, as defined pursuant to the provisions of the Treaty, provided that the individual does not own directly or indirectly a shareholding exceeding 10% of the financial rights and voting rights.

**US Taxes****Ownership of the Securities**

Deposits and withdrawals by a US holder of ordinary shares in exchange for ADSs, will not be taxable events for US federal income tax purposes. For US tax purposes, holders of ADSs will be treated as owners of the ordinary shares represented by such ADSs. Accordingly, the discussion that follows regarding the US federal income tax consequences of acquiring, owning and disposing of ordinary shares is equally applicable to ADSs.

**Information Reporting and Backup Withholding Tax**

Distributions made to holders and proceeds paid from the sale, exchange, redemption or disposal of Securities may be subject to information reporting to the Internal Revenue Service. Such payments may be subject to backup withholding taxes unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not US persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non-US status in connection with payments received within the United States or through a US-related financial intermediary to establish that it is an exempt recipient. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder's US federal income tax liability. A holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any

required information.

### **Foreign Asset Reporting**

In addition, a US holder that is an individual (and, to the extent provided in future regulations, an entity), may be subject to

recently-enacted reporting obligations with respect to ordinary shares and ADSs if the aggregate value of these and certain other specified foreign financial assets exceeds \$50,000. If required, this disclosure is made by filing Form 8938 with the US Internal Revenue Service. Significant penalties can apply if holders are required to make this disclosure and fail to do so. In addition, a US holder should consider the possible obligation to file online a FinCEN Form 114 Foreign Bank and Financial Accounts Report as a result of holding ordinary shares or ADSs. Holders are encouraged to consult their US tax advisors with respect to these and other reporting requirements that may apply to their acquisition of ordinary shares and ADSs.

### **State and Local Taxes**

In addition to US federal income tax, US holders of Securities may be subject to US state and local taxes with respect to such Securities. *Holders of Securities are advised to consult their own tax advisers with regard to the application of US state and local income tax law to their particular situation.*

### **ADSS-ORDINARY SHARES**

#### **French Taxes**

##### **Taxation of Dividends**

Under French law, dividends paid by a French corporation, such as Sanofi, to non-residents of France are generally subject to French withholding tax at a rate of 30% (12.8% for distributions made to individuals, and 15% for distributions made to not-for-profit organizations with a head office in a Member State of the European Economic Area which would be subject to the tax regime set forth under article 206 paragraph 2 of the French General Tax Code if its head office were located in France and which meet the criteria set forth in the Regulations BOI-RPPM-RCM-30-30-10-70-20171004, n° 130). Dividends paid by a French corporation, such as Sanofi, towards non-cooperative States or territories, as defined in Article 238-0 A of the French General Tax Code, will generally be subject to French withholding tax at a rate of 75%, irrespective of the tax residence of the beneficiary of the dividends if the dividends are received in such States or territories; however, eligible US holders entitled to Treaty benefits under the Limitation on Benefits provision contained in the Treaty who are US residents, as defined pursuant to the provisions of the Treaty and who receive dividends in non-cooperative States or territories, will not be subject to this 75% withholding tax rate.

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible US holder who is a US resident as defined pursuant to the provisions of the Treaty and whose ownership of the ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such US holder has in France, is reduced to 15%, or to 5% if such US holder is a corporation and owns directly or indirectly at least 10% of the share

**Table of Contents**

ITEM 10. ADDITIONAL INFORMATION

capital of the issuing company; such US holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any. For US holders that are not individuals but are US residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates contained in the Limitation on Benefits provision of the Treaty, are complicated, and certain technical changes were made to these requirements by the protocol of January 13, 2009. US holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits in light of their own particular circumstances.

Dividends paid to an eligible US holder may immediately be subject to the reduced rates of 5% or 15% provided that such holder establishes before the date of payment that it is a US resident under the Treaty by completing and providing the depositary with a treaty form (Form 5000). Dividends paid to a US holder that has not filed the Form 5000 before the dividend payment date will be subject to French withholding tax at the rate of 30% and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid. Pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other US holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

The depositary agrees to use reasonable efforts to follow the procedures established, or that may be established, by the French tax authorities (i) to enable eligible US holders to qualify for the reduced withholding tax rate provided by the Treaty, if available at the time the dividends are paid, or (ii) to recover any excess French withholding taxes initially withheld or deducted with respect to dividends and other distributions to which such US holders may be eligible from the French tax authorities and (iii) to recover any other available tax credits. In particular, associated forms (including Form 5000 and Form 5001, together with their instructions), will be made available by the depositary to all US holders registered with the depositary, and are also generally available from the US Internal Revenue Service.

The withholding tax refund, if any, ordinarily is paid within 12 months of filing the applicable French Treasury Form, but not before January 15 of the year following the calendar year in which the related dividend is paid.

**Tax on Sale or Other Disposition**



In general, under the Treaty, a US holder who is a US resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption (other than redemption proceeds characterized as dividends under French domestic law), sale or exchange of ordinary shares or ADSs unless the ordinary shares or the ADSs form part of the business property of a permanent

establishment or fixed base that the US holder has in France. Special rules apply to holders who are residents of more than one country.

## US Taxes

### Taxation of Dividends

For US federal income tax purposes, the gross amount of any distribution paid to US holders (that is, the net distribution received plus any tax withheld therefrom) will be treated as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of Sanofi (as determined under US federal income tax principles). Dividends paid by Sanofi will not be eligible for the dividends-received deduction generally allowed to corporate US holders.

Subject to certain exceptions for short-term and hedged positions, the US dollar amount of dividends received by an individual US holder with respect to the ADSs or our ordinary shares is currently subject to taxation at a maximum rate of 20% if the dividends are qualified dividends. Dividends paid on the ordinary shares or ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has approved for the purposes of the qualified dividend rules and (ii) the issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a passive foreign investment company ( PFIC ). The Treaty has been approved for the purposes of the qualified dividend rules. Based on our audited financial statements and relevant market and shareholder data, we believe Sanofi was not a PFIC for US federal income tax purposes with respect to its 2017 taxable year. In addition, based on its current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, we do not anticipate that Sanofi will become a PFIC for its 2018 taxable year. *Holders of ordinary shares and ADSs should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.*

If you are a US holder, dividend income received by you with respect to ADSs or ordinary shares generally will be treated as foreign source income for foreign tax credit purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. Distributions out of earnings and profits with respect to the ADSs or ordinary shares generally will be treated as passive category income (or, in the case of certain US holders, general category income). Subject to certain limitations, French income tax withheld in connection with any distribution with respect to the ADSs or ordinary shares may be claimed as a credit against the US federal income tax liability of a US holder if such US holder elects for that year to credit all foreign income taxes. Alternatively, such French withholding tax may be taken as a deduction against taxable income. Foreign tax

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**Table of Contents**

## ITEM 10. ADDITIONAL INFORMATION

credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in Securities and may not be allowed in respect of certain arrangements in which a US holder's expected economic profit is insubstantial. *The US federal income tax rules governing the availability and computation of foreign tax credits are complex. US holders should consult their own tax advisers concerning the implications of these rules in light of their particular circumstances.*

To the extent that an amount received by a US holder exceeds the allocable share of our current and accumulated earnings and profits, such excess will be applied first to reduce such US holder's tax basis in its ordinary shares or ADSs and then, to the extent it exceeds the US holder's tax basis, it will constitute capital gain from a deemed sale or exchange of such ordinary shares or ADSs (see Tax on Sale or Other Disposition, below).

The amount of any distribution paid in euros will be equal to the US dollar value of the euro amount distributed, calculated by reference to the exchange rate in effect on the date the dividend is received by a US holder of ordinary shares (or by the depository, in the case of ADSs) regardless of whether the payment is in fact converted into US dollars on such date. *US holders should consult their own tax advisers regarding the treatment of foreign currency gain or loss, if any, on any euros received by a US holder that are converted into US dollars on a date subsequent to receipt.*

Distributions to holders of additional ordinary shares (or ADSs) with respect to their ordinary shares (or ADSs) that are made as part of a *pro rata* distribution to all ordinary shareholders generally will not be subject to US federal income tax. However, if a US holder has the option to receive a distribution in shares (or ADSs) or to receive cash in lieu of such shares (or ADSs), the distribution of shares (or ADSs) will be taxable as if the holder had received an amount equal to the fair market value of the distributed shares (or ADSs), and such holder's tax basis in the distributed shares (or ADSs) will be equal to such amount.

**Tax on Sale or Other Disposition**

In general, for US federal income tax purposes, a US holder that sells, exchanges or otherwise disposes of its ordinary shares or ADSs will recognize capital gain or loss in an amount equal to the US dollar value of the difference between the amount realized for the ordinary shares or ADSs and the US holder's adjusted tax basis (determined in US dollars and under US federal income tax rules) in the ordinary shares or ADSs. Such gain or loss generally will be US-source gain or loss, and will be treated as long-term

capital gain or loss if the US holder's holding period in the ordinary shares or ADSs exceeds one year at the time of disposition. If the US holder is an individual, any capital gain generally will be subject to US federal income tax at preferential rates (currently a maximum of 20%) if specified minimum holding periods are met. The deductibility of capital losses is subject to significant limitations.

### **Medicare Tax**

Certain US holders who are individuals, estates or trusts are required to pay a Medicare tax of 3.8% (in addition to taxes they would otherwise be subject to) on their net investment income which would include, among other things, dividends and capital gains from the ordinary shares and ADSs.

### **F. Dividends and Paying Agents**

N/A

### **G. Statement by Experts**

N/A

### **H. Documents on Display**

We are subject to the information requirements of the US Securities Exchange Act of 1934, as amended, or Exchange Act, and, in accordance therewith, we are required to file reports, including this annual report on Form 20-F, and other information with the US Securities and Exchange Commission, or Commission, by electronic means.

You may review a copy of our filings with the Commission, as well as other information furnished to the Commission, including exhibits and schedules filed with it, at the Commission's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information. In addition, the Commission maintains an Internet site at <http://www.sec.gov> that contains reports and other information regarding issuers that file electronically with the Commission (these documents are not incorporated by reference in this annual report).

### **I. Subsidiary Information**

N/A

**Table of Contents**

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Item 11. Quantitative and Qualitative Disclosures about Market Risk<sup>(1)</sup>

**General Policy**

Liquidity risk, foreign exchange risk and interest rate risk, as well as related counterparty risks, are managed centrally by our dedicated treasury team within the Group Finance Department. Where it is not possible to manage those risks centrally in particular due to regulatory restrictions (such as foreign exchange controls) or local tax restrictions credit facilities and/or currency lines, guaranteed whenever necessary by the parent company, are contracted by our subsidiaries locally with banks, under the supervision of the central treasury team.

Our financing and investment strategies, and our interest rate and currency hedging strategies, are reviewed monthly by the Group Finance Department.

Our policy prohibits the use of derivatives for speculative purposes.

**Liquidity Risk**

We operate a centralized treasury platform whereby all surplus cash and financing needs of our subsidiaries are invested with or funded by the parent company (where permitted by local legislation). The central treasury department manages our current and projected financing, and ensures that Sanofi is able to meet its financial commitments by maintaining sufficient cash and confirmed credit facilities for the size of our operations and the maturity of our debt (see Notes D.17.c and D.17.g to the consolidated financial statements).

We diversify our short-term investments with leading counterparties using money-market products with instant access or with a maturity of less than three months. As of December 31, 2017, cash and cash equivalents amounted to 10,315 million, and our short-term investments predominantly comprised:

collective investments in short-term money market and money market euro-denominated funds based on the European classification used by the *Autorité des marchés financiers*. All such funds can be traded on a daily basis and the amount invested in each fund may not exceed 10% of the aggregate amount invested in such funds; amounts invested directly with banks and non-financial institutions in the form of instant access deposits, term deposits, and Negotiable European Commercial Paper with a maturity of no more than three months.

As of December 31, 2017, the Group also had 8 billion of undrawn general corporate purpose confirmed credit facilities, half expiring December 2020 and half December 2021. Those credit facilities are not subject to financial covenant ratios.

Our policy is to diversify our sources of funding through public or private issuances of debt securities, in the United States (shelf registration statement) and Europe (Euro Medium Term Note program). In addition, our A-1+/P-1 short-term rating gives us access to commercial paper programs in the United States and, to a lesser extent, in France. The average maturity of our total debt was 4.9 years as of December 31, 2017, compared with 5.1 years as of December 31, 2016. During 2017, we did not draw down on our French commercial paper program. Average drawdowns under the US commercial paper program during 2017 were 1.6 billion (maximum 3.4 billion); the average maturity of those drawdowns was two months. As of December 31, 2017, neither of those programs was being utilized.

In the event of a liquidity crisis, we could be exposed to difficulties in calling up our available cash, a scarcity of sources of funding including the above-mentioned programs, and/or a deterioration in their terms. This situation could damage our capacity to refinance our debt or to issue new debt on reasonable terms.

### Interest Rate Risk

We manage our net debt mainly in two currencies: the euro and the US dollar (see note D.17 to the consolidated financial statements). The floating-rate portion of this debt exposes Sanofi to rises in interest rates, primarily in the Eonia and Euribor benchmark rates (for the euro) and in the US Libor and Federal Fund Effective rates (for the US dollar). To optimize (or reduce the volatility of) our cost of debt, we use interest rate swaps, cross-currency swaps and where appropriate interest rate options, that alter the fixed/floating rate split of our debt. Those derivative instruments are predominantly denominated in euros and in US dollars.

*(1) The disclosures in this section supplement those provided in Note B.8.8. to the consolidated financial statements as regards the disclosure requirements of IFRS 7, and are covered by the independent registered public accounting firms' opinion on the consolidated financial statements.*

**Table of Contents**

## ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The projected full-year sensitivity to interest rate fluctuations of our debt, net of cash and cash equivalents for 2018 is as follows:

	Impact on pre-tax net income ( million)	Impact on pre-tax income/(expense) recognized directly in equity ( million)
<i>Change in EUR and USD short-term interest rates</i>		
+100 bp	45	-
+25 bp	11	-
-25 bp	(11)	-
-100 bp	(45)	-

**Foreign Exchange Risk****A. Operating Foreign Exchange Risk**

A substantial portion of our net sales is generated in countries where the euro, which is our reporting currency, is not the functional currency. In 2017, for example, 33.8% of our net sales were generated in the United States, 29.3% in Emerging Markets (including countries that are, or may in future become, subject to exchange controls), and 5.1% in Japan. Although we also incur expenses in those countries, the impact of those expenses is not enough wholly to offset the impact of exchange rates on our net sales. Consequently, our operating income may be materially affected by fluctuations in exchange rates between the euro and other currencies.

We operate a foreign exchange risk hedging policy to reduce the exposure of our operating income to exchange rate movements.

This policy involves regular assessments of our worldwide foreign currency exposure, based on foreign-currency transactions carried out by the parent company and its subsidiaries. Those transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of those

transactions to exchange rate movements, we contract hedges using liquid derivative instruments, mainly forward currency purchases and sales, and also currency swaps.

The table below shows operating currency hedging instruments in place as of December 31, 2017, with the notional amount translated into euros at the relevant closing exchange rate (see Note D.20. to the consolidated financial statements for the accounting classification of those instruments as of December 31, 2017).

### Operating foreign exchange derivatives as of December 31, 2017

<i>( million)</i>	<b>Notional amount</b>	<b>Fair value</b>
<b>Forward currency sales</b>	<b>3,592</b>	<b>11</b>
of which US dollar	1,043	15
of which Singapore dollar	870	1
of which Chinese yuan renminbi	327	(1)
of which Japanese yen	248	1
of which Saudi Arabian Riyal	144	2
<b>Forward currency purchases</b>	<b>1,649</b>	<b>(8)</b>
of which Japanese yen	373	(3)
of which Singapore dollar	360	(4)
of which US dollar	205	(2)
of which Chinese yuan renminbi	196	-
of which Hungarian forint	81	1
<b>Total</b>	<b>5,241</b>	<b>3</b>

**Table of Contents**

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The above positions mainly hedge future material foreign-currency cash flows arising after the end of the reporting period in relation to transactions carried out during the year ended December 31, 2017 and recognized in the balance sheet at that date. Gains and losses on hedging instruments (forward contracts) have been and will continue to be calculated and recognized in parallel with the recognition of gains and losses on the hedged items. Due to this hedging relationship, the commercial foreign exchange gain or loss on these items (hedging instruments and hedged transactions) will be immaterial in 2018.

**B. Financial Foreign Exchange Risk**

The cash pooling arrangements for our foreign subsidiaries outside the euro zone, and some of our financing activities, expose certain of our entities to financial foreign exchange risk (i.e. the risk of changes in the value of borrowings and loans denominated in a

currency other than the functional currency of the borrower or lender). That foreign exchange exposure is hedged by the parent company using firm financial instruments (usually currency swaps or forward contracts) contracted with banking counterparties.

Although we incur more of our costs in euros than in any other currency, the US dollar accounts for a higher proportion of our revenues than any other currency. Consequently, we maintain a significant portion of our indebtedness in US dollars.

The table below shows financial currency hedging instruments in place as of December 31, 2017, with the notional amounts translated into euros at the relevant closing exchange rate (see also Note D.20 to the consolidated financial statements for the accounting classification of these instruments as of December 31, 2017).

**Financial foreign exchange derivatives as of December 31, 2017**



<i>( million)</i>	<b>Notional amount</b>	<b>Fair value</b>	<b>Expiry</b>
<b>Forward currency sales</b>	<b>5,074</b>	<b>86</b>	
of which US dollar	3,542	50	2018
of which Japanese yen	867	34	2018
of which Australian dollar	281	1	2018
<b>Forward currency purchases</b>	<b>4,657</b>	<b>(18)</b>	
of which Singapore dollar	2,281	(23)	2018
of which Canadian dollar	907	6	2018
of which Czech koruna	431	6	2018
<b>Total</b>	<b>9,731</b>	<b>68</b>	

These forward currency contracts generate a net financial foreign exchange gain or loss arising from the interest rate differential between the hedged currency and the euro, given that the foreign exchange gain or loss on the foreign-currency borrowing and loans is offset by the change in the intrinsic value of the hedging instruments.

We may also hedge some future foreign-currency investment or divestment cash flows.

### **C. Other Foreign Exchange Risks**

A significant proportion of our net assets is denominated in US dollars (see Note D.35. to the consolidated financial statements). As a result, any fluctuation in the exchange rate of the US dollar against the euro automatically impacts the amount of our equity as expressed in euros. As of December 31, 2017, we had no derivative instruments in place to limit the effect of such fluctuations, but a significant proportion of our debt is still denominated in US dollars.

In addition, we use the euro as our reporting currency. Consequently, if one or more European Union Member States were to abandon the euro as a currency, the resulting economic upheavals – in particular, fluctuations in exchange rates could have a significant impact on the terms under which we can obtain financing and on our financial results, the extent and consequences of which are not currently foreseeable.

### **Counterparty Risk**

Our financing and investing transactions, and our currency and interest rate hedges, are contracted with leading counterparties. We set limits for investment and derivative transactions with individual financial institutions, depending on the rating of each institution. Compliance with these limits, which are based on notional amounts weighted by the residual maturity and the nature of the commitment, is monitored on a daily basis.

**Table of Contents**

## ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The table below shows our total exposure as of December 31, 2017 by rating and in terms of our percentage exposure to the dominant counterparty.

	<b>Cash and cash equivalents (excluding mutual funds)<sup>(a)</sup></b>	<b>Notional amounts of currency hedges<sup>(b)</sup></b>	<b>Notional amounts of interest rate hedges<sup>(b)</sup></b>	<b>General corporate purpose credit facilities</b>
<i>( million)</i>				
AA	42	-	-	-
AA-	771	1,248	817	500
A+	811	6,645	1,958	3,000
A	942	5,091	799 <sup>(c)</sup>	2,000
A-	176	940	508	1,000
BBB+	152	1,046	200	1,500
BBB	75	-	-	-
Unallocated	139	2	-	-
<b>Total</b>	<b>3,108</b>	<b>14,972</b>	<b>4,283</b>	<b>8,000</b>
% / rating of dominant counterparty	21 % / AA-	17 % / A	20 % / A+	6 % / BBB+

*(a) Cash equivalents include mutual fund investments of 7,207 million.*

*(b) The notional amounts are translated into euros at the relevant closing exchange rate as of December 31, 2017.*

*(c) Includes interest rate swaps hedging fixed-rate bonds of 99 million held in a Professional Specialized Investment Fund dedicated to Sanofi, recognized in Long-term loans, advances and other non-current receivables (see note D.7. to our consolidated financial statements).*

As of December 31, 2017, we held investments in short-term money market and money market euro-denominated funds based on the European classification used by the *Autorité des marchés financiers*. Those instruments have low volatility, low sensitivity to interest rate risk, and a very low probability of loss of principal. The depository banks of the mutual funds, and of Sanofi itself, have a long-term rating of at least A.

