2022

FORM 20-F

sanofi

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, 2022

Or

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

Or

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

Date of event requiring this shell company report

For the transition period from to

Commission File Number: 001-31368

Sanofi

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

France

(Jurisdiction of incorporation or organization)

46, avenue de la Grande Armée, 75017 Paris, France

(Address of principal executive offices)

Roy Papatheodorou , Executive Vice President, General Counsel & Head of Legal, Ethics and Business Integrity
46, avenue de la Grande Armée, 75017 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class:	Trading Symbol	Name of each exchange on which registered:
American Depositary Shares, each representing one half of one ordinary share, par value €2 per share	SNY	NASDAQ Global Select Market
Ordinary shares, par value €2 per share	*	NASDAQ Global Select Market*

Securities registered or to be registered pursuant to Section 12(g) of the Act: None
Securities for which there is a reporting obligation pursuant to Section 15(d) 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, 2022 was:
Ordinary shares: 1,260,835,732

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐.
If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒.
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐.
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐.
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company. See definition of "large accelerated filer", "accelerated filer" or "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards[(1)] provided pursuant to Section 13(a) of the Exchange Act. ☐
(1) The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☒
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive- based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐
Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17. ☐ Item 18. ☐
If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒.
*Not for trading but only in connection with the registration of American Depositary Shares representing such ordinary shares.

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 endorsed by the European Union, as of December 31, 2022.

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®, a trademark of Actavis or Procter & Gamble depending on the country; Aldurazyme®, a trademark of the Biomarin/Genzyme LLC Joint Venture; Alprolix®, a trademark of Swedish Orphan Biovitrum AB in Europe; ALTUVIIIO™, a trademark of Sobi in Europe and in Africa; ANKET™, a trademark of Innate Pharma; AtomNet®, a trademark of Atomwise, Inc.; Cialis®, a trademark of Eli Lilly; Elaprase®, a trademark of Shire Human Genetic Therapies, Inc.; Eloctate®, a trademark of Swedish Orphan Biovitrum AB in Europe; Stamaril®, a trademark of *Institut Pasteur;* Tamiflu®, a trademark of Hoffmann-La Roche; Vaxelis®, a trademark of MSP Vaccine Company (US) and MCM Vaccine B.V. (Netherlands); Zaltrap®, a trademark of Regeneron in the United States;
- trademarks sold by Sanofi and/or its affiliates to a third party, such as Altace®, a trademark of King Pharmaceuticals in the United States; Hyalgan®, a trademark of Fidia Farmaceutici S.p.A.; Libtayo®, a trademark of Regeneron; Praluent®, a trademark of Regeneron in the United States; Seprafilm®, a trademark of Baxter International Inc.; StarLink®, a trademark of Bayer;
- other third party trademarks such as Eylea®, a trademark of Regeneron; Humalog®, a trademark of Eli Lilly; Novolog® and Novorapid®, trademarks of Novo Nordisk A/S; Plan Bee®, a trademark of Amélie Perennou in France; Revlimid®, a trademark of Celgene Corporation; Stoxx®, a trademark of Stoxx Ltd; Unisom®, a trademark of J&J on certain geographic areas and Paladin Labs Inc. in Canada; Velcade®, a trademark of Millenium Pharmaceuticals Inc.; and Zantac®, a trademark of Glaxo Group Limited (except in the US and Canada).

Not all trademarks related to products under development have been authorized as of the date of this annual report by the relevant health authorities.

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 primarily on sales data excluding vaccines and in constant euros (unless otherwise indicated) on a September 2022 MAT (Moving Annual Total) basis. The data are primarily from a IQVIA local sales audit, supplemented by country-specific sources.

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 certain forward-looking statements within the meaning of applicable federal securities law, including the Private Securities Litigation Reform Act of 1995, as amended. 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.

Words such as “believe”, “anticipate”, “can”, “contemplate”, “could”, “plan”, “expect”, “intend”, “is designed to”, “may”, “might”, “plan”, “potential”, “objective” “target”, “estimate”, “project”, “predict”, “forecast”, “ambition”, “guideline”, “should”, “will”, or the negative of these 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 actual future results to differ materially from those expressed or implied in the forward-looking statements.

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

As a result of these factors, we cannot assure you that the forward-looking statements in this annual report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. Moreover, 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, future developments or otherwise, except as required by law. These forward-looking statements are based upon information, assumptions and estimates available to us as of the date of this annual report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information.

You should read this annual report and the documents that we reference in this annual report and have filed as exhibits completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these statements.

Abbreviations

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

ADR	American Depositary Receipt
ADS	American Depositary Share
AFEP	*Association française des entreprises privées* (French Association of Large Companies)
AMF	*Autorité des marchés financiers* (the French market regulator)
ANDA	Abbreviated New Drug Application
BLA	Biologic License Application
BMS	Bristol-Myers Squibb
CEO	Chief Executive Officer
CER	Constant exchange rates
CGU	Cash generating unit
CHC	Consumer Healthcare
CHMP	Committee for Medicinal Products for Human Use
COVALIS	Sanofi committee for internal occupational exposure limits *(Comité des Valeurs Limites Internes Sanofi)*
CVR	Contingent value right
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union
FCF	Free cash flow
FDA	US Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunisation
GBU	Global Business Unit
GERS	*Groupement pour l'Élaboration et la Réalisation de Statistiques* (French pharmaceutical industry statistics partnership)
GCP	Good clinical practices
GDP	Good distribution practices
GLP	Good laboratory practices
GLP-1	Glucagon-like peptide-1
GMP	Good manufacturing practices
GRI	Global Reporting Initiative
Hib	Haemophilus influenzae type b
HSE	Health, Safety and Environment
IASB	International Accounting Standards Board
ICH	International Council for Harmonization
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IFRIC	International Financial Reporting Interpretations Committee
IFRS	International Financial Reporting Standards
IPV	Inactivated polio vaccine
ISIN	International Securities Identification Number
J-MHLW	Japanese Ministry of Health, Labor and Welfare
LSD	Lysosomal storage disorder
MEDEF	*Mouvement des entreprises de France* (French business confederation)
MS	Multiple sclerosis
NASDAQ	National Association of Securities Dealers Automated Quotations
NDA	New Drug Application
NHI	National Health Insurance (Japan)
NYSE	New York Stock Exchange
OECD	Organisation for Economic Co-operation and Development
OPV	Oral polio vaccine
OTC	Over the counter
PhRMA	Pharmaceutical Research and Manufacturers of America
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PRV	Priority Review Voucher
PTE	Patent Term Extension
QIV	Quadrivalent influenza vaccine
R&D	Research and development
ROA	Return on assets
SA	*Société anonyme* (French public limited corporation)
SEC	US Securities and Exchange Commission
SPC	Supplementary Protection Certificate
TRIBIO	Sanofi Committee for Biological Risk Prevention (Biosafety, Biosecurity, Biosurveillance)
TSR	Total shareholder return
UNICEF	United Nations Children's Emergency Fund
US	United States of America
WHO	World Health Organization

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KEY FIGURES

sanofi

1994

FOUNDED

GLOBAL HEALTHCARE

LEADER

90
COUNTRIES
WHERE WE OPERATE

MARKET CAP
No. 5
IN THE CAC 40, DECEMBER 31, 2022

180
COUNTRIES WHERE WE DISTRIBUTE

≈ 91,000
EMPLOYEES

€31.7bn
GROSS PROFIT

€10.3bn
BUSINESS NET INCOME

€43.0bn
NET SALES

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

N/A

B. Capitalization and indebtedness

N/A

C. Reasons for offer and use of proceeds

N/A

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 and elsewhere in this document 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

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

Product liability is a significant risk for any pharmaceutical company, given that liability claims relating to our industry are unforeseeable by nature. The evolving regulatory environment worldwide (the ever-more stringent regulatory requirements applicable to the pharmaceutical industry, plus more stringent data, quality and supply obligations) clearly impacts our potential liability, and we may incur different liability claims to what we have handled in the past, with regard to their nature, scope and level. Substantial damages have been awarded by some jurisdictions 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 lead to product recalls, withdrawals, or declining sales, and/or be accompanied by consumer fraud claims by customers, third-party payers seeking reimbursement of the cost of the product and/or other claims, including potential civil or criminal governmental actions.

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) notably with respect to Taxotere®, Zantac® and Depakine® and there can be no assurance that we will be successful in defending these claims, or that we will not face additional claims in the future.

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 data and clinical trials provide additional information – for example, potential evidence of rare, population-specific or long-term adverse events or of drug interactions that were not observed in preapproval clinical studies. This causes product labeling to evolve over time following interactions with regulatory authorities, which may include 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 (see Note D.22.a.) to the consolidated financial statements included at Item 18. of this annual report).

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" below).

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 financial risk associated with product liability in 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 damage awards 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 due to market-driven insurance limitations and exclusions. 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 our defense, are costly, divert management's attention, may harm our reputation, and can impact the demand for our products and generate speculative news flows and/or rumors relating to such claims. Substantial product liability claims could materially adversely affect our business, results of operations and financial condition, and/or may have an impact on market perception of our company and negatively affect our stock price.

Claims and investigations relating to ethics and business integrity, competition law, marketing practices, pricing, human rights of workers, data protection and other legal matters could adversely affect our business, results of operations and financial condition

Our industry is heavily regulated and legal requirements vary from country to country, and new requirements are imposed on our industry from time to time. 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 ethical requirements with respect to medical and scientific research, interactions with healthcare professionals and payers, respect of the human rights of workers, and data protection legislation. We also operate in an environment that relies on the collection, processing, analysis and interpretation of large sets of patients' and other individuals' personal information, and the operation of our business requires data to flow freely across borders of numerous countries.

We have adopted a Code of Conduct 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 officers, employees, agents, intermediaries and other third parties comply with applicable laws and regulations (including but not limited to the U.S. Foreign Corrupt Practices Act (FCPA), the UK Bribery Act, the OECD Anti-Bribery Convention, the French Anti-Corruption measures law ("Sapin II"), the French duty of vigilance law and other anti-bribery laws and regulations).

Notwithstanding these efforts, failure to comply with laws and regulations (including as a result of a business partner's breach) may occur and could result in liabilities for us and/or our management.

With respect to data protection, legislation such as the General Data Protection Regulation (GDPR) in Europe, the Personal Information Protection Law (PIPL) enacted in 2021 in China, or other significant privacy legislation, including in the United States the California Consumer Privacy Act (CCPA), and case law bring legal uncertainty regarding cross border data flows. Such uncertainty could result in an operational risk limiting or preventing the transfer of data across borders, which may have an impact on our activities (e.g. on clinical trials). The breach of these regulations could also carry financial sanctions and may also harm our reputation and those of our activities that rely on personal data processing. In addition, some uncertainty remains with respect to the legal and regulatory environment for these evolving privacy and data protection laws in the absence of clear guidance.

Sanofi and certain of its subsidiaries could become the subject of investigations or proceedings by various government entities or could face audits and/or litigation, including allegations of corruption, claims related to employment matters, patent and intellectual property disputes, consumer law claims and tax audits. We are currently defending ourselves in a number of lawsuits relating to pricing and marketing practices (including, for example, "whistleblower" litigation in the United States). With respect to tax issues, the complexity of the fiscal environment is such that the ultimate resolution of any tax matter may result in payments that are greater or less than the amounts we have accrued. 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. In addition, responding to such investigations is costly and may divert management's attention from our business.

Unfavorable outcomes in any of these matters, or in similar matters that may arise in the future, could preclude the commercialization of our products, harm our reputation, negatively affect the profitability of existing products and subject us to substantial fines, 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 which could have a material adverse effect on our business, results of operations or financial condition.

The unpredictability of these proceedings could lead Sanofi, after consideration of all relevant factors, to enter into settlement agreements to settle certain claims. Such settlements may involve significant monetary payments and/or potential criminal penalties, and may include admissions of wrongdoing and may require entering into a Corporate Integrity Agreement ("CIA") or a Deferred Prosecution Agreement (in the United States), which is intended to regulate company behavior for a specified number of years. For example, on February 28, 2020, Sanofi US entered into a civil settlement with the United States Department of Justice and agreed to pay approximately $11.85 million to resolve allegations regarding certain charitable donations Sanofi US made to an independent patient assistance foundation that assisted patients being treated for Multiple Sclerosis. In connection with this settlement, Sanofi US also entered into a CIA with the Office of the Inspector General for the United States Department of Health and Human Services effective the same day, which will require us to meet and maintain certain compliance requirements in the United States.

Our activities (including our products and manufacturing activities) are subject to significant government regulations and regulatory approvals, which are often costly and could result in adverse consequences to our business if we fail to anticipate the regulations, comply with them, maintain the required approvals, and/or adapt to changes in applicable regulations

Obtaining a marketing authorization for a product is a long and highly regulated process requiring us to present extensive documentation and data to the relevant regulatory authorities 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. Each regulatory authority may also delay or refuse to grant approval even though a product has already been approved in another country. Regulatory authorities are increasingly strengthening their requirements on product safety and risk/benefit profiles. All of these requirements, including post-marketing requirements, have increased the costs associated with maintaining marketing authorizations.

Moreover, to monitor our compliance with applicable regulations, the FDA, EMA, WHO and comparable national agencies in other jurisdictions routinely conduct regulatory inspections of our facilities, distribution centers, commercial activities and development centers (including hospitals), and may identify potential deficiencies. For example, in November 2020, the FDA issued a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) for sutimlimab, an investigational monoclonal antibody being studied for the treatment of hemolysis in adults with cold agglutinin disease, referring to certain deficiencies identified by the agency during a pre-license inspection of a third-party facility responsible for manufacturing. More generally, if we fail to adequately respond to regulatory inspection observations identified during 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 (such as a Warning Letter, injunction, seizure or cease and desist order), the EMA or other regulatory authorities. In addition, we have an obligation to monitor and report adverse events and safety signals. In order to comply with these duties, we must regularly train our employees and certain third parties (such as external sales forces and distributor employees) on regulatory matters, including on pharmacovigilance. If we fail to train these people, or fail to train them appropriately, or if 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.

Due to geopolitical constraints, we may face delays in our clinical trials due to restrictions imposed on clinical trial sites, and/or delays in the initiation and enrollment of patients in our clinical trials, and/or disruptions related to regulatory approvals and/or delays in label expansions for existing products. We may not be able to fully mitigate these delays, which could negatively impact the timing of our pipeline development programs and may have a negative impact on our product development and launches and hence on future product sales, business and results of operations.

In addition, all aspects of our business, including research and development, manufacturing, marketing, reimbursement, pricing and sales, are subject to extensive legislation and governmental regulation. Changes in applicable laws and the costs of compliance with such laws and regulations could have an adverse effect on our business.

For example, in response to the European Union regulations for Medical Devices (EU MDR), which entered into force in May 2021, Sanofi created the EU MDR task force. This task force was commissioned to address the risk of potential delays in approvals (for new drug-device combination products, for substantial changes to the design or intended purpose of the device component of already approved drug-device combination products, and for medical devices) and of product discontinuation (for some legacy medical devices), as well as compliance risks for existing products due to increased requirements for post-marketing surveillance, clinical evaluations, traceability and transparency. A similar task force was set up in the first quarter of 2021 to examine risks related to the new regulations for In-Vitro Diagnostic Devices (IVDR) implemented in May 2022.

For information about risks related to changes:

- in proprietary rights rules and regulations, see "– We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products. If such patents and other rights were limited, invalidated or circumvented, our financial results could be adversely affected" below; and
- in environmental rules and regulations, see "– Management of the historical contamination related to our past industrial activities could adversely impact our results of operations and reputation" below.

In addition, changes in tax laws or regulations or their interpretation or exposures to additional tax liabilities around the world could negatively impact our operating results. Changes to tax laws or regulations may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

Furthermore, most of the jurisdictions in which we operate have double tax treaties with other foreign jurisdictions, which provide a framework for mitigating the impact of double taxation on our revenues and capital gains. However, the outcome of those mechanisms developed to resolve such conflicting claims can be uncertain and can be expected to be very lengthy. Accruals for tax contingencies are made based on experience, interpretations of tax law, and judgments about potential actions by tax authorities. However, due to the complexity of tax contingencies, the ultimate resolution of any tax matter may result in payments materially different from the amounts accrued.

In addition, the Organization for Economic Co-operation and Development (OECD) launched a new initiative to work toward a global tax framework that ensures inter alia a reallocation of taxing rights to market jurisdictions and also introduces a global standard on minimum taxation combined with new tax dispute resolution processes. We expect there to be a continued focus on tax reform, driven by initiatives by the OECD, as well as the European Union and several jurisdictions where we operate, to address the aforementioned tax challenges, which may result in significant changes to established tax principles and an increase in tax authority disputes. These may be costly, divert management attention and adversely impact our reputation and relationship with key stakeholders.

We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products. If such patents and other rights were limited, invalidated or circumvented, our financial results could be 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. Furthermore, patents and other proprietary rights do not always provide effective protection for our products. We cannot be certain that we will obtain adequate patent protection for new products and technologies in important markets or that such protections, once granted, will last as long as originally anticipated.

For example, governmental authorities are increasingly looking to facilitate generic and biosimilar competition for existing products through new regulatory proposals intended to achieve, or resulting in, changes to the scope of patent or data exclusivity rights and through the 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.

Moreover, 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 our patents. 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. Moreover, 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 2009, in Australia, our patent on clopidogrel was ultimately held invalid. Following this decision, the Australian Government sought 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. The Australian Government's claim was dismissed following a decision of the Federal Court of Australia on April 28, 2020. Sanofi is awaiting the judgment to be delivered by the Federal Court of Australia, following the appeal of the first instance decision by the Australian Government on May 26, 2020.

We also rely on unpatented proprietary technology, know-how, trade secrets and other confidential information, which we seek to protect through various measures, including confidentiality agreements with licensees, employees, third-party collaborators, and consultants who may have access to such information. If these agreements are breached or our other protective measures should fail, then our contractual or other remedies may not be adequate to cover our losses.

In certain cases, to terminate or avoid patent litigation we or our collaboration partners may be required to obtain licenses from the holders of third-party intellectual property rights. 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 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. If third parties obtain a preliminary or permanent injunction or if we fail to obtain a required license for a country where 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.

In addition, the pursuit of valid business opportunities may require us to challenge intellectual property rights held by others that we believe were improperly granted, including through negotiation and litigation, and such challenges may not always be successful. Third parties may claim that our products infringe one or more patents owned or controlled by them. Claims of intellectual property infringement can be costly and time-consuming to resolve, may delay or prevent product launches, and may result in significant royalty payments or damages.

Furthermore, 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 small molecule therapeutics, because of the types of patents allowed by national patent offices. Further, our ability to successfully challenge third-party patent rights is dependent on the legal interpretation and case law of national courts. In addition, we expect to face increasing competition from biosimilars in the future. With the accelerated regulatory pathways provided in the United States 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. If a biosimilar version of one of our products were to be approved, it could reduce our sales and/or profitability of that product.

We currently hold trademark registrations and have trademark applications pending in many jurisdictions, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the trademark. As our products mature, our reliance on our trademarks and trade dress to differentiate us from our competitors increases and, as a result, our business could be adversely affected if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our rights.

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

Risks relating to our business

The pricing and reimbursement of our products is negatively affected by increasing cost containment pressures and decisions of governmental authorities and other third parties

The commercial success of our existing products and our product candidates depends in part on their pricing and reimbursement conditions. Our products are negatively affected by continued downward pricing pressure and scrutiny due, inter alia, to:

- stricter price and access controls imposed by governments and other payers around the world:
  - requirements for greater transparency around drug pricing and drug development costs,
  - widespread use of international reference pricing and therapeutic reference pricing, among other pricing methodologies and caps,
  - mandatory price cuts, renegotiations, industry payback and rebates,
  - delisting from reimbursement and restrictions on the label population,
  - access restrictions for high-priced innovative medicines,
  - prescribing guidelines and binding medicine utilization controls,
  - greater use of tendering and centralized procurement (national/regional/class-wide level),
  - cross-country cooperation in price negotiations, contracting or procurement, which is already occurring to some extent (for example the COVID-19 Vaccines Global Access (COVAX) initiative, the BeNeLuxA alliance in Europe, and the Pan American Health Organization (PAHO)),
  - shifting of the payment burden to US patients and access disruptions through co-pay accumulator and maximizer programs as well as alternative funding programs,
  - increased utilization management and restrictive formularies (including stepped therapy, strict prior authorization criteria, formulary exclusions) mainly by US insurers and pharmacy benefits managers (PBMs), and
  - discriminatory and non-transparent pricing and procurement policies (e.g. government procurement restrictions, import bans) in favor of domestic pharmaceutical companies;
- widespread use of health technology assessment (HTA) to inform coverage and reimbursement decisions:
  - more stringent evidence and value requirements (e.g. comparative effectiveness, patient preferences, real-word evidence, health economic modelling) by payers and HTA authorities, raising the bar for market entry,
  - unreasonable thresholds for cost-effectiveness, and
  - increasingly restrictive HTA decisions with significant variation across markets;
- increased generic and biosimilar competition, accelerating price erosion:
  - next-generation biosimilars coming to the market across major therapeutic areas,
  - potential savings from increased biosimilar use, expected to be a cumulative $285 billion globally through 2025 according to the IQVIA Institute, and
  - evolving regulatory landscapes to support interchangeability (e.g. in the US and EU) and pharmacy substitution (e.g. in the EU Nordic countries, Germany and France).

In the United States, which accounted for 42.5% of our net sales in 2022, the Inflation Reduction Act (IRA) was enacted in August 2022 with drug pricing provisions that became effective in 2022, and will become effective in 2025 and 2026. Key policies related to federal government price negotiations, inflation penalties and Medicare Part D benefit redesign are likely to have a negative impact on industry revenue growth and future innovation, though there remains significant uncertainty over the negotiation provision and the impact of Medicare reforms.

In addition, the continuing vertical integration and consolidation of the US health insurance market exposes the industry to greater pricing pressure. With the three largest pharmacy benefit manager group purchasing organizations (PBM GPOs) (i.e. Ascent, Emisar and Zinc) now covering over 85% of prescription drug claims, consolidation has led to increased utilization management and restrictive formularies, resulting in strong bargaining power to negotiate discounted prices, thereby adversely impacting our sales.

Other risks include the increasing focus on price transparency, persistent supply chain challenges due to high dependency on API imports and interest in "Buy American" procurement rules. If we had to source APIs from the US, where they are more expensive than in other countries, the current cost containments would not allow us to reflect the corresponding increase on our prices which would impact the margins on our products. Other risks also include continued growth of the federal 340B drug pricing program.

In China, we continue to face increasing local competition. Price pressure is likely to intensify across our portfolio as a growing number of our products are subject to national reimbursement drug list (NRDL) price negotiations and national volume-based procurement (VBP) tenders, with the lowest prices prevailing. Innovative oncology products, in particular, are experiencing additional access challenges, as seen with the exclusion of imported PD-1 inhibitors from the NRDL in the last two years, in favor of domestically developed treatments. Further expansion of the (VBP) policy to biologics and biosimilars also poses a growing threat to our key established products, with over 500 drugs targeted for inclusion by 2025.

In Europe, there are risks of tighter cost-containment policies exacerbated by the COVID-19 pandemic, rising inflation and volatile energy prices. Industry payback and mandatory rebates are expected to increase at unprecedented rates in 2023 in major EU markets, particularly in Germany and the UK.

At EU level, there continue to be growing concerns over the current direction of the European Commission's wide-ranging Pharmaceutical Strategy for Europe, and the related ongoing review of intellectual property protections and the Orphan Medicines Regulation. The policies under consideration could have a far-reaching impact on our Rare Diseases pipelines, and have the potential to jeopardize incentives for EU innovation and competitiveness. We will pursue our current efforts towards shaping and improving the EU pharmaceutical legislation, while creating the conditions of an EU biopharma innovation ecosystem, based on a vision combining pharmaceutical and industrial strategies.

In addition, significant uncertainty remains regarding the impact of the EU HTA Regulation by 2025. Sanofi created an internal EU HTA task force in early 2022 in order to engage with stakeholders with one voice and ensure preparedness for the new EU framework.

Furthermore, the EU joint procurement initiative aimed at combining the procurement actions of two or more contracting authorities, as used in the context of COVID-19 pandemic, may gain traction outside the health emergency context, in particular for high-cost medicines and vaccines. We therefore anticipate greater pricing pressure and potential risk of net price transparency. This could have an impact an impact on our Specialty Care portfolio, especially for oncology and rare diseases.

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 expiration and termination of regulatory data exclusivity, introduction of lower-priced generics, or competition from new products of competitors that are perceived as being superior or equivalent to our products. 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 2022, we spent €6,706 million on research and development, amounting to 15.6% of our net sales. Failure to invest in the right technology platforms, therapeutic areas, product classes, geographic markets and/or licensing opportunities could adversely impact the productivity of our pipeline.

We prioritize five potentially transformative therapies in areas of high unmet patient need: fitusiran and ALTUVIIIO™ (efanesoctocog alfa) for hemophilia; amlitelimab (atopic dermatitis); Beyfortus® (nirsevimab) for respiratory syncytial virus; and tolebrutinib (multiple sclerosis). We also announced our decision to discontinue our research efforts in diabetes and cardiovascular diseases and refocus our R&D strategy on oncology, immunology and inflammation, multiple sclerosis, neurology and rare diseases and rare blood disorders. In 2021, Sanofi acquired Translate Bio to accelerate the deployment of mRNA technology for the development of new vaccines, including for seasonal influenza, and beyond vaccines, therapeutics where there is a strong unmet medical need. However, mRNA technology is still in its early days and the ability of this technology to produce strong results and safety still remains to be fully asserted; we may also fail to improve our development productivity sufficiently to sustain our pipeline (see also "– We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments or divestments" below). Other new innovations under investigations, such as natural killer (NK) cells and conditionally activated biologics, raise similar uncertainties.

In addition, the competitive landscape includes a high level of uncertainty as numerous companies are working on or may be evaluating similar targets and a product considered as promising at the beginning of its development may become less attractive if a competitor addressing the same unmet need reaches the market earlier. There can be no assurance that any of our product candidates will be proven safe or effective (see "Item 4. Information on the Company — B. Business Overview — B.5. Global Research & Development"). Over these research and development cycles, usually spanning several years, there is a substantial risk at each stage of development – including pre-clinical activities and clinical trials – 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. For instance, in 2022 patient enrollment of Phase III tolebrutinib trials paused globally after a decision of the FDA regarding potential side effects. As another example, the global clinical development program of amcenestrant (breast cancer) was discontinued in August 2022 following the outcome of the prespecified interim analysis of a Phase III trial. More and more trials are designed with clinical endpoints of superiority; failure to achieve those endpoints could damage the product's outlook and our overall development 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 regulatory authorities for approval.

In addition, following (or in some cases contemporaneously with) the marketing authorization, the dossier is also submitted to governmental agencies and/or national or regional third-party payers (HTA bodies) for review. These HTA bodies evaluate evidence on the value of the new product, assess the medical need it serves, and provide recommendations on the corresponding reimbursement. Such analyses may require additional studies, including comparative studies, which may effectively delay marketing, change the population which the new product treats, and add costs to its development. Our continuous investments in research and development for future products and for the launches of newly registered molecules could therefore result in increased costs without a proportionate increase in revenues, which would negatively affect our operating results and profitability.

Lastly, there can be no assurance that all the products approved or launched will achieve commercial success.

In addition, even after a product reaches the market, certain developments following regulatory approval may decrease demand for our products. Clinical trials and post-marketing surveillance of certain marketed drugs have the potential to raise concerns among some prescribers and patients relating to the safety or efficacy of pharmaceutical products in general, which could negatively affect the sales of such products or lead to increased volatility in market reaction.

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

Our business depends heavily on the use of interdependent information technology systems, including internet-based systems and digital tools. 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 are therefore vulnerable to cybersecurity attacks and incidents and misuse or manipulation of any of these IT systems could result in exposure of confidential information or the modification of critical data.

We and our third-party service providers, suppliers, contract manufacturers, distributors or other contracting third parties use, to the best of our ability, secure information technology systems for the protection of data and threat detection. Like many companies, we may experience certain of the following events which pose a risk to the security and availability of these systems and networks, and the confidentiality, integrity, and availability of our sensitive data: breakdown, outages, service disruption or impairment, data loss or deterioration in the event of a system malfunction or increasing threat of data theft or corruption in the event of a cyber-attack, security breach, industrial espionage attacks, insider threat attacks, cybercrimes, including state-sponsored cybercrimes, malware, misplaced or lost data, programming or human errors or other similar events. Also, in the event of an attack, U.S. and European legislation related to the financing of terrorism imposes increasing restrictions on payments of ransom. As a result, our ability to recover the data might be limited. Therefore, our business continuity could be at risk if we are unable to recover data through back-ups and restorations.

Each of these events could negatively impact important processes, such as scientific research and clinical trials, the submission of outcomes to health authorities for marketing authorizations, the functioning of production processes and the supply chain, compliance with legal requirements, trade secrets, security strategies and other key activities, including Sanofi's employees' ability to communicate between themselves as well as with third parties (see also "– Product liability claims could adversely affect our business, results of operations and financial condition" above). This could result in material financial, legal, competitive, operational, business or reputational harm.

Although we maintain relevant insurance coverage, this insurance may not be sufficiently available in the future to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. For example, certain types of cyber-attacks could be considered as an Act of War subject to insurance exclusion.

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 with production constraints, including the need for specialized facilities, trained and certified employees, and highly specific raw materials. We must ensure that all manufacturing processes comply with (i) current Good Manufacturing Practices (cGMP), (ii) other applicable regulations issued by governmental health authorities around the world, as well as (iii) our own quality standards. 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 in line with quality standards or if they experience financial difficulties. For example, in 2021 Genzyme sold a manufacturing facility located in Allston Landing in the United States to a third party, which is in particular involved in the production of Cerezyme®. We now rely on that third party for certain manufacturing and testing operations pursuant to the terms and conditions of relevant contractual agreements with such third party. The manufacturing and testing operations performed on Genzyme's behalf at the Allston Landing facility are subject to the terms of a consent decree requiring ongoing compliance therewith, which was entered into between Genzyme and the US government in 2010. We now rely on the third party that acquired the Allston Landing site to perform manufacturing and testing services on our behalf and to ensure compliance with the terms and conditions of the aforementioned consent decree. We could be subject to product supply risk if the third party is unable to supply product to us and to regulatory action if the third party acquirer of the Allston Landing site fails to comply with applicable laws and regulations, including cGMP, when performing the relevant services.