Realization of counterparty risk could impact our liquidity in certain circumstances.

### **Stock Market Risk**

It is our policy not to trade on the stock market for speculative purposes.

**Table of Contents**

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

Item 12. Description of Securities other than Equity Securities

**12.A Debt Securities**

Not applicable.

**12.B Warrants and Rights**

Not applicable.

**12.C Other Securities**

Not applicable.

**12.D American Depositary Shares**

**General**

JPMorgan Chase Bank, N.A. ( JPMorgan ), as depositary, issues Sanofi ADSs in certificated form (evidenced by an ADR) or book-entry form. Each ADR is a certificate evidencing a specific number of Sanofi ADSs. Each Sanofi ADS represents one-half of one Sanofi ordinary share (or the right to receive one-half of one Sanofi ordinary share) deposited with the Paris, France office of BNP Paribas, as custodian. Each Sanofi ADS also represents an interest in any other securities, cash or other property that may be held by the depositary under the deposit agreement. The depositary's office is located at 4 New York Plaza, 1<sup>st</sup> Floor, New York, New York 10004.

A holder may hold Sanofi ADSs either directly or indirectly through his or her broker or other financial institution. The following description assumes holders hold their Sanofi ADSs directly, in certificated form evidenced by ADRs. Holders who hold the Sanofi ADSs indirectly must rely on the procedures of their broker or other financial institution

to assert the rights of ADR holders described in this section. Holders should consult with their broker or financial institution to find out what those procedures are.

Holders of Sanofi ADSs do not have the same rights as holders of Sanofi shares. French law governs shareholder rights. The rights of holders of Sanofi ADSs are set forth in the deposit agreement between Sanofi and JPMorgan and in the ADR. New York law governs the deposit agreement and the ADRs.

The following is a summary of certain terms of the deposit agreement, as amended. Our form of second amended and restated deposit agreement was filed as an exhibit to our Post-Effective Amendment No. 1 to Form F-6 filed on February 13, 2015. To the extent any portion of the amendment and restatement would prejudice any substantial existing right of holders of ADSs under the first amended and restated deposit agreement, such portion shall not become effective as to such holders until 30 days after holders have received notice thereof. For more complete

information, holders should read the entire second amended and restated deposit agreement and the ADR itself. Holders may also inspect a copy of the current deposit agreement at the depository's office.

## Share Dividends and Other Distributions

### Receipt of dividends and other distributions

The depository has agreed to pay to holders of Sanofi ADSs the cash dividends or other distributions that it or the custodian receives on the deposited Sanofi ordinary shares and other deposited securities after deducting its fees and expenses. Holders of Sanofi ADSs will receive these distributions in proportion to the number of Sanofi ADSs that they hold.

*Cash.* The depository will convert any cash dividend or other cash distribution paid on the shares into U.S. dollars if, in its judgment, it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If the depository determines that such a conversion and transfer is not possible, or if any approval from the French government is needed and cannot be obtained within a reasonable period, then the depository may (1) distribute the foreign currency received by it to the holders of Sanofi ADSs or (2) hold the foreign currency distribution (uninvested and without liability for any interest) for the account of holders of Sanofi ADSs.

In addition, if any conversion of foreign currency, in whole or in part, cannot be effected to some holders of Sanofi ADSs, the deposit agreement allows the depository to distribute the dividends only to those ADR holders to whom it is possible to do so. It will hold the foreign currency it cannot convert into U.S. dollars for the account of the ADR holders who have not been paid. It will not invest the funds it holds and it will not be liable for any interest.

Before making a distribution, any withholding taxes that must be paid under French law will be deducted. The depository will distribute only whole U.S. dollars and cents and will round fractional cents down to the nearest whole cent. ***Exchange rate fluctuations during a period when the depository cannot convert euros into U.S. dollars may result in holders losing some or all of the value of a distribution.***

*Shares.* The depository may, and at our request will, distribute new ADRs representing any shares we distribute as a dividend or free distribution, if we furnish it promptly with satisfactory evidence that it is legal to do so. At its option, the depository may distribute fractional Sanofi ADSs. If the depository does not distribute additional Sanofi ADSs, the outstanding ADRs will also represent the new shares. The depository may withhold any tax or other governmental charges, or require the payment of any required fees and expenses, prior to making any distribution of additional Sanofi ADSs.



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**Table of Contents**

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

*Rights to Receive Additional Shares.* If we offer holders of Sanofi ordinary shares any rights to subscribe for additional shares or any other rights, the depositary, after consultation with us, will, in its discretion, either (1) make these rights available to holders or (2) dispose of such rights on behalf of holders and make the net proceeds available to holders. The depositary may make rights available to certain holders but not others if it determines it is lawful and feasible to do so. However, if, under the terms of the offering or for any other reason, the depositary may not make such rights available or dispose of such rights and make the net proceeds available, it will allow the rights to lapse. In that case, holders of Sanofi ADSs will receive no value for them.

In circumstances where rights would not otherwise be distributed by the depositary to holders of Sanofi ADSs, a holder of Sanofi ADSs may nonetheless request, and will receive from the depositary, any instruments or other documents necessary to exercise the rights allocable to that holder if the depositary first receives written notice from Sanofi that (1) Sanofi has elected, in its sole discretion, to permit the rights to be exercised and (2) such holder has executed the documents Sanofi has determined, in its sole discretion, are reasonably required under applicable law.

If the depositary makes rights available to holders of Sanofi ADSs, upon instruction from such holders, it will exercise the rights and purchase the shares on such holder's behalf. The depositary will then deposit the shares and deliver ADRs to such holders. It will only exercise rights if holders of Sanofi ADSs pay it the exercise price and any other charges the rights require such holders to pay.

U.S. securities laws may restrict the sale, deposit, cancellation or transfer of ADRs issued upon exercise of rights. For example, holders of Sanofi ADSs may not be able to trade Sanofi ADSs freely in the United States. In this case, the depositary may deliver Sanofi ADSs under a separate restricted deposit agreement that will contain the same provisions as the deposit agreement, except for changes needed to implement the required restrictions.

*Other Distributions.* The depositary will distribute to holders of Sanofi ADSs anything else we may distribute on deposited securities (after deduction or upon payment of fees and expenses or any taxes or other governmental charges) by any means it thinks is legal, equitable and practical. If, for any reason, it cannot make the distribution in that way, the depositary may sell what we distributed and distribute the net proceeds of the sale in the same way it distributes cash dividends, or it may choose any other method to distribute the property it deems equitable and practicable.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of Sanofi ADSs. We have no obligation to register Sanofi ADSs, shares, rights or other securities under the U.S. Securities Act of 1933, as amended. We also have no obligation to take any other action to permit the distribution

of ADRs, shares, rights or anything else to holders of Sanofi ADSs. This means that holders may not receive the distribution we make on our shares or any value for them if it is

illegal or impractical for the depositary to make them available to such holders.

*Elective Distributions.* Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to holders of Sanofi ADSs. In that case, we will assist the depositary in determining whether that distribution is lawful and reasonably practicable. The depositary will make the election available to holders of Sanofi ADSs only if it is reasonably practicable and if we have provided all the documentation contemplated in the deposit agreement. In that case, the depositary will establish procedures to enable holders of Sanofi ADSs to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement. If the election is not made available to holders of Sanofi ADSs, such holders will receive either cash or additional Sanofi ADSs, depending on what a shareholder in France would receive for failing to make an election, as more fully described in the deposit agreement.

## **Deposit, Withdrawal and Cancellation**

### **Delivery of ADRs**

The depositary will deliver ADRs if the holder or his or her broker deposit shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of Sanofi ADSs in the names the holder requests and will deliver the ADRs to the persons the holder requests at its office.

### **Obtaining Sanofi ordinary shares**

A holder may turn in his or her ADRs at the depositary's office. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver (1) the underlying shares to an account designated by the holder and (2) any other deposited securities underlying the ADR at the office of a custodian or, at the holder's request, risk and expense, the depositary will deliver the deposited securities at its office.

## **VOTING RIGHTS**

A holder may instruct the depositary to vote the Sanofi ordinary shares underlying his or her Sanofi ADSs at any meeting of Sanofi shareholders, but only if we request that the depositary ask for holder instructions. Otherwise, holders will not be able to exercise their right to vote unless they withdraw the underlying ordinary shares from the ADR program and vote as an ordinary shareholder. However, holders may not know about the meeting sufficiently in advance to timely withdraw the underlying ordinary shares.



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**Table of Contents**

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

If we ask for holder instructions in connection with a meeting of Sanofi shareholders, the depositary will provide materials to holders of Sanofi ADSs in the manner described under the heading Notices and Reports; Rights of Holders to Inspect Books below. For any instructions to be valid, the depositary must receive them on or before the date specified in the materials distributed by the depositary. The depositary will endeavor, in so far as practical, subject to French law and the provisions of our *statuts*, to vote or to have its agents vote the shares or other deposited securities as holders may validly instruct. The depositary will only vote or attempt to vote shares as holders validly instruct.

We cannot guarantee holders that they will receive the voting materials with sufficient time to enable them to return any voting instructions to the depositary in a timely manner to vote their shares. As long as they act in good faith, neither the depositary nor its agents will be responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that holders may not be able to exercise their right to vote and there may be nothing holders can do if their shares are not voted as they requested.*

Similar to our shares, Sanofi ADSs evidenced by ADRs that are registered in the name of the same owner for at least two (2) years are eligible for double voting rights so long as certain procedures are followed, as set out in the deposit agreement. For additional information regarding double voting rights, see Item 10. Additional Information B. Memorandum and Articles of Association Voting Rights .

The deposit agreement allows the depositary and Sanofi to change the voting procedures or require additional voting procedures in addition to the ones described above if necessary or appropriate. *For example, holders might be required to arrange to have their Sanofi ADSs deposited in a blocked account for a specified period of time prior to a shareholders meeting in order to be allowed to give voting instructions.*

**Notices and Reports; Rights of Holders to Inspect Books**

On or before the first date on which we give notice, by publication or otherwise, of any meeting of holders of shares or other deposited securities, or of any adjourned meeting of such holders, or of the taking of any action in respect of any cash or other

distributions or the offering of any rights, we will transmit to the depositary a copy of the notice.

Upon notice of any meeting of holders of shares or other deposited securities, if requested in writing by Sanofi, the depositary will, as soon as practicable, mail to the holders of Sanofi ADSs a notice, the form of which is in the discretion of the depositary, containing (1) a summary in English of the information contained in the notice of meeting provided by Sanofi to the depositary, (2) a statement that the holders as of the close of business on a specified record date will be entitled, subject to any applicable provision of French law and of our *statuts*, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the amount of shares or other deposited securities represented by their respective ADSs and (3) a statement as to the manner in which such instructions may be given. Notwithstanding the above, the depositary may, to the extent not prohibited by law or regulations, or by the requirements of the NYSE, in lieu of distribution of the materials provided to the depositary as described above, distribute to the holders a notice that provides holders with, or otherwise publicizes to holders, instructions on how to retrieve such materials or receive such materials upon request (i.e., by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

The depositary will make available for inspection by ADS holders at the depositary's office any reports and communications, including any proxy soliciting material, received from us that are both (1) received by the depositary as the holder of the deposited securities and (2) made generally available to the holders of such deposited securities by us. The depositary will also, upon written request, send to ADS holders copies of such reports when furnished by us pursuant to the deposit agreement. Any such reports and communications, including any such proxy soliciting material, furnished to the depositary by us will be furnished in English to the extent such materials are required to be translated into English pursuant to any regulations of the SEC.

The depositary will keep books for the registration of ADRs and transfers of ADRs that at all reasonable times will be open for inspection by the holders provided that such inspection is not for the purpose of communicating with holders in the interest of a business or object other than our business or a matter related to the deposit agreement or the ADRs.

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**Table of Contents**

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

**Fees and Expenses**

**Fees Payable By ADS Holders**

Pursuant to the deposit agreement, holders of our ADSs may have to pay to JPMorgan, either directly or indirectly, fees or charges up to the amounts set forth in the table below.

**Associated Fee**

\$5.00 or less per 100 ADSs (or portion thereof)

\$0.05 or less per ADS (or portion thereof)

**Depository Action**

Execution and delivery of ADRs for distributions and dividends in shares and rights to subscribe for additional shares or rights of any other nature and surrender of ADRs for the purposes of withdrawal, including the termination of the deposit agreement

Any cash distribution made pursuant to the deposit agreement, including, among other things:

cash distributions or dividends,

distributions other than cash, shares or rights,

distributions in shares, and

rights of any other nature, including rights to subscribe for additional shares.

## Edgar Filing: Sanofi - Form 20-F

Registration fees in effect for the registration of transfers of shares generally on the share register of the company or foreign registrar and applicable to transfers of shares to or from the name of JPMorgan or its nominee to the custodian or its nominee on the making of deposits and withdrawals	As applicable
A fee equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities	Distributions of securities other than cash, shares or rights
A fee for the reimbursement of such fees, charges and expenses as are incurred by JPMorgan, its agents (and their agents), including BNP Paribas, as custodian (by deductions from cash dividends or other cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them)	Compliance with foreign exchange control regulations or any law or regulation relating to foreign investment, servicing of shares or other deposited securities, sale of securities, delivery of deposited securities or otherwise
Expenses incurred by JPMorgan	Cable, telex and facsimile transmission (where expressly provided for in the deposit agreement)
	Foreign currency conversion into U.S. dollars

In addition to the fees outlined above, each holder will be responsible for any taxes or other governmental charges payable on his or her Sanofi ADSs or on the deposited securities underlying his or her Sanofi ADSs. The depositary may refuse to transfer a holder's Sanofi ADSs or allow a holder to withdraw the deposited securities underlying his or her Sanofi ADSs until such taxes or other charges are paid. It may apply payments owed to a holder or sell deposited securities underlying a holder's Sanofi ADSs to pay any taxes owed, and the holder will remain liable for any deficiency. If it sells deposited securities, it will, if appropriate, reduce the number of Sanofi ADSs to reflect the sale and pay to the holder any proceeds, or send to the holder any property, remaining after it has paid the taxes. For additional information regarding taxation, see Item 10. Additional Information E. Taxation.

### **Fees Paid to Sanofi by the Depositary**

JPMorgan, as depositary, has agreed to reimburse Sanofi for certain expenses (subject to certain limits) Sanofi incurs relating to legal fees, investor relations servicing, investor-related presentations, ADR-related advertising and public relations in those jurisdictions in which the ADRs may be listed or otherwise quoted, investor relations channel, perception studies, accountants' fees in relation to our annual report or Form 20-F or any other expenses directly or indirectly relating to managing the program or servicing the ADR holders. The depositary has also agreed to provide additional amounts to us based on certain performance indicators relating to the ADR facility and fees collected by it. From January 1, 2017 to December 31, 2017, we received a total amount of

**Table of Contents**

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

\$18,317,000 from JPMorgan. In addition to these payments, JPMorgan has agreed to waive servicing fees we may incur in connection with routine corporate actions such as annual general meetings and dividend distributions, as well as for other assistance JPMorgan may provide to us, such as preparation of tax and regulatory compliance documents for holders and investor relations advisory services.

**Changes Affecting Deposited Securities**

If we:

change the nominal or par value of our Sanofi ordinary shares;

recapitalize, reorganize, merge or consolidate, liquidate, sell assets, or take any similar action;

reclassify, split up or consolidate any of the deposited securities; or

distribute securities on the deposited securities that are not distributed to holders;  
then either:

the cash, shares or other securities received by the depositary will become deposited securities and each Sanofi ADS will automatically represent its equal share of the new deposited securities; or

the depositary may, and will if we ask it to, distribute some or all of the cash, shares or other securities it receives. It may also deliver new ADRs or ask holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

## Disclosure of Interests

The obligation of a holder or other person with an interest in our shares to disclose information under French law and under our *statuts* also applies to holders and any other persons, other than the depositary, who have an interest in the Sanofi ADSs. The consequences for failing to comply with these provisions are the same for holders and any other persons with an interest as a holder of our ordinary shares. For additional information regarding these obligations, see Item 10. Additional Information B. Memorandum and Articles of Association Requirements for Holdings Exceeding Certain Percentages .

## Amendment and Termination

We may agree with the depositary to amend the deposit agreement and the ADRs without the consent of the ADS holders for any reason. If the amendment adds or increases fees or charges, except for taxes and other governmental charges or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses, or prejudices a substantial right of holders of Sanofi ADSs, it will only become effective 30 days after the

depositary notifies such holders of the amendment. However, we may not be able to provide holders of Sanofi ADSs with prior notice of the effectiveness of any modifications or supplements that are required to accommodate compliance with applicable provisions of law, whether or not those modifications or supplements could be considered to be materially prejudicial to the substantial rights of holders of Sanofi ADSs. ***At the time an amendment becomes effective, such holders will be considered, by continuing to hold their ADR, to have agreed to the amendment and to be bound by the ADR and the deposit agreement as amended.***

The depositary will terminate the agreement if we ask it to do so. The depositary may also terminate the agreement if the depositary has told us that it would like to resign and we have not appointed a new depositary bank within 90 days. In both cases, the depositary must notify holders of Sanofi ADSs at least 30 days before termination.

After termination, the depositary and its agents will be required to do only the following under the deposit agreement: (1) collect distributions on the deposited securities, (2) sell rights and other property as provided in the deposit agreement and (3) deliver shares and other deposited securities upon cancellation of ADRs. Six months or more after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it receives on the sale, as well as any other cash it is holding under the deposit agreement, for the pro rata benefit of the holders of Sanofi ADSs that have not surrendered their Sanofi ADSs. It will have no liability for interest. Upon termination of the deposit agreement, the depositary's only obligations will be to account for the proceeds of the sale and other cash and with respect to indemnification. After termination, our only obligation will be with respect to indemnification and to pay certain amounts to the depositary.

## Limitations on Obligations and Liability to Holders of Sanofi ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary, and it limits our liability and the liability of the depositary. In particular, please note the following:

we and the depositary are obligated only to take the actions specifically set forth in the deposit agreement without gross negligence or bad faith;

we and the depositary are not liable if either is prevented or delayed by law or circumstances beyond its control from performing its obligations under the deposit agreement;

we and the depositary are not liable if either exercises, or fails to exercise, any discretion permitted under the deposit agreement;

we and the depositary have no obligation to become involved in a lawsuit or other proceeding related to the Sanofi ADSs or the deposit agreement on holders' behalf or on behalf of any other party, unless indemnity satisfactory to it against all expense and liability is furnished as often as may be required;

**Table of Contents**

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

we and the depositary are not liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system or the custodian, subject to certain exceptions and to the extent the custodian is not a branch or affiliate of JPMorgan;

the depositary is not liable for the price received in connection with any sale of securities, the timing thereof or any delays, acts, omissions to act, errors, defaults or negligence on the part of the party so retained in connection with any such sale or proposed sale;

we and the depositary may rely without any liability upon any written notice, request, direction, instruction or other document believed by either of us to be genuine and to have been signed or presented by the proper parties; and

we and the depositary are not liable for any action or nonaction taken in reliance upon the advice of or information from legal counsel, accountants, any person presenting ordinary shares for deposit, any ADS holder, or any other person believed in good faith to be competent to give such advice or information.

In addition, the depositary will not be liable for any acts or omissions made by a successor depositary. Moreover, neither we nor the depositary nor any of our respective agents will be liable to any holder of Sanofi ADSs for any indirect, special, punitive or consequential damages.

Pursuant to the terms of the deposit agreement, we and the depositary have agreed to indemnify each other under certain circumstances.

**Requirements for Depositary Actions**

Before the depositary will deliver or register the transfer of Sanofi ADSs, make a distribution on Sanofi ADSs or process a withdrawal of shares, the depositary may require:

payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;



production of satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver Sanofi ADSs, register transfers of Sanofi ADSs or permit withdrawals of shares when the transfer books of the depositary or our transfer books are closed, or at any time if the depositary or we think it advisable to do so.

### **Right to Receive the Shares Underlying the Sanofi ADSs**

Holders have the right to cancel their Sanofi ADSs and withdraw the underlying Sanofi ordinary shares at any time except:

when temporary delays arise when we or the depositary have closed our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends;

when the holder or other holders of Sanofi ADSs seeking to withdraw shares owe money to pay fees, taxes and similar charges; or

when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to Sanofi ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

### **Pre-Release of Sanofi ADSs**

Unless we instruct the depositary not to, the deposit agreement permits the depositary to deliver Sanofi ADSs before deposit of the underlying shares. This is called a pre-release of the Sanofi ADSs. The depositary may also deliver shares upon cancellation of pre-released Sanofi ADSs (even if the Sanofi ADSs are cancelled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depositary. The depositary may receive Sanofi ADSs instead of shares to close out a pre-release. Unless otherwise agreed in writing, the depositary may pre-release Sanofi ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made must represent to the depositary in writing that it or its customer (i) owns the shares or Sanofi ADSs to be deposited, (ii) assigns all beneficial rights, title and interest in such shares or ADRs to the depositary in its capacity as depositary and (iii) will not take any action with respect to such shares or ADRs that is inconsistent with the transfer of beneficial ownership, other than in satisfaction of such pre-release; (2) the pre-release must be fully collateralized with cash, U.S. government securities or other collateral that the depositary considers appropriate; (3) the depositary must be able to close out the pre-release on not more than five business days' notice; and (4) the depositary may require such further indemnities and credit regulations as it deems appropriate. In addition, the depositary will limit the number of Sanofi ADSs that may be outstanding at any time as a result of pre-release, although the depositary may disregard the limit from time to time, if it thinks it is appropriate to do so. The depositary may retain for its own account any compensation received by it in connection with the foregoing. Any holder of pre-release ADRs should consult its tax and other advisors about the implications of pre-release for its particular situation.



**Table of Contents**

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

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230

**Table of Contents**

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

N/A

Item 14. Material Modifications to the Rights of Security Holders

N/A

Item 15. Controls and Procedures

(a) Our Chief Executive Officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 20-F, have concluded that, as of such date, our disclosure controls and procedures were effective to ensure that material information relating to Sanofi was timely made known to them by others within Sanofi.

(b) Report of Management on Internal Control Over Financial Reporting.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2017 based on the framework in Internal Control Integrated Framework (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

The Boehringer Ingelheim Consumer Healthcare business combination that was consummated during 2017 has been excluded from the scope of management's assessment of and conclusion on internal control over financial reporting as of December 31, 2017. Boehringer Ingelheim Consumer Healthcare business is included in the 2017 consolidated financial statements of the Company and represented less than 1% of total assets as of December 31, 2017 and less than 5% of revenues for the year then ended.

Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2017 to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting has been audited by PricewaterhouseCoopers Audit and Ernst & Young et Autres, independent registered public accounting firms, as stated in their report on the Company's internal control over financial reporting as of December 31, 2017, which is included herein. See paragraph (c) of the present Item 15, below.

(c) See report of PricewaterhouseCoopers Audit and Ernst & Young et Autres, independent registered public accounting firms, included under Item 18. Financial Statements on page 3.

(d) There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

**Item 16A. Audit Committee Financial Expert**

Our Board of Directors has determined that Robert Castaigne, Fabienne Lecorvaisier and Christian Mulliez, directors serving on the Audit Committee, are independent financial experts within the meaning of paragraph 407 of the Sarbanes-Oxley Act of 2002.

The Board of Directors deemed Robert Castaigne to be a financial expert based on his education and his experience as Chief Financial Officer of Total, a major corporation, and as member of the audit committees of Vinci, Société Générale and Novatek. The Board of Directors deemed Fabienne Lecorvaisier to be a financial expert taking into account her education and her experience in corporate finance in various international banks and as Chief Financial Officer of Essilor and Air Liquide. She is now Executive Vice President, in charge of Finance, Operations Control

and General Secretariat of Air Liquide Group. The Board of Directors deemed Christian Mulliez to be a financial expert taking into account his experience as Executive Vice President, Chief Financial Officer of L'Oréal and graduate of the *Ecole Supérieure des Sciences Economiques et Commerciales* (ESSEC).

The Board of Directors has determined that all four directors meet the independence criteria of US Securities and Exchange Commission Rule 10A-3, although only Robert Castaigne, Fabienne Lecorvaisier and Carole Piwnica meet the French AFEP-MEDEF Code criteria of independence applied by the Board of Directors for general corporate governance purposes (see Item 16G, below).

**Item 16B. Code of Ethics**

We have adopted a financial code of ethics, as defined in Item 16B. of Form 20-F under the Exchange Act. Our financial code of ethics applies to our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and other officers performing similar functions, as designated from time to time. Our financial code of ethics is available on our website at [www.sanofi.com](http://www.sanofi.com) (information on our

website is not incorporated by reference in this annual report). A copy of our financial code of ethics may also be obtained free of charge by addressing a written request to the attention of Individual Shareholder Relations at our headquarters in Paris. We will disclose any amendment to the provisions of such financial code of ethics on our website.

**Item 16C. Principal Accountants Fees and Services**

See Note E. to our consolidated financial statements included at Item 18 of this annual report.

**Item 16D. Exemptions from the Listing Standards for Audit Committees**

N/A

**Table of Contents**

## ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

## Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In 2017, Sanofi made the following purchases of its ordinary shares.

<b>Period</b>	<b>(A) Total Number of Shares Purchased</b>	<b>(B) Average Price Paid per Share</b>	<b>(C) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs<sup>(a)</sup></b>	<b>(D) Approximate Value of Shares that May Yet Be Purchased Under the Plans or Programs<sup>(b)</sup></b>
January 2017	9,319,822	76.49	9,319,822	13,456
February 2017	3,702,888	77.55	3,702,888	13,168
March 2017	3,430,286	82.55	3,430,286	12,885
April 2017	1,857,246	84.02	1,857,246	12,729
May 2017	116,359	87.73	116,359	15,494
June 2017	2,813,722	85.73	2,813,722	15,253
July 2017	703,594	83.53	703,594	15,194
August 2017	3,682,397	81.25	3,682,397	14,895
September 2017	1,229,222	82.02	1,229,222	14,794

(a) The Company was authorized to repurchase up to 15,504,267,840 of shares for a period of eighteen months (i.e., through November 10, 2018) by the Annual Shareholders Meeting held on May 10, 2017.

(b) Millions of euros.

This schedule does not include purchases and sales conducted by Rothschild & Cie Banque under a liquidity contract that is still in



effect. For more information see Item 10.B *Memorandum and Articles of Association* *Use of Share Repurchase Programs*.

**Item 16F.** Change in Registrant's Certifying Accountant

N/A

**Item 16G.** Corporate Governance

Sanofi is incorporated under the laws of France, with securities listed on regulated public markets in the United States (New York Stock Exchange) and France (Euronext Paris). Consequently, as described further in our annual report, our corporate governance framework reflects the mandatory provisions of French corporate law, the securities laws and regulations of France and the United States and the rules of the aforementioned public markets. In addition, we generally follow the AFEP-MEDEF corporate governance recommendations for French listed issuers (hereafter referred to as the AFEP-MEDEF Code). As a result, our corporate governance framework is similar in many respects to, and provides investor protections that are comparable to or in some cases, more stringent than the corresponding rules of the New York Stock Exchange. Nevertheless, there are important differences to keep in mind.

In line with New York Stock Exchange rules applicable to domestic issuers, Sanofi maintains a board of directors of which at least half of the members are independent. We evaluate the independence of members of our Board of Directors using the standards of the French AFEP-MEDEF Code as the principal reference. We believe that AFEP-MEDEF's overarching criteria for independence—no relationship of any kind whatsoever with the Company, its group or the management of either that is such as to color a Board member's judgment—are on the whole consistent with the goals of the New York Stock Exchange's rules although the specific tests proposed under the two standards may vary on some points. We have complied with the audit committee independence and other requirements of the Rule 10A-3 under the US Securities Exchange Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002. Our Compensation Committee includes one

**Table of Contents**

ITEM 16G. CORPORATE GOVERNANCE

non-independent member, Christian Mulliez, which is permitted under the AFEP-MEDEF Code but would not be compliant with the rules of the New York Stock Exchange for domestic issuers.

Under French law, the committees of our Board of Directors are advisory only, and where the New York Stock Exchange Listed Company Manual would vest certain decision-making powers with specific committees by delegation (e.g. appointment or audit committees), under French law our Board of Directors remains the only competent body to take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the Shareholders' General Meeting of Sanofi that is competent to appoint our auditors upon the proposal of our Board of Directors, although our Board Charter provides that the Board of Directors will make its proposal on the basis of the recommendation of our Audit Committee. We believe that this requirement of French law, together with the additional legal requirement that two sets of statutory auditors be appointed, share the New York Stock Exchange's underlying goal of ensuring that the audit of our accounts be conducted by auditors independent from company management.

In addition to the oversight role of our Compensation Committee for questions of management compensation including by way of equity, under French law any option or restricted share plans or other share capital increases, whether for the benefit of senior management or employees, may only be adopted by the Board of Directors pursuant to and within the limits of a shareholder resolution approving the related capital increase and delegating to the Board the authority to implement such operations.

As described above, a number of issues, which could be resolved directly by a board or its committees in the United States, require the additional protection of direct shareholder consultation in France. Our Audit Committee is entirely composed of independent directors as that term is defined in Rule 10A-3 under the US Securities Exchange Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002. The composition of our Audit Committee, Compensation Committee, and Strategy Committee includes directors who are also officers of our largest shareholder.

As a foreign private issuer under the US securities laws, our Chief Executive Officer and our Chief Financial Officer issue the certifications required by §302 and §906 of the Sarbanes Oxley Act of 2002 on an annual basis (with the filing of our annual report on U.S. Form 20-F) rather than on a quarterly basis as would be the case of a U.S. corporation filing quarterly reports on U.S. Form 10-Q.

French corporate law provides that the Board of Directors must vote to approve a broadly defined range of transactions that could potentially create conflicts of interest between Sanofi on the one hand and its Directors and Chief Executive Officer on the other hand, which are then presented to shareholders for approval at the next annual meeting. This legal safeguard provides shareholders with an opportunity to approve significant aspects of the Chief Executive Officer's compensation package, and it operates in place of certain provisions of the NYSE Listed Company Manual.

Item 16H. Mine Safety Disclosure

N/A

**Table of Contents**

ITEM 17. FINANCIAL STATEMENTS

PART III

Item 17. Financial Statements

See Item 18.

Item 18. Financial Statements

See pages F-1 through F-110 incorporated herein by reference.

Item 19. Exhibits

1.1 Articles of association (*statuts*) of Sanofi (English translation)

1.2 Board Charter (*Règlement Intérieur*) of Sanofi (English translation)

2. The total amount of long-term debt securities authorized under any instrument does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. We hereby agree to furnish to the SEC, upon

its request, a copy of any instrument defining the rights of holders of long-term debt of the Company or of its subsidiaries for which consolidated or unconsolidated financial statements are required to be filed.

- 4.1 Form of Contingent Value Rights Agreement by and among Sanofi and Trustee (on file with the SEC as Annex B to Amendment No.2 to the Registration Statement on Form F-4 filed on March 24, 2011)
  
- 8.1 List of significant subsidiaries, see Item 4. Information on the Company C. Organizational Structure of this 20-F.
  
- 12.1 Certification by Olivier Brandicourt, Chief Executive Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002
  
- 12.2 Certification by Jérôme Contamine, Principal Financial Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002
  
- 13.1 Certification by Olivier Brandicourt, Chief Executive Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
  
- 13.2 Certification by Jérôme Contamine, Principal Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
  
- 23.1 Consent of Ernst & Young et Autres dated March 6, 2018
  
- 23.2 Consent of PricewaterhouseCoopers Audit dated March 6, 2018

Table of Contents

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Sanofi  
By: /s/ OLIVIER BRANDICOURT  
Name: **Olivier Brandicourt**  
Title: **Chief Executive Officer**

Date: March 6, 2018

236

**Table of Contents**

2017 Annual Consolidated Financial Statements

The financial statements are presented in accordance with International Financial Reporting Standards (IFRS).

<u>CONSOLIDATED BALANCE SHEETS – ASSETS</u>	F-4
<u>CONSOLIDATED BALANCE SHEETS – EQUITY AND LIABILITIES</u>	F-5
<u>CONSOLIDATED INCOME STATEMENTS</u>	F-6
<u>CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME</u>	F-7
<u>CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY</u>	F-8
<u>CONSOLIDATED STATEMENTS OF CASH FLOWS</u>	F-10
<u>NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS</u>	F-12
<u>A/ BASIS OF PREPARATION</u>	F-12
<u>B/ SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES</u>	F-15
<u>C/ PRINCIPAL ALLIANCES</u>	F-31
<u>D/ PRESENTATION OF THE FINANCIAL STATEMENTS</u>	F-33
<u>E/ PRINCIPAL ACCOUNTANTS – FEES AND SERVICES</u>	F-108
<u>F/ LIST OF PRINCIPAL COMPANIES INCLUDED IN THE CONSOLIDATION DURING 2017</u>	F-109
<u>G/ EVENTS SUBSEQUENT TO DECEMBER 31, 2017</u>	F-113

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED**

**PUBLIC ACCOUNTING FIRMS**

To the Board of Directors and Shareholders of Sanofi,

**Opinion on the consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of Sanofi and its subsidiaries (together the Company) as of December 31, 2017, 2016, and 2015, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, 2016, and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board and in conformity with International Financial Reporting Standards as endorsed by the European Union.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in the Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 6, 2018 expressed an unqualified opinion thereon.

**Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are public accounting firms registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting



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principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers Audit

Ernst & Young et Autres

/s/ Philippe Vogt

/s/ Stéphane Basset

Ernst & Young et Autres and PricewaterhouseCoopers Audit have respectively served as the Company's auditors since 2012 (Ernst & Young Audit and its predecessor firms served as Company's auditor from 1986 to 2011) and 1999.

Neuilly-sur-Seine and Paris-La Défense, March 6, 2018

F-2

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**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS**

To the Board of Directors and Shareholders of Sanofi,

**Opinion on Internal Control over Financial Reporting**

We have audited Sanofi and its subsidiaries (together the Company) internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) (the COSO criteria). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

As indicated in the accompanying Report of Management on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Boehringer Ingelheim's Consumer Healthcare business, because it was acquired by the Company in a purchase business combination during 2017. Boehringer Ingelheim's Consumer Healthcare business is included in the 2017 consolidated financial statements of the Company and represented less than 1% of total assets as of December 31, 2017 and less than 5% of revenues for the year then ended. We have also excluded Boehringer Ingelheim's Consumer Healthcare business from our audit of internal control over financial reporting of the Company.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2017, 2016 and 2015, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2017, including the related notes (collectively referred to as the consolidated financial statements), and our report dated March 6, 2018 expressed an unqualified opinion thereon.

**Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial

reporting based on our audit. We are public accounting firms registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### **Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

/s/ PricewaterhouseCoopers Audit

Ernst & Young et Autres

/s/ Philippe Vogt

/s/ Stéphane Basset

Ernst & Young et Autres and PricewaterhouseCoopers Audit have respectively served as the Company's auditors since 2012 (Ernst & Young Audit and its predecessor firms served as Company's auditor from 1986 to 2011) and 1999.

Neuilly-sur-Seine and Paris-La Défense, March 6, 2018

**Table of Contents**

## CONSOLIDATED BALANCE SHEETS ASSETS

## CONSOLIDATED BALANCE SHEETS ASSETS

<i>( million)</i>	Note	December 31, 2017	December 31, 2016	December 31, 2015
Property, plant and equipment	D.3.	9,579	10,019	9,943
Goodwill	D.4.	40,264	40,287	39,557
Other intangible assets	D.4.	13,080	10,879	12,026
Investments accounted for using the equity method	D.6.	2,863	2,890	2,676
Other non-current assets	D.7.	3,364	2,820	2,725
Deferred tax assets	D.14.	4,290	4,669	4,714
<b>Non-current assets</b>		<b>73,440</b>	<b>71,564</b>	<b>71,641</b>
Inventories	D.9.	6,816	6,892	6,516
Accounts receivable	D.10.	7,216	7,311	7,386
Other current assets	D.11.	2,005	2,211	1,878
Cash and cash equivalents	D.13. D.17.	10,315	10,273	9,148
<b>Current assets</b>		<b>26,352</b>	<b>26,687</b>	<b>24,928</b>
Assets held for sale or exchange	D.8. D.36.	34	6,421	5,752
<b>TOTAL ASSETS</b>		<b>99,826</b>	<b>104,672</b>	<b>102,321</b>

F-4

**Table of Contents**

## CONSOLIDATED BALANCE SHEETS EQUITY AND LIABILITIES

## CONSOLIDATED BALANCE SHEETS EQUITY AND LIABILITIES

<i>( million)</i>	Note	December 31, 2017	December 31, 2016	December 31, 2015
Equity attributable to equity holders of Sanofi	D.15.	58,089	57,554	58,049
Equity attributable to non-controlling interests	D.16.	169	170	161
<b>Total equity</b>		<b>58,258</b>	<b>57,724</b>	<b>58,210</b>
Long-term debt	D.17.	14,326	16,815	13,118
Non-current liabilities related to business combinations and to non-controlling interests	D.18.	1,026	1,378	1,121
Non-current provisions and other non-current liabilities	D.19.	9,154	8,834	9,169
Deferred tax liabilities	D.14.	1,605	2,292	2,895
<b>Non-current liabilities</b>		<b>26,111</b>	<b>29,319</b>	<b>26,303</b>
Accounts payable		4,633	4,297	3,817
Current liabilities related to business combinations and to non-controlling interests	D.18.	343	198	130
Current provisions and other current liabilities	D.19.5.	9,206	10,175	9,442
Short-term debt and current portion of long-term debt	D.17.	1,275	1,764	3,436
<b>Current liabilities</b>		<b>15,457</b>	<b>16,434</b>	<b>16,825</b>
Liabilities related to assets held for sale or exchange	D.8. D.36.	-	1,195	983
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>99,826</b>	<b>104,672</b>	<b>102,321</b>



**Table of Contents**

## CONSOLIDATED INCOME STATEMENTS

## CONSOLIDATED INCOME STATEMENTS

<i>( million)</i>	Note	2017 <sup>(a)</sup>	2016 <sup>(a)</sup>	2015 <sup>(a) (b)</sup>
<b>Net sales</b>	<b>D.35.1.</b>	<b>35,055</b>	<b>33,821</b>	<b>34,060</b>
Other revenues		1,149	887	801
Cost of sales		(11,611)	(10,702)	(10,919)
<b>Gross profit</b>		<b>24,593</b>	<b>24,006</b>	<b>23,942</b>
Research and development expenses		(5,472)	(5,172)	(5,082)
Selling and general expenses		(10,058)	(9,486)	(9,382)
Other operating income	D.25.	237	355	254
Other operating expenses	D.26.	(233)	(482)	(462)
Amortization of intangible assets		(1,866)	(1,692)	(2,137)
Impairment of intangible assets	D.5.	(293)	(192)	(767)
Fair value remeasurement of contingent consideration	D.18.	(159)	(135)	53
Restructuring costs and similar items	D.27.	(731)	(879)	(795)
Other gains and losses, and litigation	D.28.	(215)	211	-
<b>Operating income</b>		<b>5,803</b>	<b>6,534</b>	<b>5,624</b>
Financial expenses	D.29.	(420)	(924)	(559)
Financial income	D.29.	147	68	178
<b>Income before tax and investments accounted for using the equity method</b>	<b>D.35.1.</b>	<b>5,530</b>	<b>5,678</b>	<b>5,243</b>
Income tax expense	D.30.	(1,722)	(1,326)	(709)
Share of profit/(loss) from investments accounted for using the equity method	D.31.	104	134	(22)
<b>Net income excluding the exchanged/held-for-exchange Animal Health business</b>		<b>3,912</b>	<b>4,486</b>	<b>4,512</b>
Net income/(loss) of the exchanged/held-for-exchange Animal Health business	D.36.	4,643	314	(124)
<b>Net income</b>	<b>D.32.</b>	<b>8,555</b>	<b>4,800</b>	<b>4,388</b>
		121	91	101