Epidemics and other public health crises, such as the ongoing COVID-19 pandemic, expose us to risks of a slowdown or temporary suspension in the production of our APIs, raw materials, and some of our products. Any prolonged restrictive measures put in place in order to control an outbreak of contagious disease or other adverse public health development, in any of our principal production sites, may have a material and adverse effect on our manufacturing operations. 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 and "The extent to which the COVID-19 pandemic and related developments, including measures implemented in response thereto, may adversely impact our business, operations and financial performance remains uncertain" below).

Our business may require the transformation and adaptation of our plants in order to ensure the continuity of production of our products in sufficient quantities to satisfy demand. This may be necessary to meet the need for the production of new products, including biologics, or to ensure the scaling up production of products under development once approved. This need may also result from new regulatory requirements; for example, the fact that insulin is no longer regulated by the FDA as a drug but rather as a biologic requires significant transformation and adaptation of our insulin manufacturing plant in Frankfurt, with no guarantee that we will manage to complete that plan within the expected time. Furthermore, 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. In addition, specific storage and distribution conditions are required for many biological products (for example, cold storage is required for certain vaccines, insulin-based products and some hemophilia products). These production difficulties may also be encountered during testing, which is a mandatory requirement prior to drug products being released. For example, in early 2022, we encountered supply constraints of Kevzara® (sarilumab) due to an increase in the global demand for IL-6 receptor blockers and the tocilizumab shortage announced in mid-August 2021. We therefore needed to prioritize access for indicated patients with rheumatoid arthritis.

The complexity of our production processes, as well as standards required 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). In addition, some of our production sites, and some of our suppliers' and/or contractors' sites, are located in areas exposed to natural disasters such as floods, earthquakes and hurricanes. Such disasters could be exacerbated by climate change. In the event of a major disaster, we could experience severe destruction or interruption of our operations and production capacity at these sites.

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 and generally require dedicated facilities. 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 and prior approval by health authorities.

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 specific 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.

A substantial share of the revenue and income of Sanofi depends on the performance of certain flagship products

As part of the presentation of our strategy in December 2019 we announced our intent to prioritize our activities on growth drivers including Dupixent® and our Vaccines operations, which we have identified as key growth drivers. Nevertheless market expansion and new launches of medicines and vaccines may not deliver the expected benefits. We may also encounter failures or delays in our launch strategy (in terms of timing, pricing, market access, marketing efforts and dedicated sales forces), such that our products that may not deliver the expected benefits. 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 or hamper the launch or expansion of some of our products.

Also, we currently generate a substantial share of our net sales from certain key products (see "Item 5. Operating and Financial Review and Prospects — A.2. Results of Operations — Year ended December 31, 2022 compared with year ended December 31, 2021 — A.2.1.3/Net Sales — Pharmaceuticals segment"). For example, Dupixent® generated net sales of €8,293 million in 2022 representing 19.3% of our net sales for the year and is Sanofi's biggest product in terms of sales.

Among our flagship products, Lantus®, Lovenox® and Plavix® already face generic competition on the market. Lantus® is particularly important; it was one of Sanofi's leading products in 2022 with net sales of €2,259 million. Aubagio®, another leading product, is expected to face generic competition in the U.S. starting from March 2023, following a settlement agreement entered into in 2017. In Europe, Aubagio® generic competition is expected in the fourth quarter of 2023. Jevtana® has faced generic competition since the end of March 2021 in Europe.

More generally, an expiration of effective intellectual property protections for our products typically results in the market entry of one or more lower-priced generic competitors, often leading to a rapid and significant decline in revenues on those products (for information regarding ongoing patent litigation see Note D.22.b.) to the consolidated financial statements included at Item 18. of this annual report).

The introduction of a generic product results in adverse price and volume effects for our branded or genericized products. For example, although 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 2022 and 2021 for the main products affected by generic and biosimilar competition shows a loss of €325 million of net sales on a reported basis (see "Item 5. Operating and Financial Review and Prospects — A.1.2. Impacts of Competition from Generics and Biosimilars"). However, other parameters may have contributed to the loss of sales, such as a fall in the average price of certain products (e.g. Lantus®).

Furthermore, in general, if one or more of our flagship products were to encounter problems (such as material product liability litigation, unexpected side effects, product recalls, non-approval by the health authorities of a new indication for a marketed product, pricing pressure and manufacturing or supply issues), the adverse impact on our business, results of operations and financial condition could be significant.

We rely on third parties for the discovery, manufacture, marketing and distribution 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 for the development and commercialization of Dupixent®, Kevzara® (sarilumab) and SAR440340 (REGN3500- itepekimab) (see "Item 5. Financial Presentation of Alliances — A.1.7.1/ Alliance Arrangements with Regeneron Pharmaceuticals Inc"). We rely upon Regeneron to successfully carry out their responsibilities with regard to the manufacture and supply of these collaboration antibodies. (see "Item 4. Information on the Company — B. Business Overview"). Finally, we may also rely on partners to design and manufacture medical devices, notably for the administration of our products.

As regards products recently launched or under development for which we have a collaboration agreement with partners, the terms of the applicable alliance agreement 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.

We could also be subject to the risk that we may not properly manage the decision-making process with our partners. Decisions may be controlled by, 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 our collaboration partners are responsible for the performance of certain key tasks or functions, for example related to manufacturing. Any such failures in the development process or differing priorities may adversely affect our business, including the activities conducted through our collaboration arrangements. We also cannot guarantee that third-party manufacturers will be able to meet our near-term or long-term manufacturing requirements. For instance, following the completion of the spin-off of EUROAPI in May 2022, EUROAPI became a third-party manufacturer and will continue to manufacture a certain number of APIs for Sanofi. We are also subject to the risk that contract research organizations or other vendors (for instance regarding digital activities) retained by us or our collaboration partners may not perform effectively.

Any conflicts or difficulties 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, manufacturing, launch and/or 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.

We are subject to the risk of non-payment by our customers[1]

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 and retailers, as well as by uncertainties around global credit and economic conditions, in particular in emerging markets. As a result, we may be affected by fluctuations in the buying patterns of such customers. The United States poses particular customer credit risk issues because of the concentrated distribution system: our three main customers represented respectively 12%, 8% and 7% of our consolidated net sales in 2022. 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 could 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.

Global economic conditions and an unfavorable financial environment could have negative consequences for our business[2]

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. For example, unpredictable political conditions that currently exist in various parts of the world could have a material negative impact on our business. In particular, armed conflict between Russia and Ukraine escalated in 2022. The degree of impact of the war between Russia and Ukraine is difficult to predict and will depend on developments outside Sanofi's control, including, but not limited to the duration and severity of the conflict, and the consequences of the ongoing and additional financial and economic sanctions imposed by governments in response. Other related issues have arisen or are arising such as regional instability; geopolitical uncertainties; adverse effects on fuel and energy costs, supply chains, macroeconomic conditions, inflation, and currency exchange rates in various regions of the world; and exposure of third parties to gas shortages. Collectively, such unstable conditions could, among other things, disturb the international flow of goods and increase the costs and difficulties associated with international transactions.

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 among others (see "— The pricing and reimbursement of our products is negatively affected by increasing cost containment pressures and decisions of governments and other third parties" above).

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 has been a significant increase in the number of beneficiaries 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, employers may seek to transfer a greater portion of healthcare costs to their employees due to rising costs, which could lead to further downward price pressure and/or lower demand.

Our Consumer Healthcare business could also be adversely impacted by difficult economic conditions, as the financial resources of our customers may be reduced as a result of the economic situation.

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, our financial situation, the profitability and results of our operations and the distribution channels of our products may be adversely affected. See also "— We are subject to the risk of non-payment by our customers" above.

The extent to which the COVID-19 pandemic and related developments, including measures implemented in response thereto, may adversely impact our business, operations and financial performance remains uncertain

We are unable to predict the impact on our business, operations and financial results that the COVID-19 pandemic would have if it continued or resumed with force, including insofar it could lead to lower sales and reduced patient demand and usage of certain of our products.

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[1] The information in this section supplements the disclosures required under IFRS 7 as presented in Notes B.8.7., D.10. and D.34. to our consolidated financial statements, provided at Item 18. of this annual report.

[2] The information in this section supplements the disclosures required under IFRS 7 as presented in Note B.8.7. to our consolidated financial statements, provided at Item 18. of this annual report.

While economies around the world tend to reopen their economies, the degree to which COVID-19 adversely impacts our results in the future is outside the Company's knowledge or control and will depend on the evolution of the outbreak, its mutation, its severity, the actions taken by government authorities to contain the virus or mitigate its impact, and how quickly and to what extent normal economic and operating conditions can resume. Any resurgence in COVID-19 infections or emergence of new epidemics could result in the imposition of new constraints and prolonged restrictive measures implemented in order to control the spread of the disease.

In an increasingly budget-constrained healthcare environment as economic disruption have continued due to the pandemic, we expect to see a higher pressure on drug prices worldwide and, in the longer term, a reallocation of funding across therapeutic areas, driven in particular by evolving public health priorities, which could negatively impact our business operations (see "— The pricing and reimbursement of our products is negatively affected by increasing cost containment pressures and decisions of governmental authorities and other third parties" above). For example, the pandemic may reduce our sales in targeted markets due to lower healthcare spending on other diseases and fewer promotional activities.

The global COVID-19 pandemic has also exposed us to a disruption or temporary suspension in production of APIs, raw materials and some of other products. A revival of the COVID-19 pandemic or any other pandemic could expose us to a revival of this risk. Extension of the restrictive measures put in place in order to control the pandemic may lead to manufacturing delays or disruptions and supply chain interruptions (including to the extent those measures apply to our third-party suppliers) and may have an adverse effect on our business (see "— 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). Also, a sudden increase in demand for selected medicinal products can result in short-term unavailability or shortages of raw materials.

Finally, we cannot predict or reasonably estimate the impact of any potential long-term changes to the healthcare and pharmaceutical industries from the COVID-19 pandemic.

The increasing use of social media platforms and new technologies present risks and challenges for our business and reputation

We increasingly rely on social media, new technologies and digital tools to communicate about our products and about diseases or to provide health services. The use of these media requires specific attention, monitoring programs and moderation of comments. Political and market pressures may be generated by social media because of rapid news cycles. 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 image and reputation and 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. Such uses of social media and mobile technologies could have an adverse effect on our reputation, business, financial condition and results of operations.

Risks relating to Sanofi's structure and strategy

We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments or divestments

We pursue a strategy of selective acquisitions, in-licensing and collaborations in order to reinforce our pipeline and portfolio. We are also proceeding to selective divestments to focus on key business areas. The implementation of this strategy depends on our ability to identify transaction opportunities, mobilize the appropriate resources in order to enter into agreements in a timely manner, and execute these transactions on acceptable economic 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, marketing and distribution of some of our products" above). Once a strategic transaction is agreed upon with a third party, we may not be able to complete the transaction in a timely manner or at all.

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

- we are unable to quickly or efficiently integrate those activities or businesses;
- key employees leave; or
- we have higher than anticipated integration costs.

For instance, in 2019 we had to book a €2.8 billion impairment on Eloctate®, acquired through the Bioverativ acquisition completed in 2018, due to revisions of previous sales projections. As another example, the Translate Bio acquisition referred to above which was completed in 2021 may not generate the expected results in terms of developing new mRNA-based products to meet existing or future needs, and the potential of Translate Bio's mRNA platform may not be realized to its full extent or because of the difficulty of integrating the activity quickly and efficiently into the Group.

We may also miscalculate the risks associated with business development transactions at the time they are made or may lack the resources or ability to access all the relevant information to evaluate such risks properly, including with regard to the potential of research and development pipelines, manufacturing issues, tax or accounting 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. Acquired businesses may not always be in full compliance with legal, regulatory or Sanofi standards, including, for example, current Good Manufacturing Practices (cGMP), which can be costly and time consuming to remedy. As a result, risk management and coverage of such risks, particularly through insurance policies, may prove to be insufficient or ill-adapted.

With respect to divestments, their financial benefit could be impacted if we face significant financial claims or significant post-closing price adjustments. Furthermore, the value of the assets to be divested may deteriorate while we are in the process of executing our divestment strategy, with the risk that we do not realize the anticipated benefits.

Because of the active competition among pharmaceutical groups for 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

As part of the presentation of our strategy in December 2019, we identified our strong presence in China among our core drivers, with revenue amounting to 7.3% of our net sales in 2022.

Nevertheless, the difficulties in operating in emerging markets, a significant decline in the anticipated growth rate or an unfavorable movement of the exchange rates of currencies against the euro could impair our ability to take advantage of growth opportunities and could adversely affect our business, results of operations or financial condition. For instance, while it continues to be impossible as of the date of this report to predict the economic impact and the magnitude of the ongoing COVID-19 pandemic, if a long-lasting epidemic and prolonged or repeated restrictive measures to control the outbreak were to result in an economic slowdown in any of our targeted markets, it would reduce our sales due to lower healthcare spending on other diseases and fewer promotional activities, and could significantly impact our business operations. Furthermore, it is not possible to predict if or how the current health crisis will impact any particular affected jurisdiction, or to what extent (see also "— Global economic conditions and an unfavorable financial environment could have negative consequences for our business" and "The extent to which the COVID-19 pandemic and related developmental authorities, including measures implemented in response thereto, may impact our business, operations and financial performance remains uncertain" above).

Emerging markets also expose us to more volatile economic conditions, political instability (including a backlash in certain areas against free trade), 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), and compliance issues including corruption and fraud (see particularly "— Claims and investigations relating to ethics and business integrity, competition law, marketing practices, pricing, human rights of workers, data protection and other legal matters could adversely affect our business, results of operations and financial condition" above).

We may fail to develop or take advantage of digitalization and prioritizing data as an organizational asset

We have undertaken a number of digital initiatives. Examples include the opening in March 2022 of our Accelerator, an internal unit that functions like a startup within Sanofi to develop products and solutions that will support our mission to transform the practice of medicine with the use of digital, data and artificial intelligence; the Future4Care initiative of June 2021, where we joined a startup incubator along with other CAC40 companies to help nurture the latest and greatest in health tech; our enabled manufacturing facility in the US; and our Darwin real-world data platform. Our success in these efforts will depend on many factors including data quality; technology architecture; entering into successful partnerships and alliances with technology companies; a profound transformation of the organization, including a cultural change among our employees and the development of relevant skills; attracting and retaining employees with appropriate skills and mindsets in a tight labor market; and successfully innovating across a variety of technology fields. The COVID-19 pandemic has accelerated our digital transformation, including in the ways we engage and interact with our stakeholders. However, there is no guarantee that our efforts toward a digital transformation will succeed. More generally, we may fail to capture the benefits of digitalization and valuing data as an enterprise asset at an appropriate cost and/or in a timely manner, and/or enter into appropriate partnerships. Competitors, including new entrants such as tech companies, may outpace us in this fast-moving area. If we fail to adequately integrate digital capabilities into our organization and business model, we could lose patients and market share. This could have an adverse impact on our business, prospects and results of operations.

The success of digital initiatives will also depend on our ability to shift our culture to a data-driven culture. This calls for clear ownership and a collectively-owned operating model with supporting tools and competencies to manage data as an asset, and for the definition of a robust life-cycle management process for data that is applied consistently across Sanofi. Good overall management of data supports our overall operations and the delivery of exponential capabilities, including artificial intelligence and machine learning to fulfil our innovation and efficiency ambitions. Failure to do so could result in business, operational and financial harm.

We may fail to accelerate our operational efficiency

As part of our strategy, we announced our intent to improve our operating efficiencies to fund growth and expand our business operating income margin. Nevertheless, there is no guarantee that we will be able to fully deliver these operating efficiencies within the targeted timeline or generate the expected benefits.

Unsuccessful management of environmental, social and governance matters could adversely affect our reputation and we may experience difficulties to meet the expectations of our stakeholders

Companies are increasingly expected to behave in a responsible manner on a variety of environmental, social and governance (ESG) matters, by governmental and regulatory authorities, counterparties such as vendors and suppliers, customers, investors, the public at large and others. This context, driven in part by a rapidly changing regulatory framework in the US and in Europe, is raising new challenges and influencing strategic decisions that companies must take if they wish to optimize their positive impact and mitigate their negative impact on ESG matters.

We have adopted an ESG strategy that aims at ensuring global access and affordability, addressing unmet needs with transformative therapies, and minimizing the impact of our activities and products on the climate and the environment. The strategy includes leveraging our personnel's experience and making societal impact a key driver of our employees' engagement. However, despite our strong commitment we could be unable to meet our ESG or other strategic objectives in an efficient and timely manner, or at all.

We may also be unable to meet the ever more demanding criteria used by rating agencies in their ESG assessments process, leading to a downgrading in our rating. Financial investments in companies which perform well in ESG assessments are increasingly popular, and major institutional investors have made known their interest in investing in such companies. Depending on ESG assessments and on the rapidly changing views on acceptable levels of action across a range of ESG topics from investors, we may be unable to meet society's or investors' expectations, our reputation may be harmed, we may face increased compliance or other costs and demand for securities issued by us and our ability to participate in the debt and equity markets may decrease.

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

Our success depends on the expertise of our senior management team and other key employees. In 2022, there were 2,361 "Senior Leaders" within Sanofi. 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, or digital and artificial intelligence. Our ability to hire qualified personnel also depends in part on our ability to reward performance, incentivize our employees and pay competitive compensation. Laws and regulations on executive compensation may restrict our ability to attract, motivate and retain the required level of talented people. 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 and safety risks of our industrial activities

Risks from manufacturing activities and the handling of hazardous materials could adversely affect our results of operations and reputation

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 risks of industrial accidents that may lead to discharges or releases of toxic or pathogenic substances or other events that can cause personal injury, property damage and environmental contamination, and may result in additional operational constraints, including the shutdown of affected facilities and/or the imposition of civil, administrative, criminal penalties and/or civil damages, and affect Sanofi's reputation.

The occurrence of an industrial accident may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results and reputation. Although we maintain property damage, 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.

Management of the historical contamination related to our past industrial activities could adversely impact our results of operations and reputation

The environmental laws of various jurisdictions impose actual and potential obligations on our Company to manage and/or 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 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" 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 an adverse effect on our results of operations and 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 and Notes B.12. and D.19.3. to the consolidated financial statements".

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 or obligations in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligations, 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 or operated by the Company. An adverse outcome in such disputes might have an 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 the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation; the Classification and Labelling regulations applicable to hazardous chemicals; directives related to the control of major-accident hazards (the "Seveso" directives); the Industrial Emission regulations; the Waste Framework Directive; the Emission Trading Scheme Directive; the Water Framework Directive; the Directive on Taxation of Energy Products and Electricity; as well as other regulations aimed at preventing climate change. 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 capital expenditures as well as other costs and liabilities, thereby adversely affecting our business, results of operations or financial condition.

Risks related to financial markets[(3)]

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 U.S. dollar, the Japanese yen, the Chinese yuan, and currencies in emerging markets. In 2022, 42.5% of our net sales were generated in the United States, 23.3% in Europe, and 34.2% in the Rest of the World region (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 (including 7.3% in China and 3.8% 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".

[(3)] *The information in this section supplements the disclosures required under IFRS 7 as presented in Note B.8.7. to our consolidated financial statements, provided at Item 18. of this annual report.*

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) regardless of our operating performance

Holders of ADSs face exchange rate risks. Our ADSs trade in US dollars and our shares trade in euros. The value of the ADSs and our shares could fluctuate substantially 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 NASDAQ Global Select Market (NASDAQ) 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 pro rata portion of the new issuance, the depositary is allowed, at its own discretion, to sell this right to subscribe for new shares for the benefit of the ADS holders instead of making that right available to such holders. In that case, ADS holders could be substantially diluted. Holders of ADSs must also instruct the depositary how to vote their shares. Because of this additional 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. US investors may have difficulty in serving process or enforcing a judgment against us or our directors or executive officers.

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.

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

As of December 31, 2022, L'Oréal held approximately 9.38% of our issued share capital, accounting for approximately 16.77% 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.

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.

Sanofi has three principal activities: Pharmaceuticals, Consumer Healthcare, and Vaccines. These activities are operating segments within the meaning of the IFRS 8 accounting standard (see Note D.35. to our consolidated financial statements, included at Item 18. of this annual report).

Our activities comprise: Dupixent®; Neurology & Immunology; Rare Diseases; Oncology; Rare Blood Disorders; General Medicines Core products and General Medicines Non-Core products; Consumer Healthcare; and Vaccines. Unlike our Vaccines and Consumer Healthcare activities, which are also operating segments within the meaning of IFRS 8, our Pharmaceuticals 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.

For a presentation of the net sales of our activities for the year ended December 31, 2022, refer to "Item 5.A.2. — Results of Operations — Year Ended December 31, 2022 Compared with Year Ended December 31, 2021".

In 2022, healthcare authorities issued a number of marketing approvals for Sanofi products. In the United States and Europe, *Dupixent®* (dupilumab) obtained full authorization for the treatment of eosinophilic esophagitis, and extensions to expand the severe asthma indication to children aged 6 to 11 years and the moderate-to-severe atopic dermatitis indication to children aged 6 months to 5 years. At the end of September 2022, the US Food and Drug Administration (FDA) approved Dupixent® as the first and only treatment indicated to treat prurigo nodularis for adult patients in the United States, and on December 15, 2022, Dupixent® became the first and only targeted medicine approved by the European Commission (EC) to treat prurigo nodularis.

The FDA also approved *Xenpozyme®* (olipudase alfa-rpcp) for the treatment of non-central nervous system (non-CNS) manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

The EC granted marketing authorization for *Enjaymo®* (sutimlimab) for the treatment of hemolytic anemia in adult patients with cold agglutinin disease (CAD). CAD is a rare, serious and chronic autoimmune hemolytic anemia, in which the body's immune system mistakenly attacks healthy red blood cells and causes their rupture, known as hemolysis.

In Vaccines, the EC approved *Beyfortus®* (nirsevimab) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in newborns and infants during their first RSV season. Beyfortus® is the first and only single-dose passive immunization for the broad infant population; it is being developed jointly by Sanofi and AstraZeneca. The EC also approved *VidPrevtyn®* Beta as a booster for the prevention of COVID-19 in adults aged 18 years and older. Designed to provide broad protection against multiple variants, this protein-based vaccine is based on the Beta variant antigen and includes GSK's pandemic adjuvant. VidPrevtyn® Beta is indicated as a booster for active immunization against SARS-CoV-2 in adults who have previously received an mRNA or adenoviral COVID vaccine.

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 46, avenue de la Grande Armée – 75017 Paris – France, our main telephone number is +33 1 53 77 40 00, and our website (which contains information about the company and information filed with and provided to the SEC) is www.sanofi.com. Our principal US subsidiary's office is located at 55 Corporate Drive, Bridgewater, NJ 08807; telephone: +1 (908) 981 5000.

The SEC maintains an internet site at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Main events over the last three years

On January 23, 2020, following a tender offer, we acquired control of *Synthorx*, a US clinical-stage biotechnology company based in La Jolla, California, focused on prolonging and improving the lives of people suffering from cancer and autoimmune disorders.

On September 28, 2020, we completed the acquisition of *Principia Biopharma Inc.*, a late-stage biopharmaceutical company focused on developing treatments for autoimmune diseases.

On April 8, 2021, Sanofi acquired the entire share capital of *Kymab*, a clinical-stage biopharmaceutical company developing fully human monoclonal antibodies with a focus on immune-mediated diseases and immuno-oncology therapeutics.

On September 14, 2021, Sanofi finalized the acquisition of *Translate Bio*, a clinical-stage mRNA therapeutics company.

On November 9, 2021, Sanofi completed the acquisition of *Kadmon Holdings, Inc*. a biopharmaceutical company that discovers, develops, and markets transformative therapies for disease areas of significant unmet medical need.

On February 8, 2022, Sanofi acquired the entire share capital of the immuno-oncology company *Amunix Pharmaceuticals, Inc.* (Amunix), thereby gaining access to Amunix's innovative Pro-XTEN™ technology and a promising pipeline of immunotherapies.

On May 3, 2022, Sanofi's General Meeting of Shareholders approved the decision to distribute approximately 58% of the share capital of *EUROAPI*, a European leader in the development, manufacture, marketing and distribution of Active Pharmaceutical Ingredients (APIs), in the form of an exceptional dividend in kind to Sanofi shareholders. On the dividend payment date of May 10, 2022 (further to the admission of EUROAPI shares to listing on the regulated market of Euronext Paris on May 6, 2022), Sanofi divested control over EUROAPI and its subsidiaries, resulting in their deconsolidation from the Sanofi consolidated financial statements as of that date. On June 17, 2022 (the date of delivery of the EUROAPI shares to the French State via the French Tech Souveraineté fund), EPIC Bpifrance acquired a 12% equity interest in EUROAPI. Following completion of those transactions, Sanofi retains an equity interest of 30.1% in EUROAPI, which has been accounted for using the equity method since the date of loss of control (see note D.6. to the consolidated financial statements).

More detailed information about these changes is provided in Note D.1. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F.

B. Business overview

B.1. Strategy

The market context for Sanofi

A number of fundamental trends continue to point to a positive outlook for the pharmaceutical industry. The global population is growing, and aging, and unmet medical needs remain high. Since the beginning of the COVID-19 pandemic, health needs have further increased, strengthening the key roles of innovation in R&D activities and cutting-edge manufacturing. The industry has taken steps to increase R&D productivity, with the objective of launching a higher number of innovative medicines and vaccines. Patients around the world – including a rising middle class in emerging markets – are demanding better healthcare, empowered by access to more and more information. It is a particularly exciting time scientifically and technologically: the promise of genomics is being realized, immuno-oncology is transforming cancer treatments, and big data is generating new insights into how to diagnose and treat diseases. Digital technologies and advanced data analytics are having a transformative effect across sales and marketing activities, R&D and manufacturing, and are acting as enablers for new businesses.

At the same time, increased geopolitical uncertainties, the economic crisis linked to the COVID-19 pandemic, inflation, supply shortages, and issues around budget tightening will continue to put pressure on healthcare costs, and on the entire healthcare value chain. Although we believe that pharmaceuticals and vaccines will remain a fundamentally attractive business within that value chain, the bar for innovation will most likely continue to rise. Payers will continue to put scrutiny on prices and reimbursement criteria, and demand demonstration of real-life outcomes to confirm the efficacy of medicines and vaccines. This will be coupled with more innovative pricing and contracting practices, and more transparent policies. In view of growing concerns over increasing healthcare costs across global markets, the pharmaceutical industry will be increasingly judged by its contribution to improved access for patients and to the development of innovative, highly cost-effective medicines.

Strategic framework

The Sanofi "Play to Win" strategy is organized around four key priorities: (1) focus on growth; (2) lead with innovation; (3) accelerate efficiency; and (4) reinvent how we work to drive innovation and growth.

1) Focus on growth

- Dupixent® (dupilumab)[1] – By leveraging the product's unique mechanism of action targeting the type 2 inflammation pathway and its favorable safety profile. Sanofi has raised the Dupixent® sales peak ambition to more than €13 billion [2].
- Vaccines – Our Vaccines business is expected to deliver mid-to-high single digit net sales growth[3] through differentiated products, market expansions and launches. Contributors to growth are expected to be pediatric combinations, boosters, influenza vaccines, meningitis and the launch of nirsevimab, a monoclonal antibody addressing Respiratory Syncytial Virus (RSV)[4]. Sanofi has progressed in the field of mRNA technology with the recently established Center of Excellence and the integration of Translate Bio. Of the 10 new vaccine candidates planned to enter the clinic by 2025, 6 will use mRNA technologies to target diseases with high unmet needs and disease burden such as chlamydia and acne. The long-term ambition is to more than double Vaccines sales by the end of the decade based on 2018 sales.
- Pipeline – We are focusing our investments on priority projects, including six potentially transformative therapies in oncology, immunology, hematology, neurology, and vaccines.

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[1] *In partnership with Regeneron.*
[2] *This new ambition does not include the potential for further potential sales of Dupixent® to treat chronic obstructive pulmonary disease (COPD), and upcoming indications.*
[3] *Cumulative Annual Growth Rate (CAGR), 2018-2025.*
[4] *In partnership with AstraZeneca.*

2) Lead with innovation

Sanofi has prioritized five potentially practice-changing assets in areas of high unmet patient need. These investigational therapies are listed below:

- Fitusiran is a small interference RNA therapeutic in development for the treatment of hemophilia A and B with or without inhibitors, with the potential to be a first-in-class therapeutic option.
- ALTUVIIIO™ (efanesoctocog alpha / antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl)[(5)] is a new recombinant factor VIII to prolong protection against bleeding on a once-weekly prophylactic dose in adults and children with hemophilia A. The weekly dose has the ability to maintain factor concentrations at normal or near-normal levels for virtually the entire week, and to provide longer-lasting protection. On February 22, 2023, the US Food and Drug Administration (FDA) approved ALTUVIIIO™.
- Amlitelimab, a non-depleting aOX40Ligand monoclonal antibody, has the potential to be a best-in-class treatment for a range of immune-mediated diseases and inflammatory disorders, including moderate-to-severe atopic dermatitis. By targeting OX40-Ligand, amlitelimab aims to restore immune homeostasis between pro-inflammatory and anti-inflammatory T cells.
- Beyfortus® (Nirsevimab) [(6)], a monoclonal antibody, is a potentially cost-effective prevention against respiratory syncytial virus (RSV), for all infants. Its high affinity to RSV could potentially allow a single injection to cover the entire RSV season. On November 4, 2022, the European Commission (EC) granted the first approval worldwide of Beyfortus® (nirsevimab) for the prevention of RSV disease in infants.
- Tolebrutinib is an oral selective, brain penetrant BTK inhibitor with the potential to be the first disease-modifier to address sources of multiple sclerosis damage in the brain.

To continue fueling our promising pipeline and enhance our position in our core therapeutic areas, we have:

i. established a strategic research collaboration and license agreement with Exscientia to develop up to 15 novel small-molecule candidates across oncology and immunology, leveraging Exscientia's end-to-end AI-driven platform utilizing actual patient samples;

ii. entered into a global collaboration and license agreement with ABL Bio, Inc. to advance ABL301 for the treatment of Parkinson's Disease;

iii. completed the acquisition of Amunix Pharmaceuticals, Inc, adding a promising pipeline of T-cell engagers and cytokine therapies;

iv. signed a strategic risk-sharing collaboration with Blackstone under which funds managed by Blackstone Life Sciences (BXLS) will contribute up to €300 million to accelerate global pivotal studies and the clinical development program for the subcutaneous formulation and delivery of the anti-CD38 antibody Sarclisa®, to treat patients with multiple myeloma (MM);

v. entered into an exclusive collaboration agreement with Seagen Inc. to design, develop, and commercialize antibody-drug conjugates (ADCs) for up to three cancer targets;

vi. signed an exclusive worldwide collaboration agreement with IGM Biosciences, Inc. to create, develop, manufacture, and commercialize IgM antibody agonists against three oncology targets and three immunology/inflammation targets;

vii. signed an exclusive worldwide collaboration agreement with Skyhawk Therapeutics, Inc to discover and develop novel small molecules that modulate RNA splicing for challenging oncology and immunology targets;

viii. announced a strategic collaboration with Scribe Therapeutics Inc. for the use of Scribe's CRISPR genome editing technologies to enable genetic modification of novel natural killer (NK) cell therapies for cancer. The agreement grants Sanofi non-exclusive rights to Scribe's proprietary CRISPR platform of wholly-owned enzymes to create ex vivo NK cell therapies;

ix. entered into a co-promotion service agreement with Provention Bio, Inc. for the commercialization of teplizumab in the United States. Teplizumab, developed by Provention, is an anti-CD3 monoclonal antibody approved by the FDA on November 17, 2022 for the delay of clinical type 1 diabetes (T1D) in at-risk individuals, as indicated by the presence of two or more T1D-related autoantibodies.