Net income attributable to non-controlling interests				
<b>Net income attributable to equity holders of Sanofi</b>		<b>8,434</b>	<b>4,709</b>	<b>4,287</b>
Average number of shares outstanding (million)	D.15.9.	1,256.9	1,286.6	1,306.2
Average number of shares outstanding after dilution (million)	D.15.9.	1,266.8	1,296.0	1,320.7
Basic earnings per share (in euros)		6.71	3.66	3.28
Basic earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)		3.02	3.42	3.38
Diluted earnings per share (in euros)		6.66	3.63	3.25
Diluted earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)		2.99	3.39	3.34

(a) *The results of the Animal Health business, and the gain on the divestment of that business, are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); see Notes D.1. and D.36.*

(b) *Following a change in accounting presentation in 2016, VaxServe sales of non-Sanofi products are included in **Other revenues**. The presentation of 2015 **Net sales** and **Other revenues** has been amended accordingly (see Note B.13.).*



**Table of Contents**

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

( million)	Note	2017	2016	2015
<b>Net income</b>		<b>8,555</b>	<b>4,800</b>	<b>4,388</b>
<i>Attributable to equity holders of Sanofi</i>		8,434	4,709	4,287
<i>Attributable to non-controlling interests</i>		121	91	101
Other comprehensive income:				
Actuarial gains/(losses)	<b>D.15.7.</b>	(28)	(106)	652
Tax effects	<b>D.15.7.</b>	(90)	(22)	(187)
<b>Sub-total: items not subsequently reclassifiable to profit or loss (a)</b>		<b>(118)</b>	<b>(128)</b>	<b>465</b>
Available-for-sale financial assets	<b>D.15.7.</b>	838	(105)	(37)
Cash flow hedges	<b>D.15.7.</b>	(24)	31	(3)
Change in currency translation differences	<b>D.15.7.</b>	(3,240)	1,090	1,915
Tax effects	<b>D.15.7.</b>	(137)	40	20
<b>Sub-total: items subsequently reclassifiable to profit or loss (b)</b>		<b>(2,563)</b>	<b>1,056</b>	<b>1,895</b>
<b>Other comprehensive income for the period, net of taxes (a+b)</b>		<b>(2,681)</b>	<b>928</b>	<b>2,360</b>
<b>Comprehensive income</b>		<b>5,874</b>	<b>5,728</b>	<b>6,748</b>
<i>Attributable to equity holders of Sanofi</i>		5,768	5,634	6,641
<i>Attributable to non-controlling interests</i>		106	94	107

F-7

**Table of Contents**

## CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

## CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

<i>( million)</i>	Share capital	Additional paid-in capital and retained earnings	Treasury shares	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders Sanofi	Attributable to non-controlling interests	Total equity
<b>Balance at January 1, 2015</b>	<b>2,639</b>	<b>52,553</b>	<b>(694)</b>	<b>2,599</b>	<b>(977)</b>	<b>56,120</b>	<b>148</b>	<b>56,268</b>
Other comprehensive income for the period	-	465	-	-	1,889	2,354	6	2,360
Net income for the period	-	4,287	-	-	-	4,287	101	4,388
<b>Comprehensive income for the period</b>	<b>-</b>	<b>4,752</b>	<b>-</b>	<b>-</b>	<b>1,889</b>	<b>6,641</b>	<b>107</b>	<b>6,748</b>
Dividend paid out of 2014 earnings ( 2.85 per share)	-	(3,694)	-	-	-	(3,694)	-	(3,694)
Payment of dividends to non-controlling interests	-	-	-	-	-	-	(110)	(110)
Share repurchase program <sup>(a)</sup>	-	-	(1,781)	-	-	(1,781)	-	(1,781)
Reduction in share capital <sup>(a)</sup>	(52)	(2,124)	2,176	-	-	-	-	-
Share-based payment plans:								
Exercise of stock options <sup>(a)</sup>	18	555	-	-	-	573	-	573
Issuance of restricted shares <sup>(a)</sup>	6	(6)	-	-	-	-	-	-
Proceeds from sale of treasury shares on exercise of stock options	-	-	1	-	-	1	-	1
	-	-	-	205	-	205	-	205

Value of services obtained from employees								
Tax effects of the exercise of stock options	-	-	-	10	-	10	-	10
Change in non-controlling interests without loss of control	-	(26)	-	-	-	(26)	16	(10)
<b>Balance at December 31, 2015</b>	<b>2,611</b>	<b>52,010</b>	<b>(298)</b>	<b>2,814</b>	<b>912</b>	<b>58,049</b>	<b>161</b>	<b>58,210</b>
Other comprehensive income for the period	-	(127)	-	-	1,052	925	3	928
Net income for the period	-	4,709	-	-	-	4,709	91	4,800
<b>Comprehensive income for the period</b>	<b>-</b>	<b>4,582</b>	<b>-</b>	<b>-</b>	<b>1,052</b>	<b>5,634</b>	<b>94</b>	<b>5,728</b>
Dividend paid out of 2015 earnings ( 2.93 per share)	-	(3,759)	-	-	-	(3,759)	-	(3,759)
Payment of dividends to non-controlling interests	-	-	-	-	-	-	(110)	(110)
Share repurchase program <sup>(a)</sup>	-	-	(2,905)	-	-	(2,905)	-	(2,905)
Reduction in share capital <sup>(a)</sup>	(45)	(1,655)	1,700	-	-	-	-	-
Share-based payment plans:								
Exercise of stock options <sup>(a)</sup>	7	212	-	-	-	219	-	219
Issuance of restricted shares <sup>(a)</sup>	7	(7)	-	-	-	-	-	-
Employee share ownership plan <sup>(a)</sup>	4	96	-	-	-	100	-	100
Value of services obtained from employees	-	-	-	227	-	227	-	227
Tax effects of the exercise of stock options	-	-	-	(9)	-	(9)	-	(9)
Change in non-controlling interests without loss of control	-	(2)	-	-	-	(2)	27	25
Change in non-controlling interests arising from divestment	-	-	-	-	-	-	(2)	(2)
<b>Balance at December 31, 2016</b>	<b>2,584</b>	<b>51,477</b>	<b>(1,503)</b>	<b>3,032</b>	<b>1,964</b>	<b>57,554</b>	<b>170</b>	<b>57,724</b>

**Table of Contents**

## CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (Continued)

<i>( million)</i>	Share capital	Additional paid-in capital and retained earnings	Treasury shares	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders non- controlling interests	Total equity	
<b>Balance at December 31, 2016</b>	<b>2,584</b>	<b>51,477</b>	<b>(1,503)</b>	<b>3,032</b>	<b>1,964</b>	<b>57,554</b>	<b>170</b>	<b>57,724</b>
Other comprehensive income for the period	-	(117)	-	-	(2,549)	(2,666)	(15)	(2,681)
Net income for the period	-	8,434	-	-	-	8,434	121	8,555
<b>Comprehensive income for the period</b>	<b>-</b>	<b>8,317</b>	<b>-</b>	<b>-</b>	<b>(2,549)</b>	<b>5,768</b>	<b>106</b>	<b>5,874</b>
Dividend paid out of 2016 earnings ( 2.96 per share)	-	(3,710)	-	-	-	(3,710)	-	(3,710)
Payment of dividends to non-controlling interests	-	-	-	-	-	-	(99)	(99)
Share repurchase program <sup>(a)</sup>	-	-	(2,159)	-	-	(2,159)	-	(2,159)
Reduction in share capital <sup>(a)</sup>	(94)	(3,554)	3,648	-	-	-	-	-
Share-based payment plans:								
Exercise of stock options <sup>(a)</sup>	8	215	-	-	-	223	-	223
Issuance of restricted shares <sup>(a)</sup>	7	(7)	-	-	-	-	-	-
Employee share ownership plan <sup>(a)</sup>	3	103	-	-	-	106	-	106

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Value of services obtained from employees	-	-	-	263	-	263	-	263
Tax effects of the exercise of stock options	-	-	-	3	-	3	-	3
Other changes arising from issuance of restricted shares <sup>(b)</sup>	-	16	-	-	-	16	-	16
Change in non-controlling interests without loss of control	-	25	-	-	-	25	(1)	24
Change in non-controlling interests arising from divestment	-	-	-	-	-	-	(7)	(7)
<b>Balance at December 31, 2017</b>	<b>2,508</b>	<b>52,882</b>	<b>(14)</b>	<b>3,298</b>	<b>(585)</b>	<b>58,089</b>	<b>169</b>	<b>58,258</b>

(a) See Notes D.15.1., D.15.3., D.15.4. and D.15.5.

(b) Issuance of restricted shares to former employees of the Animal Health business subsequent to the date of divestment.

**F-9**

**Table of Contents**

## CONSOLIDATED STATEMENTS OF CASH FLOWS

## CONSOLIDATED STATEMENTS OF CASH FLOWS

<i>( million)</i>	Note	2017 <sup>(a)</sup>	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>
<b>Net income attributable to equity holders of Sanofi</b>		<b>8,434</b>	<b>4,709</b>	<b>4,287</b>
Net (income)/loss of the exchanged/held-for-exchange Animal Health business		(4,643)	(314)	124
Non-controlling interests, excluding BMS <sup>(b)</sup>	D.32.	38	5	7
Share of undistributed earnings from investments accounted for using the equity method		(66)	(83)	115
Depreciation, amortization and impairment of property, plant and equipment and intangible assets		3,686	3,301	4,276
Gains and losses on disposals of non-current assets, net of tax <sup>(c)</sup>		(97)	(244)	(136)
Net change in deferred taxes		(909)	(542)	(1,253)
Net change in non-current provisions and other non-current liabilities <sup>(d)</sup>		321	20	(13)
Cost of employee benefits (stock options and other share-based payments)	D.15.2. - D.15.3. - D.15.8.	263	241	193
Impact of the workdown of acquired inventories remeasured at fair value	D.35.1.	166	-	-
Unrealized (gains)/losses recognized in income		38	(83)	(365)
<b>Operating cash flow before changes in working capital and excluding the exchanged/held-for-exchange Animal Health business</b>		<b>7,231</b>	<b>7,010</b>	<b>7,235</b>
(Increase)/decrease in inventories		(145)	(323)	(466)
(Increase)/decrease in accounts receivable		(529)	168	(493)
Increase/(decrease) in accounts payable		577	447	241
		245	536	1,773

Net change in other current assets and other current liabilities			
<b>Net cash provided by/(used in) operating activities excluding the exchanged/held-for-exchange Animal Health business<sup>(e)</sup></b>		<b>7,379</b>	<b>7,838</b>
<b>Net cash provided by/(used in) operating activities of the exchanged/held-for-exchange Animal Health business</b>		<b>-</b>	<b>346</b>
Acquisitions of property, plant and equipment and intangible assets	D.3. - D.4.	(1,956)	(2,083)
Acquisitions of investments in consolidated undertakings and investments accounted for using the equity method <sup>(f)/(h)</sup>	D.2. - D.18.	(1,151)	(426)
Acquisitions of available-for-sale financial assets	D.7.	(161)	(208)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax <sup>(g)</sup>		535	209
Net change in loans and other financial assets		(163)	(3)
<b>Net cash provided by/(used in) investing activities excluding the exchanged/held-for-exchange Animal Health business</b>		<b>(2,896)</b>	<b>(2,511)</b>
<b>Net cash provided by/(used in) investing activities of the exchanged/held-for-exchange Animal Health business</b>	<b>D.36.</b>	<b>-</b>	<b>(126)</b>
<b>Net cash inflow from the exchange of the Animal Health business for BI's Consumer Healthcare business<sup>(i)</sup></b>	<b>D.36.</b>	<b>3,535</b>	<b>-</b>

F-10

**Table of Contents**

## CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

( million)	Note	2017 <sup>(a)</sup>	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>
Issuance of Sanofi shares	D.15.1.	319	305	573
Dividends paid:				
to shareholders of Sanofi		(3,710)	(3,759)	(3,694)
noncontrolling interests, excluding BMS <sup>(b)</sup>		(15)	(21)	(12)
Payments received/(made) on changes of ownership interest in a subsidiary without loss of control		(37)	(11)	(8)
Additional long-term debt contracted	D.17.	41	4,773	2,253
Repayments of long-term debt	D.17.	(2,368)	(2,576)	(708)
Net change in short-term debt		30	96	(199)
Acquisitions of treasury shares	D.15.4.	(2,162)	(2,908)	(1,784)
Disposals of treasury shares, net of tax	D.15.	-	-	1
<b>Net cash provided by/(used in) financing activities excluding the exchanged/held-for-exchange Animal Health business</b>		<b>(7,902)</b>	<b>(4,101)</b>	<b>(3,578)</b>
<b>Net cash provided by/(used in) financing activities of the exchanged/held-for-exchange Animal Health business</b>		<b>-</b>	<b>111</b>	<b>(23)</b>
<b>Impact of exchange rates on cash and cash equivalents</b>		<b>(74)</b>	<b>(101)</b>	<b>(232)</b>
<b>Impact on cash and cash equivalents of the reclassification of the Animal Health business to Assets held for sale or exchange<sup>(c)</sup></b>	<b>D.36.</b>	<b>-</b>	<b>-</b>	<b>(23)</b>
<b>Net change in cash and cash equivalents</b>		<b>42</b>	<b>1,125</b>	<b>1,807</b>
<b>Cash and cash equivalents, beginning of period</b>		<b>10,273</b>	<b>9,148</b>	<b>7,341</b>
<b>Cash and cash equivalents, end of period</b>	<b>D.13.</b>	<b>10,315</b>	<b>10,273</b>	<b>9,148</b>
<b>Net change in cash and cash equivalents excluding the Animal Health business (2015)</b>		<b>-</b>	<b>-</b>	<b>1,469</b>
<b>Net change in cash and cash equivalents of the Animal Health business (2015)</b>		<b>-</b>	<b>-</b>	<b>361</b>

(a) For 2015 and 2016, cash flows of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations). For 2017, all of the cash flows generated from the exchange of the Animal Health business for the Consumer Healthcare business of Boehringer Ingelheim (BI)



are described in note (i) below.

(b) See Note C.2. to the financial statements for the year ended December 31, 2017.

(c) Includes available-for-sale financial assets.

(d) This line item includes contributions paid to pension funds (see Note D.19.1.).

(e) Including:

	2017	2016	2015
Income tax paid	(1,734)	(2,096)	(1,706)
Interest paid (excluding cash flows on derivative instruments used to hedge debt)	(347)	(401)	(404)
Interest received (excluding cash flows on derivative instruments used to hedge debt)	56	56	57
Dividends received from consolidated entities	8	9	9

(f) This line item includes payments made in respect of contingent consideration identified and recognized as a liability in business combinations.

(g) This line item includes proceeds from disposals of investments in consolidated entities and of other non-current financial assets.

(h) The main cash effect of the exchange of the Animal Health business for BI's Consumer Healthcare business was the receipt by Sanofi of a balancing cash payment of 4,207 million. Consequently, all of the cash flows arising from this exchange transaction during 2017 are presented in a separate line item, **Net cash inflow from the exchange of the Animal Health business for BI's Consumer Healthcare business** (see Note D.1.).

(i) For the year ended December 31, 2017, this line item comprises (i) the receipt by Sanofi of a balancing cash payment of 4,207 million; (ii) reimbursements of intragroup accounts with Meril entities totaling 967 million; (iii) payment of 1,784 million of tax due on the gain arising from the divestment; and (iv) the cash held by the BI subsidiaries acquired by Sanofi. The total consideration for the sale of the Animal Health business to BI was 10,557 million (see Note D.36.), and the consideration for the acquisition of BI's Consumer Healthcare business was 6,239 million (see Note D.1.).

(j) Cash and cash equivalents of the Animal Health business are presented within the line item **Assets held for sale or exchange** for the years ended December 31, 2015 and 2016.



**Table of Contents**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

**INTRODUCTION**

Sanofi, together with its subsidiaries (collectively Sanofi or the Company ), is a global healthcare leader engaged in the research, development and marketing of therapeutic solutions focused on patient needs.

Sanofi is listed in Paris (Euronext: SAN) and New York (NYSE: SNY).

The consolidated financial statements for the year ended December 31, 2017, and the notes thereto, were signed off by the Sanofi Board of Directors on February 7, 2018.

**A/ Basis of preparation**

**A.1. International financial reporting standards (IFRS)**

The consolidated financial statements cover the twelve-month periods ended December 31, 2017, 2016 and 2015.

In accordance with Regulation No. 1606/2002 of the European Parliament and Council of July 19, 2002 on the application of international accounting standards, Sanofi has presented its consolidated financial statements in accordance with IFRS since January 1, 2005. The term IFRS refers collectively to international accounting and financial reporting standards (IASs and IFRSs) and to interpretations of the interpretations committees (SIC and IFRIC) with mandatory application as of December 31, 2017.

The consolidated financial statements of Sanofi as of December 31, 2017 have been prepared in compliance with IFRS as issued by the International Accounting Standards Board (IASB) and with IFRS as endorsed by the European Union as of December 31, 2017.

IFRS as endorsed by the European Union as of December 31, 2017 are available under the heading IFRS Financial Statements via the following web link:

<https://www.efrag.org/Endorsement>.

The consolidated financial statements have been prepared in accordance with the IFRS general principles of fair presentation, going concern, accrual basis of accounting, consistency of presentation, materiality, and aggregation.

**A.2. New standards, amendments and interpretations**

### **A.2.1. New standards, amendments and interpretations applicable in 2017**

The new standards, amendments to standards, and interpretations that are mandatorily applicable with effect from the 2017 financial

year have no material impact on the financial statements, or on their presentation.

In accordance with the amendment to IAS 7 (Statement of Cash Flows), with effect from the year ended December 31, 2017 Sanofi discloses changes in debt arising from financing activities, showing cash and non-cash movements separately (see Note D.17.).

### **A.2.2. New pronouncements issued by the IASB and applicable from 2018 or later**

The note below describes standards, amendments and interpretations issued by the IASB that will have mandatory application in 2018 or subsequent years, and Sanofi's position regarding future application. Sanofi has not early adopted any of those standards, amendments or interpretations.

#### **A.2.2.1. Standards**

At the end of May 2014 the IASB issued IFRS 15 (Revenue from Contracts with Customers). IFRS 15 is a converged standard common to both IFRS and US generally accepted accounting principles (US GAAP), and replaces IAS 18 (Revenue) and IAS 11 (Construction Contracts) with effect from January 1, 2018.

In April 2016 the IASB issued clarifications (amendments to IFRS 15 applicable from January 1, 2018) on how to (i) identify a performance obligation, (ii) determine whether a company is a principal or an agent, and (iii) account for the revenue from granting a license.

IFRS 15 includes new revenue recognition principles, in particular as regards identifying a performance obligation and allocating the transaction price in the case of contracts with multiple components. It also changes how contracts are analyzed in the case of revenue generated by licensing arrangements, and how variable consideration is recognized. The standard also contains new disclosure requirements.

To date, the conclusions of our analysis of the impacts of first-time application in 2018 of IFRS 15 are as follows:

Revenue recognized within *Net sales* by Sanofi arises from sales of pharmaceutical products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. The concepts of transfer of control and variable consideration do not materially affect the way in which Sanofi recognizes revenue. Consequently, Sanofi does not anticipate any significant change in the timing or amount of net sales recognized.

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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**Other revenues** recognized by Sanofi mainly comprise license royalties under collaboration agreements, and VaxServe sales of products sourced from third-party manufacturers. Sanofi does not anticipate any significant change in the timing or amount of other revenues recognized.

**Other operating income** mainly comprises revenue arising from the sharing of costs and profits on product commercialization operations carried out in collaboration with partners, generating revenue under complex partnership and co-promotion agreements. Sanofi does not anticipate any significant change in the timing or amount of other operating income recognized. Other operating income also includes realized and unrealized foreign exchange gains and losses on operating activities, and gains on disposals of non-financial assets not regarded as major disposals, which are outside the scope of IFRS 15.

**Share of profits or losses from investments accounted for using the equity method:** Sanofi does not expect IFRS 15 to have a major impact on the determination of the share of profits or losses from the associates and joint ventures concerned.

Sanofi will apply IFRS 15 with effect from January 1, 2018, using the full retrospective method of adoption: the opening balance of equity at the start of the first period presented (January 1, 2016) will be adjusted to reflect the cumulative impact of applying IFRS 15, and comparative information for the years ended December 31, 2016 and 2017 will be presented in accordance with IFRS 15. Consequently, in the financial statements for the year ended December 31, 2018 all periods will be presented as though IFRS 15 had always been applied. The adjustments to net sales for the years ended December 31, 2016 and 2017 are regarded as immaterial.

In July 2014 the IASB issued IFRS 9 (Financial Instruments). With effect from January 1, 2018, IFRS 9 replaces the currently applicable standards on the presentation, recognition and measurement of financial instruments (IAS 39).

To date, the conclusions of our analysis of the impacts of first-time application in 2018 of IFRS 9 are as follows:

**Classification and measurement of financial assets**

IFRS 9 alters the main accounting categories used for financial assets. Financial assets held by Sanofi that are classified as available-for-sale under IAS 39 will be reclassified as of January 1, 2018 into one of two categories:

financial assets at fair value through profit or loss or financial assets at fair value through other comprehensive income. With effect from January 1, 2018 any gains on equity investments that Sanofi elects to classify as financial assets at fair value through other comprehensive income will no longer be recognized in profit or loss when the investment is sold. However, all dividends received from such investments will continue to be recognized in profit or loss.

In accordance with paragraph B5.2.3 of IFRS 9, Sanofi will continue to use acquisition cost as an appropriate estimate of the

fair value of certain investments in unquoted companies. That method will cease to be used if any of the indicators listed in paragraphs B5.2.4 and B5.2.5 of IFRS 9 become apparent.

#### Classification and measurement of financial liabilities

In October 2017, the IASB issued an amendment to IFRS 9 clarifying the treatment of modifications of financial liabilities. Because Sanofi does not enter into transactions of that type, first-time application of the amendment will have no impact on the consolidated financial statements.

#### Impairment

The new credit risk recognition model based on expected losses changes the way in which allowances for impairment of accounts receivable are calculated, in that receivables that are not yet past due must be included in the base used to calculate the allowance. Sanofi sells medicines and vaccines to wholesalers, public authorities, hospitals, clinics, pharmacies, and non governmental organizations (NGOs). Given the nature of the accounts receivable recognized by Sanofi and the associated guarantees entered into, IFRS 9 does not materially alter the amount of allowances for impairment of accounts receivable.

#### Hedge accounting

IFRS 9 does not alter the way in which Sanofi currently accounts for hedging transactions. Such transactions are carried out as part of our policies on foreign exchange and interest rate risk hedging.

At this stage of our analyses the amount of the adjustment to be recognized within equity is estimated to be immaterial.

Sanofi will apply IFRS 9 with effect from January 1, 2018. Under the transitional provisions of IFRS 9, only financial instruments held as of January 1, 2018 require retrospective application; presentation of comparatives is optional. Sanofi will decide which option to elect during the first half of 2018.

In January 2016 the IASB issued IFRS 16 (Leases), which aligns the accounting treatment of operating leases with that already applied to finance leases (i.e. recognition in the balance sheet of a liability for future lease payments, and of an asset for the

associated rights of use). The first-time application of IFRS 16 will also lead to a change in presentation:

In the income statement: the rental expense currently recognized as a component of *Operating income* will, under IFRS 16, be recognized partly as depreciation expense within *Operating income*, and partly as interest expense within *Financial expenses*.

In the statement of cash flows: the rental payments currently presented within *Net cash provided by/(used in) operating activities* will, under IFRS 16, be presented within *Net cash provided by/(used in) financing activities* to the extent that those payments are allocated to repayment of the lease liability.

IFRS 16 is applicable to annual reporting periods beginning on or after January 1, 2019. Most of the leases contracted by Sanofi are

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**Table of Contents**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

operating leases in which Sanofi is the lessee. The main assets leased are office premises, cars, and computer hardware. An impact assessment is ongoing. For information, Sanofi's obligations under non-cancelable operating leases are disclosed in Note D.21.1.

In addition, some supply and service contracts are also being assessed.

Sanofi's IFRS 16 project is being led by a team composed of representatives from the various support functions affected (purchasing, real estate, information systems, finance, shared services). The assessment continued throughout 2017, looking at three key topics: identification and analysis of contracts, selection of IT application, and implementation methods.

Sanofi has not elected to early adopt IFRS 16.

As regards the method of first-time application, Sanofi has yet to make a decision. IFRS 16 may be applied either as of January 1, 2019 without restatement of comparative periods if the simplified transition option is elected, or as of January 1, 2017 with the 2017 and 2018 comparative periods restated under IFRS 16 if the retrospective transition option is elected.

***A.2.2.2. Amendments, annual improvements and interpretations***

Sanofi does not expect a material impact from the application of:

IFRIC 22 (Foreign Currency Transactions and Advance Consideration), issued in December 2016 and applicable from 2018 onwards; and

IFRIC 23 (Uncertainty over Income Tax Treatments), issued in June 2017 and applicable from 2019 onwards. The other amendments issued, whether within or outside the 2014-2016 Annual Improvements cycle (IFRS 2 various clarifications, IAS 28 long-term interests in associates and joint ventures, etc), will have no impact on Sanofi's financial statements.

**A.3. Use of estimates and judgments**

The preparation of financial statements requires management to make reasonable estimates and assumptions based on information available at the date of the finalization of the financial statements. Those estimates and assumptions may affect the reported amounts of assets, liabilities, revenues and expenses in the financial statements, and disclosures of



contingent assets and contingent liabilities as of the date of the review of the financial statements. Examples of estimates and assumptions include:

amounts deducted from sales for projected sales returns, chargeback incentives, rebates and price reductions (see Notes B.13.1. and D.23.);

impairment of property, plant and equipment, intangible assets, and investments accounted for using the equity method (see Notes B.6. and D.5.);

the valuation of goodwill and the valuation and useful life of acquired intangible assets (see Notes B.3.2., B.4.3., D.4. and D.5.);

the measurement of contingent consideration receivable in connection with asset divestments (see Notes B.8.6. and D.7.);

the amount of post-employment benefit obligations (see Notes B.23. and D.19.1.);

the amount of provisions for restructuring, litigation, tax risks and environmental risks (see Notes B.12., B.19., B.20., B.22., D.19. and D.22.);

the amount of deferred tax assets resulting from tax losses available for carry-forward and deductible temporary differences (see Notes B.22. and D.14.);

the direct and indirect impacts recorded in 2017 of the US tax reform (Tax Cuts and Jobs Act of 2017), including the estimated tax charge on deemed repatriation that is attributable to the accumulated earnings of non-US operations. The estimate of such tax charge will be finalized based on further analysis and, as the case may be, computations taking into account any future clarifications and supplementary guidance issued by the US Congress, the US Internal Revenue Service, the US Securities and Exchange Commission or other regulators.

the measurement of contingent consideration (see Notes B.3. and D.18.); and

which exchange rate to use at the end of the reporting period for the translation of accounts denominated in foreign currencies, and of financial statements of foreign subsidiaries, in cases where more than one exchange rate exists for a given currency (see Note A.4.).

Actual results could differ from these estimates.

Management is also required to exercise judgment in assessing whether the criteria specified in IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations) are met, and hence whether a non-current asset or asset group should be classified as held for sale or exchange and whether a discontinued operation should be reported separately. Such assessments are reviewed at each reporting date based on the facts and circumstances.

#### **A.4. Consolidation and foreign currency translation of the financial statements of Venezuelan subsidiaries**

Sanofi continues to account for subsidiaries based in Venezuela using the full consolidation method, on the basis that the criteria for control as specified in IFRS 10 (Consolidated Financial Statements) are still met.

Prior to 2016, the Venezuelan foreign exchange system consisted of three exchange rates: (i) the CENCOEX rate, set at a fixed rate of 6.3 bolivars per US dollar and restricted to essential goods; (ii) an administered exchange rate (the SICAD rate), which was 13.5 bolivars per US dollar as of December 31, 2015 and applied to certain specific business sectors; and (iii) the SIMADI rate, of

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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

approximately 200 bolivars per US dollar, applied to specified transactions. In preparing the consolidated financial statements, the financial statements of the Venezuelan subsidiaries were translated into euros using the SICAD official exchange rate, which was the estimated rate at which the profits generated by the operations of those subsidiaries would be remitted to the parent.

In February 2016, the Venezuelan government reformed the foreign exchange system, which from that date had two exchange rates that applied to two categories of goods:

a first category for essential goods to which was applied the DIPRO rate, set at a fixed exchange rate of 10 bolivars per US dollar;

a second category to which was applied the DICOM rate, which was a floating exchange rate against the US dollar that initially stood at 206 bolivars per US dollar and was approximately 3,345 bolivars per US dollar as of December 31, 2017.

In light of those changes to the foreign exchange system, recent economic and political developments and the scarcity of US dollar cash in Venezuela, Sanofi changed the exchange rate used to translate its Venezuelan operations and from 2016 onwards has applied the DICOM rate. This change led to the recognition of a foreign exchange loss of 102 million in 2016.

The Venezuelan subsidiaries made an immaterial contribution to net sales in 2017 ( 18 million in 2016, 455 million in 2015) and had a cash position of 7 million as of December 31, 2017 ( 6 million as of December 31, 2016) 90 million as of December 31, 2015). The net assets of the Venezuelan subsidiaries were not material as of December 31, 2017.

At the end of January 2018 the Venezuelan government made further changes to the foreign exchange system, abolishing the DIPRO rate of 10 bolivars per US dollar. The DICOM rate must now be used for all foreign currency transactions.

**A.5. Change in the operational structure of Sanofi**

Sanofi acquired the Consumer Healthcare operations of Boehringer Ingelheim (BI) on January 1, 2017, and during 2017 gradually integrated those operations into its Consumer Healthcare Global Business Unit (GBU). Following

completion of the integration process and with effect from December 31, 2017, Sanofi has identified the Consumer Healthcare business as an operating segment, the financial information for which is reported separately to, and reviewed separately by, the Chief Executive Officer. Until that date, the results of the Consumer Healthcare business were included in the Pharmaceuticals segment.

In addition, during 2017 Sanofi finalized a complete realignment of its internal management reporting to match its organizational structure. As a result, the costs of Sanofi's global functions (Medical Affairs, External Affairs, Finance, Human Resources, Legal Affairs, Information Solutions & Technologies, Sanofi Business Services, etc.) are now managed centrally at group-wide level and are no longer allocated to operating segments for internal management reporting purposes. For the year ended

December 31, 2017 and subsequent years, the costs of those functions are presented within the Other category. That category also includes other reconciling items such as retained commitments in respect of divested activities.

Sanofi has amended the presentation of its segment information accordingly (see Note D.35.), and now performs impairment testing of goodwill at the level of three Cash Generating Units (CGUs): Pharmaceuticals, Consumer Healthcare and Human Vaccines (see Note D.5.).

## **B/ Summary of significant accounting policies**

### **B.1. Basis of consolidation**

In accordance with IFRS 10 (Consolidated Financial Statements), the consolidated financial statements of Sanofi include the financial statements of entities that Sanofi controls directly or indirectly, regardless of the level of the equity interest in those entities. An entity is controlled when Sanofi has power over the entity, exposure or rights to variable returns from its involvement with the entity, and the ability to affect those returns through its power over the entity. In determining whether control exists, potential voting rights must be taken into account if those rights are substantive, in other words they can be exercised on a timely basis when decisions about the relevant activities of the entity are to be taken.

Entities consolidated by Sanofi are referred to as subsidiaries. Entities that Sanofi controls by means other than voting rights are referred to as consolidated structured entities.

In accordance with IFRS 11 (Joint Arrangements), Sanofi classifies its joint arrangements (i.e. arrangements in which Sanofi exercises joint control with one or more other parties) either as a joint operation or a joint venture. In the case of a joint operation, Sanofi recognizes the assets and liabilities of the operation in proportion to its rights and obligations relating to those assets and liabilities. Joint ventures are accounted for using the equity method.

Sanofi exercises joint control over a joint arrangement when decisions relating to the relevant activities of the arrangement require the unanimous consent of Sanofi and the other parties with whom control is shared.

Sanofi exercises significant influence over an entity when it has the power to participate in the financial and operating policy decisions of that entity, but does not have the power to exercise control or joint control over those policies.

In accordance with IAS 28 (Investments in Associates and Joint Ventures), the equity method is used to account for joint ventures (i.e. entities over which Sanofi exercises joint control) and for associates (i.e. entities over which Sanofi exercises significant influence).

Under the equity method, the investment is initially recognized at cost, and subsequently adjusted to reflect changes in the net assets of the associate or joint venture. IAS 28 does not specify the treatment to be adopted on first-time application of the equity

**F-15**

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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

method to an investee following a step acquisition. Consequently, by reference to paragraph 10 of IAS 28, Sanofi has opted to apply the cost method, whereby the carrying amount of the investment represents the sum of the historical cost amounts for each step in the acquisition. As of the date on which the equity method is first applied, goodwill (which is included in the carrying amount of the investment) is determined for each acquisition step. The same applies to subsequent increases in the percentage interest in the equity-accounted investment.

When the criteria of IFRS 5 are met, Sanofi recognizes the equity interest within the balance sheet line item *Assets held for sale or exchange*. The equity method is not applied to equity interests that are classified as held-for-sale assets.

Transactions between consolidated companies are eliminated, as are intragroup profits.

A list of the principal companies included in the consolidation in 2017 is presented in Note F.

**B.2. Foreign currency translation****B.2.1. Accounting for foreign currency transactions in the financial statements of consolidated entities**

Non-current assets (other than receivables) and inventories acquired in foreign currencies are translated into the functional currency using the exchange rate prevailing at the acquisition date.

Monetary assets and liabilities denominated in foreign currencies are translated using the exchange rate prevailing at the end of the reporting period. The gains and losses resulting from foreign currency translation are recorded in the income statement. However, foreign exchange gains and losses arising from the translation of advances between consolidated subsidiaries for which settlement is neither planned nor likely to occur in the foreseeable future are recognized in equity, in the line item *Change in currency translation differences*.

**B.2.2. Foreign currency translation of the financial statements of foreign entities**

Sanofi presents its consolidated financial statements in euros (€). In accordance with IAS 21 (The Effects of Changes in Foreign Exchange Rates), each subsidiary accounts for its transactions in the currency that is most representative of its economic environment (the functional currency).

All assets and liabilities are translated into euros using the exchange rate of the subsidiary's functional currency prevailing at the end of the reporting period. Income statements are translated using a weighted average exchange rate for the period, except in the case of foreign subsidiaries in a hyperinflationary economy. The resulting currency translation difference is recognized as a separate component of equity in the consolidated statement of comprehensive income, and is recognized in the income statement only when the subsidiary is sold or is wholly or partially liquidated.

### B.3. Business combinations and transactions with non-controlling interests

#### B.3.1. Accounting for business combinations, transactions with non-controlling interests and loss of control

Business combinations are accounted for in accordance with IFRS 3 (Business Combinations) and IFRS 10 (Consolidated Financial Statements).

Business combinations are accounted for using the acquisition method. Under this method, the acquirer's identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 (Business Combinations) are measured initially at their fair values as at the date of acquisition, except for (i) non-current assets classified as held for sale (which are measured at fair value less costs to sell) and (ii) assets and liabilities that fall within the scope of IAS 12 (Income Taxes) and IAS 19 (Employee Benefits). Restructuring liabilities are recognized as a liability of the acquiree only if the acquiree has an obligation as of the acquisition date to carry out the restructuring.

The principal accounting rules applicable to business combinations and transactions with non-controlling interests include:

Acquisition-related costs are recognized as an expense on the acquisition date, as a component of *Operating income*.

Contingent consideration is recognized in equity if the contingent payment is settled by delivery of a fixed number of the acquirer's equity instruments; otherwise, it is recognized in *Liabilities related to business combinations*. Contingent consideration is recognized at fair value at the acquisition date irrespective of the probability of payment. If the contingent consideration was originally recognized as a financial liability, subsequent adjustments to the liability are recognized in profit or loss in the line item *Fair value remeasurement of contingent consideration*, unless the adjustment is made within the twelve months following the acquisition date and relates to facts and circumstances existing as of that date. Subsequent contingent consideration adjustments in respect of business combinations completed before January 1, 2010 continue to be accounted for in accordance with the pre-revision IFRS 3 (i.e. through goodwill).

In the case of a step acquisition, the previously-held equity interest is remeasured at its acquisition-date fair value. The difference between this fair value and the carrying amount is recorded in profit or loss, along with any gains or losses relating to the previously-held interest that were recognized in other comprehensive income and are reclassifiable to profit or loss.

Goodwill may be calculated on the basis of either (i) the entire fair value of the acquiree, or (ii) a share of the fair value of the acquiree proportionate to the interest acquired. This option may be elected for each acquisition individually.

The effects of (i) a buyout of non-controlling interests in a subsidiary already controlled by Sanofi, and (ii) a disposal of a percentage interest without loss of control, are recognized in equity.

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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In a partial disposal resulting in loss of control, the retained equity interest is remeasured at fair value at the date of loss of control. The gain or loss recognized on the disposal includes the effect of that remeasurement, and items that were initially recognized in equity are reclassified to profit or loss.

Adjustments to the values of assets and liabilities initially determined provisionally (pending the results of independent valuations or further analysis) are recognized as a retrospective adjustment to goodwill if they are made within twelve months of the acquisition date. Once this twelve-month period has elapsed, the effects of any adjustments are recognized directly in profit or loss, unless they qualify as an error correction.

Purchase price allocations are performed under the responsibility of management, with assistance from an independent valuer in the case of major acquisitions. The revised IFRS 3 does not specify an accounting treatment for contingent consideration arising from a business combination made by an entity prior to the acquisition of control in that entity and carried as a liability in the acquired entity's balance sheet. The accounting treatment applied by Sanofi to such a liability is to measure it at fair value as of the acquisition date and to report it in the line item ***Liabilities related to business combinations and to non-controlling interests***, with subsequent remeasurements recognized in profit or loss. This treatment is consistent with the accounting applied to contingent consideration in the books of the acquirer.

**B.3.2. Goodwill**

The excess of the cost of an acquisition over Sanofi's interest in the fair value of the identifiable assets and liabilities of the acquiree is recognized as goodwill at the date of the business combination.

Goodwill arising on the acquisition of subsidiaries is shown in a separate balance sheet line item, whereas goodwill arising on the acquisition of investments accounted for using the equity method is recorded in ***Investments accounted for using the equity method***.

Goodwill arising on foreign operations is expressed in the functional currency of the country concerned and translated into euros using the exchange rate prevailing at the end of the reporting period.

In accordance with IAS 36 (Impairment of Assets), goodwill is carried at cost less accumulated impairment (see Note B.6.).

Goodwill is tested for impairment annually and whenever events or circumstances indicate that impairment might exist. Such events or circumstances include significant changes more likely than not to have an other-than-temporary



impact on the substance of the original investment.

#### **B.4. Other intangible assets**

Other intangible assets are initially measured at acquisition cost or production cost, including any directly attributable costs of

preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. Intangible assets are amortized on a straight line basis over their useful lives.

The useful lives of other intangible assets are reviewed at the end of each reporting period. The effect of any adjustment to useful lives is recognized prospectively as a change in accounting estimate.

Amortization of other intangible assets is recognized in the income statement within *Amortization of intangible assets* except for amortization charged against (i) acquired or internally-developed software and (ii) other rights of an industrial or operational nature, which is recognized in the relevant classification of expense by function.

Sanofi does not own any intangible assets with an indefinite useful life, other than goodwill.

Intangible assets (other than goodwill) are carried at cost less accumulated amortization and accumulated impairment, if any, in accordance with IAS 36 (see Note B.6.).

##### **B.4.1. Research and development not acquired in a business combination**

###### *Internally generated research and development*

Under IAS 38, research expenses are recognized in profit or loss when incurred.

Internally generated development expenses are recognized as an intangible asset if, and only if, all the following six criteria can be demonstrated: (a) the technical feasibility of completing the development project; (b) Sanofi's intention to complete the project; (c) Sanofi's ability to use the project; (d) the probability that the project will generate future economic benefits; (e) the availability of adequate technical, financial and other resources to complete the project; and (f) the ability to measure the development expenditure reliably.