3) Accelerate efficiency

We aim to increase our business operating income (BOI) margin through efficiency initiatives, and by the end of 2022, we had achieved €2.7 billion of accumulated savings since 2019. We expect that these savings will fund investments in growth drivers, as well as support an increase in our BOI margin. In 2022, we achieved around €330 million of savings from (i) limiting spending on lower priority business lines, (ii) smart spending initiatives in procurement, and (iii) operational excellence in manufacturing and organizational productivity.

To better adapt our industrial capability to our evolving manufacturing needs, we announced in February 2020 a plan to create a leading European company, EUROAPI, dedicated to the development, production and marketing of active pharmaceutical ingredients (API) to third parties as well as to Sanofi. EUROAPI was listed on Euronext Paris in May 2022.

To embrace the transformative effect offered by digital technologies and advanced data analytics, we are investing to become the leading digital healthcare platform for employees, patients and providers. This will help us discover, test and deliver medicines faster, run our business more efficiently, and create engaging digital experiences. The digital transformation required to meet our ambition is under way. We are using advanced algorithms to harvest real world data to support our R&D efforts. We are also developing new go-to-market models by closer physician engagement through a variety of channels, building precision marketing, and providing better e-commerce capabilities. And in parallel, we are investigating the possibility of integrating drugs, devices, data and services, to bring innovative solutions to patients across many different disease areas such as diabetes and atopic dermatitis.

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(5) In partnership with Swedish Orphan Biovitrum (Sobi).
(6) In partnership with AstraZeneca.

4) Reinvent how we work

Transformation and simplification have started, with the aim of increasing empowerment and accountability. To drive implementation of our new culture built on stronger focus, diversity and teamwork, we have streamlined our executive leadership team from fifteen to ten members. One new member was appointed to the executive leadership team: Roy Papatheodorou as General Counsel and Head of Legal, Ethics & Business Integrity in February 2022 (succeeding Karen Linehan). The complete Sanofi Executive Committee now includes the four managers who head up our global business units (Specialty Care, Vaccines, General Medicines, and Consumer Healthcare) as well as the heads of each of the following support functions: Research and Development, Manufacturing & Supply (previously named Industrial Affairs), Finance, People & Culture, Digital and Legal, Ethics & Business Integrity.

The creation of our standalone Consumer Healthcare business unit has progressed in 2022. By year end, we have set up almost all of the legal entities relating to this standalone business, with integrated R&D and manufacturing functions plus dedicated support functions and information technology. We believe this is a unique opportunity to adapt our business model specifically to the needs of the Consumer Healthcare sector, helping us to gain in agility as well as to accelerate our digital transformation.

Sanofi's Corporate Social Responsibility (CSR) strategy aims to build a healthier, more resilient world by contributing access to healthcare for the world's poorest people and bringing focus to addressing broader unmet needs. We will continue the fight against infectious diseases such as sleeping sickness and poliomyelitis, while seeking to reduce the environmental impact of our products and of our worldwide operations. Key to tackling the global challenges that face society are our people, who each have a role to play in building a diverse and inclusive workplace.

Sanofi's CSR Strategy focuses on four building blocks aligned with our Play to Win core business strategy:

- affordable access – to ensure affordable global access to health, while helping healthcare systems to remain sustainable;
- R&D for unmet needs – to be at the cutting edge of R&D innovation, to help people live fully and drive growth;
- Planet Care – to minimize the environmental impact of our business through environmental sustainability; and
- in & beyond the workplace – to give all Sanofi colleagues the chance to become a leader of change, unlocking the potential of our diverse teams.

Capital allocation policy

We will continue to pursue our focused and disciplined capital allocation policy. Our priorities in deploying the cash generated from our three core GBUs and the standalone CHC business are, in the following order: (i) organic investment; (ii) business development and merger & acquisition activities, focusing on bolt-on, value-enhancing opportunities to drive scientific and commercial leadership in core therapeutic areas; (iii) growing the annual dividend; and (iv) anti-dilutive share buybacks. We also have the potential to raise capital through asset disposals, including streamlining "tail" brands in our Established Products and Consumer Healthcare business.

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 "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 — A. Operating Results".

Specialty Care

Dupixent®

Dupixent® (dupilumab) is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) pathways and is not an immunosuppressant. Dupilumab is jointly developed by Sanofi and Regeneron under a global collaboration agreement. To date, dupilumab has been studied across more than 60 clinical trials involving more than 10,000 patients with various chronic diseases driven in part by type 2 inflammation. The dupilumab development program has shown significant clinical benefit and a decrease in type 2 inflammation in Phase III trials, establishing that IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in multiple inflammatory diseases, such as atopic dermatitis (AD), asthma, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis and prurigo nodularis. Dupixent® comes in either a pre-filled syringe for use in a clinic or at home by self-administration as a subcutaneous injection or in a pre-filled pen for at-home administration, providing patients with a more convenient option. Dupixent® is available in all major markets including the US (since April 2017), most European Union countries (the first launch was in Germany in December 2017), and Japan (since April 2018).

Atopic Dermatitis

Moderate-to-severe AD, a form of eczema and a chronic inflammatory disease, is characterized by rashes that sometimes cover much of the body and can include intense, persistent itching and skin dryness, cracking, redness, crusting and oozing. 85 to 90 percent of patients first develop symptoms before 5 years of age, which can often continue through adulthood.

In 2014 the FDA granted Dupixent® Breakthrough Therapy designation and after a Priority Review evaluation, in March 2017 it granted Dupixent® marketing authorization for the treatment of adults with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. In 2016, the FDA granted Dupixent® Breakthrough Therapy designation for adolescent patients aged 12 to 17 years and in March 2019, the FDA extended the marketing authorization for this age group.

In 2016, the FDA granted Breakthrough Therapy designation for Dupixent® for the treatment of severe AD in children aged 6 months to 11 years. On May 26, 2020, Dupixent® was approved as the first biologic medicine for children aged 6 to 11 years with moderate-to-severe AD. On June 7, 2022, after accepting Dupixent® for Priority Review in February, the FDA approved Dupixent® for children aged 6 months to 5 years with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable, making Dupixent® the first biologic medicine to significantly reduce signs and symptoms in children as young as 6 months.

The European Commission (EC) approved Dupixent® in September 2017 for use in adults with moderate-to-severe AD who are candidates for systemic therapy, and extended the marketing authorization in August 2019 to include adolescents aged 12 to 17 years. On November 30, 2020, the EC extended the marketing authorization to children aged 6 to 11 years with severe AD and on June 28, 2021, the Dupixent® Summary of Product Characteristics (SmPC) was updated with long-term data for up to 3 years, reinforcing the product's well-established safety profile in adults with moderate-to-severe AD. On January 27, 2023 the CHMP adopted a positive opinion for Dupixent® recommending expanded approval in the EU to treat severe atopic dermatitis in children 6 months to 5 years old who are candidates for systemic therapy. The EC is expected to announce a final decision on the Dupixent application in the coming months.

On June 19, 2020, the National Medical Products Administration (NMPA) in China approved Dupixent® for adults for the treatment of moderate-to-severe AD after identifying dupilumab as an overseas medicine regarded as urgently needed in clinical practice, leading to an expedited review and approval process. On December 28, 2020, the National Healthcare Security Administration (NHSA) officially announced the results of the 2020 National Reimbursement Drug List (NRDL) negotiations, with Dupixent® 300 mg included in the updated NRDL effective March 1, 2021. Dupixent® was approved in China in September 2021 for adolescents aged 12-17 years with moderate-to-severe atopic dermatitis. The indication for children aged 6 years and over, along with the adolescent and adult AD indications, was included in the current NRDL reimbursement scope, which was reviewed during the Dupixent® NRDL renewal in 2022 in accordance with the two-year cycle for the China access process.

In March 2022, at the annual meeting of the American Academy of Dermatology (AAD 2022), Sanofi presented results from a long-term efficacy open-label study where dupilumab demonstrated robust and sustained efficacy with progressive improvement of AD signs and symptoms in adults with moderate-to-severe AD who completed up to 4 years of treatment: the longest duration of data for any biologic medicine in this disease. Additionally, the long-term safety data from a 52-week open-label extension trial in 6 months to 5 years reinforces the well-established safety profile of Dupixent® observed across all other approved age groups. This data built on the existing wealth of evidence supporting the selective way Dupixent® inhibits IL4/IL-13 pathways, both key and central drivers of the type 2 inflammation, thereby significantly improving itch and skin lesions and other important measures that impact a patient's quality of life.

Asthma

Dupixent® was granted marketing authorization by the FDA in October 2018 as an add-on maintenance therapy in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma. In May 2019, the European Commission approved Dupixent® for use as an add-on maintenance treatment in severe asthma patients aged 12 years and older with type 2 inflammation whose symptoms are inadequately reduced by other treatments.

In September 2020, new long-term data from a Phase III open-label extension trial showed sustained improvement in lung function and reduction in severe exacerbations in adults and adolescents with moderate-to-severe asthma. On May 17, 2021, detailed results from a Phase III trial showed Dupixent® significantly reduced severe asthma attacks, and within two weeks rapidly improved lung function in children aged 6 to 11 years with uncontrolled moderate-to-severe asthma with evidence of type 2 inflammation. Moreover, Dupixent® significantly improved overall asthma symptom control and reduced an airway biomarker of type 2 inflammation, called fractional exhaled nitric oxide (FeNO), that plays a major role in asthma.

In October 2021, the FDA approved Dupixent® as an add-on maintenance treatment for patients aged 6 to 11 years with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid-dependent asthma, thereby bringing a new treatment for children who may be suffering from life-threatening asthma attacks and poor lung function affecting their ability to breathe, which could potentially continue into adulthood. On April 7, 2022, the European Commission approved Dupixent® for use in children aged 6 to 11 years as an add-on maintenance treatment for severe asthma with type 2 inflammation characterized by raised blood eosinophils and/or raised fractional exhaled nitric oxide (FeNO), whose symptoms are inadequately reduced with medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

CRSwNP is a chronic disease of the upper airway that obstructs the sinuses and nasal passages. It can lead to breathing difficulties, nasal congestion and discharge, reduced or loss of sense of smell and taste, and facial pressure.

In June 2019, the FDA approved Dupixent® for use with other medicines to treat CRSwNP in adults whose disease is not controlled. In October 2019, the European Commission approved Dupixent® for use as an add-on therapy with intranasal corticosteroids in adults with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

Eosinophilic esophagitis (EoE)

EoE is a chronic and progressive inflammatory disease that damages the esophagus and prevents it from working properly; swallowing even small amounts of food can be a painful and worrisome choking experience. In severe cases, a feeding tube may be the only option to ensure proper calorific intake and adequate nutrition. Of the approximately 209,000 patients aged 12 years and older living with EoE in the US who are currently treated with therapies not specifically approved for the disease, about 42,000 continue to experience symptoms despite multiple treatments.

On September 14, 2020, the FDA granted Breakthrough Therapy designation to Dupixent® for the treatment of patients 12 years and older with EoE, and subsequently accepted the file for Priority Review on April 4, 2022. On May 20, 2022, the FDA approved Dupixent® to treat patients with EoE aged 12 years and older. With this approval, Dupixent® became the first and only medicine specifically indicated to treat EoE in the U.S.

On December 16, 2022, EMA's CHMP adopted a positive opinion, recommending the approval of dupilumab in the EU to treat adults and adolescents with EoE. On January 30, 2023, the EC expanded marketing authorization for Dupixent in the EU to treat EoE in adults and adolescents 12 years and older, submissions to regulatory authorities in additional countries are planned in 2023.

There are currently no approved treatments specifically indicated for children under 12 years of age with EoE. On July 14, 2022, a Dupixent® Phase III trial showed positive results in children aged 1 to 11 years with EoE, making this the fifth pediatric pivotal trial across three type 2 inflammatory diseases to reinforce the well-established efficacy and safety profile of Dupixent®. The corresponding data will be submitted to regulatory authorities around the world, starting with the FDA in 2023.

Prurigo Nodularis (PN)

Prurigo nodularis is a chronic, debilitating skin disease with underlying type 2 inflammation and has one of the highest impacts on a patient's quality of life among inflammatory skin diseases due to the extreme itch it causes. Those with prurigo nodularis experience intense, persistent itch, with thick skin lesions (called nodules) that can cover most of the body. The disease is often painful – with burning, stinging and tingling of the skin – and can negatively affect mental health, daily living activities and social interactions. High-potency topical steroids are commonly prescribed but are associated with safety risks if used long-term.

The FDA evaluated the Dupixent® application for prurigo nodularis under Priority Review on May 31, 2022. On September 29, 2022, the FDA approved Dupixent® for the treatment of adult patients with prurigo nodularis. With this approval, Dupixent® became the first and only medicine specifically indicated to treat prurigo nodularis in the US. The FDA approval was based on data from two Phase III trials evaluating the efficacy and safety of Dupixent® in adults with prurigo nodularis. Efficacy in these trials assessed the proportion of subjects with clinically meaningful reduction in itch, clearing of skin, or both. On December 15, 2022, the EC has expanded the marketing authorization for Dupixent® in the EU to treat adults with moderate-to-severe prurigo nodularis who are candidates for systemic therapy, after the positive recommendation earlier on November 11, 2022.

Chronic Spontaneous Urticaria (CSU)

CSU is a chronic inflammatory skin disease characterized by the sudden onset of hives on the skin and/or swelling deep under the skin. Despite standard-of-care treatment, people with CSU often experience symptoms including a persistent itch or burning sensation, which can be debilitating and significantly impact quality of life. Swelling often occurs on the face, hands and feet, but can also affect the throat and upper airways. On July 29, 2021 a pivotal Phase III trial evaluating Dupixent® in patients with moderate-to-severe CSU met its primary endpoints and all key secondary endpoints at 24 weeks. Adding Dupixent® to standard-of-care antihistamines significantly reduced itch and hives for biologic-naive patients, compared to those treated with antihistamines alone (placebo) in Study A (the first of two trials) of the LIBERTY CUPID clinical program.

Study B of the clinical trial evaluated Dupixent® in adults and adolescents who remain symptomatic despite standard-of-care treatment and are intolerant or incomplete responders to an anti-IgE therapeutic (omalizumab). Although positive numerical trends in reducing itch and hives were observed, the study was stopped due to futility based on a pre-specified interim analysis. The safety data were generally consistent with the known safety profile of Dupixent® in its approved indications. In December 2022, CSU was submitted to FDA, if granted Dupixent® has the potential to add additional ~308K patients in the US.

Life cycle management

Dupixent® is currently being evaluated in clinical development programs for diseases that are driven by type 2 inflammation. These include, chronic obstructive pulmonary disease (COPD), chronic inducible cold urticaria (CINDU), bullous pemphigoid (BP), chronic rhinosinusitis without nasal polyposis (CRSsNP), and allergic fungal rhinosinusitis (AFRS). See "— B.5. Global Research & Development".

Dupixent® is developed and commercialized in collaboration with Regeneron. For additional information on the collaboration, see "Item 5. Operating and Financial Review and Prospects — A.1.7. Financial Presentation of Alliances — Alliance Arrangements with Regeneron".

There are ongoing opposition proceedings in Europe related to Dupixent® initiated by Sanofi and Regeneron against Amgen and Immunex. See Note D.22.b.) to the consolidated financial statements included at Item 18. of this annual report.

Neurology & Immunology

Multiple Sclerosis

Multiple sclerosis (MS) is an autoimmune neurological 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® (teriflunomide), a once-daily, oral immunomodulator, and Lemtrada® (alemtuzumab), a monoclonal antibody. Both products treat patients with relapsing forms of MS.

Aubagio®

Aubagio® (teriflunomide), a small molecule immunomodulatory agent with anti-inflammatory properties, is a once-daily oral therapy.

Aubagio® is approved in more than 80 countries around the world including the US (since September 2012) for the treatment of patients with relapsing forms of MS; the EU (since August 2013) for the treatment of adult patients with relapsing remitting MS; and China (since July 2018). In June 2021, the European Commission (EC) approved Aubagio® for the treatment of pediatric patients aged 10 to 17 years with relapsing-remitting multiple sclerosis (RRMS). In the European Union, generic competition is expected in the fourth quarter of 2023.

In 2017, Sanofi reached settlement with all 20 generic Aubagio® ANDA first filers, granting each a royalty-free license to enter the US market on March 12, 2023.

Lemtrada®

Lemtrada® (alemtuzumab) is a humanized monoclonal antibody targeting the CD52 antigen. Lemtrada® is administered by intravenous infusion 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® is approved in more than 70 countries including the EU (since September 2013) and the US (since November 2014). Because of its safety profile, the FDA approved the use of Lemtrada® in patients with relapsing forms of MS 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. In the US, Lemtrada® is only available through a restricted distribution program called the Lemtrada® Risk Evaluation and Mitigation Strategy (REMS) Program. In January 2020, the EMA updated the indication for Lemtrada® to include treatment of relapsing-remitting multiple sclerosis if the disease is highly active despite treatment with at least one disease-modifying therapy, or if the disease is worsening rapidly. The EMA also added new contra-indications for patients with certain heart, circulation or bleeding disorders, and those who have autoimmune disorders other than MS.

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

Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic inflammatory autoimmune disease causing inflammation, pain, and eventually joint damage and disability.

Kevzara®

Kevzara® (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. Kevzara® is available in 20 countries, including the US.

In May 2017, the FDA approved Kevzara® for the treatment of adult patients with moderately to severely active RA who have had an inadequate response or intolerance to one or more disease modifying anti-rheumatic drugs (DMARDs), such as methotrexate. In June 2017, the European Commission granted marketing authorization for Kevzara® 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. An sBLA for Kevzara® in polymyalgia rheumatica (PMR) is currently under priority review by the FDA, and the product is also being investigated in Polyarticular Juvenile Idiopathic Arthritis and Systemic Juvenile Arthritis. See "— B.5. Global Research & Development".

Kevzara® is developed and commercialized in collaboration with Regeneron. For additional information, see "Item 5. Operating and Financial Review and Prospects — A.1.7. Financial Presentation of Alliances — Alliance Arrangements with Regeneron".

Rare diseases

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

Cerezyme®

Cerezyme® (imiglucerase) is an enzyme replacement therapy used to treat Gaucher disease, a chronic, inherited, progressive and potentially life-threatening LSD. Gaucher disease is caused by deficiency of the enzyme glucocerebrosidase; this causes a fatty substance called glucosylceramide (also called GL-1) to build up in certain areas of the body including the spleen, liver, and bone. Gaucher disease exhibits diverse manifestations, a broad range of age of onset of symptoms, and a wide clinical spectrum of disease severity. 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 incidence and patient severity vary among regions. Cerezyme® has been marketed in the US since 1994, in the EU since 1997, in Japan since 1998 and in China since 2008, and is approved to treat Type 1 Gaucher disease in more than 85 countries. It has also been approved to treat the systemic symptoms of Type 3 Gaucher disease in most non-US markets, including the EU and Japan.

Cerezyme® is typically given by intravenous infusions for 1-2 hours every two weeks at an infusion center, a doctor's office, or at home as medically appropriate.

Cerdelga®

Cerdelga® (eliglustat) is the first and only first-line oral therapy for Gaucher disease Type 1 adult patients. A potent, highly specific ceramide analog 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. Cerdelga® has been approved to treat Type 1 Gaucher disease in the US (2014), and in the EU and Japan (2015). It is also in development for the treatment of type I Gaucher disease in pediatric patients. See "— B.5. Global Research & Development".

Myozyme® and Lumizyme®

Myozyme® (alglucosidase alfa) is an enzyme replacement therapy used to treat both Infantile Onset and Late Onset Pompe disease (IOPD and LOPD). Pompe disease is an inherited, progressive and often fatal neuromuscular disease, caused by a genetic deficiency or dysfunction of the lysosomal enzyme acid alpha-glucosidase (GAA) that results in the build-up of glycogen in the muscles' cells. For infantile-onset Pompe disease, symptoms begin within a few months of birth and there is impact to the heart in addition to skeletal muscle weakness. Other symptoms include difficulties breathing, frequent chest infections, problems feeding that result in failure to gain weight as expected, and failure to meet certain developmental milestones. Patients with late-onset Pompe disease typically present symptoms any time after the first year of life to late adulthood and rarely manifest cardiac problems. The hallmark symptom of late-onset Pompe disease is skeletal muscle weakness, which often leads to walking disability and reduced respiratory function. Patients often require wheelchairs to assist with mobility and may require mechanical ventilation to help with breathing. Pompe disease occurs in approximately one in 40,000 newborns worldwide, but incidence and patient severity vary among regions.

Myozyme® was first approved in 2006 in the EU and has since been approved in more than 70 countries. In the US, alglucosidase alfa has been marketed as Lumizyme® since 2010.

Nexviazyme®

Nexviazyme® (avalglucosidase alfa-ngpt) is a monotherapy treatment designed for the entire spectrum of infantile-onset and late-onset Pompe disease (IOPD, LOPD), for both switch and naïve patients. It is the first new treatment option approved for the Pompe community in more than 15 years. Nexviazyme® was first approved in the US by the FDA on August 6, 2021 for LOPD patients aged one and above, and has successfully launched in countries like the US, Japan and Australia, where the majority of eligible patients have switched to Nexviazyme®. On June 24, 2022, the European Commission granted marketing authorization for Nexviadyme® as a potential new standard of care for the long-term treatment of both LOPD and IOPD.

In 2023, it is anticipated that Nexviazyme® will be launched in many additional markets worldwide. Investment in the clinical development of Nexviazyme® continues with an ongoing trial in patients with IOPD aged less than 12 months.

Nexviazyme® is administered as a monotherapy enzyme replacement therapy every two weeks.

Fabrazyme®

Fabrazyme® (agalsidase beta) is an enzyme replacement therapy used to treat Fabry disease. Fabry disease (FD) is a multisystemic, progressive, X-linked inherited disorder of glycosphingolipid metabolism due to deficient or absent lysosomal α-galactosidase A activity resulting in progressive globotriaosylceramide (GL-3) accumulation in the lysosomes of various tissues. Fabry disease affects both genders. With age, progressive organ damage develops, leading to potentially life-threatening renal, cardiac and/or cerebrovascular complications. Fabry disease is characterized by different symptom severities and rates of progression, ranging from classic disease with early symptom onset to late onset disease with cardiac and/or renal complications later in life. Fabry disease occurs in approximately one in 35,000 newborns worldwide, but incidence and patient severity vary among regions. Fabrazyme® has been marketed in the EU since 2001 and in the US since 2003, and is approved in more than 70 countries.

Aldurazyme®

Aldurazyme® (laronidase) is the only approved enzyme replacement therapy for mucopolysaccharidosis type 1 (MPS I), an inherited lysosomal storage disorder caused by a deficiency of alpha-L-iduronidase, a lysosomal enzyme normally required for the breakdown of certain complex carbohydrates known as glycosaminoglycans (GAGs). MPS I is multi-systemic, and children with MPS I are described as having either a severe or attenuated form of the disorder based on age of onset, severity of symptoms, rate of disease progression and whether there is early and direct involvement of the brain. MPS I occurs in approximately one per 100,000 live births worldwide, but incidence and patient severity vary among regions. Aldurazyme® has been marketed in the EU and the US since 2003, and is approved in more than 75 countries.

Xenpozyme®

Xenpozyme® (olipudase alfa) is an enzyme replacement therapy (ERT) designed to replace deficient or defective acid sphingomyelinase (ASMD), an enzyme that allows for the breakdown of the lipid sphingomyelin. In individuals with ASMD, an insufficiency of the ASM enzyme means sphingomyelin is poorly metabolized, potentially leading to lifelong accumulation in and damage to multiple organs.

The significance of the unmet need that Xenpozyme® addresses has been recognized by Japan's PMDA with Sakigake designation, by the EU with PRIME designation, and by the FDA with Breakthrough designation.

Xenpozyme® was approved first in Japan on March 28, 2022, followed by Europe on June 24, 2022, a few months before the FDA approval on August 31, 2022

Xenpozyme® is the first and only ERT for the treatment of non central nervous system manifestations of ASMD, with demonstrated improvements in hepatosplenomegaly, pulmonary, liver and hematologic function, dyslipidemia, and growth (children only) in clinical trials of adults and children with ASMD. Xenpozyme® is given as an intravenous infusion once every 2 weeks, and the dose is based on body weight.

Oncology

Sarclisa®

Sarclisa® (isatuximab) is a monoclonal antibody that binds a specific epitope on the human CD38 receptor and has antitumor activity via multiple mechanisms of action. It was approved in March 2020 in the US in combination with pomalidomide and dexamethasone for the treatment of adults with relapsed refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor, and by the European Commission in May 2020 in combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy. Sarclisa® is now approved for this indication in more than 50 countries.

Sarclisa® was approved for a label extension in combination with carfilzomib and dexamethasone in March 2021 in the US for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) who have received one to three prior lines of therapy, and by the European Commission in April 2021 for the treatment of adult patients with multiple myeloma (MM) who have received at least one prior therapy. The Japanese Ministry of Health, Labor and Welfare (MHLW) granted approval for Sarclisa® in combination with carfilzomib and dexamethasone, in combination with dexamethasone, and as monotherapy for RRMM patients in November 2021. Sarclisa® is under investigation in the phase III IMROZ trial as a first line treatment for patients with newly diagnosed multiple myeloma who are transplant ineligible. In addition, the phase III IRAKLIA trial investigating the development of a new subcutaneous formulation with an on-body device system was initiated in the second half of 2022.

Sarclisa is also being investigated in Phase II studies as a first/second line treatment for pediatric acute myeloid leukemia (AML), acute lymphocytic leukemia (ALL), and warm autoimmune hemolytic anemia.

Libtayo®

Libtayo® (cemiplimab-rwlc), an immune therapy drug, is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1). This may restore immune function through the activation of cytotoxic T cells, thereby avoiding tumor evasion from host immunity.

In September 2018, the FDA approved Libtayo® for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. The European Commission granted conditional marketing authorization in July 2019. Libtayo® is the only treatment specifically approved and available for advanced CSCC in the EU. CSCC is the second most common form of skin cancer.

Libtayo® received approval in the US for the treatment of adult patients with metastatic basal cell carcinoma (mBCC) and for the treatment of adult patients with locally advanced basal cell carcinoma (laBCC) in February 2021. The European Commission granted marketing authorization for Libtayo® for the treatment of adult patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have progressed on or are intolerant to a hedgehog pathway inhibitor (HHI) in June 2021. Libtayo® received approval in the US in February 2021 for the treatment of adult patients with non-small lung cancer (NSCLC) whose tumors have high PD-L1 expression (Tumor Proportion Score of at least 50%) and are not candidates for surgical resection or definitive chemoradiation or have metastatic disease. In June 2021, the European Commission granted marketing authorization for the first-line treatment of adult patients with NSCLC expressing PD-L1 (in 50% tumor cells), with no EGFR, ALK or ROS1 aberrations, who have locally advanced NSCLC and who are not candidates for definitive chemoradiation, or who have metastatic NSCLC. Libtayo® is currently approved in 37 countries.

Libtayo® was filed for label extensions with the FDA and the EMA in 2L+ cervical cancer in 2021. On January 27, 2022, Sanofi and Regeneron announced the voluntary withdrawal of the supplemental Biologics License Application. Discussions with regulatory authorities outside of the US are ongoing.

In November 2022, Libtayo® received approval in the US in combination with platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced non-small cell lung cancer with no EGFR, ALK or ROS1 aberrations who are not candidates for surgical resection or definitive chemoradiation, or whose disease is metastatic. Discussions with regulatory authorities outside of the US are ongoing.

On June 1, 2022, Sanofi and Regeneron restructured their IO License and Collaboration Agreement (IO LCA), as signed in 2015, amended in January 2018 and subsequently in September 2021. Under the terms of the Amended and Restated IO LCA, Regeneron holds exclusive worldwide licensing rights to Libtayo® with effect from July 1, 2022.

Sanofi received an upfront payment of $900 million in July 2022 and a regulatory milestone payment of $100 million in December 2022, following FDA approval of Libtayo® in combination with chemotherapy as a first line treatment for advanced NSCLC. A $65 million sales-related milestone payment was also earned in December 2022.

Sanofi stopped consolidating non-US Libtayo® sales from the third quarter of 2022 and is entitled to receive a royalty of 11% on worldwide net sales of Libtayo®, recognized in line with the pattern of sales. The transaction also includes a time-limited transitional services agreement with Regeneron which includes manufacturing, distribution (for which Sanofi acts as agent), and promotion.

Jevtana®

Jevtana® (cabazitaxel), a chemotherapy drug and cytotoxic agent, is a semi-synthetic second-generation taxane that prevents many cancer cells from dividing, which ultimately results in destroying many such cells. It is approved in combination with prednisone for the treatment of patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing treatment regimen. Jevtana® 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 marketed in over 75 countries. In Europe, generic competition started for Jevtana® from the end of March 2021. In the US, the Jevtana® composition of matter patent expired in September 2021. Sanofi has filed patent infringement suits under the US Hatch-Waxman Act against generic manufacturers for cabazitaxel in the US District Court for the District of Delaware asserting three Orange Book listed US patents for Jevtana®. Sanofi has entered settlement agreements with some of the defendants and the suit against the remaining defendants is ongoing; see Note D.22.b. to the consolidated financial statements, included at Item 18. of this annual report.

Fasturtec®/Elitek®

Fasturtec®/Elitek® is used for the management of plasma uric levels in patients with leukemia, lymphoma, and solid tumor malignancies receiving anticancer therapies.

Rare blood disorders

The Rare Blood Disorders franchise was created in 2018 following Sanofi's acquisition of Bioverativ and Ablynx (see "— A. History and Development of the Company").

Eloctate®

Eloctate® (antihemophilic factor (recombinant), Fc fusion protein) is an extended half-life clotting-factor therapy to control and prevent bleeding episodes in adults and children with hemophilia A. In the US, it is indicated for use in adults and children with hemophilia A for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.

Hemophilia A is a rare, x-linked genetic bleeding disorder characterized by a deficiency of functional coagulation Factor VIII, resulting in a prolonged patient plasma-clotting time. As a consequence, people with hemophilia A bleed for a longer time than normal. Eloctate® temporarily replaces the missing coagulation Factor VIII by intravenous injection.

We market Eloctate® primarily in the US (since 2014), Japan, Canada, Australia, South Korea, Taiwan and Hong Kong.

Eloctate® is developed and commercialized in collaboration with Swedish Orphan Biovitrum AB (Sobi), whose territories include Europe, Russia, the Middle East, and some countries in North Africa.

Alprolix®

Alprolix® (coagulation Factor IX (recombinant), Fc fusion protein) is an extended half-life clotting-factor therapy to control and prevent bleeding episodes in adults and children with hemophilia B. In the US, it is indicated for use in adults and children with hemophilia B for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.

Hemophilia B is a rare, x-linked genetic bleeding disorder characterized by a deficiency of functional coagulation Factor IX, resulting in a prolonged patient plasma-clotting time. As a consequence, people with hemophilia B bleed for a longer time than normal. Alprolix® temporarily replaces the missing coagulation Factor IX by intravenous injection.

We market Alprolix® primarily in the US (since 2014), Japan, Canada, Australia, New Zealand, South Korea, Taiwan and Hong Kong.

Alprolix® is developed and commercialized in collaboration with Swedish Orphan Biovitrum AB (Sobi), whose territories include Europe, Russia, the Middle East, and some countries in North Africa.

Cablivi®

Cablivi® (caplacizumab) is a bivalent anti-von Willebrand Factor (vWF) Nanobody® for the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP). Cablivi® is the first therapeutic specifically indicated for the treatment of aTTP.

Acquired thrombotic thrombocytopenic purpura is an ultra-rare (3.5-4.5 episodes per million of population), life-threatening, autoimmune-based blood clotting disorder characterized by extensive clot formation in small blood vessels throughout the body, leading to severe thrombocytopenia (very low platelet count); microangiopathic hemolytic anemia (loss of red blood cells through destruction); ischemia (restricted blood supply to parts of the body); and widespread organ damage, especially in the brain and heart. Cablivi® has an immediate effect on platelet adhesion and the ensuing formation and accumulation of the micro-clots.

Cablivi® was granted marketing authorization by the European Commission in September 2018; by the FDA in February 2019; and by the Japanese PMDA in September 2022. Cablivi® is currently available in 25 countries including the US, the majority of European countries (17), Brazil, Colombia, and five Greater Gulf region states. Additional commercial launches are ongoing.

Cablivi® was developed by Ablynx, a Sanofi company since mid-2018. See "- A. History and Development of the Company".

Enjaymo®

Enjaymo® (sutimlimab; formerly known as BIVV009) is a monoclonal antibody targeting the classical complement pathway (CP) specific serine protease (C1s), thereby inhibiting CP activity which is associated with a variety of immune disorders involving the presence of autoantibodies. Enjaymo® is the first-and-only approved therapeutic option approved for hemolytic anemia in adult patients with cold agglutinin disease (CAD).

CAD is a rare, serious, and chronic autoimmune hemolytic anemia, where the body's immune system mistakenly attacks healthy red blood cells and causes their rupture, known as hemolysis. The disease impacts the lives of an estimated 12,000 people in the US, Europe, and Japan and is associated with profound fatigue and increased risk of thromboembolic events and mortality.

Enjaymo® has previously received Breakthrough Therapy Designation (BTD) and Orphan Drug Designations (ODD) from the FDA, and orphan medicine designation by the European Medicines Agency. After priority review, the product was approved in February 2022 as the first treatment to decrease the need for red blood cell transfusion due to hemolysis in adults with CAD. Enjaymo® was approved by the Japanese Ministry of Health, Labor and Welfare in June 2022 and granted marketing authorization by the European Commission in November 2022.

Those approvals were based on the CARDINAL Phase III data, which were published in the New England Journal of Medicine. Additionally, the Enjaymo® efficacy sBLA has been granted priority review by the FDA based on the CADENZA trial, with the aim of broadening the indication and including long-term efficacy and safety data.

General Medicines

Sanofi has prioritized core assets with differentiated and/or established profiles that have significant opportunity for growth in key markets. Some of these well-established medicines are the standard-of-care for patients living with diabetes or cardiovascular disease. These core assets include Toujeo®, Soliqua®, Praluent®, Multaq®, Lovenox®, and Plavix®.

Core assets

Toujeo®

Toujeo® (insulin glargine 300 units/mL) is a long-acting analog of human insulin, indicated for the treatment of diabetes mellitus in adults. Toujeo® has been granted marketing authorization by the FDA (February 2015); the EC (April 2015); and the Ministry of Health, Labor and Welfare (J-MHLW) in Japan, where its approved brand name is Lantus® XR (June 2015). Toujeo® has now been launched in more than 60 countries, including China since the end of 2020. In January 2020, the EC approved an expansion of the indication to include the treatment of diabetes in adolescents and children (aged 6 years and above).

Toujeo® is available in Toujeo® SoloSTAR®, 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® SoloSTAR®. In the US (since 2018) and the EU (since 2019), Toujeo® is also available in a disposable prefilled pen which contains 900 units of insulin glargine. In India, Toujeo® is also available in a dedicated 450-unit cartridge in combination with a dedicated reusable pen (TouStar®).

Lovenox®/Clexane®

Lovenox® or Clexane® (enoxaparin sodium) is a low molecular weight heparin (LMWH) indicated for use in the prophylaxis and treatment of venous thromboembolism and in the treatment of acute coronary syndrome. Enoxaparin generics are available in the US, and biosimilar enoxaparin products have gradually become available across various European countries and in a growing number of international markets. Lovenox® or Clexane® is marketed in more than 100 countries.

Plavix®/Iscover®

Plavix® or Iscover® (clopidogrel bisulfate) is a platelet adenosine diphosphate (ADP) receptor antagonist. It 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), and for patients with acute coronary syndrome (ACS). Plavix® is also indicated in combination with acetylsalicylic acid (ASA) for the prevention of atherothrombotic and thromboembolic events in atrial fibrillation, including stroke.

CoPlavix®/DuoPlavin®, 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.

A number of clopidogrel bisulfate generics have been launched in most markets. Plavix® or Iscover® are available in more than 80 countries. For additional information on the commercialization of these products, see "Item 5. Operating and Financial Review and Prospects — Financial Presentation of Alliances — Alliance Arrangements with Bristol-Myers Squibb".

Sanofi is involved in two Plavix® product lawsuits. See Note D.22.c) to our consolidated financial statements, included at Item 18. of this annual report.

Praluent®

Praluent® (alirocumab) is a human monoclonal antibody (mAb) for self-administered injection every two weeks or once-monthly. It 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® is indicated as an adjunct to diet and maximally tolerated statin therapy in certain adult patients with uncontrolled LDL cholesterol. Praluent® has been approved in more than 60 countries worldwide, including the US (in 2015), Canada and Switzerland, as well as in the European Union (in 2015). In 2018, the FDA approved a Praluent® label update for some patients currently requiring LDL apheresis therapy. In March 2019 in the EU and in April 2019 in the US, Praluent® was approved for use in patients with established cardiovascular disease to reduce the risk of cardiovascular events.

In December 2019, Praluent® was approved in China, where it started to be commercialized in May 2020.

Since April 2020, Regeneron is responsible for commercialization of Praluent® in the US, and Sanofi is responsible for all other markets outside the US. For additional information on the commercialization of this product, see "Item 5. Operating and Financial Review and Prospects — Financial Presentation of Alliances — Alliance Arrangements with Regeneron".

Multaq®

Multaq® (dronedarone) is an oral multichannel blocker with anti-arrhythmic properties for prevention of atrial fibrillation recurrences in certain patients with a history of paroxysmal or persistent atrial fibrillation. Multaq® was approved in the US and in the EU in 2009. Multaq® is available in about 35 countries.

Thymoglobulin®

Thymoglobulin® (anti-thymocyte Globulin) is a polyclonal anti-human thymocyte antibody preparation that acts as a broad immunosuppressive and immunomodulating agent. In the US, Thymoglobulin® is indicated for the prophylaxis and treatment of acute rejection in patients receiving a kidney transplant, used in conjunction with concomitant immunosuppression. Outside the US, 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. Thymoglobulin® is currently marketed in over 65 countries.

Mozobil®

Mozobil® (plerixafor injection) is a hematopoietic stem cell mobilizer. It is 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). Mozobil® is marketed in over 65 countries.

Rezurock®

Rezurock® (belumosudil) is a selective ROCK2 (rho-associated coiled-coil–containing protein kinase-2) inhibitor. It was approved in July 2021 by the FDA for the treatment of adult and pediatric patients aged 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy. Activities are ongoing to ensure registration in other territories. In April 2022, results from a pooled analysis of Rezurock® showed certain organ clinical responses correlated with clinically meaningful changes in patient-reported outcomes (PROs).

Soliqua® – 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. 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; and in February 2019 for patients uncontrolled on oral antidiabetic medicines. In January 2017, Suliqua® (the product's brand name in Europe) was approved 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 either by metformin alone or by metformin combined with another oral glucose-lowering medicinal product or with basal insulin. In Japan, Soliqua® was approved in May 2020 for type 2 diabetes mellitus, where treatment with insulin is required. Suliqua® is available in over 40 countries.

Apidra®

Apidra® (insulin glulisine) is a rapid-acting analog of human insulin, indicated to improve glycemic control in adults and children with diabetes mellitus. It is administered around meal time, and is used in a regimen with an intermediate or long-acting insulin (Apidra® has a more rapid onset and shorter duration of action than fast-acting human insulin). Apidra® is available in over 100 countries worldwide.

Admelog®/Insulin lispro Sanofi®

Admelog® (or Insulin lispro Sanofi®) is a rapid-acting insulin similar to Humalog®, another insulin lispro 100 Units/mL. Admelog® was approved by the FDA in December 2017, and was also granted marketing authorization as a biosimilar (under the proprietary name Insulin lispro Sanofi®) 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 (aged 3 years and above) with type 1 diabetes. Admelog® was launched in the US and several European countries during 2018.

Truvelog®/Insulin aspart Sanofi®

Truvelog® (also known as TruRapi® or Insulin aspart Sanofi®) is a rapid-acting insulin similar to Novorapid®/Novolog®, another insulin aspart 100 Units/mL. It was granted marketing authorization as a biosimilar (under the proprietary name Insulin aspart Sanofi®) by the European Commission in June 2020. It is used to improve blood sugar control in adults with type 2 diabetes, and in adults and children (aged 1 year and above) with type 1 diabetes. Insulin aspart Sanofi® was launched in several European countries during 2020.

Integrated Digital Care Solutions

Sanofi, in collaboration with Abbott and Biocorp, Health2Sync and Roche, is building a connected set of digital tools and features to support people living with diabetes and taking insulin. Sanofi intends to use aggregated de-identified data to generate insights to inform patients and providers, and to evaluate additional clinical or quality-of-life outcomes. Successful launches in several countries demonstrate the value of the integration of digital tools into a fully connected ecosystem.

Non-Core Assets

Lantus®

Lantus® (insulin glargine 100 units/mL) is a long-acting analog of human insulin, indicated for once-daily administration for the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. Lantus® relies on more than 15 years of clinical evidence in diabetes treatment and a well-established safety profile. Approved in the US and the EU in 2000 and in Japan in 2008, Lantus® is available in over 130 countries worldwide. Two insulin glargine biosimilars are available in the US, two in European markets, and two in Japan.

There are ongoing patent infringement proceedings in the US against Mylan. See "Item 8. Financial information — A. Information on Legal or Arbitration Proceedings".

Aprovel®/Avapro®/Karvea®

Aprovel®, also known as Avapro® or Karvea® (irbesartan), is an angiotensin II receptor antagonist indicated as a first-line treatment for hypertension and for the treatment of nephropathy in hypertensive patients with type 2 diabetes. We also market CoAprovel®/Avalide®/Karvezide®, a combination of irbesartan and the diuretic hydrochlorothiazide. A combination with amlodipine (Aprovasc®) has been launched in several emerging market countries.

A number of irbesartan generics have been launched in most markets. Aprovel® and CoAprovel® 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.

Renagel® and Renvela®

Renagel® (sevelamer hydrochloride) and Renvela® (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 hyperphosphatemia, or elevated phosphorus levels, which is associated with heart and bone disease. Renvela® is a second-generation buffered phosphate binder.

Generics of sevelamer carbonate are available in the US and in various European countries. A generic of sevelamer hydrochloride was approved in the US in February 2019, and was subsequently launched. Renagel® and Renvela® are marketed in more than 85 countries. In Japan and several Pacific Rim countries, Renagel® is marketed by Chugai Pharmaceutical Co., Ltd and its sublicensee, Kyowa Hakko Kirin Co., Ltd.

Synvisc®/Synvisc-One®

Synvisc® and Synvisc-One® (hylan G-F 20) are viscosupplements used to treat pain associated with osteoarthritis. Synvisc® and Synvisc-One® are marketed in over 60 countries.

Depakine®

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 50 years and remains a reference treatment for epilepsy worldwide. Depakine® is also a mood stabilizer, registered in the treatment of manic episodes associated with bipolar disorder (in some countries this indication is branded differently, for example as Depakote® in France). We hold no rights to Depakine® in the US, and sodium valproate generics are available in most markets.

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

Taxotere®

Taxotere® (docetaxel), a chemotherapy drug and cytotoxic agent, is a semi-synthetic taxane. 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® product litigation in the US. See Note D.22.a) to our consolidated financial statements, included at Item 18. of this annual report.

Eloxatin®

Eloxatin® (oxaliplatin), a chemotherapy drug, is a platinum-based cytotoxic agent. In combination with the infusional administration of two other chemotherapy drugs (5-fluorouracil/leucovorin, in the FOLFOX regimen), Eloxatin® is approved by the FDA for adjuvant treatment of people with stage III colon cancer who have had their primary tumors surgically removed. It is also approved for the treatment of advanced colorectal cancer and in some countries for the treatment of early-stage gastric cancer. Generics of oxaliplatin have been launched globally. Eloxatin® is in-licensed from Debiopharm.

Zaltrap®

Zaltrap® (aflibercept/ziv-aflibercept) is a recombinant fusion protein. The FDA approved Zaltrap® in August 2012 for use in combination with FOLFIRI (a chemotherapy regimen made up 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 marketed in 50 countries. For additional information on the commercialization of Zaltrap®, see “Item 5. Operating and Financial Review and Prospects — Financial Presentation of Alliances — Alliance Arrangements with Regeneron”.

Amaryl®/Amarel®/Solosa®

Amaryl® (glimepiride) is an orally administered once-daily sulfonylurea available in single form or in combination with metformin, indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. A number of glimepiride generics are available in most markets.

Generics

On September 30, 2018, we completed the divestment of our European generics business Zentiva to Advent International, a US global private equity firm. We have retained our presence in Generics in emerging markets, especially in Latin America with two top-of-mind brands – Medley (Brazil) and Genfar (Colombia, Peru, Ecuador and Central America) – and also in Russia, South Africa and Turkey.

B.3. Vaccine products

The Vaccines division of Sanofi is a world leader in the vaccine industry and a key supplier of life-saving vaccines all over the world and for publicly funded international stakeholders such as UNICEF, the Pan American Health Organization (PAHO) and the Global Alliance for Vaccines and Immunization (GAVI).

The Vaccines portfolio includes the following vaccines:

Poliomyelitis, pertussis and Hib pediatric vaccines

Sanofi 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.

Tetraxim®, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis and poliomyelitis (polio), was first marketed in 1998. To date, the vaccine has been launched in close to 90 countries outside the US.

Pentaxim®, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis, polio and Hemophilus influenzae type b (Hib), was first marketed in 1997. To date, the vaccine has been launched in more than 100 countries outside the US. In most European, Latin American, Asian and Middle Eastern markets, Pentaxim® is being gradually replaced by Hexaxim®.

Hexaxim®/Hexyon®/Hexacima® is a fully liquid, ready-to-use 6-in-1 (hexavalent) pediatric combination vaccine that provides protection against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. Hexaxim® is the only combination vaccine including acellular pertussis (acP) and inactivated polio vaccines (IPV) currently prequalified by the WHO. Hexaxim® is now available in more than 100 countries outside the US.

Pentacel®, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis, polio and Hib, was launched in the US in 2008.

Quadracel® is a vaccine indicated for active immunization against diphtheria, tetanus, pertussis and poliomyelitis, used in children aged 4 through 6 years as a fifth dose in the diphtheria, tetanus, pertussis vaccination (DTaP) series, and as a fourth or fifth dose in the inactivated poliovirus vaccination (IPV) series.

Shan5® is a 5-in-1 (whole-cell pertussis based) combination vaccine protecting against five diseases (diphtheria, tetanus, pertussis, Hib and hepatitis B). Following a strategic assessment of the whole-cell pertussis market, Sanofi has decided to cease the production of the Shan5® and Shan6® vaccines produced in Hyderabad, India.

Act-Hib® is a standalone vaccine protecting against Hib, and is mainly distributed in the US, Japan and China in conjunction with pertussis combination vaccines that do not contain the Hib valence.

Sanofi is a leading provider of polio vaccines and has been a partner of the Global Polio Eradication Initiative (GPEI) for over 30 years, with more than 13 billion doses of oral polio vaccines (OPV) delivered during that time.

Between 2014 and 2022, Sanofi has provided 395 million doses of inactivated polio vaccine to Unicef , to support the WHO "Polio End Game" strategy for the world's 73 poorest countries.

Vaxelis® is a hexavalent combination vaccine protecting against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. This vaccine (developed and distributed in partnership with Merck) was approved in 2016 by the EMA and is distributed in various EU countries. Vaxelis® was approved by the FDA in December 2018, becoming the first hexavalent vaccine to be approved in the US, and launched in this country in June 2021.

Meningitis vaccines

Menactra®, the first quadrivalent conjugate vaccine against meningococcal meningitis (serogroups: A, C, Y, and W-135), one of the deadliest forms of meningitis, is indicated for people aged 9 months through 55 years. Since launch, it has become a strong leader in the meningitis quadrivalent market, globally and in the US. It is also commercialized in a number of countries including Canada, several Middle Eastern countries, and numerous other countries (excluding Europe). Menactra® was the first fully liquid (no reconstitution needed) meningitis quadrivalent conjugated vaccine, and more than 100 million doses of this vaccine have been distributed since launch.

MenQuadfi® is a novel fully-liquid meningococcal quadrivalent conjugated vaccine expected to have a broad age indication from infants (6 weeks) to the elderly, with flexible dosing schedules. MenQuadfi® is the first and only quadrivalent ACWY vaccine to demonstrate superior immune response against serogroup C in toddlers compared to a monovalent serogroup C vaccine (standard-of-care in multiple markets in Europe and internationally). It is expected to be available worldwide, progressively replacing Menactra®, and allowing Sanofi to enter the European meningococcal market. MenQuadfi® was approved in the US in April 2020 for people aged two years and above. It was also approved in Australia, Canada, the EU and other European Economic Area countries in the fourth quarter of 2020, and subsequently in Argentina, Brazil and Chile, for people aged 12 months and above. MenQuadfi® has also recently been approved in Japan, and marketing authorization is pending in numerous other countries. Extension of the age indication down to six weeks of age will follow submission of additional Phase III data. MenQuadfi® was launched in the US and Europe in 2021.

Booster vaccines

Adacel® is the first trivalent booster vaccine offering protection against diphtheria, tetanus and pertussis. The vaccine can be used from 4 years of age following primary immunization and is the first Tdap vaccine indicated for use during pregnancy for protection against pertussis in newborns. It is available in 55 countries including the US and other countries mostly in Europe, Asia and Latin America.

Repevax®/Adacel®-Polio is a combination vaccine that provides protection against diphtheria, tetanus, pertussis and polio. It is the first Tdap-IPV vaccine indicated for use during pregnancy for protection against pertussis in newborns. It is currently marketed in 26 countries outside the US, with a strong focus on European markets (such as France and Germany).

Travel and endemic vaccines

Sanofi provides a wide range of travel and endemic vaccines including hepatitis A, typhoid, cholera, yellow fever and rabies vaccines. These products 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.

Influenza vaccines

Sanofi is a world leader in the production and marketing of influenza vaccines, offering several distinct influenza vaccines that are sold globally to meet growing demand.

Fluzone® Quadrivalent is a quadrivalent inactivated influenza vaccine, produced in the US, containing two type A antigens and two type B antigens in order to provide increased protection against more circulating strains of influenza viruses. Fluzone® Quadrivalent/FluQuadri® is available in 7 countries (including the US) for children aged over six months, adolescents and adults. Fluzone® 0.5 ml QIV is the currently-licensed standard dose (15 μg/strain) quadrivalent influenza vaccine for ages 6 months and older.

Fluzone® High-Dose Quadrivalent, designed specifically to provide greater protection against influenza for people aged 65 years and older, was approved by the FDA in November 2019. It has now fully replaced Fluzone® High-Dose Trivalent, and contains two influenza A and two influenza B strains at 60 μg/strain. Fluzone® High-Dose Quadrivalent was approved in the EU in the second quarter of 2020, under the name Efluelda®, indicated for adults aged 60 years and above. Both Fluzone® High-Dose Quadrivalent and Efluelda® have been available since the 2020/21 influenza season. To date, this product has been distributed to 16 countries worldwide.

Flublok® is a quadrivalent recombinant protein based influenza vaccine indicated for adults aged 18 years of age and older. Flublok® is currently licensed in the US and Hong Kong. This same recombinant protein-based influenza vaccine is also licensed under the brand name Supemtek® in Canada, the United Kingdom, the European Union and Switzerland.

Vaxigrip® is a trivalent influenza vaccine, containing two antigens against type A influenza viruses and one antigen against type B influenza viruses. It has now been replaced by VaxigripTetra® in most countries in which it is commercialized.

VaxigripTetra® is the quadrivalent (QIV) version of Vaxigrip®, including two antigens against A strains of influenza viruses and two antigens against B strains. Compared to the trivalent influenza vaccine, it contains an additional influenza B strain; it was licensed in 2016 and has been launched in more than 95 countries since 2017. VaxigripTetra® is not licensed in the US where Fluzone® Quadrivalent, which is produced in the US, is distributed.

COVID Vaccine

COVID-19 recombinant adjuvanted vaccine: VidPrevtyn® Beta is a recombinant spike protein vaccine developed in partnership with GSK and using GSK's AS03 adjuvant. It is indicated as an adult booster to protect against SARS-CoV-2 infections. Phase III results demonstrated significant vaccine efficacy against symptomatic infection with a Beta variant-containing vaccine in the face of an Omicron variant predominated pandemic period. Significant efficacy was demonstrated in naive individuals and individuals previously infected or vaccinated. These results, coupled with data from comprehensive studies to evaluate the vaccine as a heterologous booster for people initially vaccinated with Emergency Use Authorization (EUA) vaccines, supported VidPrevtyn® Beta's full marketing authorization for the booster indication in both the EU and the UK. The first doses were supplied at the end of 2022.

B.4. Consumer Healthcare

In 2022, we progressed further in building and simplifying our stand-alone Consumer Healthcare (CHC) organization within Sanofi. Almost all of the newly-created CHC legal entities required to establish the standalone organization are now operational, and our portfolio has been significantly simplified by way of divestments with just 140 brands currently, down from 250 eighteen months ago. Recently, additional critical support functions have been brought together under the single CHC umbrella including People & Culture, Finance, Digital and Legal, Ethics & Business Integrity. This represents a key step in our journey to build a stand-alone CHC business, accelerating the full integration of our operating model while enhancing the speed and relevancy of our engagement with our consumers.

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

Allergy, Cough & Cold

- Allegra® comprises a range of fexofenadine HCl-based products. Fexofenadine is an anti-histamine for relief from allergy symptoms including sneezing, runny nose, itchy nose or throat, and itchy, watery eyes. The Allegra® brand family is sold in more than 80 countries across the world.
- Mucosolvan® is a cough brand with many different formulations. It contains the mucoactive agent ambroxol; this stimulates synthesis and release of surfactant. It is sold in various countries in Europe, Latin America, Asia and Russia.

Pain

- Doliprane® 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® range (hyoscine butylbromide) has an antispasmodic action that specifically targets the source of abdominal pain and discomfort. It is sold across the globe.
- We also have local pain brands such as Eve® in Japan; Dorflex® and Novalgina® in Brazil; and Icy Hot® and Aspercreme® in the US.

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 or sodium picosulfate, which works directly on the colon to produce a bowel movement.
- Enterogermina® is a probiotic 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 360°™ products are for the prevention and relief of heartburn, with a new formula launched in 2021 in North America.

Nutritional

- Nutritionals include a range of products to maintain general health, provide immune system support, or supplement vitamin deficiencies. These products help manage energy, stress, sleep and anxiety, and include a number of brands across the globe including Nature's Own® in Australia to improve and maintain health; Pharmaton® (mainly in Europe and Latin America); Magne B6® in Europe; and a range of sleep brands, including Novanuit® in Europe, Unisom® in US and Drewell® in Japan.

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.5. Global research & development

Sanofi's 'Play to Win' strategy (see section "*Item 4. Information on the Company — B. Business Overview — B.1. Strategy*") has been implemented to drive innovation and growth so that we can seek breakthroughs with our most promising medicines, to address significant patient needs. Global research and development (R&D) has focused efforts in therapeutic areas where patient needs are most urgent: oncology, immunology, neurology, rare diseases, and rare blood disorders. As part of our strategic framework, five potentially transformative therapies in areas of high unmet patient need were prioritized: fitusiran and efanesoctocog alfa (hemophilia); amlitelimab (Immunology & Inflammation); tolebrutinib (multiple sclerosis); and nirsevimab (prevention of respiratory syncytial virus).

Our aspiration is to build an R&D pipeline of first-in-class or truly differentiated best-in-class medicines, with two-thirds of the biologic compounds and two-thirds of the pipeline directly derived from Sanofi internal research. However, discovering and developing new medicines is a costly, lengthy, and uncertain process and our continuous investments in R&D for future products and for the launches of newly registered medicines could result in increased costs without a proportionate increase in revenues. See "*Item 3. Key Information — D. Risk Factors"* for further information.

In 2022, the reshaping and consolidation of our R&D portfolio in oncology and immune diseases was pursued, as exemplified by the acquisition of Amunix Pharmaceuticals, Inc. (adding to our early portfolio SAR446309, a HER2 T cell engager, formerly known as AMX-818); the restructuring of our global immuno-oncology license and collaboration agreement with Regeneron Pharmaceuticals, Inc.; and collaboration and license agreements with Exscientia, Blackstone Life Sciences, Seagen, IGM Biosciences, Innovent Biologics and Innate Pharma (for further information, see sections *"Item 4. Information on the Company — A. History and development of the Company"; "— B.1. Strategy"; "— B.2. Main pharmaceutical products"; "Item 5. Operating and Financial Review and Prospects — A.1.1. 2022 Overview"*). For more details on R&D assets in the scope of these agreements, see section *B.5.1.1. Products in development* and section *B.5.1.2. Line extensions* below.

B.5.1. Pharmaceuticals

For 2022, the main pipeline changes related to the pharmaceuticals portfolio were:

Project	Potential Indication	Change	Reason
SAR444200 – Anti-GPC3/TCR NANOBODY® VHH	Solid tumors	Added	Entered confirmatory development
SAR445877 – Anti-PD1 x IL15 fusion protein	Solid tumors	Added	Entered confirmatory development
SAR446309 – HER2 T cell engager (AMX-818)	Solid tumors	Added	Acquired from Amunix
SAR444419 – Anti-TNFa x IL6 NANOBODY® VHH	Inflammatory indication	Added	Entered confirmatory development
SAR444559 – Anti-CD38 mAb – Next generation	Inflammatory indication	Added	Entered confirmatory development
SAR446159 – Anti-alpha-synuclein x IGF1R mAb	Parkinson's disease	Added	Entered confirmatory development[(a)]
Xenpozyme® – olipudase alfa	Acid sphingomyelinase deficiency	Removed	Commercialized
Enjaymo® – sutimlimab	Cold agglutinin disease	Removed	Commercialized
Libtayo® - cemiplimab	1st line NSCLC[(d)] with chemotherapy	Removed	Commercialized[(b)]
Libtayo® - cemiplimab	2nd line cervical cancer; Adjuvant CSCC[(e)]	Removed	Development discontinued[(b)]
amcenestrant – Selective estrogen receptor degrader	Breast cancer	Removed	Development discontinued
SAR442720 – SHP2 inhibitor	Solid tumors	Removed	Development discontinued[(c)]
SAR442999 – Anti-TNFa/IL23A NANOBODY® VHH	Inflammatory indication	Removed	Development discontinued
SAR443726 – Anti-IL13/OX40L NANOBODY® VHH	Atopic dermatitis	Removed	Development discontinued
SAR339375 – miRNA-21	Alport syndrome	Removed	Development discontinued

mAb: monoclonal antibody.
(a) SAR446159: developed in collaboration with ABL Bio.
(b) Libtayo®: worldwide exclusive license rights granted to Regeneron.
(c) SAR442720: termination of the collaborative agreement with Revolution Medicines.
(d) NSCLC: non-small cell lung cancer.
(e) CSCC: cutaneous squamous cell carcinoma.

The clinical portfolio of products as of December 31, 2022 is summarized in the table below; where several indications are being developed for one product, each indication is regarded as a separate project and specified individually.