Due to the risks and uncertainties relating to regulatory approval and to the research and development process, the six criteria for capitalization are usually considered not to have been met until the product has obtained marketing approval from the regulatory authorities. Consequently, internally generated development expenses arising before marketing approval has been obtained, mainly the cost of clinical trials, are generally expensed as incurred within *Research and development expenses*.

Some industrial development expenses (such as those incurred in developing a second-generation synthesis process) are incurred after marketing approval has been obtained, in order to improve the industrial process for an active ingredient. To the extent that the six IAS 38 criteria are considered as having been met, such expenses are recognized as an asset in the balance sheet within *Other intangible assets* as incurred. Similarly, some clinical trials,

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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

for example those undertaken to obtain a geographical extension for a molecule that has already obtained marketing approval in a major market, may in certain circumstances meet the six capitalization criteria under IAS 38, in which case the related expenses are recognized as an asset in the balance sheet within *Other intangible assets*.

***Separately acquired research and development***

Payments for separately acquired research and development are capitalized within *Other intangible assets* provided that they meet the definition of an intangible asset: a resource that is (i) controlled by Sanofi, (ii) expected to provide future economic benefits for Sanofi, and (iii) identifiable (i.e. it is either separable or arises from contractual or legal rights). Under paragraph 25 of IAS 38, the first condition for capitalization (the probability that the expected future economic benefits from the asset will flow to the entity) is considered to be satisfied for separately acquired research and development. Consequently, upfront and milestone payments to third parties related to pharmaceutical products for which marketing approval has not yet been obtained are recognized as intangible assets, and amortized on a straight line basis over their useful lives beginning when marketing approval is obtained.

Payments under research and development arrangements relating to access to technology or to databases and payments made to purchase generics dossiers are also capitalized, and amortized over the useful life of the intangible asset.

Subcontracting arrangements, payments for research and development services, and continuous payments under research and development collaborations which are unrelated to the outcome of that collaboration, are expensed over the service term.

**B.4.2. Other intangible assets not acquired in a business combination**

Licenses other than those related to pharmaceutical products and research projects, in particular software licenses, are capitalized at acquisition cost, including any directly attributable cost of preparing the software for its intended use. Software licenses are amortized on a straight line basis over their useful lives for Sanofi (three to five years).

Internally generated costs incurred to develop or upgrade software are capitalized if the IAS 38 recognition criteria are satisfied, and amortized on a straight line basis over the useful life of the software from the date on which the software is ready for use.

**B.4.3. Other intangible assets acquired in a business combination**

Other intangible assets acquired in a business combination which relate to in-process research and development and currently marketed products and are reliably measurable are identified separately from goodwill, measured at fair value and capitalized within *Other intangible assets* in accordance with IFRS 3

(Business Combinations) and IAS 38 (Intangible Assets). The related deferred tax liability is also recognized if a deductible or taxable temporary difference exists.

In-process research and development acquired in a business combination is amortized on a straight line basis over its useful life from the date of receipt of marketing approval.

Rights to products currently marketed by Sanofi are amortized on a straight line basis over their useful lives, determined on the basis of cash flow forecasts which take into account the patent protection period of the marketed product.

### **B.5. Property, plant and equipment**

Property, plant and equipment is initially measured and recognized at acquisition cost, including any directly attributable cost of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. The component-based approach to accounting for property, plant and equipment is applied. Under this approach, each component of an item of property, plant and equipment with a cost which is significant in relation to the total cost of the item and which has a different useful life from the other components must be depreciated separately.

After initial measurement, property, plant and equipment is carried at cost less accumulated depreciation and impairment, except for land which is carried at cost less impairment.

Subsequent costs are not recognized as assets unless (i) it is probable that future economic benefits associated with those costs will flow to Sanofi and (ii) the costs can be measured reliably.

Borrowing costs attributable to the financing of items of property, plant and equipment, and incurred during the construction period, are capitalized as part of the acquisition cost of the item.

Government grants relating to property, plant and equipment are deducted from the acquisition cost of the asset to which they relate.

In accordance with IAS 17 (Leases), items of property, plant and equipment leased by Sanofi as lessee under finance leases are recognized as an asset in the balance sheet, with the related lease obligation recognized as a liability. A lease qualifies as a finance lease if it transfers substantially all of the risks and rewards of ownership of the asset to Sanofi. Assets held under finance leases are carried at the lower of the fair value of the leased asset or the present value of the minimum lease payments, and are depreciated over the shorter of the useful life of the asset or the term of the lease.

The depreciable amount of items of property, plant and equipment, net of any residual value, is depreciated on a straight line basis over the useful life of the asset. The useful life of an asset is usually equivalent to its economic life.

**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The customary useful lives of property, plant and equipment are as follows:

Buildings	15 to 40 years
Fixtures	10 to 20 years
Machinery and equipment	5 to 15 years
Other	3 to 15 years

Useful lives and residual values of property, plant and equipment are reviewed annually. The effect of any adjustment to useful lives or residual values is recognized prospectively as a change in accounting estimate.

Depreciation of property, plant and equipment is recognized as an expense in the income statement, in the relevant classification of expense by function.

## **B.6. Impairment of property, plant and equipment, intangible assets, and investments accounted for using the equity method**

### **B.6.1. Impairment of property, plant and equipment and intangible assets**

In accordance with IAS 36 (Impairment of Assets), assets that generate separate cash flows and assets included in cash-generating units (CGUs) are assessed for impairment when events or changes in circumstances indicate that the asset or CGU may be impaired. A CGU is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets.

Under IAS 36, each CGU to which goodwill is allocated must (i) represent the lowest level within the entity at which the goodwill is monitored for internal management purposes, and (ii) not be larger than an operating segment determined in accordance with IFRS 8 (Operating Segments), before application of the IFRS 8 aggregation criteria (see Note B.26.).

Quantitative and qualitative indications of impairment (primarily relating to the status of the research and development portfolio, pharmacovigilance, patent litigation, and the launch of competing products) are reviewed at the end of each reporting period. If there is any internal or external indication of impairment, Sanofi estimates the recoverable amount of the asset or CGU.

Other intangible assets not yet available for use (such as capitalized in-process research and development), and CGUs that include goodwill, are tested for impairment annually whether or not there is any indication of impairment, and more frequently if any event or circumstance indicates that they might be impaired. Such assets are not amortized.

When there is an internal or external indication of impairment, Sanofi estimates the recoverable amount of the asset and

recognizes an impairment loss if the carrying amount of the asset exceeds its recoverable amount. The recoverable amount of the asset is the higher of its fair value less costs to sell or its value in use. To determine value in use, Sanofi uses estimates of future cash flows generated by the asset or CGU, prepared using the same methods as those used in the initial measurement of the asset or CGU on the basis of medium-term strategic plans.

In the case of goodwill, estimates of future cash flows are based on a medium-term strategic plan, an extrapolation of the cash flows beyond that plan, and a terminal value. In the case of other intangible assets, the period used is based on the economic life of the asset.

Estimated cash flows are discounted at long-term market interest rates that reflect the best estimate by Sanofi of the time value of money, the risks specific to the asset or CGU, and economic conditions in the geographical regions in which the business activity associated with the asset or CGU is located.

Certain assets and liabilities that are not directly attributable to a specific CGU are allocated between CGUs on a basis that is reasonable, and consistent with the allocation of the corresponding goodwill.

Impairment losses arising on property, plant and equipment, on software and on certain rights are recognized in the relevant classification of expense by function.

Impairment losses arising on other intangible assets are recognized within *Impairment of intangible assets* in the income statement.

#### **B.6.2. Impairment of investments accounted for using the equity method**

In accordance with IAS 28 (Investments in Associates and Joint Ventures), Sanofi applies the criteria specified in IAS 39 (Financial Instruments: Recognition and Measurement) to determine whether investments accounted for using the equity method may be impaired (see Note B.8.2.). If an investment is impaired, the amount of the impairment loss is determined by applying IAS 36 (see Note B.6.1.) and recognized in *Share of profit/(loss) from investments accounted for using the equity method*.

#### **B.6.3. Reversals of impairment losses charged against property, plant and equipment, intangible assets, and investments accounted for using the equity method**

At the end of each reporting period, Sanofi assesses whether events or changes in circumstances indicate that an impairment loss recognized in a prior period in respect of an asset (other than goodwill) or an investment accounted for using the equity method can be reversed. If this is the case, and the recoverable amount as determined based on the revised estimates exceeds the carrying amount of the asset, Sanofi reverses the impairment loss only to the extent of the carrying amount that would have been determined had no impairment loss been recognized for the asset.



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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Reversals of impairment losses in respect of other intangible assets are recognized within the income statement line item *Impairment of intangible assets*, while reversals of impairment losses in respect of investments accounted for using the equity method are recognized within the income statement line item *Share of profit/(loss) from investments accounted for using the equity method*. Impairment losses taken against goodwill are never reversed, unless the goodwill is part of the carrying amount of an investment accounted for using the equity method.

**B.7. Assets held for sale or exchange and liabilities related to assets held for sale or exchange**

In accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations), non-current assets and groups of assets are classified as held for sale in the balance sheet if their carrying amount will be recovered principally through a sale transaction rather than through continuing use. Within the meaning of IFRS 5, the term sale also includes exchanges for other assets.

Non-current assets or asset groups held for sale must be available for immediate sale in their present condition, subject only to terms that are usual and customary for sales of such assets, and a sale must be highly probable. Criteria used to determine whether a sale is highly probable include:

the appropriate level of management must be committed to a plan to sell;

an active program to locate a buyer and complete the plan must have been initiated;

the asset must be actively marketed for sale at a price that is reasonable in relation to its current fair value;

completion of the sale should be foreseeable within the twelve months following the date of reclassification to *Assets held for sale or exchange*; and

actions required to complete the plan should indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn.

Before initial reclassification of the non-current asset (or asset group) to *Assets held for sale or exchange*, the carrying amounts of the asset (or of all the assets and liabilities in the asset group) must be measured in accordance with the applicable standards.

Subsequent to reclassification to *Assets held for sale or exchange*, the non-current asset (or asset group) is measured at the lower of carrying amount or fair value less costs to sell, with any write-down recognized by means of an impairment loss. Once a non-current asset has been reclassified as held for sale or exchange, it is no longer depreciated or amortized.

In a disposal of an equity interest leading to loss of control, all the assets and liabilities of the entity involved are classified as held-for-sale assets or liabilities within the balance sheet line items *Assets held for sale or exchange* or *Liabilities related to assets*

*held for sale or exchange*, provided that the disposal satisfies the IFRS 5 classification criteria.

The profit or loss generated by a held-for-sale asset group is reported in a separate line item in the income statement for the current period and for the comparative periods presented, provided that the asset group:

represents a separate major line of business or geographical area of operations; or,

is part of a single coordinated plan to dispose of a separate major line of business or geographical area of operations; or,

is a subsidiary acquired exclusively with a view to resale.

In accordance with IFRS 10, transactions between companies that are held for sale or treated as discontinued operations and other consolidated companies are eliminated.

Events or circumstances beyond Sanofi's control may extend the period to complete the sale or exchange beyond one year without precluding classification of the asset (or disposal group) in *Assets held for sale or exchange* provided that there is sufficient evidence that Sanofi remains committed to the planned sale or exchange. Finally, in the event of changes to a plan of sale that require an asset no longer to be classified as held for sale, IFRS 5 specifies the following treatment:

The assets and liabilities previously classified as held for sale are reclassified to the appropriate balance sheet line items, with no restatement of comparative periods.

Each asset is measured at the lower of (a) its carrying amount before the asset was reclassified as held for sale, adjusted for any depreciation, amortization or revaluation that would have been recognized if the asset had not been reclassified as held for sale, or (b) its recoverable amount at the date of reclassification.

The backlog of depreciation, amortization and impairment not recognized while non-current assets were classified as held for sale must be reported in the same income statement line item that was used to report impairment losses arising on initial reclassification of assets as held for sale and gains or losses arising on the sale of such assets. In the consolidated income statement, those impacts are reported within the line item *Other gains and losses, and litigation*.



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The net income of a business previously classified as discontinued or as held for sale or exchange and reported on a separate line in the income statement must be reclassified and included in net income from continuing operations, for all periods presented.

In addition, segment information relating to the income statement and the statement of cash flows (acquisitions of non-current assets) must be disclosed in the notes to the financial statements in accordance with IFRS 8 (Operating Segments), and must also be restated for all prior periods presented.

**F-20**

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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**B.8. Financial instruments****B.8.1. Non-derivative financial assets**

In accordance with IAS 39 (Financial Instruments: Recognition and Measurement) and IAS 32 (Financial Instruments: Presentation), Sanofi has adopted the following classification for non-derivative financial assets, based on the type of asset and on management intention at the date of initial recognition. The designation and classification of such financial assets are subsequently reassessed at the end of each reporting period.

Non-derivative financial assets are recognized on the date when Sanofi becomes party to the contractual terms of the asset. On initial recognition, financial assets are measured at fair value, plus direct transaction costs in the case of financial assets not classified as fair value through profit or loss.

Classification, presentation and subsequent measurement of non-derivative financial assets are as follows:

***Financial assets at fair value through profit or loss***

These assets are classified in the balance sheet within the line items ***Other non-current assets***, ***Other current assets*** and ***Cash and cash equivalents***.

Financial assets at fair value through profit or loss comprise assets held for trading (financial assets acquired principally for the purpose of reselling them in the near term, usually within less than 12 months), and financial instruments designated as fair value through profit and loss on initial recognition in accordance with the conditions for application of the fair value option.

Such financial assets are carried at fair value, without any deduction for transaction costs that may be incurred on sale. Realized and unrealized gains and losses resulting from changes in the fair value of these assets are recognized in the income statement, in ***Financial income*** or ***Financial expenses***.

Realized and unrealized foreign exchange gains and losses on financial assets in currencies other than functional currencies are recognized in the income statement in ***Financial income*** or ***Financial expenses***.

***Available-for-sale financial assets***

Available-for-sale financial assets are non-derivative financial assets that are (i) designated by management as available-for-sale or (ii) not classified as Financial assets at fair value through profit or loss Held-to-maturity investments or Loans and receivables . This category includes equity interests in quoted or unquoted companies other than investments accounted for using the equity method (associates and joint ventures). Available-for-sale financial assets are classified in *Other non-current assets*.

Available-for-sale financial assets are measured at fair value, without any deduction for transaction costs that may be incurred on sale. Gains and losses arising from changes in the fair value of

these assets, including unrealized foreign exchange gains and losses, are recognized directly in equity in the consolidated statement of comprehensive income in the period in which they occur, except for impairment losses and foreign exchange gains and losses on debt instruments. On derecognition of an available-for-sale financial asset, or on recognition of an impairment loss on such an asset, the cumulative gains and losses previously recognized in equity are recognized in the income statement for the period within *Financial income* or *Financial expenses*.

Interest income and dividends on equity instruments are recognized in the income statement within *Financial income* when Sanofi is entitled to receive payment.

Available-for-sale financial assets in the form of equity interests in companies not quoted in an active market are measured at cost if their fair value cannot be measured reliably; an impairment loss is recognized when there is objective evidence that such an asset is impaired.

Contingent consideration receivable in connection with divestments is recognized as an available-for-sale financial asset at fair value (plus any transaction costs), provided that it represents an unconditional right to receive cash as of the date of the divestment. Fair value is initially measured on the basis of estimated future cash flows.

Subsequent adjustments to fair value arising from revisions to those estimates are recognized immediately in profit or loss. Interest income generated on such assets is calculated using the effective interest method, and recognized in profit or loss on an accruals basis. An impairment loss is taken against contingent consideration arising on divestments where counterparty credit risk suggests its value may have become impaired.

Other adjustments to fair value, such as those arising from a change in the discount rate, are recognized in equity within the statement of comprehensive income in the period in which they occur.

#### *Held-to-maturity investments*

Held-to-maturity investments are non-derivative financial assets with fixed or determinable payments and fixed maturities that Sanofi has the positive intention and ability to hold to maturity.

Such investments are measured at amortized cost using the effective interest method.

#### *Loans and receivables*

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are presented within the line items *Other current assets*, *Accounts receivable* and *Cash and cash equivalents*. Loans with a maturity of more than 12 months are presented in Long-term loans and advances within *Other non-current assets*.



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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Those financial assets are measured at amortized cost using the effective interest method.

**B.8.2. Impairment of non-derivative financial assets**

Indicators of impairment are reviewed for all non-derivative financial assets at the end of each reporting period. Such indicators include default in contractual payments, significant financial difficulties of the issuer or debtor, probability of bankruptcy, or a prolonged or significant decline in quoted market price. An impairment loss is recognized in the income statement if there is objective evidence of impairment resulting from one or more events after the initial recognition of the asset (a loss event) and that loss event has a reliably measurable impact on the estimated future cash flows of the financial asset (or group of financial assets).

The impairment loss on loans and receivables, which are measured at amortized cost, is the difference between the carrying amount of the asset and the present value of estimated future cash flows discounted at the financial asset's original effective interest rate.

When an impairment loss is identified on an available-for-sale financial asset, the cumulative losses previously recognized directly in equity are recorded in the income statement. The loss recognized in the income statement is the difference between the acquisition cost (net of principal repayments and amortization) and the fair value at the time of impairment, less any impairment loss previously recognized in the income statement.

The impairment loss on investments in companies not quoted in an active market and measured at cost is the difference between the carrying amount of the investment and the present value of its estimated future cash flows, discounted at the current market interest rate for similar financial assets.

Impairment losses in respect of loans are recognized within *Financial expenses* in the income statement.

Impairment losses in respect of trade receivables are recognized within *Selling and general expenses* in the income statement.

Impairment losses on equity instruments classified as available-for-sale financial assets cannot be reversed through the income statement.

**B.8.3. Derivative instruments**

Derivative instruments that do not qualify for hedge accounting are initially and subsequently measured at fair value, with changes in fair value recognized in the income statement in *Other operating income* or in *Financial income* or *Financial expenses*, depending on the nature of the underlying economic item which is hedged.

Derivative instruments that qualify for hedge accounting are measured in accordance with the hedge accounting requirements of IAS 39 (see Note B.8.4.).

IFRS 13 (Fair Value Measurement) requires counterparty credit risk to be taken into account when measuring the fair value of financial instruments. This risk is estimated on the basis of observable, publicly-available statistical data.

### ***Policy on offsetting***

In order for a financial asset and a financial liability to be presented as a net amount in the balance sheet under IAS 32, there must be (a) a legally enforceable right to offset and (b) the intention either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

In addition, IFRS 7 (Financial Instruments: Disclosures) requires the notes to the financial statements to include a schedule showing a list of any offsets recognized under IAS 32 and of transactions for which only criterion (a) is met, i.e. potential offsets such as those specified in close out netting agreements (positions offset only in the event of default, as specified in the International Swaps and Derivatives Association (ISDA) standard).

### **B.8.4. Hedging**

Hedging involves the use of derivative financial instruments. Changes in the fair value of such instruments are intended to offset the exposure of the hedged items to changes in fair value.

As part of its overall interest rate risk and foreign exchange risk management policy, Sanofi enters into various transactions involving derivative instruments. Derivative instruments used in connection with Sanofi's hedging policy may include forward exchange contracts, currency options, interest rate swaps and interest rate options.

Derivative financial instruments qualify as hedging instruments for hedge accounting purposes when (a) at the inception of the hedge there is formal designation and documentation of the hedging relationship and of the risk management strategy and objective; (b) the hedge is expected by management to be highly effective in offsetting the risk; (c) the forecast transaction being hedged is highly probable and presents an exposure to variations in cash flows that could ultimately affect profit or loss; (d) the effectiveness of the hedge can be reliably measured; and (e) the effectiveness of the hedge is assessed on an ongoing basis and the hedge is determined actually to have been highly effective throughout the reporting periods for which the hedge was designated.

The above criteria are applied when Sanofi uses derivative instruments designated as a fair value hedge, a cash flow hedge or a hedge of a net investment in a foreign operation.

### ***Fair value hedge***

A fair value hedge is a hedge of the exposure to changes in fair value of a recognized asset or liability or unrecognized firm commitment that could affect profit or loss.