	Phase I	**Phase II**	**Phase III/registration**
Oncology	SAR444245 dose optimization (solid tumors) SAR441000 (solid tumors) SAR442257 (multiple myeloma/non Hodgkins lymphoma) SAR444881 (solid tumors) SAR445419 (acute myeloid leukemia) SAR443216 (gastric cancer) SAR443579 (acute myeloid leukemia) SAR445710 (solid tumors) SAR446309 (solid tumors) SAR444200 (solid tumors) SAR445877 (solid tumors)	alomfilimab (solid tumors) tusamitamab ravtansine + pembrolizumab (non-small cell lung cancer 1st line) tusamitamab ravtansine + ramucirumab (non-small cell lung cancer 2nd/3rd line) tusamitamab ravtansine (exploratory solid tumors) tusamitamab ravtansine + ramucirumab (gastric cancer) Sarclisa® (1st/2nd line acute myeloid leukemia/acute lymphoblastic leukemia) Sarclisa® + combinations (relapsed, refractory multiple myeloma)	tusamitamab ravtansine (non-small cell lung cancer 2nd/3rd line) Sarclisa® + combinations (1st line newly diagnosed multiple myeloma not eligible for transplant) Sarclisa® + combinations (1st line newly diagnosed multiple myeloma eligible for transplant) Sarclisa® + combinations (smoldering multiple myeloma) Sarclisa® subcutaneous + combinations (2nd/3rd line relapsed, refractory multiple myeloma)
Immunology & Inflammation	SAR441566 (inflammatory indication) SAR444656 (atopic dermatitis) SAR442970 (inflammatory indication) SAR443765 (inflammatory indication) SAR444336 (inflammatory indication) SAR444419 (inflammatory indication) SAR444559 (inflammatory indication)	amlitelimab (atopic dermatitis) amlitelimab (asthma) rilzabrutinib (IgG4 related disease) rilzabrutinib (atopic dermatitis) rilzabrutinib (asthma) rilzabrutinib (chronic spontaneous urticaria) eclitasertib (cutaneous lupus erythematosus) eclitasertib (ulcerative colitis) atuzabrutinib (atopic dermatitis) frexalimab (Sjogren's syndrome) frexalimab (systemic lupus erythematosus) SAR445088 (antibody-mediated rejection) Kevzara® (polyarticular juvenile idiopathic arthritis) Kevzara® (systemic juvenile idiopathic arthritis)	itepekimab (chronic obstructive pulmonary disease) Dupixent® (bullous pemphigoid) Dupixent® (chronic spontaneous urticaria) Dupixent® (chronic obstructive pulmonary disease) Dupixent® (chronic inducible cold urticaria) Dupixent® (chronic rhinosinusitis without nasal polyposis) Dupixent® (allergic fungal rhinosinusitis) Dupixent® (chronic pruritis of unknown origin)
Neurology	SAR446159 (Parkinson's disease)	frexalimab (multiple sclerosis) SAR445088 (chronic inflammatory demyelinating polyneuropathy) SAR443820 (amyotrophic lateral sclerosis)	tolebrutinib (relapsing multiple sclerosis) tolebrutinib (primary progressive multiple sclerosis) tolebrutinib (secondary progressive multiple sclerosis)
Rare Diseases	SAR442501 (achondroplasia) SAR443809 (rare renal diseases) SAR439459 (Osteogenesis imperfecta)		Nexviazyme® (Pompe disease – Infantile onset) venglustat (GM2 gangliosidosis) venglustat (Gaucher disease type 3) venglustat (Fabry disease)
Rare Blood Disorders		rilzabrutinib (warm autoimmune hemolytic anemia) SAR445088 (cold agglutinin disease) Sarclisa® (warm autoimmune hemolytic anemia)	ALTUVIIIO™ (hemophilia A) [(a)] fitusiran (hemophilia A&B) fitusiran (hemophilia A&B pediatric) rilzabrutinib (immune thrombocytopenia)

(a) ALTUVIIIO™ was approved by the FDA on Feb 22nd, 2023.

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.

B.5.1.1. Products in development

a) Oncology

Tusamitamab ravtansine (SAR408701) is an antibody drug conjugate (ADC) that binds to CEACAM-5, a cell-surface glycoprotein that is highly expressed in non-small cell lung cancer (NSCLC), gastric cancer and other cancers. The compound is being evaluated in Phase III (CARMEN-LC03) for the second- and third-line treatment of metastatic non-squamous NSCLC (NSQ NSCLC) with CEACAM-5 positive tumors. In addition, two Phase II studies are ongoing to evaluate the activity of the drug in combination with ramucirumab (CARMEN-LC04) or with pembrolizumab (CARMEN-LC05) in patients with metastatic NSQ NSCLC. Tusamitamab ravtansine is also being evaluated in two Phase II studies, respectively in patients with CEACAM-5 positive advanced solid tumors (CARMEN-BT01) and in patients with gastric cancer in combination with ramucirumab (CARMEN-GC01). According to the agreement between Sanofi and Innovent Biologics (see details in section *"Item 4. Information on the Company — B.1. Strategy"*), both companies are committed to accelerating the development and commercialization of tusamitamab ravtansine, combining with sintilimab, the leading checkpoint inhibitor in China.

Alomfilimab (SAR445256) is a fully human IgG1 anti-ICOS antibody with a dual mode of action, depleting ICOS high intra-tumoral T regulatory cells and stimulating ICOS low T effector cells, currently being investigated in Phase II for the treatment of solid tumors.

SAR444245 is a non-alpha durably pegylated interleukin-2 (IL-2) for which a new Phase I/II program is planned to be initiated in 2023 in solid tumors, to solidify the foundation for a best-in-class target profile. The revision of the clinical program was based on emerging external and internal data about non-alpha IL-2's mechanism of action and therapeutic potential. A decision was taken in 2022 to discontinue the Phase II trials (in advanced skin cancers, head & neck cancers, non-small cell lung cancer/mesothelioma and lymphoma) with the current 3-weekly dose schedule, as the efficacy observed in an early look at the data was lower than projected; however, this decision was not based on any safety-related issues.

SAR441000 is an intratumoral immunotherapy that uses mRNA to encode cytokines and stimulate both innate and adaptive arms of the immune system to maximize anti-tumor activity. It is developed in collaboration with BioNTech for the treatment of solid tumors. A Phase I study assessing SAR441000 as monotherapy and in combination with cemiplimab in patients with advanced solid tumors, including melanoma, is ongoing.

SAR442257, an anti-CD3/CD28/CD38 trispecific monoclonal antibody, is currently being evaluated in Phase I for the treatment of multiple myeloma/non-Hodgkin lymphoma.

SAR444881, a monoclonal antibody targeting the Ig-like transcript 2 (ILT2) receptor developed with Biond Biologics for the treatment of solid tumors, is currently being evaluated in Phase I.

SAR445419 is an off-the-shelf NK cell therapy currently being evaluated in Phase I. A new patient cohort in the Ohio State University study evaluating SAR445419 for the treatment of relapsed/refractory acute myeloid leukemia started enrollment in 2022.

SAR443216 is a T cell engager with a trispecific antibody format designed to target HER2 (on tumor cells), CD3 (on T cells) and CD28 (a co-receptor for T cell activation), respectively. SAR443216 is currently being evaluated in Phase I for the treatment of gastric cancer.

SAR443579 is a NKp46/CD16-based NK cell engager with a multispecific antibody format developed in partnership with Innate Pharma. SAR443579 is being investigated in a Sanofi-sponsored Phase I/II clinical trial in patients with relapsed or refractory acute myeloid leukemia, B-cell acute lymphoblastic leukemia or high risk-myelodysplasia.

SAR445710 is an anti PD-L1/IL-15 fusion protein currently being evaluated in Phase I in patients with solid tumors.

SAR446309 (formerly AMX-818), an HER2-based T cell engager acquired from Amunix Pharmaceuticals, entered clinical development in 2022 for the treatment of solid tumors. SAR446309 is currently evaluated, alone and in combination with pembrolizumab, in a Phase I clinical trial in patients with locally advanced or metastatic HER2-expressing cancers.

SAR444200 is a GPC3-based T cell engager designed with a NANOBODY® VHH format that entered clinical development in 2022. SAR444200 is currently being evaluated in Phase I in patients with advanced solid tumors.

SAR445877 is an anti PD1/IL-15 fusion protein that entered clinical development in 2022, with a Phase I trial initiated in patients with solid tumors.

b) Immunology & Inflammation

Itepekimab (SAR440340) is a human anti-IL33 monoclonal antibody derived from our alliance with Regeneron that is currently being evaluated in a Phase III clinical program (AERIFY-1 and AERIFY-2 studies) for the treatment of chronic obstructive pulmonary disease in former smokers; a cohort of current smokers is also assessed in AERIFY-2. In October 2022, a two-part open label prospective mechanistic study in former and current smokers (AERIFY-3) enrolled its first patients.

Amlitelimab (SAR445229), an anti-OX40L monoclonal antibody, is currently in Phase II for the treatment of adults with moderate to severe atopic dermatitis. In 2022, a Phase II study (TIDE-asthma) was initiated to assess add-on therapy with amlitelimab in adults with moderate-to-severe asthma.

Rilzabrutinib (SAR444671) is a covalent and reversible inhibitor of Bruton's tyrosine kinase under development for the treatment of autoimmune/inflammatory diseases. In 2022, the ongoing Phase II trials assessing rilzabrutinib for the treatment of IgG4-related disease and atopic dermatitis, respectively, were pursued. In addition, two Phase II studies have enrolled their first participants in adults with moderate-to-severe asthma and in chronic spontaneous urticaria (CSU), respectively. Rilzabrutinib is also being evaluated for the treatment of immune thrombocytopenia and warm autoimmune hemolytic anemia (see details below in section *e) Rare Blood Disorders*).

Eclitasertib (SAR443122) is a small molecule against the receptor-interacting serine/threonine-protein kinase 1 (RIPK1) developed in collaboration with Denali. A proof-of-concept Phase II study assessing the efficacy and safety of eclitasertib in patients with cutaneous lupus erythematosus is ongoing. In 2022, a Phase II study evaluating eclitasertib in patients with ulcerative colitis was initiated.

Atuzabrutinib (SAR444727), an inhibitor of Bruton's tyrosine kinase, is currently under investigation in Phase II as a topical agent for the treatment of atopic dermatitis.

Frexalimab (SAR441344), an anti-CD40L monoclonal antibody developed in collaboration with Immunext, is being investigated in two Phase II trials for the treatment of Sjogren's syndrome and systemic lupus erythematosus, respectively. SAR441344 is also being evaluated in multiple sclerosis (see section *c) Neurology*).

SAR445088, a complement C1s inhibitor already under clinical development (see details in section *e) Rare Blood Disorders* and section *c) Neurology*), entered an additional Phase II study in 2022, assessing the compound for the treatment of patients at risk of antibody-mediated rejection (AMR) or diagnosed with AMR.

SAR444656 is an IRAK4 degrader with potential therapeutic application across multiple indications, including atopic dermatitis. SAR444656 is developed in collaboration with Kymera Therapeutics and is currently under evaluation in Phase I.

SAR441566, the first oral small molecule TNFa inhibitor currently evaluated in Phase I, is intended to provide patients an oral alternative to anti-TNFa monoclonal antibodies in the range of inflammatory indications where these have been approved.

SAR442970, a bispecific NANOBODY® VHH that combines blockade of TNFa and the immune co-stimulatory regulator OX40L for the treatment of inflammatory indications, is under evaluation in Phase I.

SAR443765 is a bispecific NANOBODY® VHH targeting TSLP and IL-13 currently evaluated in Phase I for the treatment of inflammatory indications.

SAR444336, a pegylated non-beta IL-2 designed to selectively engage CD4+ regulatory T cells (and not on effector T or NK cells) for the treatment of inflammatory indications, is currently evaluated in Phase I.

SAR444419 is a bispecific NANOBODY® VHH blocking TNFa and IL6 that entered clinical development in November 2022 for the treatment of inflammatory indications.

SAR444559, an anti-CD38 monoclonal antibody with engineered format, entered clinical development in December 2022 for the treatment of inflammatory indications.

c) Neurology

Tolebrutinib (SAR442168), an orally administered Bruton's tyrosine kinase (BTK) inhibitor designed to access the brain and spinal cord by crossing the blood-brain barrier and impacting immune cell and brain cell signaling, is currently being investigated in Phase III trials. Following written notification from the FDA in July 2022 requesting additional data, Sanofi provided the information with the aim of lifting the partial clinical hold (recruitment pause). In relapsing multiple sclerosis (MS), the Phase III studies GEMINI 1 and GEMINI 2 reached their respective target enrollment in 2022. Recruitment was completed in December 2022 in the Phase III trial HERCULES in non-relapsing secondary progressive MS, an area of highest unmet medical need in MS with no treatment currently available. In primary progressive MS, recruitment is ongoing in the Phase III trial PERSEUS. The Phase III study URSA evaluating tolebrutinib in patients with moderate-to-severe myasthenia gravis (MG) was discontinued in 2022 after careful evaluation of the emerging competitive treatment landscape.

Frexalimab (SAR441344) is a monoclonal antibody against CD40L (see section *b) Immunology & Inflammation*), a key immune costimulatory component involved in MS, currently being evaluated in a Phase II trial.

SAR445088, a complement C1s inhibitor (see details in section *e) Rare Blood Disorders*), is being assessed in a Phase II trial in patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

SAR443820 (also known as DNL788) is a RIPK1 inhibitor developed in collaboration with Denali for the treatment of amyotrophic lateral sclerosis (ALS). In 2022, a Phase II study assessing the safety and efficacy of SAR443820 for the treatment of ALS started enrollment.

SAR446159 (also known as ABL301) is a bispecific antibody targeting both alpha-synuclein and insulin-like growth factor 1 receptor (IGF1R) developed in collaboration with ABL Bio for the treatment of Parkinson's disease; a Phase I study assessing the safety and tolerability of intravenous SAR446159 was initiated in December 2022.

d) Rare Diseases

Nexviazyme® (avalglucosidase alfa) is a long-term enzyme replacement therapy targeting the mannose-6-phosphate receptor to effectively clear glycogen build-up in muscle cells. This enzyme replacement therapy is approved in the US, in Japan and in Europe (see section below *"— B.5.1.2. Line extensions"*) for the treatment of patients with Pompe disease, a rare disease caused by a deficiency of the enzyme acid alpha-glucosidase (GAA). Nexviazyme® is currently being investigated in a Phase III study for the treatment of patients aged 6 months or younger who are affected by infantile onset Pompe disease.

Venglustat (GZ402671) is an orally administered brain penetrant glucosylceramide synthase (GCS) inhibitor that blocks the conversion of ceramide to glucosylceramide (GL-1). Venglustat is currently in development for the treatment of three lysosomal storage diseases: late-onset GM2 gangliosidosis (Tay-Sachs disease and Sandhoff disease), Fabry disease, and Gaucher disease type 3. Recruitment of participants to the Phase III study in late-onset GM2 gangliosidosis was completed early 2022; in this trial, the efficacy and pharmacodynamics of venglustat is being assessed over a two-year period. In 2022, two Phase III trials were initiated to evaluate the impact of venglustat on Fabry disease-specific personalized endpoints. In respect to Gaucher disease type 3, the Phase III study enrolled its first participants in 2022.

SAR442501 is an anti-FGFR3 (fibroblast growth factor receptor 3) antibody (Fab format) that directly targets overactive FGFR3 in achondroplasia, a skeletal dysplasia with high unmet medical need. SAR442501 is being investigated in a Phase I study for the treatment of patients with achondroplasia with unfused growth plates (typically younger than 18 years of age).

SAR443809, a humanized monoclonal antibody that selectively inhibits the activated fragment of factor B (termed Bb) in the alternative pathway of the complement system, is being evaluated in a Phase I trial for the treatment of rare renal diseases.

SAR439459 is a monoclonal antibody targeting transforming growth factor beta (TGFβ); in December 2022, a Phase I study was initiated to evaluate the safety, tolerability, and activity of a single dose of SAR439459 in adult participants with Osteogenesis imperfecta, also called brittle bone disease, a rare disease in which bones fracture easily. Orphan Drug Designation was granted by the FDA for this indication.

e) Rare Blood Disorders

ALTUVIIIO™ (efanesoctocog alfa/BIVV001) is an investigational factor VIII replacement therapy developed in collaboration with Sobi® for people with hemophilia A, a rare and life-threatening bleeding disorder. In 2022, the FDA accepted for priority review the Biologics License Application (BLA) for ALTUVIIIOTM for the treatment of hemophilia A. On February 22, 2023, the US Food and Drug Administration (FDA) approved ALTUVIIIO™. The approval was supported by data from the pivotal XTEND-1 Phase III study, that demonstrated a clinically meaningful prevention of bleeds and superiority to prior factor prophylaxis based on an intra-patient comparison in people 12 years of age or older. A Phase III study evaluating efanesoctocog alfa in pediatric patients younger than 12 years of age is ongoing; availability of data and regulatory submission in the European Union are expected in 2023.

Fitusiran (SAR439774) is a siRNA targeting antithrombin developed in collaboration with Alnylam for the prophylactic treatment of patients with hemophilia A or B, rare congenital bleeding disorders caused by a deficiency of factor VIII and IX, respectively. In 2022, positive data were reported from the Phase III ATLAS-PPX study evaluating the efficacy and safety of once-monthly fitusiran (80 mg) in adults and adolescents (aged 12 years and over) with severe hemophilia A or B who were previously treated with prior factor or bypassing agent prophylaxis. Collectively with results from the ATLAS A/B and ATLAS-INH Phase III studies, these data add to a growing body of evidence supporting the potential of 80 mg dose, monthly fitusiran prophylaxis to transform treatment for all people with hemophilia. The clinical program is continuing with an amended protocol with two lower doses to optimize the benefit/risk profile of fitusiran. Data with lower doses are expected in the second half of 2023; the first submission is planned for 2024. The ATLAS-PEDS study assessing fitusiran in pediatric patients aged 12 years and under is ongoing.

Rilzabrutinib (SAR444671) is being investigated in a Phase III trial for the treatment of adults and adolescents with persistent or chronic immune thrombocytopenia (ITP); the FDA has granted Fast Track Designation for this indication. In 2022, a Phase II study assessing rilzabrutinib in adults with warm autoimmune hemolytic anemia (wAIHA) enrolled its first participants.

SAR445088 is a humanized IgG4 monoclonal antibody that binds to and inhibits C1s, thereby inhibiting classical pathway (CP) of complement activity. Activation of the CP of complement is associated with a variety of immune disorders involving the presence of autoantibodies. Inhibition of autoantibody-mediated CP activation on the surface of erythrocytes via C1s binding prevents complement opsonin deposition on red blood cells and protects them from phagocytosis and extravascular hemolysis in autoimmune hemolytic anemia such as cold agglutinin disease (CAD); SAR445088 is currently under evaluation in a Phase II study in this indication.

B.5.1.2. Line extensions

For more information on Libtayo®, Sarclisa®, Dupixent®, Kevzara®, Cerdelga®, Nexviazyme® and Cablivi® see also *"Item 4. Information on the Company — B. Business Overview — B.2. Main Pharmaceutical Products"*.

Sarclisa® (isatuximab) is a monoclonal antibody designed to selectively bind to CD38, a cell surface antigen expressed in multiple myeloma (MM) cancer cells and other hematological malignancies. Based on the Phase III studies ICARIA-MM and IKEMA, Sarclisa® is approved in several countries in combination settings for the treatment of adults with relapsed refractory multiple myeloma (RRMM).

In 2022, R&D efforts were pursued to evaluate Sarclisa® in combination with current standard and novel treatments across the MM treatment continuum:

- the IMROZ Phase III study is assessing the clinical benefit of Sarclisa® in combination with bortezomib, lenalidomide and dexamethasone versus bortezomib, lenalidomide and dexamethasone in patients with newly diagnosed MM not eligible for transplant; filing in this indication is expected in 2024;
- the IRAKLIA Phase III study comparing subcutaneous to intravenous administration of Sarclisa® in combination with pomalidomide and dexamethasone in RRMM patients who have received at least one prior line of therapy enrolled its first participants in July 2022;
- the GMMG HDF Phase III study is evaluating the clinical benefit of Sarclisa® in combination with lenalidomide, bortezomib and dexamethasone for induction and with lenalidomide for maintenance in patients with newly diagnosed MM. This study is being conducted in collaboration with the German-speaking Myeloma Multicenter Group (GMMG);
- the ITHACA Phase III trial is assessing Sarclisa® in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone in patients with high-risk smoldering MM;
- a Phase II study is ongoing to evaluate Sarclisa® in new combinations with emerging novel mechanisms of action in patients with RRMM or in newly diagnosed MM patients.

A Phase II study assessing Sarclisa® in combination with chemotherapy in pediatric patients with relapsed/refractory B or T acute lymphoblastic leukemia or acute myeloid leukemia in first or second relapse is ongoing.

Sarclisa® is also under investigation in a Phase II trial for the subcutaneous treatment of adults with warm autoimmune hemolytic anemia (wAiHA), a rare blood disorder.

Libtayo® (cemiplimab) is a monoclonal antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1), approved in several countries for the treatment of skin cancers (metastatic or locally advanced cutaneous squamous cell carcinoma and basal cell carcinoma), for the treatment of NSCLC, and for second-line treatment of cervical cancer. Libtayo® has been jointly developed by Regeneron and Sanofi under a global collaboration agreement originally entered into in 2015. As detailed in section *"— B.5. Global research & development",* the agreement was amended and restated in June 2022 and Sanofi granted Regeneron worldwide exclusive license rights to Libtayo®.

In January 2022, Sanofi and Regeneron announced the voluntary withdrawal of the supplemental Biologics License Application for second-line treatment of cervical cancer in the US. In the last quarter of 2022, Libtayo® was approved in Europe and in Japan for second-line treatment of cervical cancer.

In November 2022, Libtayo® in chemotherapy combination was approved by the FDA for the first-line treatment of non small cell lung cancer. Libtayo® is currently under review by the EMA in the same indication; the final decision is expected in February 2023.

Dupixent® (dupilumab) is a human monoclonal antibody that binds to the IL-4 receptor α subunit and inhibits IL-4 and IL-13 signaling, jointly developed with Regeneron. Dupixent® has received regulatory approvals in several countries for use in patients with AD, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), EoE or prurigo nodularis in different age populations; details are provided below.

Atopic dermatitis

In February 2022, the product was approved in China for the treatment of children aged 6-11 years with moderate-to-severe AD.

In June 2022, it was approved in the US for the treatment of children aged 6 months to 5 years with moderate-to-severe AD.

Asthma:

Dupixent® was approved in the EU in April 2022 for children aged 6 to 11 years with severe asthma with type 2 inflammation. The approval was based on Phase III data showing significant reduction of severe asthma attacks and also improvement of lung function and health-related quality of life for children.

Eosinophilic esophagitis (EoE)

In May 2022, the FDA approved Dupixent® to treat patients with EoE aged 12 years and older after granting the medicine Priority Review. In January 2023, Dupixent® was approved by European Commission for the treatment of patients with EoE aged 12 years and older.

A Phase III trial assessing the investigational use of Dupixent® in children aged 1 to 11 years with EoE met its primary endpoint of histological disease remission at 16 weeks with both higher and lower dose weight-tiered regimens. Filing for the treatment of this pediatric population is expected in 2023.

Prurigo nodularis

Dupixent® was approved in the US in September 2022 after Priority Review for the treatment of adults with prurigo nodularis. With this approval, Dupixent® became the first and only medicine specifically indicated to treat prurigo nodularis in the US. In December 2022, the European Commission expanded the marketing authorization for Dupixent® (dupilumab) in the EU to treat adults with moderate-to-severe prurigo nodularis who are candidates for systemic therapy.

Prurigo nodularis is a chronic, debilitating skin disease with underlying type 2 inflammation and its impact on quality of life is one of the highest among inflammatory skin diseases.

Other indications

Phase III clinical studies are currently investigating Dupixent® for the treatment of a range of dermatology and respiratory diseases:

- chronic spontaneous urticaria: submission of the product for this indication in the US was completed in December 2022;
- bullous pemphigoid;
- chronic inducible cold urticaria;
- chronic pruritis of unknown origin;
- chronic obstructive pulmonary disease;
- chronic rhinosinusitis without nasal polyps; and
- allergic fungal rhinosinusitis.

Kevzara® (sarilumab), a monoclonal antibody against the IL-6 receptor developed with Regeneron is already marketed in the treatment of moderate to severe rheumatoid arthritis. The product is currently being evaluated in pivotal Phase IIb studies in pediatric populations for two indications:

- polyarticular juvenile idiopathic arthritis; filing in this indication is expected in 2023; and
- systemic juvenile idiopathic arthritis.

Cerdelga® (eliglustat) is a potent, highly specific ceramide analog inhibitor of GL-1 synthesis marketed for Gaucher disease type 1 (GD1) in adult patients. A Phase III trial is currently evaluating Cerdelga® for the treatment of pediatric patients with GD1.

Nexviadyme® (avalglucosidase alfa) was approved in Europe in 2022 for the long-term treatment of both late-onset and infantile-onset Pompe disease, a rare, progressive and debilitating muscle disorder caused by a deficiency of the enzyme acid alpha-glucosidase (GAA). Outside of Europe, the treatment is marketed under the brand name Nexviazyme®.

Cablivi® was approved by the Japanese Ministry of Health, Labor and Welfare (MHLW) in September 2022 for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP).

B.5.2. Vaccines

The Vaccines R&D portfolio includes 11 projects in advanced development (including one monoclonal antibody candidate), as shown in the table below.

Phase I	Phase II	Phase III	Registration
mRNA quadrivalent influenza vaccine	Meningococcal B Vaccine Prevention of invasive disease caused by N.Meningitidis serogroup B	MenQuadfi Advanced generation meningococcal ACYW conjugated vaccine US/EU infants aged 6 weeks & above	Nirsevimab[(a)], mAb Passive prevention of RSV infections in all infants Licensed in EU and the UK; pending licensure in the US
mRNA RSV vaccine Prevention of RSV infections in older adults	21-valent Pneumo Conjugate Vaccine (PCV21)[(a)] Prevention of pneumococcal disease	VRVg Purified vero rabies vaccine	Shan6® DTwP-HepB-Polio-Hib[(b)] Pediatric hexavalent vaccine Licensed in India and WHO pre-qualified
	RSV vaccine (PhI/II) Prevention of RSV infections in toddlers aged 6 months & older		
	Vero Yellow Fever vaccine (vYF)		
	Fluzone® QIV HD Quadrivalent inactivated influenza vaccine – High dose for pediatric use		

(a) Partnered and/or in collaboration: Sanofi may have limited or shared rights to some of these products.
(b) Hib = Haemophilus influenzae type b.

Enhancements of existing vaccines

Fluzone®: QIV HD is a higher dose quadrivalent influenza vaccine licensed in the US and in Europe for the elderly population, who do not respond as well to standard-dose influenza vaccines due to aging of the immune system (immuno-senescence). Safety and efficacy in the pediatric population will be assessed in a Phase III trial.

mRNA Quadrivalent influenza vaccine is a quadrivalent influenza vaccine based on mRNA technology, which is currently in Phase I. Following results of Phase I, the product should be moving to Phase III in 2023.

Shan6®is an all-in-one liquid hexavalent combination vaccine. It comprises detoxified whole-cell pertussis as well as diphtheria toxoid, tetanus toxoid, Hemophilus influenzae type b PRP-T, inactivated poliovirus types 1, 2, and 3 and hepatitis B virus components. Shan6® has been approved in India and obtained WHO pre-qualification in November 2022. Following a strategic assessment of the whole-cell pertussis market, Sanofi has decided to cease the production of the Shan5® and Shan6® vaccines produced in Hyderabad, India.

MenQuadfi®: Sanofi's Men ACYW-TT vaccine is our latest advance in meningococcal quadrivalent conjugate vaccination, designed to help protect an expanded patient group including infants and adolescents through older adults. MenQuadfi® is already licensed in the US (for people aged 2 years and over), and in Europe and several other countries (for people aged 12 months and over). Marketing authorization is also pending in additional countries. In January 2022, MenQuadfi® received WHO for pre-qualification for people aged 12 months and above. Additionally, Phase III trials are ongoing to evaluate immunogenicity and safety in infants aged 6 weeks and above, and allow for extension of the age indication down to 6 weeks of age.

Rabies Vaccine: a next-generation purified human rabies vaccine (VRVg) is under development, aimed at replacing both of Sanofi's currently commercialized rabies vaccines (Imovax® Rabies and Verorab®). It will be cultured on Vero cells and will be free of animal or human material. VRVg is currently in Phase III trials in order to support pre and post exposure indications.

Vero Yellow Fever (vYF) vaccine candidate is a next generation freeze-dried live-attenuated yellow fever vaccine produced on a Vero cell line, for subcutaneous and intra-muscular administration in people aged nine months and older. This vaccine aims to replace Stamaril® and YF-VAX® with a single product. In January 2020, the first Phase I/II trial was initiated in the US. In the first quarter of 2023, Phase II data against standard of care will be available.

Novel targets

Nirsevimab is a monoclonal antibody engineered to have a long half-life, so that only one dose would be needed for the entire respiratory syncytial virus (RSV) season to provide passive immunity and prevent RSV infection in all infants for their first RSV season (and in high-risk infants, for their first and second RSV seasons). Sanofi has an agreement with AstraZeneca to develop and commercialize nirsevimab. The positive primary analysis of the Phase IIb trial, published in the New England Journal of Medicine in July 2020, which demonstrated the safety and efficacy of nirsevimab, has been confirmed and enhanced in other Phase II and Phase III trials. The Phase III MELODY study, initiated in 2019, achieved its primary endpoint of protection against medically attended RSV lower respiratory tract infection in healthy full-term and late pre-term infants. The MEDLEY Phase II/III study, conducted in preterm infants and infants with chronic lung disease or congenital heart disease, showed positive safety and pharmacokinetics when compared to standard of care. Regulatory submissions started in 2022. Nirsevimab, which will be commercialized under the name of Beyfortus®, received European and UK approvals in November 2022. The file was also submitted in the US, and FDA acceptance was received in January 2023. First launches are expected in 2023. Nirsevimab was also selected by the Japanese Agency for Medical Research and Development as a priority medicine, and received breakthrough therapy designation in China in January 2021. We initiated a Phase III study in China in November 2021.

RSV toddler vaccine: Sanofi has a Cooperative Research and Development Agreement (CRADA) with the US National Institute of Health (NIH) to develop a live attenuated RSV vaccine for immunization of infants aged 6 months and older. We initiated the Phase I/II study in the US in September 2020, evaluating the safety and effectiveness of two doses of an intranasal delivery device in infants, the goal being to extend the immunity offered by nirsevimab to additional RSV seasons. Positive data from this study were obtained in the fourth quarter of 2022.

RSV older adult vaccine: Sanofi initiated Phase I with an mRNA vaccine against RSV for the older adults population. This vaccine aims at providing protection against RSV as a standalone vaccine, and in combination with other respiratory viruses in the future.

Meningococcal Group B (Men B): this vaccine candidate is intended to provide active immunization against invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B (Men B) for all age groups. A Phase I/II study was initiated in March 2021 with positive interim data in the fourth quarter of 2022. Early-stage development studies are underway to combine the four meningococcal serogroups represented in MenQuadfi® with Men B to advance a pentavalent meningococcal vaccine candidate.

Pneumococcal Conjugate Vaccine (PCV): Sanofi is collaborating with SK Chemicals (South Korea) to develop a 21-valent pneumococcal conjugate vaccine that will provide expanded protection against pneumococcal disease globally in at risk populations and in different age groups. Data from Phase II studies assembled between mid-2022 and mid-2023 will define the pathway to Phase III.

B.5.3. R&D Expenditures for late stage development

Expenditures on research and development amounted to €6,706 million in 2022 (€5,692 million in 2021), comprising €5,067 million in the Pharmaceuticals segment; €187 million in the Consumer Healthcare segment; €936 million in the Vaccines segment; and €516 million allocated to "Other", representing the R&D support function. Research and development expenditures represented approximately 15.6% of our net sales in 2022, compared with approximately 15.1% in 2021.

The increase was mainly due to additional investments in Immunology and the mRNA vaccines platform, while cost control efforts continue. Preclinical research expenditures in the Pharmaceuticals segment amounted to €884 million in 2022, compared with €718 million in 2021. Clinical development expenditure in the Pharmaceuticals segment amounted to €3,460 million in 2022; compared with €2,892 million in 2021.

B.6. Markets

A breakdown of revenues by business segment and by geographical region for 2022, 2021, and 2020 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 September 2022 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) and HMR (Portugal).

B.6.1. Marketing and distribution

We have business operations in approximately 90 countries and our products are available in more than 180 countries. 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, 2022 Compared with Year Ended December 31, 2021." Sanofi is the ninth largest pharmaceutical company globally by sales. Our main markets in terms of net sales are respectively:

- United States: we rank twelfth with a market share of 3.6%;
- Europe: we are the sixth largest pharmaceutical company in France where our market share is 4.7%, and we rank eighth in Germany with a 3.3% market share; and
- other countries: we are ranked eighteenth in Japan with a market share of 1.8%, and twelfth in China with a market share of 1.5%.

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. Some products in Rare Diseases and Oncology may also be 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. Our Consumer Healthcare products are also sold and distributed through e-commerce, which is a growing trend in consumer behavior. 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.

We use a range of channels from in-person to digital to disseminate information about and promote our products among healthcare professionals, 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 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 conduct and to internal policies on 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."

B.6.2. Competition

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

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

- competition among pharmaceutical companies to research and develop new patented products or address unmet medical needs;
- competition among different patented pharmaceutical products marketed for the same therapeutic indication;
- competition among original and generic products or original biological products and biosimilars, at the end of regulatory exclusivity or patent protection; and
- competition among generic or biosimilar products.

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, such launches may also significantly impair the profitability of the pharmaceutical company whose product is challenged.

Drug manufacturers may also face intra-product competition through parallel trading, or parallel importation or reimportation, where permitted. This may take place when drugs sold in a foreign market under the same brand name as in a domestic market are permitted to be imported into that domestic market by parallel traders or importers, 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 with its common market, where such practices have been encouraged by the current regulatory framework. Parallel traders or importers 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 substandard and falsified drugs. The WHO estimates that falsified products account for 10% in low- and middle-income countries. All therapeutic areas are affected, including vaccines.

Worldwide, falsified products are an issue in part due to the exponential increase in internet connectivity of those engaged in the manufacture, distribution and supply of substandard and falsified medical products.

The same types of competition apply in Consumer Healthcare, except that in this business there are two types of generic products: private labels and store brands.

In Vaccines, there are two primary types of competition:

- competition among vaccine companies to research and develop new patented products or address unmet medical needs; and
- competition among different patented (or non-patented) vaccine products marketed for the same therapeutic indication.

Generics and biosimilars are not an issue in vaccines at present, since vaccines are still mostly produced from proprietary viral or bacterial strains. As with pharmaceutical drugs, vaccine manufacturers can face competition through parallel trading. However, the extent of such practices is limited by the need for cold chain distribution of vaccines, and by the fact that vaccines are sold and administered through pharmacies or dispensing physicians.

B.6.3. Regulatory framework

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 (including testing in human subjects) and quality standards to maximize the safety and efficacy of a new medical product. These authorities also regulate product labeling, manufacturing, importation/exportation, safety reporting and marketing, as well as mandatory post-approval requirements and commitments.

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

Product review and approval can vary from six months or less to several years from the date of application submission depending upon the country and regulatory jurisdiction. Factors such as the quality of data and evidence, 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, and whether or not the product is ultimately licensed or approved.

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 for human use is submitted to the EMA, the scientific evaluation of the application is carried out by the EMA's 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.

In the EU, vaccines are treated as pharmaceutical products, and therefore have to obtain marketing authorization under the centralized procedures described above.

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.

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.

In the US, applications for pharmaceutical approval and biological product licensure are submitted for review to the FDA, which has broad regulatory jurisdiction 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 product outweigh its risks; whether the product labeling is adequate; and if the manufacturing of the product and the controls used for maintaining quality are adequate to preserve the product's identity, strength, quality and purity. Based upon this review, the FDA can stipulate post-approval commitments and requirements. Changes to an approved product, including but not limited to a new indication, require submission of a supplemental NDA (sNDA) for a drug or a supplemental BLA (sBLA) for a biological product.

The FD&C Act provides another option for NDA product approval via the 505(b)(2) pathway. This 505(b)(2) application contains full reports of investigations of safety and effectiveness but at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, under the 505(b)(2) pathway an applicant may seek to rely on literature or earlier FDA findings of safety and effectiveness for approved drugs.

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 efficacy but need to demonstrate that their product is bioequivalent (i.e., performs in humans in the same manner as the originator's product) to a reference 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 that can be referenced as having been approved under the FD&C Act.

In Japan, the entire process of approval review from review-related inspections and clinical trial consultation to review for the drugs approved by the Ministry of Health, Labour and Welfare (MHLW) is undertaken by the Pharmaceuticals and Medical Devices Agency (PMDA). The PMDA conducts first scientific review of the NDA submitted, assessing particularly the safety, efficacy and quality of the product or medical device proposed. Results of this primary evaluation are then submitted to the PMDA's external experts. After a second evaluation based on the external experts' feedback, a report is provided; the Pharmaceutical Affairs and Foods Sanitation Council (PAFCS) – one of the councils organized under the J-MHLW as advisory commission – is consulted, and advises the MHLW on final approvability.

For Japanese registrations, clinical data for Japanese patients are necessary. The regulatory authorities can require local clinical studies, though they also accept multi-regional studies including Japan. In some cases, bridging studies have been conducted to verify extrapolability of foreign clinical data to Japanese patients and to obtain data to determine the appropriateness of the dosages for Japanese patients.

The MHLW may require additional post-approval studies (Phase IV) for some specific cases, to further evaluate safety and/or to gather information on the use of the product under specified conditions. In approval of new drugs, new indications, new dosages or new administrations, the re-examination period is determined by the MHLW. Post-marketing information on a drug for the predetermined period after approval is collected to reconfirm its efficacy, safety and quality at the end of the period. This collection process involves both post-marketing surveillance (PMS), which is a non-interventional study, and post-marketing clinical trials.

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 biopharmaceutical. Common Technical Document (CTD) submission for generics has been mandatory since March 2017.

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) was created in 1990 and reformed in 2015.

The ICH currently includes 20 Members and 35 Observers. Harmonization is achieved through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side.

In addition to the joint efforts, 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.

B.6.4. Pricing & reimbursement

We are operating in a highly complex and volatile market access and launch environment globally.

Faced with mounting budget pressure, governments and payers are using various drug price control policies, among others, price referencing for imported drugs, increased patient co-payments, restrictive formularies, prescribing guidelines, tendering procedures, generic and biosimilar substitution, and medico-economic evaluations of healthcare products.

In addition, pharmaceutical companies are expected to continuously demonstrate value throughout the product life cycle (such as through comparative efficacy studies, real-world patient data, and budget modelling), while stringent payer evidence requirements that differ from country to country are raising the bar for market entry.

Despite many challenges, payers and regulators are becoming more committed to providing early access to new innovative therapies, with greater emphasis on real-world evidence (RWE).

These trends are likely to continue in the coming year, mainly driven by the COVID-19 pandemic, macroeconomic and geopolitical headwinds.

United States

Overview of the US health insurance system:

Commercial insurance is offered widely as part of employee benefit packages and is the main source of employee access to subsidized healthcare. Some individuals purchase private health plans directly or through marketplaces established under the Affordable Care Act, while publicly subsidized programs provide coverage for retirees, the indigent, the disabled, uninsured children, and serving or retired military personnel. Double coverage can occur.

Commercial insurance includes:

- Managed Care Organizations (MCOs), which combine the functions of health insurance, delivery of care, and administration. MCOs use specific provider networks and specific services and products. There are four primary types of managed care plans: Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), Exclusive Provider Organizations (EPOs), and Point of Service (POS) plans; and
- Pharmacy Benefit Managers (PBMs), which serve as intermediaries between insurance companies, pharmacies and manufacturers to negotiate rebates and discounts on formulary placement for commercial health plans, self-insured employer plans, Medicare Part D plans, and federal and state government employee plans.

Government insurance includes:

- *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 coverage. Almost two-thirds of all Medicare beneficiaries have enrolled in Part D plans; and
- *Medicaid*, which provides health insurance for low-income families, certain qualified pregnant women and children, individuals receiving supplemental security income, and other eligible persons determined on a state-by-state basis;
- *TRICARE*, which provides health insurance for uniformed service members, retirees, and their families including comprehensive healthcare, prescription and dental coverage.

The Biden administration's efforts remain focused on lowering health care and prescription drug costs.

In August 2022, the Inflation Reduction Act (IRA) was enacted with drug pricing provisions, which will be phased in over the next few years. For the first time, the federal government will negotiate the prices of selected drugs with high budget impact on Medicare Part B (physician-administered) and Part D (retail prescription drugs), starting with 10 drugs in 2026 and increasing to 20 drugs in 2029 and beyond. Manufacturers will also be required to pay mandatory rebates if drug prices increase faster than the rate of inflation (based on the Consumer Price Index, all urban consumers [CPI-U]), beginning in October 2022 for Part D and January 2023 for Part B). Other measures of the Act will redesign the Medicare Part D benefit, including a monthly $35 insulin cap in 2023 and an annual $2,000 out-of-pocket (OOP) spending cap in 2025 for Medicare beneficiaries. Altogether, the IRA is expected to reduce federal drug spending by about $290 billion over the next decade according to estimates from the Congressional Budget Office (CBO). The new legislation is also likely to have a negative impact on industry revenue growth and future innovation, through there remains significant uncertainty over the price negotiation provision and the impact of Medicare reforms.

Federal and state governments are also seeking to step up price transparency requirements for hospitals, insurers and health plans as contained in the CMS Transparency in Coverage Rule, officially effective since July 1, 2022. In addition, more than half of US states have passed or are pursuing laws to bring greater transparency and prevent price gouging – an issue that has led to intense debate on insulin costs in recent years.

After years of slow growth, biosimilar adoption is likely to accelerate with 36 biosimilars approved to date by the FDA, including two interchangeable products (insulin glargine and adalimumab). According to IQVIA, savings are projected to potentially exceed $100 billion over the next five years, though uncertainty remains on the impact of interchangeability on biosimilar uptake and pricing in the long term.

Moreover, the continuing vertical integration and consolidation within the US health insurance market exposes the industry to greater pricing pressure. With the three largest PBM group purchasing organizations (GPOs) (i.e., Ascent, Emisar and Zinc) now covering over 85% of US prescription drug claims, consolidation has led to increased utilization management and restrictive formularies, resulting in strong bargaining power for negotiating discounted prices, thereby adversely impacting sales.

China

China continues to pursue reforms towards Healthy China 2030. Healthcare is one of the growth priorities under the country's 14th Five-Year Plan (2021-2025), with policies aimed at addressing a large and increasing burden of disease (especially cancer, diabetes and cardiovascular diseases), while balancing access to innovation and costs.

China continues to improve regulatory timelines. For example, Dupixent® received approval for the treatment of adults with moderate-to-severe atopic dermatitis in June 2020, within 6 months of filing through an accelerated review process.

Pricing pressure is expected to intensify as a growing number of products are subject to National Reimbursement Drug List (NRDL) price negotiations and volume-based procurement (VBP) tenders, with the lowest price prevailing to compete with domestic companies.

Access to innovative therapies has been rapidly increasing in recent years, fueled by annual NRDL updates, albeit with steep price cuts across therapy areas. According to the National Healthcare Security Administration (NHSA), 111 new drugs were added to the National Reimbursement Drug List (NRDL) in January 2023, an increase of 36% over 2022. The latest additions included 23 cancer drugs, 17 treatments for infectious diseases, 7 for rare diseases and 2 for COVID-19, with an average price reduction of 60.1% – in line with recent years. Over the past five years, 618 – drugs have been added to the NRDL, bringing the total number of covered medicines to 2,967 – 1,586 Western drugs and 1,381 traditional Chinese medicines.

Further expansion of the volume-based procurement (VBP) policy will drive down the prices of a growing number of products, with more than 500 drugs targeted for inclusion by 2025.

Europe

In Europe, health systems are under mounting financial pressure caused by high public debt, rising inflation and slow economic growth. Biosimilar uptake and tighter cost-containment policies will continue to exert downward pressure on EU drug prices. Importantly, industry payback and mandatory rebates are expected to increase at unprecedented rates in 2023 in major EU markets, particularly in Germany and the UK.

The new EU HTA regulation was adopted in December 2021, after years of joint work between Member States, and will be implemented in a staged process by 2025. Under the new rules, Member States will be cooperating on conducting future joint clinical assessments (JCAs) and joint scientific consultations (JCSs). However, significant uncertainty remains over the implementation of the new framework.

Furthermore, the access environment is poised to become more challenging in the context of the European Commission's wide-ranging Pharmaceutical Strategy for Europe adopted in November 2020. The European Commission's most concerning proposals relate to revamping incentives in unmet need areas such as rare and pediatric diseases, reducing intellectual property for earlier market entry of generics and biosimilars, promoting greater transparency around pricing and drug development costs, and cross-border collaboration on pricing and procurement. Policy options under consideration could have far-reaching impacts on the rare disease pipeline, and have the potential to undermine EU innovation and competitiveness.

Similar pressures are being felt in other regions and countries around the globe.

To address the multiple challenges mentioned above, we are continuously adapting and future-proofing our pricing and market access strategies.

B.7. Patents, intellectual property and other rights

B.7.1. Patents

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; technology platforms; delivery systems; digital applications; 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 (PTE).

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, applications for new patents may be submitted to the European Patent Office (EPO). A European Patent (EP) application may cover the 38 European Patent Convention Member States, including all Member States of the EU. The granted EP establishes corresponding national patents with uniform patent claims among the Member States.

In 2013, EU legislation was adopted to create a European Unitary Patent and a Unified Patent Court. It is expected to come into force on June 1, 2023.

We monitor our competitors and vigorously seek to challenge patent infringers when such infringement would negatively impact our business objectives. See "Item 8. — A. Consolidated Financial Statements and Other Financial Information — 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. 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 also to be patent protected.

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 or biosimilar competitor may not rely on our clinical trial and safety data in its drug application. 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. Significant line extensions of existing NCEs may qualify for an additional three years of regulatory exclusivity if certain conditions are met. In the US, a different regulatory exclusivity period applies to biological drugs. The BPCIA (Biologics Price Competition and Innovation Act) provides that the FDA may not approve a biosimilar application until 12 years after the date on which the reference product was first licensed.

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: four years for medicinal products with new indications, formulations, dosages, or compositions with related prescriptions; six years for new drugs containing a medicinal composition or requiring a new route of administration; eight years for drugs containing a new chemical entity; and ten years for orphan drugs or new drugs requiring pharmaco-epidemiological study.

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, under certain conditions of the Hatch-Waxman Act, it 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 supplementary patent protection 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

Under certain conditions, orphan drug exclusivity may be granted in the US to drugs intended to treat rare diseases or conditions. Orphan drug exclusivities also exist in the EU and Japan.

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, which 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 poses difficulties in certain countries. Additionally, in recent years and especially during the pandemic, a number of countries 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".

Product overview

We summarize below the intellectual property coverage (in some cases through licenses) of our most significant marketed products in terms of sales, in our major markets. In the discussion of patents below, we focus on active ingredient patents (compound patents) and, in the case of 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 its 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 (in the case of NCEs for example, 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.

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**
Aubagio® (teriflunomide)	Compound: expired	Compound: expired	Compound: expired
		Later filed patent: coverage ranging through September 2030	Later filed patent: coverage ranging through March 2024
		Regulatory exclusivity: August 2024[(a) (b)]	
Alprolix® (eftrenonacog alfa)	Use: March 2028 with PTA* and PTE*	Compound: May 2024 (May 2029 with SPC* in most EU countries)	Compound: May 2024 (February 2026 with PTE*)
	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)
	Regulatory exclusivity: March 2026	Regulatory exclusivity: May 2028	
Cerezyme® (imiglucerase)	Patent: expired	Patent: expired	Patent: expired
Dupixent® (dupilumab)	Compound: October 2027 (March 2031 with PTE*)	Compound: October 2029 (September 2032 with SPC*)	Compound: October 2029 (May 2034 with PTE*)
	Later filed patents: coverage ranging through October 2041 (pending)	Later filed patents: coverage ranging through August 2040 (pending)	Later filed patents: coverage ranging through August 2040 (pending)
	Regulatory exclusivity: March 2029	Regulatory exclusivity: September 2027	Regulatory exclusivity: January 2026
Eloctate® (efmoroctocog alfa)	Compound: June 2028 with PTA* and PTE*	Use: May 2024 (November 2029 with SPC* in most EU countries)	Compound: May 2024 (August 2026 with PTE*)
	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)
	Regulatory exclusivity: June 2026	Regulatory exclusivity: November 2025	
Fabrazyme® (agalsidase beta)	Patent: expired	Patent: expired	Patent: expired Generics/biosimilars on the market
	Regulatory exclusivity: March 2028 pediatric indication (ages 2-8 with confirmed Fabry disease)		
Jevtana® (cabazitaxel)	Compound: Expired	Compound: expired	Compound: expired
	Later filed patents: coverage ranging through October 2030	Later filed patents: coverage ranging through May 2036 (pending)	Later filed patents: coverage ranging through November 2030
	NCE Regulatory exclusivity: December 2023	Regulatory exclusivity: expired	Regulatory exclusivity: July 2022
Lantus® (insulin glargine)	Compound: expired	Compound: expired	Compound: expired
	Later filed patents ranging through April 2033	Later filed patent: June 2023	Later filed patent: June 2023
	Generics/biosimilars on the market	Generics/biosimilars on the market	Generics/biosimilars on the market
Lovenox® (enoxaparin sodium)	Compound: expired	Compound: expired	Compound: expired
	Generics/biosimilars on the market	Generics/biosimilars on the market	
Lumizyme®/Myozyme® (alglucosidase alfa)	Compound: expired	Compound: expired	Compound: expired
Plavix® (clopidogrel bisulfate)	Compound: expired	Compound: expired	Compound: expired
	Generics on the market	Generics on the market	Generics on the market
Toujeo® (insulin glargine)	Compound: expired	Compound: expired	Compound: expired
	Later filed patents: coverage ranging through May 2031	Later filed patents: coverage ranging through May 2031	Later filed patents: coverage ranging through July 2033 with PTE*

** PTE: Patent Term Extension. – SPC: Supplementary Protection Certificate. – PTA: Patent Term Adjustment.*

(a) See also "Item 5. — A.1.2. Impacts of competition from generics and biosimilars".

(b) In Europe, Aubagio® competition with certain generic companies is expected in the fourth quarter of 2023.

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, invalidated 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, generic companies have filed Abbreviated New Drug Applications (ANDAs) containing challenges to patents related to a number of our small molecule 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 (safety and other technical data) as the original approved product. As a result of regulatory protection of our safety and other technical data, ANDA applications are generally four years after FDA approval, and include a challenge to a patent listed in the FDA's Orange Book. If the patent holder or licensee brings suit in response to the patent challenge within the statutory window, the FDA is barred from granting final approval to an ANDA during the 30 months following the expiry of the 5-year regulatory exclusivity (this bar is referred to in our industry as a "30-month stay") unless, before the end of the 30 months, the parties reach settlement or a court decision 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.

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. 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, invalidated 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 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.

Similarly, entities wishing to market a generic biologic can utilize an abbreviated approval pathway established in the PHS Act. This §351(k) pathway enables an applicant to rely on a reference product sponsor's data when seeking approval of a biological product shown to be biosimilar (highly similar with no clinically meaningful differences) or interchangeable with an FDA-licensed reference BLA product.

— Europe

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.

B.7.2. Trademarks – Domain names – Copyright

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. We generate new assets (trademarks, domain names, service marks) when creating global brands for new, innovative products. We support the development of the product, from the branding of biotech platforms to the protection of service marks for patient support programs.

Trademarks are particularly important to the commercial success of our products and services in a competitive marketplace, providing a strong visibility and assuring patients of the origin of the products.

Domain names are essential to inform a range of communities about what we do. We also pay close attention to ensuring that no damage is done to our reputation online.

We aim to ensure that the product trademarks we submit to healthcare authorities to obtain marketing authorizations are available, and are protected. 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 to secure our rights.

Ongoing digitization emphasizes the importance of securing copyright protection for software and web layouts.

We monitor and defend our trademarks based on a specific policy designed to prevent counterfeiting, trademark infringement and/or unfair competition.

B.8. Production and raw materials

We have opted to manufacture the majority of our products in-house. There are three principal stages in our production process: the manufacture of active ingredients, the transformation of those ingredients into drug products or vaccines, and the final packaging.

Our general policy is to produce our key active ingredients and main drug products at our own plants in order to reduce our dependence on external suppliers. We also rely on third parties for the manufacture and supply of specific 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 Sanofi 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.

Our manufacturing activities require significant amounts of energy, the costs of which have increased in 2022 and are expected to increase in 2023 and beyond as a result of inflationary pressures and supply constraints due to the war in Ukraine. The Group uses supply contracts and hedging to mitigate these costs. See "Item 3. Key Information — D. Risk Factors — Risks Relating to Our Business".

We also obtain active ingredients from third parties under collaboration agreements. This applies in particular to the monoclonal antibodies developed with Regeneron.

Our 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 products, and a number of our main solid-form products;
- regional sites, which serve markets at regional level, giving us a strong industrial presence in emerging markets; and
- local sites, which serve their domestic market only.

Vaccines produces vaccines at various sites, with the main locations situated in France, the United States, Canada, India, Mexico and China. The pharmaceutical site at Le Trait (France) also contributes to Vaccines' industrial operations by making its sterile filling facilities available for vaccine manufacturing.

All of our production facilities are good manufacturing practice (GMP) compliant, in line with international regulations.

Our main sites are approved by the US FDA:

- the Specialty Care facilities in the United States (Framingham MA and Northborough MA), France (Lyon Gerland, Vitry-sur-Seine, Le Trait), Germany (Frankfurt), Ireland (Waterford) and Belgium (Geel);
- the General Medicines facilities in Germany (Frankfurt), France (Aramon, Sisteron, Ploermel, Ambarès and Tours), Italy (Anagni and Scoppito), Singapore (Jurong) and the United States (Ridgefield NJ);
- the Consumer Healthcare facilities in France (Compiègne) and the United States (Chattanooga TN); and
- the Vaccines facilities in France (Marcy l'Étoile, Le Trait, Val-de-Reuil and Neuville-sur-Saône), the United States (Swiftwater PA) 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® and Dupixent®, for example).

More details about our manufacturing sites are given below at section "D. Property, Plant and Equipment".

B.9. Insurance and risk coverage

We are protected by five main insurance programs, relying not only on the traditional corporate insurance and reinsurance market but also on our direct insurance company, Carraig Insurance DAC (Carraig).

These five key programs cover Property & Business Interruption; General & Product Liability; Stock & Transit; loss and liability arising from cyber and digital risks; and Directors & Officers Liability.

Carraig participates in our coverage for various lines of insurance including Property, Stock & Transit, Cyber/Digital, and General & Product Liability. Carraig is run under the supervision of the Irish and European regulatory authorities, is wholly owned by Sanofi, and has sufficient resources to meet those portions of our risks that it has agreed to cover.

Carraig 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, in all territories where it is possible to use a centralized program operated by Carraig. By sharing risk between our entities, this approach enables us to set deductibles and cover appropriate to the needs of local entities before the market attachment point. It also incorporates a prevention program, including a comprehensive site visit schedule covering our production, storage, research and distribution facilities and standardized repair and maintenance procedures across all sites.

The Stock & 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 through Carraig 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.

Our Cyber/Digital insurance program protects our operations against loss originating from various sources, and against liability in respect of data security. Centralized through Carraig, the program enables us to set deductibles and cover appropriate to the needs of local entities before the market attachment point.

Our General & Product Liability program was renewed in 2022 for all our subsidiaries worldwide in all territories where it was possible to do so, despite reluctance in the insurance and reinsurance market to cover product liability risks for large pharma-biotech groups. For several years, insurers have been reducing product liability cover because of the difficulty of transferring risk for some products that have been subject to numerous claims.

The principal risk exposure for our pharmaceutical products is covered with low deductibles at country level, with a greater proportion of risk being retained. The level of risk self-insured by Sanofi (including via Carraig) before the market attachment point 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 discrepancies in risk exposure between European countries and the United States; and for specific issues arising in certain jurisdictions, such as generics or biosimilar coverage in the United States. Coverage is adjusted every year to take account of the relative weight of new product liability risks such as those arising out of biotechnologies and new technology platforms.

Our cover for risks that are not specific to the pharma-biotech industry (general liability) is designed to address the potential impacts of our operations.

For all the insurance programs handled by 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 our 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 various actuarial methods including the Bornhuetter-Ferguson method; those 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. Carraig 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 highly-rated insurers and reinsurers and are intented to be designed in such a way that we can integrate most newly acquired businesses without interruption of cover. Our insurance 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 excellent, cost effective protection.

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 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, Portland in the United States; Frankfurt in Germany; Dagenham in the United Kingdom; Valernes, Limay, 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 to the authorities as required under French regulations for environmental protection in connection with the operation of activities on French sites.

Potential environmental contingencies arising from certain business divestitures are described in Note D.22.d. to the consolidated financial statements. In 2022, Sanofi spent €39 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 and safety 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 €526 million as of December 31, 2022 versus €650 million as of December 31, 2021. 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 2022 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 (36 internal audits performed in 2022). Moreover, more than 100 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. However, despite these efforts, Sanofi may be unsuccessful in the implementation of its policy to reduce and mitigate the harmful effects of its activities on the health and safety of its employees, customers or the general public and on the environment more generally. See "Item 3.B. Risk Factors" for further information.

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 *(Comité des Valeurs Limites Internes Sanofi)* Committee is responsible for the hazard determination and 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 and safety risks of Our Industrial Activities — Risks from manufacturing activities and the handling of hazardous materials could adversely affect our results of operations and reputation".

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 chemical and biological 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 European Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and the European Regulation on Classification, Labeling and Packaging of chemicals (CLP). To fully comply with REACH, 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 and Sisteron are listed Seveso III (from the name of the European directive that deals with potentially dangerous establishments where dangerous substances may be present in quantities exceeding certain thresholds to prevent major accidents and limit their consequences). 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 are using 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. We use these data to enhance the relevance of our risk assessments.

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, although no guarantee can be given that they will prevent accidents of various kinds.

Environment

Beyond healthcare, we have committed to an ambitious policy aimed at minimizing the environmental impacts of our products and activities while strengthening our resilience in the face of environmental changes. We have identified six major environmental challenges relating to our businesses: greenhouse gas emissions and climate disruption; eco-design; 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 Care program. Reflecting our environment strategy out to 2030 and 2045, the program sets more ambitious targets for reducing environmental impacts across the entire value chain. Planet Care is a global project that involves all of the Company's resources in defining objectives and engaging with external partners.

Compared with 2019 figures, we are undertaking to reduce our carbon emissions by 55% (scope 1 and 2) by the end of 2030, building the path to carbon-neutral status by 2030 on our scope 1, 2 & 3 (direct and indirect emissions for all activities), and net zero by 2045. 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 2022, we had reduced CO_2 emissions by 29% (scope 1 and 2) and water withdrawals by 13%.

Overall waste valorization at sites is already above 86% and is expected to be more than 90% by the end of 2025. The landfill rate had dropped to 5% at the end of 2022 and we have committed to move towards no more than 1% by 2025. Biodiversity management at our 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 by 2025.

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 2022, all priority production sites have engaged specific programs to monitor, manage and reduce emissions.

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" and "Item 3.D. Risk Factors".

C. Organizational Structure

C.1. Significant Subsidiaries

Sanofi is the holding company of a consolidated group consisting of almost 270 companies. The table below sets forth our significant subsidiaries as of December 31, 2022. 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.

Significant subsidiary	Date of incorporation	Country of incorporation	Principal activity	Financial and voting interest
Aventis Inc.	July 1, 1968	United States	Pharmaceuticals	100%
Genzyme Corporation	November 21, 1991	United States	Pharmaceuticals	100%
Genzyme Europe B.V.	October 24, 1991	Netherlands	Pharmaceuticals	100%
Hoechst GmbH	July 8, 1974	Germany	Pharmaceuticals	100%
Sanofi-Aventis Deutschland GmbH	June 30, 1997	Germany	Pharmaceuticals	100%
Sanofi-Aventis Participations SAS	February 25, 2002	France	Pharmaceuticals	100%
Sanofi-Aventis Singapore Pte Ltd	May 14, 1997	Singapore	Pharmaceuticals	100%
Sanofi Biotechnology	December 23, 2013	France	Pharmaceuticals	100%
Sanofi Foreign Participations B.V.	April 29, 1998	Netherlands	Pharmaceuticals	100%
Sanofi Winthrop Industrie	December 11, 1972	France	Pharmaceuticals	100%
Sanofi Pasteur Inc.	January 18, 1977	United States	Pharmaceuticals	100%

Since 2009, we have transformed Sanofi through numerous acquisitions and divestments (see main recent events in "A. History and Development of the Company" above), in particular those of Genzyme in April 2011, Boehringer Ingelheim (BI) Consumer Healthcare in January 2017, Bioverativ in March 2018, Ablynx in June 2018, Synthorx in January 2020, Principia in September 2020, Kymab in April 2021,Translate Bio in September 2021, Amunix Pharmaceuticals, Inc in February 2022 and EUROAPI in May 2022. 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. 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 financial statements for the year ended December 31, 2016, 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 (Merial) for BI's Consumer Healthcare business. The financial effects of this transaction are presented in Note D.1. to our consolidated financial statements for the year ended December 31, 2017, included in our annual report on Form 20-F for that year. The financial effects of the Bioverativ and Ablynx acquisitions are presented in Note D.1.1. to our consolidated financial statements for the year ended December 31, 2018, included in our annual report on Form 20-F for that year. The financial effects in 2020 of the Synthorx and Principia acquisitions, and the financial effects in 2021 of the Kymab, Kiadis, Tidal, Translate Bio, Kadmon and Origimm acquisitions, are presented in Note D.2. to our consolidated financial statements for the year ended December 31, 2022, included in the annual report on Form 20-F for that year. The financial effects of the acquisition of Amunix Pharmaceuticals, Inc in February 2022 are presented in Note D.1. to our consolidated financial statements in our annual report on Form 20-F for this year. The financial effects of the deconsolidation of EUROAPI are presented in Note D.1. to our consolidated financial statements in our annual report on Form 20-F for this 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 with Regeneron relating to Zaltrap®, Praluent®, Dupixent®, Kevzara® and Libtayo®. For further information, refer to Note C. "Principal Alliances" to our consolidated financial statements.