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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Changes in fair value of the hedging instrument and changes in fair value of the hedged item attributable to the hedged risk are recognized in the income statement, within ***Other operating income*** for hedges related to operating activities, or within ***Financial income*** or ***Financial expenses*** for hedges related to investing or financing activities.

***Cash flow hedge***

A cash flow hedge is a hedge of the exposure to variability in cash flows attributable to a particular risk associated with a recognized asset or liability, or a highly probable forecast transaction, which could affect profit or loss.

Changes in fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement within ***Other operating income*** for hedges of operating activities, and within ***Financial income*** or ***Financial expenses*** for hedges of investing or financing activities.

Cumulative changes in fair value of the hedging instrument previously recognized in equity are reclassified to the income statement when the hedged transaction affects profit or loss. These transferred gains and losses are recorded within ***Other operating income*** for hedges related to operating activities, or within ***Financial income*** or ***Financial expenses*** for hedges related to investing or financing activities.

When a forecast transaction results in the recognition of a non-financial asset or liability, cumulative changes in the fair value of the hedging instrument previously recognized in equity are included in the initial measurement of that asset or liability.

When the hedging instrument expires or is sold, terminated or exercised, the cumulative gain or loss previously recognized in equity remains separately recognized in equity and is not reclassified to the income statement until the forecast transaction occurs. However, if Sanofi no longer expects the forecast transaction to occur, the cumulative gain or loss previously recognized in equity is recognized immediately in profit or loss.

***Hedge of a net investment in a foreign operation***

In a hedge of a net investment in a foreign operation, changes in the fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income

statement within *Financial income* or *Financial expenses*. When the investment in the foreign operation is sold, the changes in the fair value of the hedging instrument previously recognized in equity are reclassified to the income statement within *Financial income* or *Financial expenses*.

#### *Discontinuation of hedge accounting*

Hedge accounting is discontinued when (a) the hedging instrument expires or is sold, terminated or exercised, or (b) the hedge no longer meets the criteria for hedge accounting, or (c) Sanofi revokes the hedge designation, or (d) management no longer expects the forecast transaction to occur.

### **B.8.5. Non-derivative financial liabilities**

#### *Borrowings and debt*

Bank borrowings and debt instruments are initially measured at fair value of the consideration received, net of directly attributable transaction costs.

Subsequently, they are measured at amortized cost using the effective interest method. All costs related to the issuance of borrowings or debt instruments, and all differences between the issue proceeds net of transaction costs and the value on redemption, are recognized within *Financial expenses* in the income statement over the term of the debt using the effective interest method.

#### *Liabilities related to business combinations and to non-controlling interests*

These line items record the fair value of (i) contingent consideration payable in connection with business combinations (see Note B.3.1. for a description of the relevant accounting policy), and (ii) commitments to buy out equity holders of subsidiaries, including put options granted to non-controlling interests.

Adjustments to the fair value of commitments to buy out equity holders of subsidiaries, including put options granted to non-controlling interests, are recognized in equity.

#### *Other non-derivative financial liabilities*

Other non-derivative financial liabilities include trade accounts payable, which are measured at fair value (which in most cases equates to face value) on initial recognition, and subsequently at amortized cost.

### **B.8.6. Fair value of financial instruments**

The disclosures required under IFRS 13 relating to the fair value of the principal financial assets and liabilities reported in the consolidated balance sheet and in the notes to consolidated financial statements, and to the level of those instruments in the fair value hierarchy, are presented in Note D.12. The disclosures required under IFRS 13 relating to the sensitivity of level 3 fair value measurements are presented in Note D.18.



**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The table below shows the disclosures required under IFRS 7 relating to the measurement principles applied to financial instruments.

Note	Type of financial instrument	Measurement principle	Method used to determine fair value		
			Valuation model	Exchange rate	Market data Interest rate
D.7.	Available-for-sale financial assets (quoted equity securities)	Fair value	Quoted market price	N/A	N/A
D.7.	Available-for-sale financial assets (quoted debt securities)	Fair value	Quoted market price	N/A	N/A
D.7.	Available-for-sale financial assets (contingent consideration receivable):	Fair value	Under IAS 39, contingent consideration receivable on a divestment is a financial asset. The fair value of such assets is determined by adjusting the contingent consideration at the end of the reporting period using the method described in Note D.7.		
D.7.	Long-term loans and advances and other non-current receivables	Amortized cost	The amortized cost of long-term loans and advances and other non-current receivables at the end of the reporting period is not materially different from their fair value.		
D.7.	Financial assets recognized under the fair value option <sup>(a)</sup>	Fair value	Market value (net asset value)	N/A	N/A
D.20.	Forward currency contracts	Fair value	Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon
D.20.	Interest rate swaps	Fair value	Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon
D.20.	Cross-currency swaps	Fair value	Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market

				> 1 year: Mid Zero Coupon
D.13. Investments in mutual funds	Fair value	Market value (net asset value)	N/A	N/A
D.13. Negotiable debt instruments, commercial paper, instant access deposits and term deposits	Amortized cost	Because these instruments have a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as disclosed in the notes to the consolidated financial statements.  In the case of debt with a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as reported in the notes to the consolidated financial statements.		
D.17. Debt	Amortized cost <sup>(b)</sup>	For debt with a maturity of more than 3 months, fair value as reported in the notes to the consolidated financial statements is determined either by reference to quoted market prices at the end of the reporting period (quoted instruments) or by discounting the future cash flows based on observable market data at the end of the reporting period (unquoted instruments).		
D.18. Liabilities related to business combinations and to non-controlling interests (CVRs)	Fair value	Quoted market price	N/A	N/A
D.18. Liabilities related to business combinations and to non-controlling interests (other than CVRs)	Fair value <sup>(c)</sup>	Under IAS 32, contingent consideration payable in a business combination is a financial liability. The fair value of such liabilities is determined by adjusting the contingent consideration at the end of the reporting period using the method described in Note D.18.		

*(a) These assets are held to fund a deferred compensation plan offered to certain employees.*

*(b) In the case of debt designated as a hedged item in a fair value hedging relationship, the carrying amount in the consolidated balance sheet includes changes in fair value attributable to the hedged risk(s).*

*(c) For business combinations completed prior to application of the revised IFRS 3, contingent consideration is recognized when payment becomes probable (see Note B.3.1.).*

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**Table of Contents**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The other financial assets and liabilities included in the consolidated balance sheet are:

Non-derivative current financial assets and liabilities: because these items have a maturity close to the end of the reporting period, Sanofi regards their carrying amount (i.e. historical cost less any credit risk allowance) as a reasonable approximation of their fair value.

Equity interests in companies not quoted in an active market and the fair value of which cannot be measured reliably, which are measured at amortized cost in accordance with IAS 39.

**B.8.7. Derecognition of financial instruments**

Financial assets are derecognized when the contractual rights to cash flows from the asset have ended or have been transferred and when Sanofi has transferred substantially all risks and rewards of ownership of the asset. If Sanofi has neither transferred nor retained substantially all the risks and rewards of ownership of a financial asset, it is derecognized if Sanofi does not retain control of the asset.

A financial liability is derecognized when Sanofi's contractual obligations in respect of the liability are discharged, cancelled or extinguished.

**B.8.8. Risks relating to financial instruments**

Market risks in respect of non-current financial assets, cash equivalents, derivative instruments and debt are described in the discussions of risk factors presented in Item 3.D. and Item 11.

Credit risk is the risk that customers may fail to pay their debts. This risk also arises as a result of the concentration of Sanofi's sales with its largest customers, in particular certain wholesalers in the United States. Customer credit risk is described in Item 3.D. Risk Factors. We are subject to the risk of non-payment by our customers.

**B.9. Inventories**

Inventories are measured at the lower of cost or net realizable value. Cost is calculated using the weighted average cost method or the first-in, first-out method, depending on the nature of the inventory.

The cost of finished goods inventories includes costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

During the launch phase of a new product, any inventories of that product are written down to zero pending regulatory approval. The write-down is reversed once it becomes highly probable that marketing approval will be obtained.

#### **B.10. Cash and cash equivalents**

Cash and cash equivalents as shown in the consolidated balance sheet and statement of cash flows comprise cash, plus liquid short-term investments that are readily convertible into cash and are subject to an insignificant risk of changes in value in the event of movements in interest rates.

#### **B.11. Treasury shares**

In accordance with IAS 32, Sanofi treasury shares are deducted from equity, irrespective of the purpose for which they are held. No gain or loss is recognized in the income statement on the purchase, sale, impairment or cancellation of treasury shares.

#### **B.12. Provisions for risks**

In accordance with IAS 37 (Provisions, Contingent Liabilities and Contingent Assets), Sanofi records a provision when it has a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources.

If the obligation is expected to be settled more than twelve months after the end of the reporting period, or has no definite settlement date, the provision is recorded within *Non-current provisions and other non-current liabilities*.

Provisions relating to the insurance programs in which Sanofi's captive insurance company participates are based on risk exposure estimates calculated by management, with assistance from independent actuaries, using IBNR (Incurred But Not Reported) techniques. Those techniques use past claims experience, within Sanofi and in the market, to estimate future trends in the cost of claims.

Contingent liabilities are not recognized, but are disclosed in the notes to the financial statements unless the possibility of an outflow of economic resources is remote.

Sanofi estimates provisions on the basis of events and circumstances related to present obligations at the end of the reporting period and of past experience, and to the best of management's knowledge at the date of preparation of the financial statements.

Reimbursements offsetting the probable outflow of resources are recognized as assets only if it is virtually certain that they will be received. Contingent assets are not recognized.

Restructuring provisions are recognized if Sanofi has a detailed, formal restructuring plan at the end of the reporting period and has announced its intention to implement this plan to those affected by it.

**F-25**

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**Table of Contents**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

No provisions are recorded for future operating losses.

Sanofi records non-current provisions for certain obligations, such as legal or constructive environmental obligations and litigation, where an outflow of resources is probable and the amount of the outflow can be reliably estimated. Where the effect of the time value of money is material, those provisions are measured at the present value of the expenditures expected to be required to settle the obligation, calculated using a discount rate that reflects an estimate of the time value of money and the risks specific to the obligation.

Increases in provisions to reflect the effects of the passage of time are recognized within *Financial expenses*.

**B.13. Revenue recognition**

**B.13.1. Net sales**

Revenue arising from the sale of goods is presented in the income statement within *Net sales*. Net sales comprise revenue from sales of pharmaceutical products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities.

Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; Sanofi no longer has effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to Sanofi, in accordance with IAS 18 (Revenue). In particular, the contracts between Sanofi Pasteur and government agencies specify conditions for the supply and acceptance of batches of vaccine; revenue is recognized when those conditions are met.

Sanofi offers various types of price reductions on its products. In particular, products sold in the United States are covered by various governmental programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment.

Returns, discounts, incentives and rebates, as described above, are recognized in the period in which the underlying sales are recognized as a reduction of gross sales.

These amounts are calculated as follows:

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Provisions for chargeback incentives are estimated on the basis of the relevant subsidiary's standard sales terms and conditions, and in certain cases on the basis of specific contractual arrangements with the customer. They represent management's best estimate of the amount of chargeback incentives that will ultimately be claimed by the customer.

Provisions for rebates based on attainment of sales targets are estimated and accrued as each of the underlying sales transactions is recognized.

Provisions for price reductions under Government and State programs, largely in the United States, are estimated on the basis of the specific terms of the relevant regulations or agreements, and accrued as each of the underlying sales transactions is recognized.

Provisions for sales returns are calculated on the basis of management's best estimate of the amount of product that will ultimately be returned by customers. In countries where product returns are possible, Sanofi operates a returns policy that allows the customer to return products within a certain period either side of the expiry date (usually 12 months after the expiry date). The provision is estimated on the basis of past experience of sales returns.

Sanofi also takes into account factors such as levels of inventory in its various distribution channels, product expiry dates, information about potential discontinuation of products, the entry of competing generics into the market, and the launch of over-the-counter medicines.

In each case, the provisions are subject to continuous review and adjustment as appropriate based on the most recent data available to management.

Sanofi believes that it has the ability to measure each of the above provisions reliably, using the following factors in developing its estimates:

the nature and patient profile of the underlying product;

the applicable regulations or the specific terms and conditions of contracts with governmental authorities, wholesalers and other customers;

historical data relating to similar contracts, in the case of qualitative and quantitative rebates and chargeback incentives;

past experience and sales growth trends for the same or similar products;

actual inventory levels in distribution channels, monitored by Sanofi using internal sales data and externally provided data;

the shelf life of Sanofi products; and

market trends including competition, pricing and demand.

**B.13.2. Other revenues**

Other revenues mainly comprise royalties under licensing agreements (see Note C.), and VaxServe sales of products sourced from third-party manufacturers.

VaxServe is a Vaccines segment entity whose operations include the distribution within the United States of vaccines and other products manufactured by third parties.



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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Some sales recorded by VaxServe are presented within the line item *Other revenues* because they are not derived from the sale of products manufactured by Sanofi.

**B.14. Cost of sales**

*Cost of sales* consists primarily of the industrial cost of goods sold, payments made under licensing agreements, and distribution costs. The industrial cost of goods sold includes the cost of materials, depreciation of property, plant and equipment, amortization of software, personnel costs, and other expenses attributable to production.

**B.15. Research and development**

Note B.4.1. Research and development not acquired in a business combination and Note B.4.3. Other intangible assets acquired in a business combination describe the principles applied to the recognition of research and development costs.

Contributions or reimbursements received from alliance partners are recorded as a reduction of *Research and development expenses*.

**B.16. Other operating income and expenses****B.16.1. Other operating income**

*Other operating income* includes the share of profits that Sanofi is entitled to receive from alliance partners in respect of product marketing agreements. It also includes revenues generated under certain complex agreements, which may include partnership and co-promotion arrangements.

Upfront payments received are deferred until the service obligation is met. Milestone payments are assessed on a case by case basis, and recognized in the income statement on delivery of the products and/or upon the service obligation being met. Revenue generated in connection with these services is recognized on the basis of delivery of the goods or provision of the services to the other contracting party.

This line item also includes realized and unrealized foreign exchange gains and losses on operating activities (see Note B.8.4.), and operating gains on disposals not regarded as major disposals (see Note B.20.).

## **B.16.2. Other operating expenses**

*Other operating expenses* mainly comprise the share of profits that alliance partners are entitled to receive from Sanofi under product marketing agreements.

## **B.17. Amortization and impairment of intangible assets**

### **B.17.1. Amortization of intangible assets**

The expenses recorded in this line item comprise amortization of product rights (see Note D.4.), given that the benefit of those rights to Sanofi's commercial, industrial and development functions cannot be separately identified.

Amortization of software, and of other rights of an industrial or operational nature, is recognized as an expense in the income statement, in the relevant line items of expense by function.

### **B.17.2. Impairment of intangible assets**

This line item records impairment losses (other than those associated with restructuring) recognized against intangible assets (including goodwill, but excluding software and other rights of an industrial or operational nature), and any reversals of such impairment losses.

## **B.18. Fair value remeasurement of contingent consideration**

Changes in the fair value of contingent consideration that was (i) already carried in the books of an acquired entity, or (ii) granted in connection with a business combination and initially recognized as a liability in accordance with the revised IFRS 3, are reported in profit or loss in accordance with the principles described in Note B.3.1. Such adjustments are reported separately in the income statement, in the line item *Fair value remeasurement of contingent consideration*.

This line item also includes changes in the fair value of contingent consideration recognized in connection with divestments and classified as an available-for-sale financial asset.

Finally, it also includes the effect of the unwinding of discount, and of exchange rate movements where the asset or liability is expressed in a currency other than the functional currency of the reporting entity.

## **B.19. Restructuring costs and similar items**

Restructuring costs are expenses incurred in connection with the transformation or reorganization of Sanofi's operations or support functions. Such costs include collective redundancy plans, compensation to third parties for early termination of contracts, and commitments made in connection with transformation or reorganization decisions. They also include accelerated depreciation charges arising from site closures and losses on asset disposals resulting from such decisions.

In addition, this line item includes expenses incurred in connection with programs implemented as part of the transformation strategy announced in November 2015 intended to deliver a global information systems solution, to standardize and consolidate processes, and to transition towards a worldwide services platform.



**Table of Contents**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**B.20. Other gains and losses, and litigation**

The line item *Other gains and losses, and litigation* includes the impact of material transactions of an unusual nature or amount which Sanofi believes it necessary to report separately in the income statement in order to improve the relevance of the financial statements, such as:

gains and losses on major disposals of property, plant and equipment, of intangible assets, of assets (or groups of assets and liabilities) held for sale, or of a business within the meaning of the revised IFRS 3, other than those considered to be restructuring costs;

impairment losses and reversals of impairment losses on assets (or groups of assets and liabilities) held for sale, other than those considered to be restructuring costs;

gains on bargain purchases; and

costs and provisions relating to major litigation; and

pre-tax separation costs associated with the process of disinvesting from operations in the event of a major divestment.

**B.21. Financial expenses and income**

**B.21.1. Financial expenses**

*Financial expenses* mainly comprise interest charges on debt financing; negative changes in the fair value of financial instruments (where changes in fair value are recognized in profit or loss); realized and unrealized foreign exchange losses on financing and investing activities; impairment losses on financial instruments; and any reversals of impairment losses on financial instruments.

*Financial expenses* also include expenses arising from the unwinding of discount on long-term liabilities, and the net interest cost related to employee benefits. This line item does not include commercial cash discounts, which are deducted from net sales.

### B.21.2. Financial income

**Financial income** includes interest and dividend income; positive changes in the fair value of financial instruments (where changes in fair value are recognized in profit or loss); realized and unrealized foreign exchange gains on financing and investing activities; and gains or losses on disposals of financial assets.

### B.22. Income tax expense

**Income tax expense** includes all current and deferred taxes of consolidated companies.

Sanofi accounts for deferred taxes in accordance with IAS 12 (Income Taxes), using the methods described below:

Deferred tax assets and liabilities are recognized on taxable and deductible temporary differences, and on tax loss carry-forwards.

Temporary differences are differences between the carrying amount of an asset or liability in the balance sheet and its tax base.

French business taxes include a value added based component: CVAE (*Cotisation sur la Valeur Ajoutée des Entreprises*). Given that CVAE is (i) calculated as the amount by which certain revenues exceed certain expenses and (ii) borne primarily by companies that own intellectual property rights on income derived from those rights (royalties, and margin on sales to third parties and to Sanofi entities), it is regarded as meeting the definition of income taxes specified in IAS 12, paragraph 2 ( taxes which are based on taxable profits ).

Deferred tax assets and liabilities are calculated using the tax rate expected to apply in the period when the corresponding temporary differences are expected to reverse, based on tax rates enacted or substantively enacted at the end of the reporting period.

Deferred tax assets are recognized in respect of deductible temporary differences, tax losses available for carry-forward and unused tax credits to the extent that future recovery is regarded as probable. The recoverability of deferred tax assets is assessed on a case-by-case basis, taking into account the profit forecasts contained in Sanofi's medium-term business plan.

A deferred tax liability is recognized for temporary differences relating to interests in subsidiaries, associates and joint ventures, except in cases where Sanofi is able to control the timing of the reversal of the temporary differences. This applies in particular when Sanofi is able to control dividend policy and it is probable that the temporary differences will not reverse in the foreseeable future.

No deferred tax is recognized on eliminations of intragroup transfers of interests in subsidiaries, associates or joint ventures.

Each tax entity calculates its own net deferred tax position. All net deferred tax asset and liability positions are then aggregated and shown in separate line items on the relevant side of the consolidated balance sheet. Deferred tax assets and liabilities are offset only if (i) Sanofi has a legally enforceable right to offset current tax assets and

current tax liabilities, and (ii) the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority.

Deferred taxes are not discounted, except implicitly in the case of deferred taxes on assets and liabilities which are already impacted by discounting.

Withholding taxes on intragroup royalties and dividends, and on royalties and dividends collected from third parties, are accounted for as current income taxes.

In accounting for business combinations, Sanofi complies with the revised IFRS 3 in regards to the recognition of deferred tax assets after the initial accounting period. Consequently, any deferred tax

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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

assets recognized by the acquiree after the end of this period in respect of temporary differences or tax loss carry-forwards existing at the acquisition date are recognized in profit or loss.