C.2. Internal organization of activities

Sanofi and its subsidiaries collectively form a group organized around three activities: Pharmaceuticals (General Medicines and Specialty Care), Vaccines, and Consumer Healthcare.

Within Sanofi, responsibility for R&D in their respective fields rests with Sanofi 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, commercialize 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, Sanofi Mature IP, Sanofi Biotechnology SAS (France), Sanofi-Aventis Deutschland GmbH (Germany), Ablynx (Belgium), Genzyme Corporation, Bioverativ Inc., Kadmon Pharmaceuticals Inc., Amunix Pharmaceuticals, Inc., Kymab, and Principia Biopharma Inc.;
- vaccines: Sanofi Pasteur (France), Sanofi Pasteur, Inc. (US), Translate Bio (US) and Protein Sciences Corp;
- consumer healthcare: A. Nattermann Cie & GmbH (Germany), Chattem Inc. (US), Opella Healthcare France SAS, Opella Healthcare Italy Srl et SSP Co. Ltd (Japan).

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, Opella Healthcare International SAS and Sanofi-Aventis Recherche & Développement;
- in the United States: Sanofi Pasteur, Inc., Genzyme Therapeutics Products LP, Genzyme Corporation and Translate Bio;
- in Germany: Sanofi-Aventis Deutschland GmbH;
- in Canada: Sanofi Pasteur Limited;
- in Belgium: Genzyme Flanders BVBA; 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, 2022, the Sanofi parent company held 98% of our external financing and 91% 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 75 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	
Industrial	58%
Research	16%
Offices	14%
Logistics	10%
Other	2%

Breakdown of sites by ownership status	
Leasehold	26%
Owned	74%

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 Manufacturing & Supply department in support of our new business model.

The Manufacturing & Supply department focuses on customer needs and service quality; the sharing of "Sanofi Manufacturing System" good manufacturing practices; and the development of a common culture committed to quality.

In 2020, Manufacturing & Supply department modified its organization to align on the new Global Business Units structure comprising Specialty Care, General Medicines, Vaccines and Consumer Health Care.

In February 2020, we announced a plan to create a major leading European company dedicated to the production and marketing of active pharmaceutical ingredients (API) to third parties as well as to Sanofi. This involved creating a standalone company combining our API commercial and development activities with six of our European API production sites: Brindisi (Italy), Frankfurt Chemistry (Germany), Haverhill (UK), Saint-Aubin-les-Elbeuf (France), Újpest (Hungary), and Vertolaye (France). EUROAPI was listed on Euronext Paris on May 6, 2022. See "Item 4. Information on the Company — A. History and development of the Company".

The Manufacturing & Supply department is also responsible for Sanofi Global HSE and Global Supply Chain.

At the end of 2022, we were carrying out industrial production at 59 sites in 28 countries:

- 8 sites for our Specialty Care operations;
- 29 sites for our General Medicines operations;
- 12 sites for our Consumer Healthcare operations; and
- 10 sites for the industrial operations of Vaccines.

The quantity of units sold in 2022, including in-house and outsourced production and excluding EUROAPI, was 4.4 billion. This comprised:

- Pharmaceuticals: 2.4 billion units;
- Consumer Healthcare: 1.9 billion units; and
- Vaccines: 175 million boxes.

We believe that our production facilities are in compliance with all material regulatory requirements, are properly maintained and are generally suitable for future needs. 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.

Our main production sites by volume are:

- Le Trait (France), Frankfurt (Germany), Waterford (Ireland), Geel (Belgium) and Framingham (United States) for Specialty Care;
- Aramon, Sisteron and Ambarès (France), Frankfurt (Germany), Csanyikvölgy (Hungary), Lüleburgaz (Turkey), Campinas (Brazil), Jurong (Singapore) and Hangzhou (China) for General Medicines products;
- Compiègne and Lisieux (France), Cologne (Germany), Origgio (Italy), Chattanooga (United States) and Ocoyoacac (Mexico) for Consumer Healthcare products; and
- Marcy-l'Étoile and Val-de-Reuil (France), Toronto (Canada), Swiftwater (United States) and Hyderabad (India) for vaccines.

Research & Development sites

In Pharmaceuticals, research and development activities are conducted at the following sites:

- four operational sites in France: Chilly-Mazarin/Longjumeau, Montpellier, Strasbourg and Vitry-sur-Seine/Alfortville;
- three sites in the rest of Europe (Germany, Belgium and the Netherlands), the largest of which is in Frankfurt (Germany);
- six sites in the United States: Bridgewater, Cambridge, Framingham/Waltham, Great Valley, San Francisco and San Diego; and
- in Asia, three sites in China (Beijing, Shanghai and Chengdu).

Vaccines research and development sites are:

- Swiftwater, Cambridge and Orlando (United States);
- Marcy-l'Étoile/Lyon (France); and
- Toronto (Canada).

D.3. Acquisitions, capital expenditures and divestitures

The carrying amount of our property, plant and equipment at December 31, 2022 was €9,869 million. During 2022, we invested €1,748 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 2020, 2021 and 2022 are described in Notes D.1. & D.2. ("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, 2022, our firm commitments in respect of future capital expenditures amounted to €861 million. The principal locations involved were: for the Pharmaceuticals segment, the industrial facilities at Frankfurt (Germany); Le Trait, Maisons-Alfort, Compiègne, and Ambares (France); Cambridge (United States); Geel (Belgium); Origgio, Anagni, Brindisi, and Scoppito (Italy); and for the Vaccines segment, the facilities at Swiftwater (United States), Toronto (Canada), Marcy-l'Étoile, Neuville-sur-Saône and Val-de-Reuil (France), and Singapore.

In the medium term and assuming no changes in the scope of consolidation, we expect to invest on average some €1.4 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.

Our principal ongoing capital expenditures are described below.

Speciality care

Our Specialty Care industrial operations are organized around two end-to-end clusters. We have four dedicated biotechnology hubs: Paris/Lyon (France), Frankfurt (Germany), Geel (Belgium) and Boston Area (United States). The Bioatrium project, a joint venture between Sanofi and Lonza (Switzerland) set up in 2017 to increase bioproduction capacity, is proceeding on schedule. Exploiting the innovative techniques on which biotech relies, including cell and microbiological culture and the development of viral vectors, calls for highly specific knowledge and expertise backed by dedicated production platforms to support global product launches.

The Waterford and Le Trait sites manufacture pre-filled Dupixent® syringes.

General medicines

Our General Medicines industrial operations are organized through end-to-end clusters, with chemistry, pharmaceutical and injectable sites organized through a network of over 28 regional and local industrial sites in 18 countries, supporting growth in those markets.

This new organization encompasses a dedicated Launch Sites cluster from API manufacturing to finished goods packaging (Sisteron, Aramon, Ambarès, Scoppito).

The Frankfurt facility is our principal site for the manufacture of diabetes treatments.

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) and Cologne (Germany). We have recently invested in new production capacities in Suzano (Brazil) and Narita (Japan).

Vaccines

The industrial operations of our Vaccines business are in a major investment phase, preparing for the upcoming growth of our influenza and Polio/Pertussis/Hib franchises, plus the mid-term growth linked to our mRNA roadmap and New Vaccines pipeline. Major investments were announced in 2020 and 2021 with a new Evolutive Facility in France (Neuville-Sur-Saone) and a new facility in Singapore for our New Vaccines pipeline. Other major investments are under way in France (including construction of a new influenza vaccine building at Val-de-Reuil), Canada (a new pertussis vaccine building), the US and Mexico.

Innovation and culture of industrial excellence

The ambition of our Manufacturing & Supply department is to continue to raise safety, quality and operating 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.

In terms of operational excellence, we continue to build on our Top Decile performance program, focused on core sites and fully leveraging digital opportunities and technology innovations. We are also reinforcing the Sanofi Manufacturing System to drive more improvement directly from the sites and reach our performance goals, while creating a culture of best practices shared across the industrial network.

D.4. Office space

As we progress on our Sanofi Work Experience journey, we continue to shape our work environment by bringing our teams together and transforming our workplaces into spaces where every Sanofian feels included, valued, and able to bring their best selves to work every day.

Along with state-of-the-art projects delivered in 2022, such as the renovation of the Gentilly Campus near Paris, the Cambridge Crossing Campus in the US, and the innovative new "La Maison Sanofi" site in Paris, our roadmap continues to evolve, covering all regions worldwide. A number of projects are currently under way to deliver the next generation of work experience and hybrid work.

Divestment of sites that our non-core to our business model and office space rationalization remain an important goal to help us achieve a responsible environmental footprint.

Item 4A. Unresolved Staff Comments

N/A

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 endorsed by the European Union as of December 31, 2022.

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.

The discussion of our operating and financial review and prospects for the years ended December 31, 2021 and December 31, 2020, can be found in Part I, Item 5. of our Form 20-F filed on February 23, 2022, including a presentation of our consolidated income statements for the years ended December 31, 2021 and December 31, 2020 in "Item 5. — A.2. Results of operations" of our Form 20-F filed on February 23, 2022.

A. Operating results

A.1. Significant operating information

A.1.1. 2022 Overview

During 2022, Sanofi continued to implement its "Play to Win" strategy, involving major decisions and positive actions to support and rebuild the competitive margins necessary for Sanofi to continue to deliver on its mission. The strategy is based on four major priorities: focus on growth, lead with innovation, accelerate efficiency, and reinvent how we work. For further information about our strategy, refer to "— Item 4. — B.1. Strategy". Other significant events of the year are described below.

On January 7, 2022, Sanofi announced a research collaboration and license agreement with *Exscientia plc* (Exscientia) to develop up to 15 novel small molecule candidates across oncology and immunology, leveraging Exscientia's end-to-end AI-driven platform using actual patient samples. The companies have been working together since 2016 and in 2019, Sanofi in-licensed Exscientia's novel bispecific small molecule candidate capable of targeting two distinct targets in inflammation and immunology.

On February 8, 2022, Sanofi announced the completion of its acquisition of *Amunix Pharmaceuticals, Inc* (Amunix), adding a pipeline of T-cell engager immunotherapies and cytokine therapies. The acquisition also gives Sanofi access to Amunix's Pro-XTEN™, XPAT, and XPAC technologies to deliver next-generation Conditionally Activated Biologics. This technology platform complements our existing R&D platforms, and supports our efforts to accelerate and expand our contribution to developing innovative medicines for oncology patients, with approximately 20 molecules currently in development.

On March 15, 2022, Sanofi and *Blackstone* announced a strategic risk-sharing collaboration under which funds managed by Blackstone Life Sciences (BXLS) will invest up to €300 million to accelerate the global pivotal studies and clinical development program for the subcutaneous formulation and delivery of the anti-CD38 antibody Sarclisa® to treat patients with multiple myeloma (MM). That amount will be paid to Sanofi on the basis of development expenses incurred. In addition, Sanofi would be required to pay royalties on any future sales of any products developed as part of this program.

On March 16, 2022, Sanofi and *Seagen Inc*. announced an exclusive collaboration agreement to design, develop, and commercialize antibody-drug conjugates (ADCs) for up to three cancer targets. The collaboration will utilize Sanofi's proprietary monoclonal antibody (mAb) technology and Seagen's proprietary ADC technology. ADCs are antibodies engineered to deliver potent anti-cancer drugs to tumor cells expressing a specific protein, and Sanofi currently has one ADC in development.

During the March 29, 2022 investor conference, Sanofi gave an update on how the company is advancing its immunology strategy. The focus of the event was on *Dupixent®* (dupilumab), a key growth driver for Sanofi, and on the company's rapidly advancing pipeline of other products which features dermatological, respiratory and gastrointestinal diseases as priority therapeutic areas. Sanofi has raised its peak sales ambition for Dupixent®. This new ambition does not include the potential for further potential sales of Dupixent® to treat chronic obstructive pulmonary disease (COPD), with pivotal readouts from clinical trials in this indication anticipated in 2023.

On March 29, 2022, Sanofi and *IGM Biosciences, Inc*. announced the signing of an exclusive worldwide collaboration agreement to create, develop, manufacture, and commercialize IgM (immunoglobulin M) antibody agonists against three oncology targets and three immunology/inflammation targets. Engineered IgM antibodies represent a new class of potential therapeutics that combine the multi-valency of IgM antibodies and have ten binding sites, as opposed to conventional IgG (immunoglobulin G) antibodies that have only two target binding sites.

On June 2022, Sanofi and *Regeneron* restructured their IO LCA. Under the terms of the Amended and Restated IO LCA, Regeneron holds exclusive worldwide licensing rights to Libtayo® with effect from July 1, 2022. In July 2022, Sanofi received as consideration an upfront payment of $900 million (€856 million), which was recognized within *Other operating income* on the date of receipt. The same line item also includes a regulatory milestone payment of $100 million (€96 million) following the US FDA approval in November 2022 of Libtayo® in combination with chemotherapy as a first line treatment for NSCLC. In addition, Sanofi is entitled to royalties of 11% and to milestone payments linked to global net sales of Libtayo®, which are recognized within *Other operating income* in line with the pattern of sales (€111 million in 2022). For further information, see Note C. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F.

On May 3, 2022, Sanofi's General Meeting of Shareholders approved the decision to distribute approximately 58% of the share capital of *EUROAPI*, a European leader in the development, manufacture, marketing and distribution of Active Pharmaceutical Ingredients (APIs), in the form of an exceptional dividend in kind to Sanofi shareholders. The dividend was paid on May 10, 2022 following the admission of EUROAPI shares to listing on the regulated market of Euronext Paris; on May 6, 2022, Sanofi divested control over EUROAPI and its subsidiaries, resulting in their deconsolidation from the Sanofi consolidated financial statements as of that date. On June 17, 2022 (the date of delivery of the EUROAPI shares to the French State via the French Tech Souveraineté fund), EPIC Bpifrance acquired a 12% equity interest in EUROAPI. Following completion of those transactions, Sanofi retains an equity interest of 30.1% in EUROAPI, which has been accounted for using the equity method since the date of loss of control.

On August 4, 2022, Sanofi and *Innovent Biologics* (Innovent) announced a collaboration to bring innovative medicines to patients in China with difficult-to-treat cancers and to accelerate the development and commercialization of two Sanofi key clinical stage oncology assets – Phase III SAR408701 (tusamitamab ravtansine, an anti-CEACAM5 antibody-drug conjugate) and Phase II SAR444245 (non-alpha IL-2) – in combination with sintilimab, the leading checkpoint inhibitor in China. In addition to the collaboration and license agreement, Sanofi has invested €300 million in Innovent by subscribing to its new common shares.

On August 17, 2022, Sanofi discontinued the global clinical development program of *amcenestrant*, an investigational oral selective estrogen receptor degrader (SERD). The decision was based on the outcome of a prespecified interim analysis of the Phase III AMEERA-5 trial evaluating amcenestrant in combination with palbociclib compared to letrozole in combination with palbociclib in patients with estrogen receptor-positive (ER+)/human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer. Sanofi will continue to review the data, and plans to share the results with the scientific community in the future. All other studies of amcenestrant, including in early-stage breast cancer (AMEERA-6), will be discontinued.

At the end of the third quarter of 2022, based on external and internal data about the mechanism of action and therapeutic potential of non-alpha IL2, a new Phase I/II program was programmed for *SAR444245*, focused on schedule intensification to solidify the foundation for a best-in-class target profile. In parallel, the ongoing Phase II trials with the 3-weekly dose schedule were discontinued, as the efficacy observed in the early look at the data was lower than projected. This decision was not based on any safety-related issues.

On December 19, 2022, Sanofi and *Innate Pharma SA* (Innate) announced an expansion of their collaboration, with Sanofi licensing a natural killer (NK) cell engager program targeting B7H3 from Innate's ANKET™ (Antibody-based NK Cell Engager Therapeutics) platform. Sanofi will also have the option to add up to two additional ANKET™ targets. Upon candidate selection, Sanofi will be responsible for all development, manufacturing and commercialization. Innate and Sanofi signed a first NK cell engagers collaboration in 2016 for the generation and evaluation of up to two bispecific NK cell engagers; these are currently being evaluated by Sanofi's R&D team, with one of them already in clinical studies.

In 2022, healthcare authorities issued a number of marketing approvals for Sanofi products. In the United States and Europe, *Dupixent®* (dupilumab) obtained full authorization for the treatment of eosinophilic esophagitis, and extensions to expand the severe asthma indication to children aged 6 to 11 years and the moderate-to-severe atopic dermatitis indication to children aged 6 months to 5 years. At the end of September 2022, the US Food and Drug Administration (FDA) approved Dupixent® as the first and only treatment indicated to treat prurigo nodularis for adult patients in the United States, and on December 15, 2022, Dupixent® became the first and only targeted medicine approved by the European Commission (EC) to treat prurigo nodularis.

The FDA also approved *Xenpozyme®* (olipudase alfa-rpcp) for the treatment of non-central nervous system (non-CNS) manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

The EC granted marketing authorization for *Enjaymo®* (sutimlimab) for the treatment of hemolytic anemia in adult patients with cold agglutinin disease (CAD). CAD is a rare, serious and chronic autoimmune hemolytic anemia, in which the body's immune system mistakenly attacks healthy red blood cells and causes their rupture, known as hemolysis.

In Vaccines, the EC approved *Beyfortus®* (nirsevimab) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in newborns and infants during their first RSV season. Beyfortus® is the first and only single-dose passive immunization for the broad infant population; it is being developed jointly by Sanofi and AstraZeneca. The EC also approved *VidPrevtyn®* Beta as a booster for the prevention of COVID-19 in adults aged 18 years and older. Designed to provide broad protection against multiple variants, this protein-based vaccine is based on the Beta variant antigen and includes GSK's pandemic adjuvant. VidPrevtyn® Beta is indicated as a booster for active immunization against SARS-CoV-2 in adults who have previously received an mRNA or adenoviral COVID vaccine.

For further information about the pharmaceutical products and vaccines we sell, and about our research and development portfolio, refer to "— Item 4.B. — Business Overview".

Our net sales for 2022 amounted to €42,997 million, an increase of 13.9% from 2021. At constant exchange rates (CER[1]), net sales rose by 7.0%, mainly reflecting strong growth for Dupixent® and increased sales for our Vaccines business, more than offsetting lower sales for our Non Core assets franchise.

Net income attributable to equity holders of Sanofi amounted to €8,371 million for 2022, compared with €6,223 million in 2021, a €2,148 million increase. Earnings per share was €6.69 in 2022, compared with €4.97 in 2021. Business net income[2] was €10,341 million, up 25.9% on 2021, while business earnings per share (business EPS[2]) was 25.9% higher than in 2021 at €8.26.

Our net debt[3] decreased from €9,983 million as of December 31, 2021 to €6,437 million as of December 31, 2022. At the Annual General Meeting on May 25, 2023, we will ask our shareholders to approve a dividend of €3.56 per share for the 2022 financial year, representing a payout of 43.1% of our Business net income (see "— Item 5.B.2. — Consolidated balance sheet and debt.").

A.1.2. Impacts of competition from generics and biosimilars

Some of our flagship products continued to suffer sales erosion in 2022 under the impact of 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, 2022 and 2021 (see "— A.2. Results of Operations — Year Ended December 31, 2022 Compared with Year Ended December 31, 2021" below) for the main products affected by generic and biosimilar competition shows a loss of €325 million of net sales on a reported basis. To be noted that other parameters can also contributed to the loss of sales, such as a fall in the average selling price of certain products.

The table below sets forth the change by product.

(€ million)	2022	2021	Change on a reported basis	Change on a reported basis (%)
Aprovel® Europe	82	87	(5)	-5.7%
Lantus® Europe	426	474	(48)	-10.1%
Lovenox® Europe	658	703	(45)	-6.4%
Plavix® Europe	101	115	(14)	-12.2%
Jevtana® Europe	33	112	(79)	-70.5%
Lantus® United States	757	861	(104)	-12.1%
Lovenox® United States	17	29	(12)	-41.4%
Aprovel® Japan	22	15	7	+46.7%
Lantus® Japan	13	16	(3)	-18.8%
Plavix® Japan	53	75	(22)	-29.3%
Total	**2,162**	**2,487**	**(325)**	**-13.1%**

We expect the erosion caused by generic competition to continue in 2023, with a negative impact on our net income. The products likely to be impacted in 2023 include those that already faced generic competition in 2022, but whose sales can reasonably be expected to be subject to further sales erosion in 2023 (see products listed in the table above). We also expect generic competition in the United States for Aubagio® from March 2023 and for Mozobil® from August 2023, following expiry of exclusivity in that country. In Europe, Aubagio® generic competition is expected in the fourth quarter of 2023.

In 2022, the aggregate consolidated net sales of those products in Europe, the United States and Japan were €2,162 million; this comprised €774 million in the United States (including €757 million in net sales of Lantus®); €1,300 million in Europe; and €88 million in Japan. The negative impact on our 2023 net sales is likely to represent a substantial portion of those sales, but the actual impact will depend on a number of factors such as the impact of generics and biosimilars on our molecules, but also the market entry of generics of molecules that are in competition with our products.

In China, the authorities have implemented a range of healthcare cost containment measures, including the Volume Based Procurement (VBP) reverse auction that particularly impacts our insulin-based products, Plavix®, Aprovel®, and Lovenox® (see also "Item 4. — B.6.4. Pricing & Reimbursement"). A large number of molecules were selected to submit tenders under successive waves of the VBP program, with the successful bidders being awarded a high level of market share in return for offering lower prices. We participated in a number of VBP bids and were selected for only part of the volumes awarded for 2022 and 2023 in respect of insulins (Toujeo® and Lantus®), Plavix® and Aprovel®, in return for a considerable reduction in unit prices.

[1] *Non-IFRS financial measure: see definition in "— A.1.6. Presentation of Net Sales" below.*
[2] *Non-IFRS financial measure: see definition in "— A.1.5. Segment Information — 3. Business Net Income" below.*
[3] *Non-IFRS financial measure: see definition in "— B. Liquidity and Capital Resources" below.*

A.1.3. Purchase accounting effects

Our results of operations and financial condition for the years ended December 31, 2022, and 2021 have been significantly affected by our past acquisitions (acquisition of Aventis in August 2004, acquisition of Genzyme in April 2011, exchange of our Animal Health business (Merial) for Boehringer Ingelheim's Consumer Healthcare business in January 2017, acquisition of Bioverativ in 2018, and certain other transactions). See "— A.1.11. Critical accounting and reporting policies — 2/ 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 (€535 million in 2022, and €529 million in 2021). The exchange of Merial for Boehringer Ingelheim's Consumer Healthcare business has generated amortization of intangible assets (€188 million in 2022, and €195 million in 2021). The Bioverativ business combination has generated significant amortization of intangible assets (€377 million in 2022, and €320 million in 2021). The Kadmon acquisition has generated amortization of intangible assets (€159 million in 2022, and €20 million in 2021).

In order to isolate the purchase accounting effects of all acquisitions and certain other items, we use a non-IFRS financial measure that we refer to as "business net income" (see definition in "— A.1.5. Segment Information — 3. Business Net Income" below).

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, consumer health care 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. 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 "— A.1.7. Financial Presentation of Alliances" below.

The line item ***Other revenues*** is used to recognize all revenue that falls within the scope of IFRS 15 but does not relate to sales of Sanofi products. It mainly comprises (i) royalties received from licensing intellectual property rights to third parties; (ii) VaxServe sales of products sourced from third-party manufacturers; and (iii) revenue received under agreements for Sanofi to provide manufacturing services to third parties. Royalties received under licensing arrangements are recognized over the period during which the underlying sales are recognized. VaxServe is a Vaccines segment entity whose operations include the distribution within the United States of vaccines and other products manufactured by third parties.

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. 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 "A.1.5. Segment Information — 2/ Business Operating Income".

A.1.5. Segment information and Business net income

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 B.26. and D.35. ("Segment Information") to our consolidated financial statements, included at Item 18. of this annual report.

As indicated in Note B.26., Sanofi has three operating segments: Pharmaceuticals, Vaccines, and Consumer Healthcare.

The Pharmaceuticals segment comprises, for all geographical territories, the commercial operations of the following global franchises: Specialty Care (Dupixent®, Neurology & Immunology, Rare Diseases, Oncology, and Rare Blood Disorders) and General Medicines (Core and Non-Core Assets), together with research, development and production activities dedicated to the Pharmaceuticals segment. This segment also includes associates whose activities are related to pharmaceuticals.

The Vaccines segment comprises, for all geographical territories, the commercial operations of Vaccines, together with research, development and production activities dedicated to vaccines.

The Consumer Healthcare segment comprises, for all geographical territories, the commercial operations for Sanofi's Consumer Healthcare products, together with research, development and production activities dedicated to those products.

Inter-segment transactions are not material.

The costs of Sanofi's global support functions (Corporate Affairs, Finance, People & Culture, Legal, Ethics & Business Integrity, Information Solutions & Technologies, Sanofi Business Services, etc.) are primarily managed centrally at the group-wide level. 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.

2/ Business operating income

We report segment results on the basis of "Business operating income". This indicator is used internally by Sanofi's 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.

"Business operating income" at Group level is a non-IFRS financial measure, which is reconciled with IFRS ***Operating income***. IFRS ***Operating income*** for 2022 amounted to €10,656 million versus €8,126 million for 2021. Our ratio of ***Operating Income*** to *Net Sales* was 24.8% in 2022 versus 21.5% in 2021.

Our "Business operating income" for 2022 amounted to €13,040 million, versus €10,714 million for 2021, while our "Business operating income margin" was 30.3%, versus 28.4% for 2021. "Business operating income margin" is a non-IFRS financial measure, which we define as the ratio of our "Business operating income" to ***Net sales***.

Because our "Business operating income" and "Business operating income margin" are not standardized measures, they may not be directly comparable with the non-IFRS financial measures of other companies using the same or similar non-IFRS financial measures. Although management uses those non-IFRS measures to set goals and measure performance, they have no standardized meaning prescribed by IFRS. These non-IFRS measures are presented solely to permit investors to more fully understand how Sanofi's management assesses underlying performance. These non-IFRS measures are not, and should not be viewed as, a substitute for IFRS measures, and should be viewed in conjunction with our IFRS financials and performance measures. As a result, such measures have limits in their usefulness to investors.

3/ Business net income (non-IFRS Financial measure)

We believe that the understanding of our operational performance by our management and our investors is enhanced by reporting "Business net income". This non-IFRS financial measure represents ***Business operating income***, less net financial expenses and the relevant income tax effects.

"Business net income" is a non-IFRS financial measure, which is reconciled with IFRS ***Net income attributable to equity holders***. ***Net income attributable to equity holders of Sanofi*** amounted to €8,371 million for 2022, compared with €6,223 million in 2021.

Our "Business net income" for 2022 was €10,341 million, 25.9% up on 2021 (€8,213 million).

We also report "Business earnings per share" ("Business EPS"), a non-IFRS financial measure we define as "Business net income" divided by the weighted average number of shares outstanding. "Business EPS" was €8.26 for 2022, 25.9% higher than the 2021 figure of €6.56, based on an average number of shares outstanding of 1,251.9 million for 2022 and 1,252.5 million for 2021.

The table below reconciles our "Business operating income" to our "Business net income":

(€ million)	December 31, 2022	December 31, 2021
Business operating income	**13,040**	**10,714**
Financial income and expenses	(234)	(328)
Income tax expense	(2,465)	(2,173)
Business net income	**10,341**	**8,213**

We define "Business net income" 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 remeasurements of contingent consideration relating to business combinations or divestments or acquisition of intangible assets;
- other impacts associated with acquisitions (including impacts relating to investments accounted for using the equity method);
- restructuring costs and similar items (presented within the line item ***Restructuring costs and similar items***);
- gains and losses on major disposals of assets, asset groups or operations (presented within the line item ***Other gains and losses, and litigation***);
- costs related to major litigation (presented within the line item ***Other gains and losses, and litigation***);
- upfront payments and regulatory milestone payments recognized with the line item ***Other operating income*** and arising from transactions outside the scope of Sanofi's ordinary activities;
- the tax effects of the items listed above, and the effects of major tax disputes;
- the share of profits/losses from investments accounted for using the equity method, except for joint ventures and associates with which Sanofi has a strategic alliance;
- acquisition-related effects and restructuring costs relating to investments accounted for using the equity method (joint ventures and associates with which Sanofi has a strategic alliance); and

- the portion attributable to non-controlling interests of the items listed above.

The table below reconciles our "Business net income" to ***Net income attributable to equity holders of Sanofi***:

(€ million)	2022	2021
Net income attributable to equity holders of Sanofi (IFRS)	**8,371**	**6,223**
Amortization of intangible assets[(a)]	2,053	1,580
Impairment of intangible assets[(b)]	(454)	192
Fair value remeasurement of contingent consideration[(d)]	53	4
Expenses arising from the impact of acquisitions on inventories	3	4
Income from out-licensing[(c)]	(952)	—
Restructuring costs and similar items	1,336	820
Other gains and losses, and litigation[(d)]	370	5
Tax effects of the items listed above:	(459)	(614)
• *amortization and impairment of intangible assets*	*(268)*	*(415)*
• *fair value remeasurement of contingent consideration*	*(9)*	*(2)*
• *restructuring costs and similar items*	*(231)*	*(200)*
• *other tax effects*	*49*	*3*
Other items	20	(1)
Business net income (non-IFRS Financial measure)	**10,341**	**8,213**
Average number of shares outstanding (million)	1,251.9	1,252.5
Basic earnings per share (€)	6.69	4.97
Reconciling items per share (€)	1.57	1.59
Business earnings per share (€)	8.26	6.56

(a) Includes amortization expense related to accounting for business combinations: €1,719 million in 2022 and €1,463 million in 2021.

(b) For 2022, this line includes a reversal of €2,154 million on Eloctate franchise products following FDA approval of ALTUVIIIO™ dated February 22, 2023, partially offset by an impairment of €1,586 million relating to the development project for SAR444245 (non-alpha interleukin-2), based on revised cash flow projections reflecting unfavorable developments in the launch schedule in key indications. For 2021, this line mainly comprises the discontinuation of the development of sutimlimab in the treatment of Immune Thrombocytopenic Purpura (ITP), and to the termination of various research projects in Vaccines.