The positions adopted by Sanofi in tax matters are based on its interpretation of tax laws and regulations. Some of those positions may be subject to uncertainty. In such cases, Sanofi assesses the amount of the tax liability on the basis of the following assumptions: that its position will be examined by one or more tax authorities on the basis of all relevant information; that a technical assessment is carried out with reference to legislation, case law, regulations, and established practice; and that each position is assessed individually (or collectively where appropriate), with no offset or aggregation between positions. Those assumptions are assessed on the basis of facts and circumstances existing at the end of the reporting period. When an uncertain tax position is considered probable, a tax liability is recognized (or a deferred tax asset is not recognized) measured using Sanofi's best estimate. The amount of the liability includes any penalties and late payment interest. The line item *Income tax expense* includes the effects of tax reassessments and tax disputes, and any penalties and late payment interest arising from such disputes that have the characteristics of income taxes within the meaning of paragraph 2 of IAS 12 ( taxes which are based on taxable profits ).

**B.23. Employee benefit obligations**

Sanofi offers retirement benefits to employees and retirees. Such benefits are accounted for in accordance with IAS 19 (Employee Benefits).

Benefits are provided in the form of either defined contribution plans or defined benefit plans. In the case of defined contribution plans, the cost is recognized immediately in the period in which it is incurred, and equates to the amount of the contributions paid by Sanofi. For defined benefit plans, Sanofi generally recognizes its obligations to pay pensions and similar benefits to employees as a liability, based on an actuarial estimate of the rights vested or currently vesting in employees and retirees, using the projected unit credit method. Estimates are performed at least once a year, and rely on financial assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

Obligations relating to other post-employment benefits (healthcare and life insurance) offered by Sanofi companies to employees are also recognized as a liability based on an actuarial estimate of the rights vested or currently vesting in employees and retirees at the end of the reporting period.

Such liabilities are recognized net of the fair value of plan assets.

In the case of multi-employer defined benefit plans where plan assets cannot be allocated to each participating employer with sufficient reliability, the plan is accounted for as a defined contribution plan, in accordance with paragraph 34 of IAS 19.

The benefit cost for the period consists primarily of current service cost, past service cost, net interest cost, gains or losses arising from plan settlements not specified in the terms of the plan, and actuarial gains or losses arising from plan curtailments. Net interest cost for the period is determined by applying the discount rate specified in IAS 19 to the net liability (i.e. the amount of the obligation, net of plan assets) recognized in respect of defined benefit plans. Past service cost is recognized immediately in profit or loss in the period in which it is incurred, regardless of whether or not the rights have vested at the time of adoption (in the case of a new plan) or of amendment (in the case of an existing plan).

Actuarial gains and losses on defined benefit plans (pensions and other post-employment benefits), also referred to as Remeasurements of the net defined benefit liability (asset) , arise as a result of changes in financial and demographic assumptions, experience adjustments, and the difference between the actual return and interest cost on plan assets. The impacts of those remeasurements are recognized in *Other comprehensive income*, net of deferred taxes; they are not subsequently reclassifiable to profit or loss.

## **B.24. Share-based payment**

Share-based payment expense is recognized as a component of operating income, in the relevant classification of expense by function. In measuring the expense, the level of attainment of any performance conditions is taken into account.

### **B.24.1. Stock option plans**

Sanofi has granted a number of equity-settled share-based payment plans (stock option plans) to some of its employees. The terms of those plans may make the award contingent on the attainment of performance criteria for some of the grantees.

In accordance with IFRS 2 (Share-Based Payment), services received from employees as consideration for stock options are recognized as an expense in the income statement, with the opposite entry recognized in equity. The expense corresponds to the fair value of the stock option plans, and is charged to income on a straight-line basis over the four-year vesting period of the plan.

The fair value of stock option plans is measured at the date of grant using the Black-Scholes valuation model, taking into account the expected life of the options. The resulting expense also takes into account the expected cancellation rate of the options. The expense is adjusted over the vesting period to reflect actual cancellation rates resulting from option-holders ceasing to be employed by Sanofi.

### **B.24.2. Employee share ownership plans**

Sanofi may offer its employees the opportunity to subscribe to reserved share issues at a discount to the reference market price.



## **Table of Contents**

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Shares awarded to employees under such plans fall within the scope of IFRS 2. Consequently, an expense is recognized at the subscription date, based on the value of the discount offered to employees.

#### **B.24.3. Restricted share plans**

Sanofi may award restricted share plans to certain of its employees. The terms of those plans may make the award contingent on the attainment of performance criteria for some of the grantees.

In accordance with IFRS 2, an expense equivalent to the fair value of such plans is recognized on a straight line basis over the vesting period of the plan, with the opposite entry recognized in equity. Depending on the country, the vesting period of such plans is either three or four years. Plans with a two-year or three-year vesting period are subject to a two-year lock-up period.

The fair value of stock option plans is based on the fair value of the equity instruments granted, representing the fair value of the services received during the vesting period. The fair value of an equity instrument granted under a plan is the market price of the share at the grant date, adjusted for expected dividends during the vesting period.

#### **B.25. Earnings per share**

Basic earnings per share is calculated using the weighted average number of shares outstanding during the reporting period, adjusted on a time-weighted basis from the acquisition date to reflect the number of own shares held by Sanofi. Diluted earnings per share is calculated on the basis of the weighted average number of ordinary shares, computed using the treasury stock method.

This method assumes that (a) all outstanding dilutive options and warrants are exercised, and (b) Sanofi acquires its own shares at the quoted market price for an amount equivalent to the cash received as consideration for the exercise of the options or warrants, plus the expense arising on unamortized stock options.

#### **B.26. Segment information**

In accordance with IFRS 8 (Operating Segments), the segment information reported by Sanofi is prepared on the basis of internal management data provided to the Chief Executive Officer, who is the chief operating decision maker. The performance of those segments is monitored individually using internal reports and common indicators.

Sanofi acquired the Consumer Healthcare operations of Boehringer Ingelheim (BI) on January 1, 2017, and during 2017 gradually integrated those operations into its Consumer Healthcare Global Business Unit (GBU); see Note A.5. Following completion of the integration process and with effect from December 31, 2017, Sanofi has identified our Consumer Healthcare business as an

operating segment, the financial information for which is reported separately to, and reviewed separately by, the Chief Executive Officer. Until that date the results of the Consumer Healthcare business were included in the Pharmaceuticals segment, as described below.

Consequently, as of December 31, 2017 Sanofi has three operating segments: Pharmaceuticals, Consumer Healthcare and Human Vaccines (Vaccines).

The Pharmaceuticals segment comprises the commercial operations of the following global franchises: Specialty Care (Rare Diseases, Multiple Sclerosis, Oncology, Immunology), Diabetes & Cardiovascular, Established Prescription Products and Generics, together with research, development and production activities dedicated to our Pharmaceuticals segment. This segment also includes all associates whose activities are related to pharmaceuticals, in particular Regeneron.

The Consumer Healthcare segment comprises, for all geographical territories, the commercial operations for our Consumer Healthcare products, together with research, development and production activities dedicated to those products.

The Vaccines segment comprises, for all geographical territories (including from January 1, 2017 certain European territories previously included in the Sanofi Pasteur MSD joint venture), the commercial operations of Sanofi Pasteur, together with research, development and production activities dedicated to vaccines.

Inter-segment transactions are not material.

In addition, during 2017 Sanofi finalized a complete realignment of its internal management reporting to match its organizational structure (see Note A.5.). As a result, the costs of Sanofi's global functions (Medical Affairs, External Affairs, Finance, Human Resources, Legal Affairs, Information Solutions & Technologies, Sanofi Business Services, etc.) are now managed centrally at group-wide level and are no longer allocated to operating segments for internal management reporting purposes. For the year ended December 31, 2017 and subsequent years, the costs of those functions are presented within the Other category. That category also includes other reconciling items such as retained commitments in respect of divested activities.

Operating segment disclosures as required under IFRS 8 are provided in Note D.35. to the consolidated financial statements.

## **B.27. Management of capital**

In order to maintain or adjust the capital structure, Sanofi can adjust the amount of dividends paid to shareholders, repurchase its own shares, issue new shares, or issue securities giving access to its capital.

The following objectives are defined under the terms of Sanofi's share repurchase programs:

the implementation of any stock option plan giving entitlement to purchase shares in the Sanofi parent company;

**Table of Contents**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the allotment or sale of shares to employees under statutory profit sharing schemes and employee savings plans;

the consideration-free allotment of shares (i.e. restricted share plans);

the cancellation of some or all of the repurchased shares;

market-making in the secondary market by an investment services provider under a liquidity contract in compliance with the ethical code recognized by the *Autorité des marchés financiers* (AMF);

the delivery of shares on the exercise of rights attached to securities giving access to the capital by redemption, conversion, exchange, presentation of a warrant or any other means;

the delivery of shares (in exchange, as payment, or otherwise) in connection with mergers and acquisitions;

the execution by an investment services provider of purchases, sales or transfers by any means, in particular via off-market trading; or

any other purpose that is or may in the future be authorized under the applicable laws and regulations. Sanofi is not subject to any constraints on equity capital imposed by third parties.

Total equity includes *Equity attributable to equity holders of Sanofi* and *Equity attributable to non-controlling interests*, as shown in the consolidated balance sheet.

Sanofi defines Debt, net of cash and cash equivalents as (i) the sum of short-term debt, long-term debt and interest rate derivatives and currency derivatives used to hedge debt, minus (ii) the sum of cash and cash equivalents and interest rate derivatives and currency derivatives used to hedge cash and cash equivalents.

## C/ Principal alliances

### C.1. Alliance arrangements with Regeneron Pharmaceuticals Inc. (Regeneron)

#### Collaboration agreement on the discovery, development and commercialization of human therapeutic antibodies

In November 2007, Sanofi and Regeneron signed new agreements (amended in November 2009) for the discovery, development and commercialization of fully human therapeutic antibodies. Sanofi having decided not to extend the discovery agreement, that agreement expired on December 31, 2017. Under the 2009 amended agreements Sanofi committed to funding the discovery and pre-clinical development of fully human therapeutic antibodies by a maximum of \$160 million per year through 2017. Sanofi had an option to develop and commercialize antibodies discovered by Regeneron pursuant to the collaboration. Following the signature in July 2015 of the immuno-oncology collaboration agreement described below, \$75 million (spread over three years) was reallocated to that new agreement.

If the option was exercised, Sanofi co-develops the antibody with Regeneron and is responsible for funding. Sanofi and Regeneron share co-promotion rights and profits on sales of the co-developed antibodies. On receipt of the first positive Phase III trial results for any such antibody, the subsequent Phase III costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under those arrangements are recognized by Sanofi as a reduction in the line item **Research and development expenses**. Once a product begins to be commercialized, and provided that the share of quarterly results under the agreement represents a profit, Sanofi is entitled to an additional profit-share (capped at 10% of Regeneron's share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration. In addition, Sanofi may be required to make milestone payments based on aggregate sales of all antibodies. As of December 31, 2017 the cumulative development costs incurred by the two parties were 5.2 billion (comprising 2.9 billion funded 100% by Sanofi, and 2.3 billion funded 80% by Sanofi and 20% by Regeneron, amounts translated into euros at the closing US dollar exchange rate). On the earlier of (i) 24 months before the scheduled launch date or (ii) the first positive Phase III trial results, Sanofi and Regeneron share the commercial expenses of the antibodies co-developed under the license agreement. Sanofi recognizes all the sales of those antibodies. Profits and losses arising from commercial operations in the United States are split 50/50. Outside the United States, Sanofi is entitled to between 55% and 65% of profits depending on sales of the antibodies, and bears 55% of any losses. The share of profits and losses attributable to Regeneron under the agreement is recognized in the line items **Other operating income** or **Other operating expenses**, which are components of operating income. In addition, Regeneron is entitled to receive payments of up to \$250 million contingent on the attainment of specified levels of sales outside the United States.

Praluent<sup>®</sup>, Dupixent<sup>®</sup>, Kevzara<sup>®</sup>, and REGN3500 (SAR 440340) will continue to be developed, and commercialized as applicable, with Regeneron under the Antibody License and Collaboration Agreement (LCA) following the expiry of the discovery agreement.

#### Immuno Oncology (IO) Discovery and Development Agreement and IO Licence and Collaboration Agreement (IO LCA)

On July 1, 2015, Sanofi and Regeneron entered into a new global collaboration to discover, develop and commercialize new antibody cancer treatments in the emerging field of immuno-oncology. As part of the agreements, the two companies are jointly developing a programmed cell death protein 1 (PD-1) inhibitor antibody currently in Phase IIb (for cutaneous squamous cell carcinoma) and Phase III (for non-small cell lung cancer), and expect to initiate clinical trials with new therapeutic candidates based on ongoing innovative preclinical programs. Sanofi made an upfront payment of \$640 million to Regeneron. The two companies will then invest approximately \$1 billion from discovery through proof of concept

**F-31**

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**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(POC) development (usually a Phase IIa study) of monotherapy and novel combinations of immuno-oncology antibody candidates to be funded 25% by Regeneron (\$250 million) and 75% by Sanofi (\$750 million). Under the terms of the IO Discovery and Development Agreement, Sanofi is entitled to an additional share of profits of up to 50% of the clinical development costs initially funded by Sanofi. That additional profit-share is capped at 10% of the share of Regeneron's quarterly profits arising under the IO LCA.

Under the terms of the IO LCA Sanofi and Regeneron also committed to provide additional funding of no more than \$650 million on a 50/50 basis (\$325 million per company) for the development of REGN2810, a PD-1 inhibitor antibody. In January 2018, Sanofi and Regeneron announced an agreement to increase the PD-1 development budget from the previously disclosed \$650 million to \$1.64 billion, which will continue to be shared 50/50. In addition, Sanofi will make a one-time milestone payment of \$375 million to Regeneron in the event that sales of a PD-1 product and any other collaboration antibody sold for use in combination with a PD-1 product were to exceed, in the aggregate, \$2 billion in any consecutive 12-month period. Finally, the two companies agreed to reallocate \$75 million (spread over three years) to immuno-oncology antibody research and development from Sanofi's \$160 million annual contribution to their existing antibody discovery collaboration. Beyond the committed funding, additional funding will be allocated as programs enter post-POC development.

Under the terms of the IO Discovery and Development Agreement, Sanofi can exercise its opt-in rights to further development and commercialization under the IO LCA for candidates derived from the discovery program.

Once Sanofi has exercised its opt-in rights for a candidate, future development of that candidate will be conducted either by Sanofi or Regeneron.

Where development is conducted by Sanofi, the entire cost of developing that candidate will be funded by Sanofi, and Regeneron will reimburse half of those costs, subject to a cap of 10% of Regeneron's quarterly profits.

Where development is conducted by Regeneron, the two parties will share the development costs equally.

**Investor agreement**

In January 2014, Sanofi and Regeneron amended the investor agreement that has existed between the two companies since 2007 (the Amended Investor Agreement). Under the terms of the amendment, Sanofi accepted various restrictions. Sanofi is bound by certain standstill provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron or acquiring more than 30% of Regeneron's capital stock (consisting

of the outstanding shares of common stock and the shares of Class A stock). This prohibition will remain in place until the earlier of (i) the later of the fifth anniversaries of the expiration or earlier termination of the Zaltrap® collaboration agreement with Regeneron (related to the development and commercialization of Zaltrap®) or the collaboration

agreement with Regeneron on monoclonal antibodies (see Collaboration agreement on the discovery, development and commercialization of human therapeutics antibodies above), each as amended and (ii) other specified events.

Sanofi has also agreed to vote as recommended by Regeneron's Board of Directors, except that it may elect to vote proportionally with the votes cast by all of Regeneron's other shareholders with respect to certain change-of-control transactions, and to vote in its sole discretion with respect to liquidation or dissolution, stock issuances equal to or exceeding 20% of the outstanding shares or voting rights of Regeneron's Class A Stock and Common Stock (taken together), and new equity compensation plans or amendments if not materially consistent with Regeneron's historical equity compensation practices.

As soon as it had passed the threshold of 20% ownership of the capital stock, Sanofi exercised its right under the Amended Investor Agreement to designate an independent director, who was appointed to the Board of Directors of Regeneron. The interest held by Sanofi in Regeneron has been consolidated by the equity method since April 2014.

On the conditions set out in the Amended Investor Agreement entered into in January 2014, Sanofi's right to designate a Regeneron board member was contingent on Sanofi maintaining its percentage share of Regeneron's outstanding capital stock (measured on a quarterly basis) at a level no lower than the highest percentage level previously achieved, with the maximum requirement capped at 25%. In addition, Sanofi's interest in Regeneron was subject to a lock-up clause. Those limitations have been amended by the letter agreement of January 2018 (see Note G/).

In November 2015, the Independent Designee (as defined in the Amended Investor Agreement) designated by Sanofi as an independent director resigned from the Regeneron Board of Directors. At Sanofi's request, pursuant to the Amended Investor Agreement, Regeneron appointed N. Anthony Tony Coles, M.D. to its Board of Directors in January 2017 as a successor Sanofi designee.

The Amended Investor Agreement also gives Sanofi the right to receive certain reasonable information as may be agreed upon by the parties and which will facilitate Sanofi's ability to account for its investment in Regeneron using the equity method of accounting under IFRS.

These three agreements were amended in January 2018 (see Note G/).

**Table of Contents**

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**C.2. Alliance arrangements with Bristol-Myers Squibb (BMS)**

Two of Sanofi's leading products were jointly developed with BMS: the anti-hypertensive agent irbesartan (Aprovel®/Avapro®/Karvea®) and the anti-atherothrombosis treatment clopidogrel bisulfate (Plavix®/Iscover®).

On September 27, 2012, Sanofi and BMS signed an agreement relating to their alliance following the loss of exclusivity of Plavix® and Avapro®/Avalide® in many major markets.

Under the terms of this agreement, which took effect on January 1, 2013, BMS returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the United States and Puerto Rico, giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS will receive royalty payments on Sanofi's sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in the United States and Puerto Rico) until 2018, and will also receive a payment of \$200 million from Sanofi in December 2018, part of which will be used to buy out the non-controlling interests (see Note D.18.). Rights to Plavix® in the United States and Puerto Rico remain unchanged and continue to be governed by the terms of the original agreement until December 2019.

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/Avalide®) as defined in the new agreement, Sanofi recognizes in its consolidated financial statements the revenue and expenses generated by its own operations. The share of profits reverting to BMS subsidiaries is presented within *Net income attributable to non-controlling interests* in the income statement.

In the territory managed by BMS (United States and Puerto Rico for Plavix®), Sanofi recognizes its share of profits and losses within the line item *Share of profit/(loss) from investments accounted for using the equity method*.

**D/ Presentation of the financial statements****D.1. Exchange of the Animal Health business**

Further to the exclusivity agreement of December 2015 on a future exchange of Sanofi's Animal Health business (Merial) and

Boehringer Ingelheim's Consumer Healthcare (CHC) business, the two groups announced on June 27, 2016 that they had successfully concluded the negotiations ongoing since the end of 2015 by signing contracts to secure the deal.



Consequently, and as required by IFRS 5 (see Note B.7.), all assets of the Animal Health business included in the exchange and all liabilities directly related to those assets were classified in the line items *Assets held for sale or exchange* and *Liabilities related to assets held for sale or exchange*, respectively, in the consolidated balance sheets as of December 31, 2016 and 2015. In addition, because the Animal Health business qualifies as a discontinued operation under IFRS 5 (see Note B.7.), the net income or loss from that business was presented separately in the consolidated income statement within the line item *Net income/(loss) of the exchanged/held-for-exchange Animal Health business*. This presentation in a separate line item in the income statement applied to operations for the year ended December 31, 2016 and for the comparative periods presented. Following the finalization of the exchange deal with Boehringer Ingelheim on January 1, 2017, the Animal Health business no longer qualified as an operating segment in 2016 and the comparatives for 2015 were amended accordingly.

For detailed information about the contribution of the Animal Health business to the consolidated financial statements refer to Note D.36., Exchanged/Held-for-Exchange Animal Health business .

### **Finalization of the exchange of Sanofi's Animal Health business for Boehringer Ingelheim's CHC business**

On January 1, 2017, Sanofi finalized the exchange of its Animal Health business for Boehringer Ingelheim's CHC business.

After final enterprise value adjustments, the exchange values of the two businesses effectively transferred during 2017 were determined at 10,557 million for Sanofi's Animal Health business and 6,239 million for Boehringer Ingelheim's CHC business.