(c) For 2022, this line includes an upfront payment of $900 million and a regulatory milestone payment of $100 million in connection with the out-licensing of Libtayo® following the restructuring of the Immuno-Oncology collaboration agreement with Regeneron (see Note C.1. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F).

(d) For 2022, this line includes an impact of €(80) million attributable to non-controlling interests, related to a remeasurement of contingent consideration within a subsidiary of Sanofi.

The most significant reconciling items between "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 restructurings or transactions regarded as non-recurring, where the amounts involved are particularly significant. We believe that excluding those impacts enhances an investor's understanding of our underlying economic performance, because it gives a better representation of our recurring operating performance.

We believe that eliminating charges related to the purchase accounting effect of our acquisitions and business combinations (particularly amortization and impairment of some intangible assets) enhances comparability of our ongoing operating performance relative to our peers. Those intangible assets (principally rights relating to research, development and commercialization of products) are accounted for in accordance with IFRS 3 (Business Combinations) and hence may be subject to remeasurement. Such remeasurements are not made other than in a business combination.

We also believe that eliminating the other effects of business combinations (such as the incremental cost of sales arising from the workdown of acquired inventories remeasured at fair value in business combinations) gives a better understanding of our recurring operating performance.

Eliminating restructuring costs and similar items enhances comparability with our peers because those costs are incurred in connection with reorganization and transformation processes intended to optimize our operations.

Finally, we believe that eliminating the effects of transactions that we regard as non-recurring and that involve particularly significant amounts (such as major gains and losses on disposals, and costs and provisions associated with major litigation and other major non-recurring items) improves comparability from one period to the next.

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" and "Business EPS" are not standardized measures, they may not be directly comparable with the non-IFRS financial measures of other companies using the same or similar non-IFRS financial measures.

A.1.6. Presentation of net sales

In the discussion below, we present our consolidated net sales for 2022 and 2021. We analyze our net sales by various categories including segment, franchise, product, and geographical region. In addition to reported net sales, we analyze non-IFRS 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 presentation of consolidated net sales for 2021 compared with 2020 is available in our Form 20-F filed on February 23, 2022, Item 5., section "A.2.1. Net Sales".

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.

1/ Alliance arrangements with Regeneron Pharmaceuticals Inc. (Regeneron)

Collaboration agreements on human therapeutic antibodies

In November 2007, Sanofi and Regeneron signed two agreements (amended in November 2009) relating to human therapeutic antibodies: (i) the Discovery and Preclinical Development Agreement, and (ii) the License and Collaboration Agreement, relating to clinical development and commercialization. Under the License and Collaboration Agreement, Sanofi had an option to develop and commercialize antibodies discovered by Regeneron under the Discovery and Preclinical Development Agreement.

Discovery and development

Because Sanofi decided not to exercise its option to extend the Discovery and Preclinical Development Agreement, that agreement expired on December 31, 2017.

As a result of Sanofi's exercise of an option with respect to an antibody under the Discovery and Preclinical Development Agreement, such antibody became a "Licensed Product" under the License and Collaboration Agreement, pursuant to which Sanofi and Regeneron co-develop the antibody with Sanofi initially being wholly responsible for funding the development program. On receipt of the first positive Phase III trial results for any antibody being developed under the License and Collaboration Agreement, the subsequent development costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under the License and Collaboration Agreement are recognized by Sanofi as a reduction in the line item ***Research and development expenses***. Co-development with Regeneron of the antibodies Dupixent®, Kevzara® and REGN3500 (SAR440340 - itepekimab) is ongoing under the License and Collaboration Agreement as of December 31, 2022.

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 portion of Regeneron's profit-share (capped at 20% of Regeneron's share of quarterly profits since April 1, 2022, and at 10% until March 31, 2022) until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration (see Note D.21.1.).

On the later 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 and Collaboration Agreement.

Commercialization

Sanofi is the lead party with respect to the commercialization of all co-developed antibodies, and Regeneron has certain option rights to co-promote the antibodies. Regeneron has exercised its co-promotion rights in the United States and in certain other countries. Sanofi recognizes all sales of the 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 due to or from Regeneron under the agreement is recognized within the line items ***Other operating income or Other operating expenses***, which are components of ***Operating income***.

In addition, Regeneron is entitled to receive payments contingent on the attainment of specified levels of aggregate sales on all antibodies outside the United States, on a rolling twelve-month basis. A liability for those payments is recognized on the balance sheet when it is probable that the specified level of aggregate sales will be met. The opposite entry for that liability is capitalized within ***Other intangible assets*** on the balance sheet. Two payments of $50 million each were made in 2022, following attainment first of $2.0 billion and then of $2.5 billion in sales of all antibodies outside the United States on a rolling twelve-month basis. In the event that $3.0 billion in sales on a rolling twelve-month basis is attained, Regeneron is entitled to a final milestone payment of $50 million.

Amendments to the collaboration agreements

In January 2018, Sanofi and Regeneron signed a set of amendments to their collaboration agreements, including an amendment that allowed for the funding of additional programs on Dupixent® and REGN3500 (SAR440340 – itepekimab) with an intended focus on extending the current range of indications, finding new indications, and improving co-morbidity between multiple pathologies.

Effective April 1, 2020, Sanofi and Regeneron signed a Cross License and Commercialization Agreement for Praluent®, whereby Sanofi obtained sole ex-US rights to Praluent®, and Regeneron obtained sole US rights to Praluent® along with a right to 5% royalties on Sanofi's sales of Praluent® outside the United States. Each party is solely responsible for funding the development, manufacturing and commercialization of Praluent® in their respective territories. Although each party has responsibility for supplying Praluent® in its respective territory, Sanofi and Regeneron have entered into agreements to support manufacturing needs for each other.

Effective September 30, 2021, Sanofi and Regeneron signed an amendment to their collaboration agreement in order to specify allocations of responsibilities and associated resources between the two parties in connection with the co-promotion of Dupixent® in certain countries. The terms of the collaboration relating to REGN3500 (SAR440340 – itepekimab) are unchanged.

Effective July 1, 2022, Sanofi and Regeneron signed an amendment to their collaboration agreement in order to increase the additional portion of Regeneron's share of quarterly profits attributable to Sanofi from 10% to 20% with retroactive impact as of April 1, 2022.

Immuno-oncology (IO) collaboration agreements

On July 1, 2015, Sanofi and Regeneron signed two agreements – the IO Discovery and Development Agreement and the IO License and Collaboration Agreement (IO LCA) – relating to new antibody cancer treatments in the field of immuno-oncology.

The Amended IO Discovery Agreement, effective from December 31, 2018, was terminated through a Letter Amendment dated March 16, 2021 in which Sanofi formalized its opt-out from the BCMAxCD3 and MUC16xCD3 programs.

Libtayo® (cemiplimab)

Under the 2015 IO LCA as amended in January 2018, Sanofi and Regeneron committed funding of no more than $1,640 million, split on a 50/50 basis ($820 million per company), for the development of REGN2810 (cemiplimab, trademark Libtayo®), a PD-1 inhibitor antibody. The funding was raised to $1,840 million by way of amendment effective on September 30, 2021. Regeneron was responsible for the commercialization of Libtayo® in the United States, and Sanofi in all other territories. Sanofi has exercised its option to co-promote Libtayo® in the United States. In 2021, Regeneron exercised its option to co-promote Libtayo® in certain other countries.

The IO LCA also provided for a one-time milestone payment of $375 million by Sanofi to Regeneron in the event that sales of a PD-1 product were to exceed, in the aggregate, $2 billion in any consecutive 12-month period.

Under the IO LCA Sanofi and Regeneron shared equally in profits and losses generated by the commercialization of collaboration products, except that Sanofi was entitled to an additional portion of Regeneron's profit-share (capped at 10% of Regeneron's share of quarterly profits) until Regeneron had paid 50% of the cumulative development costs incurred by the parties under the IO Discovery Agreement, as amended.

Libtayo® is approved in the United States and Europe for the treatment of two types of locally advanced or metastatic skin cancer (cutaneous squamous cell carcinoma and basal cell carcinoma) and non-small cell lung cancer (NSCLC). It is also approved in Brazil and Canada as a second line treatment for recurring or metastatic cervical cancer. In the fourth quarter of 2022, it was approved in the United States in association with chemotherapy for the treatment of NSCLC, and in Europe and Japan as a second line treatment for recurring or metastatic cervical cancer. Libtayo® is currently approved in more than 30 countries.

In June 2022, Sanofi and Regeneron restructured their IO LCA. Under the terms of the Amended and Restated IO LCA, Regeneron holds exclusive worldwide licensing rights to Libtayo® with effect from July 1, 2022.

In July 2022, Sanofi received as consideration an upfront payment of $900 million (€856 million), which was recognized within ***Other operating income*** on the date of receipt. The same line item also includes a regulatory milestone payment of $100 million (€96 million) following the US FDA approval in November 2022 of Libtayo® in combination with chemotherapy as a first line treatment for NSCLC. In addition, Sanofi is entitled to royalties of 11% and to milestone payments (€111 million in 2022) linked to global net sales of Libtayo® which are recognized within ***Other operating income*** in line with the pattern of sales. All of the cash inflows relating to the above items (€967 million for the year ended December 31, 2022) are presented within ***Net cash provided by/(used in) operating activities*** in the consolidated statement of cash flows.

The amendment to the terms of the IO LCA resulted in Sanofi recognizing an accelerated amortization charge of €226 million; this was allocated to the Libtayo® product rights included within the residual carrying amount of the intangible asset recognized in July 2015 to reflect rights to an antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1) under the Sanofi/Regeneron alliance.

The transaction also includes a time-limited transitional services agreement with Regeneron which includes manufacturing, distribution (for which Sanofi acts as agent), and promotion.

Investor agreement

In 2014 and 2020, Sanofi and Regeneron amended the investor agreement entered into by the two companies in 2007. Under the terms of the amendments, Sanofi accepted various restrictions, including "standstill" provisions that 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 remains 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 agreements on human therapeutic antibodies" above), each as amended and (ii) other specified events.

Starting in 2018 Sanofi began to sell shares of Regeneron stock and announced on May 29, 2020 the closing of its sale of 13 million shares of Regeneron common stock in a registered offering and a private sale to Regeneron (see Note D.2.).

Pursuant to subsequent sales, as of December 31, 2022 Sanofi no longer holds any shares of Regeneron stock.

2/ Alliance arrangements with Bristol-Myers Squibb (BMS)

Two of Sanofi's 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, effective 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 ("Territory B"), giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS received royalty payments on Sanofi's sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in Territory B) until 2018, and also received a payment of $200 million from Sanofi in December 2018, part of which is for buying out the non-controlling interests. Rights to Plavix® in Territory B remained unchanged and continued to be governed by the terms of the original agreement until February 28, 2020.

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 recognized in its consolidated financial statements the revenue and expenses generated by its own operations. Since January 2019 onwards, there has no longer been any share of profits reverting to BMS (previously presented within ***Net income attributable to non-controlling interests*** in the income statement).

In Territory B for Plavix®, which was managed by BMS, the Plavix® business was conducted through the Territory B partnerships, which were jointly owned by BMS and Sanofi. Sanofi recognized its share of profits and losses within the line item ***Share of profit/(loss) from investments accounted for using the equity method***.

On February 28, 2020, Sanofi purchased all BMS's interests (50.1%) in each of the Territory B partnerships for a cumulative purchase price of $12 million. Following a transition period, Sanofi has been commercializing Plavix® under its own label since July 1, 2020.

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 2022, we earned 42.5% 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.

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 May 3, 2022, Sanofi's General Meeting of Shareholders approved the decision to distribute approximately 58% of the share capital of *EUROAPI*, a European leader in the development, manufacture, marketing and distribution of Active Pharmaceutical Ingredients (APIs), in the form of an exceptional dividend in kind to Sanofi shareholders. On the dividend payment date of May 10, 2022 (further to the admission of EUROAPI shares to listing on the regulated market of Euronext Paris on May 6, 2022), Sanofi divested control over EUROAPI and its subsidiaries, resulting in their deconsolidation from the Sanofi consolidated financial statements as of that date. On June 17, 2022 (the date of delivery of the EUROAPI shares to the French State via the French Tech Souveraineté fund), EPIC Bpifrance acquired a 12% equity interest in EUROAPI. Following completion of those transactions, Sanofi retains an equity interest of 30.1% in EUROAPI, which has been accounted for using the equity method since the date of loss of control. The cash impact of the deconsolidation of EUROAPI, presented within the line item *Disposals of consolidated undertakings and investments accounted for using the equity method* in the statement of cash flows, was a net cash inflow of €101 million.

For further details about the divestments mentioned above, see Note D.1. to our consolidated financial statements included at Item 18. of this annual report.

A.1.10. Acquisitions

On February 8, 2022, Sanofi acquired the entire share capital of the immuno-oncology company Amunix Pharmaceuticals, Inc. (Amunix), thereby gaining access to Amunix's innovative Pro-XTEN™ technology and a promising pipeline of immunotherapies. The acquisition price of Amunix comprises a fixed payment of €970 million, plus contingent consideration in the form of milestone payments based on attainment of certain future development objectives of up to $225 million, the fair value of which as of the acquisition date was €156 million. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €852 million.

On April 8, 2021, Sanofi acquired the entire share capital of Kymab for an upfront payment of $1.1 billion (€973 million) and up to $350 million (€295 million) contingent upon reaching certain development milestones. The purchase price allocation resulted in the recognition of €965 million of other intangible assets. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €932 million.

On April 16, 2021, Sanofi completed the public offering for Kiadis. As of the end of the post-closing acceptance period on April 29, 2021, Sanofi held 97.39% of the share capital of Kiadis, and launched a statutory public buy-out procedure in order to obtain 100% of the share capital. The purchase price allocation resulted in the recognition of €339 million of other intangible assets. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €326 million.

On April 9, 2021, Sanofi acquired Tidal Therapeutics for an upfront payment of $160 million (€136 million), and up to $310 million (€261 million) contingent upon reaching certain development milestones. The purchase price allocation resulted in the recognition of €130 million of other intangible assets. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €135 million.

On September 14, 2021, Sanofi completed the acquisition of Translate Bio for a purchase price of €2.6 billion. The purchase price allocation resulted in the recognition of goodwill amounting to €2,118 million. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €2,333 million.

On November 9, 2021, Sanofi completed the acquisition of Kadmon in a transaction valued at $1.9 billion (€1.6 billion) on a fully-diluted basis. The purchase price allocation resulted in the recognition of €1,739 million of other intangible assets. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €1,575 million.

On December 3, 2021, Sanofi completed the acquisition of Origimm Biotechnology GmbH, for an initial payment of €55 million, and up to €95 million contingent upon reaching certain development phases. The purchase price allocation resulted in the recognition of €55 million of other intangible assets. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows for the year ended December 31, 2021 is a net cash outflow of €50 million.

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 on Form 20-F.

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. 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, consumer healthcare 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. In accordance with IFRS 15 (Revenue from Contracts with Customers), such revenue is recognized when Sanofi transfers control over the product to the customer. Control refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from, the products. For the vast majority of contracts, revenue is recognized when the product is physically transferred, in accordance with the delivery and acceptance terms agreed with the customer.

For contracts entered into by Sanofi Pasteur, transfer of control is usually determined by reference to the terms of release (immediate or deferred) and acceptance of batches of vaccine.

As regards contracts with distributors, Sanofi does not recognize revenue when the product is physically transferred to the distributor in case of products sold on consignment, or if the distributor acts as an agent. In such cases, revenue is recognized when control is transferred to the end customer, and the distributor's commission is presented within the line item ***Selling and general expenses*** in the income statement.

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 within *Net Sales*, as a reduction of gross sales. 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*. This line item also includes revenues arising from the distribution of Eloctate® and Alprolix® under Sanofi's agreements with Swedish Orphan Biovitrum AB (Sobi) and revenue received under agreements for Sanofi to provide manufacturing services to third parties.

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 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 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/ Impairment of goodwill 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. Such indicators could include primarily but not exclusively (i) increased market competition resulting from (for example) the introduction of a competitor's product; (ii) earlier than expected loss of exclusivity; (iii) increased pricing pressure; (iv) restrictions imposed by regulatory authorities on the manufacture or sale of a product; (v) delay in the projected launch of a product; (vi) different from expected clinical trial results; (vii) higher than expected development costs or (viii) lower than expected economic performance.

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 for impairment).

Significant underlying assumptions requiring the exercise of considerable judgement are applied in the future cash flow projections used to determine the recoverability of intangible assets, including primarily but not exclusively (i) therapeutic class market growth drivers; (ii) expected impacts from competing products (including but not exclusively generics and biosimilars); (iii) projected pricing and operating margin levels; (iv) likely changes in the regulatory, legal or tax environment; and (v) management's estimates of terminal growth or attrition rates.

The recoverable amounts of intangible assets related to research and development projects are determined based on future net cash flows, which reflect the development stage of the project and the associated probability of success of marketization of the compound.

The projected cash flows are discounted to present value using a discount rate, which factors in the risks inherent in cash flow projections.

Changes in facts and circumstances, assumptions and/or estimates may lead to future additional impairment losses or reversal of impairment previously recorded.

Key assumptions relating to goodwill impairment are the perpetual growth rate and the post-tax discount rate. 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/ 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 those 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.

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.

5/ 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.

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 liability is regarded as probable, it is measured on the basis of Sanofi's best estimate and recognized as a liability; uncertain tax assets are not recognized.

6/ 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" to our consolidated financial statements included 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 economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources. We also disclose a contingent liability in circumstances where we are unable to make a reasonable estimate of the expected financial effect that will result from the ultimate resolution of the proceeding, or a cash outflow is not probable.

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.

7/ Provisions for restructuring costs

Provisions for restructuring costs include collective redundancy or 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 at 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.

A.2. Results of operations – Year ended December 31, 2022 compared with year ended December 31, 2021

Consolidated income statements

(€ million)	2022	as % of net sales	2021	as % of net sales
Net sales	**42,997**	**100.0%**	**37,761**	**100.0%**
Other revenues	2,392	5.6%	1,414	3.7%
Cost of sales	(13,695)	-31.9%	(12,255)	-32.5%
Gross profit	**31,694**	**73.7%**	**26,920**	**71.3%**
Research and development expenses	(6,706)	-15.6%	(5,692)	-15.1%
Selling and general expenses	(10,492)	-24.4%	(9,555)	-25.3%
Other operating income	1,969		859	
Other operating expenses	(2,531)		(1,805)	
Amortization of intangible assets	(2,053)		(1,580)	
Impairment of intangible assets	454		(192)	
Fair value remeasurement of contingent consideration	27		(4)	
Restructuring costs and similar items	(1,336)		(820)	
Other gains and losses, and litigation	(370)		(5)	
Operating income	**10,656**	**24.8%**	**8,126**	**21.5%**
Financial expenses	(440)		(368)	
Financial income	206		40	
Income before tax and investments accounted for using the equity method	**10,422**	**24.2%**	**7,798**	**20.7%**
Income tax expense	(2,006)		(1,558)	
Share of profit/(loss) from investments accounted for using the equity method	68		39	
Net income	**8,484**	**19.7%**	**6,279**	**16.6%**
Net income attributable to non-controlling interests	113		56	
Net income attributable to equity holders of Sanofi	**8,371**	**19.5%**	**6,223**	**16.5%**
Average number of shares outstanding (million)	1,251.9		1,252.5	
Average number of shares after dilution (million)	1,256.9		1,257.9	
• Basic earnings per share (€)	6.69		4.97	
• Diluted earnings per share (€)	6.66		4.95	

A.2.1. Net sales

Consolidated net sales for the year ended December 31, 2022 amounted to €42,997 million, 13.9% higher than in 2021 in a reported basis. Exchange rate fluctuations had a positive effect of 6.9 percentage points overall, due mainly to favorable trends of the US dollar and Chinese yuan against the euro. At constant exchange rates (CER[4]), net sales rose by 7.0%, mainly reflecting strong growth for Dupixent® and increased sales for our Vaccines business, more than offsetting lower sales for our Non Core Assets franchise.

Reconciliation of net sales to net sales at constant exchange rates

(€ million)	2022	2021	Change
Net sales (IFRS)	**42,997**	**37,761**	**+13.9%**
Effect of exchange rates	(2,585)		
Net sales at constant exchange rates (non-IFRS financial measure)	**40,412**	**37,761**	**+7.0%**

We calculate net sales CER by recalculating net sales for the relevant period using the exchange rates that were used for the previous period.

To facilitate analysis and comparisons with prior periods, some figures are given at constant exchange rates (CER).

1/ Net sales by operating segment and global business unit (GBU)

Our net sales comprise the net sales generated by our Pharmaceuticals, Vaccines and Consumer Healthcare segments.

(€ million)	2022	2021	Change on a reported basis	Change at constant exchange rates
Pharmaceuticals segment	**30,688**	**26,970**	**+13.8%**	**+6.9%**
Vaccines GBU/segment	**7,229**	**6,323**	**+14.3%**	**+6.3%**
Consumer Healthcare GBU/segment	**5,080**	**4,468**	**+13.7%**	**+8.6%**
Total net sales	**42,997**	**37,761**	**+13.9%**	**+7.0%**

[4] *Non-IFRS financial measure: see definition in "— A.1.6. Presentation of Net Sales".*

2/ Net sales by franchise, geographical region and product

(€ million)	Net sales	Change (CER)	Change (reported)	United States	Change (CER)	Europe	Change (CER)	Rest of the world	Change (CER)
Dupixent®	**8,293**	**+43.8%**	**+58.0%**	**6,346**	**+41.6%**	**940**	**+44.4%**	**1,007**	**+56.6%**
Aubagio®	2,031	-4.3%	+3.9%	1,420	-3.8%	511	—%	100	-26.0%
Lemtrada®	80	-8.5%	-2.4%	31	-20.0%	22	-8.3%	27	+8.7%
Kevzara®	339	+11.8%	+18.1%	186	+23.0%	106	+2.9%	47	—%
Total Neurology & Immunology	**2,450**	**-2.5%**	**+5.4%**	**1,637**	-1.8%	**639**	**+0.2%**	**174**	**-15.7%**
Cerezyme®	707	+2.6%	+3.5%	194	-0.6%	239	-2.0%	274	+9.0%
Cerdelga®	288	+6.7%	+13.4%	160	+7.6%	111	+5.7%	17	+5.9%
Gaucher	*995*	*+3.7%*	*+6.2%*	*354*	*+3.0%*	*350*	*+0.3%*	*291*	*+8.8%*
Fabrazyme®	938	+5.2%	+11.1%	471	+5.8%	228	+2.2%	239	+7.1%
Xenpozyme®	21	+1900.0%	+2000.0%	5	—%	15	+1400.0%	1	—%
Myozyme®/Lumizyme®	958	-8.8%	-4.5%	318	-24.1%	408	-0.5%	232	+1.8%
Nexviazyme®	196	+952.9%	+1052.9%	158	+833.3%	17	+750.0%	21	—%
Pompe	*1,154*	*+7.3%*	*+13.1%*	*476*	*+9.0%*	*425*	*+3.2%*	*253*	*+11.8%*
Aldurazyme®	267	+6.6%	+9.9%	61	—%	86	+2.4%	120	+13.3%
Elaprase®	70	-12.3%	-13.6%	—	—%	—	—%	70	-12.3%
MPS	*337*	*+1.9%*	*+4.0%*	*61*	—%	*86*	*+2.4%*	*190*	*+2.2%*
Total Rare Diseases	**3,445**	**+5.7%**	**+10.2%**	**1,367**	**+6.3%**	**1,104**	**+3.3%**	**974**	**+7.8%**
Jevtana®	391	-20.0%	-14.1%	275	-3.2%	33	-70.5%	83	-4.4%
Fasturtec®	177	+8.6%	+16.4%	113	+12.2%	48	+4.3%	16	—%
Libtayo®	88	-34.1%	-31.8%	—	—%	70	-34.3%	18	-33.3%
Sarclisa®	294	+60.2%	+67.0%	127	+68.7%	88	+35.9%	79	+82.2%
Total Oncology	**952**	**-1.5%**	**+4.4%**	**515**	**+12.0%**	**239**	**-27.5%**	**198**	**+15.4%**
Alprolix®	504	+10.4%	+21.7%	406	+8.7%	—	—%	98	+17.1%
Eloctate®	580	-5.9%	+3.0%	450	-6.8%	—	—%	130	-3.0%
Cablivi®	211	+20.7%	+28.7%	110	+21.0%	94	+16.0%	7	+200.0%
Enjaymo®	22	—%	—%	17	—%	—	—%	5	—%
Total Rare Blood Disorders	**1,317**	**+5.6%**	**+15.4%**	**983**	**+3.8%**	**94**	**+16.0%**	**240**	**+8.7%**
Lovenox®	1,310	-13.8%	-11.8%	17	-48.3%	658	-5.8%	635	-19.9%
Toujeo®	1,117	+9.8%	+15.3%	283	-3.1%	421	+7.1%	413	+23.7%
Plavix®	983	+2.5%	+5.8%	9	-11.1%	101	-12.2%	873	+4.7%
Multaq®	383	+4.3%	+16.4%	347	+5.5%	16	-27.3%	20	+26.7%
Praluent®	376	+65.1%	+72.5%	55	+860.0%	229	+41.6%	92	+61.5%
Thymoglobulin®	446	+16.9%	+27.4%	269	+15.5%	34	—%	143	+24.8%
Mozobil®	261	+4.3%	+12.0%	154	+6.2%	67	+11.7%	40	-11.4%
Soliqua®/Suliqua®	215	+1.5%	+10.3%	119	-7.8%	29	—%	67	+23.5%
Rezurock®	207	+815.0%	+935.0%	206	+815.0%	1	—%	—	—%
Other Core Assets	1,091	-0.2%	+5.0%	194	-30.8%	361	+3.4%	536	+14.4%
Total Core Assets	**6,389**	**+5.2%**	**+10.8%**	**1,653**	**+11.6%**	**1,917**	**+2.9%**	**2,819**	**+3.7%**
Lantus®	2,259	-14.4%	-9.4%	757	-22.1%	426	-10.1%	1,076	-10.4%
Aprovel®/Avapro®	478	+7.6%	+14.1%	7	-40.0%	82	-5.7%	389	+12.7%
Other Non-Core Assets	4,485	-7.7%	-5.2%	412	-10.7%	1,129	-11.6%	2,944	-5.6%
Total Non-Core Assets	**7,222**	-9.0%	-5.5%	**1,176**	-18.6%	**1,637**	-10.9%	**4,409**	-5.5%
Industrial Sales	**620**	-26.2%	-23.3%	**17**	-63.4%	**587**	-21.9%	**16**	-63.6%
Total Pharmaceuticals	**30,688**	**+6.9%**	**+13.8%**	**13,694**	**+15.9%**	**7,157**	**-0.8%**	**9,837**	**+2.8%**
Polio/Pertussis/Hib vaccines	2,285	+2.5%	+5.8%	456	-13.8%	325	+6.9%	1,504	+7.2%
Booster vaccines (incl. Adacel®)	587	+11.3%	+20.3%	330	+4.3%	154	+5.5%	103	+55.6%
Meningitis vaccines	703	-3.6%	+6.8%	531	-4.9%	15	+1400.0%	157	-8.2%
Influenza vaccines	2,977	+2.4%	+13.3%	1,737	+8.2%	681	-6.4%	559	-0.4%
Travel and endemics vaccines	510	+57.8%	+66.7%	153	+57.0%	94	+123.8%	263	+42.7%
Other vaccines	167	+86.9%	+98.8%	84	—%	72	+7100.0%	11	+22.2%
Total Vaccines	**7,229**	**+6.3%**	**+14.3%**	**3,291**	**+3.0%**	**1,341**	**+9.7%**	**2,597**	**+8.4%**
Allergy	734	+10.5%	+19.9%	439	+5.7%	55	+10.2%	240	+19.8%
Cough, Cold and Flu	478	+46.3%	+49.4%	—	—%	263	+69.2%	215	+24.4%
Pain Care	1,213	+7.9%	+11.0%	212	-4.1%	555	+8.3%	446	+13.4%
Digestive Wellness	1,318	+12.4%	+16.5%	144	+3.2%	432	+11.3%	742	+14.9%
Physical Wellness	324	-3.7%	+0.3%	—	—%	23	-20.7%	301	-2.0%
Mental Wellness	238	+7.6%	+12.8%	51	-2.2%	107	+8.0%	80	+13.8%
Personal Care	586	+2.3%	+12.9%	453	+2.3%	1	-75.0%	132	+5.0%
Non-Core/Other	189	-27.4%	-27.0%	(9)	-200.0%	65	-27.5%	133	-18.8%
Total Consumer Healthcare	**5,080**	**+8.6%**	**+13.7%**	**1,290**	**+0.8%**	**1,501**	**+13.1%**	**2,289**	**+10.0%**
Total Sanofi	**42,997**	**+7.0%**	**+13.9%**	**18,275**	**+12.2%**	**9,999**	**+2.4%**	**14,723**	**+4.8%**

3/ Net sales – Pharmaceuticals segment

In 2022, net sales for the Pharmaceuticals segment amounted to €30,688 million, up 13.8% on a reported basis and 6.9% at constant exchange rates (CER). The year-on-year reported-basis increase of €3,718 million reflects positive exchange rate effects of €1,849 million, and the following principal effects at constant exchange rates:

- solid performances from Dupixent® (+€2,297 million), the launch of Nexviazyme® (+€162 million), and sales growth for Sarclisa® (+€106 million); and
- growth for the Core Assets franchise within the General Medicines GBU (+€302 million), partly offsetting lower sales for the Non Core Assets franchise (-€689 million).

Comments on the performances of our major Pharmaceuticals segment products are provided below.

Specialty Care

Dupixent®

Dupixent® (developed in collaboration with Regeneron) generated net sales of €8,293 million in 2022, up 58.0% versus 2021 on a reported basis and 43.8% at constant exchange rates. In the United States, sales of Dupixent® reached €6,346 million in 2022, up 41.6% CER, boosted by continuing strong demand in the product's approved indications (atopic dermatitis, asthma and nasal polyps); the launches in atopic dermatitis for children aged 6 months and over, eosinophilic esophagitis, and prurigo nodularis. Total prescriptions of Dupixent rose by 38%, and new-to-brand prescriptions by 41% compared to 2021. In Europe, the product posted 2022 net sales of €940 million, up 44.4% CER, driven by continuing growth in atopic dermatitis, asthma and nasal polyps. In the Rest of the World region, Dupixent® posted net sales of €1,007 million (+56.6% CER), including €364 million in Japan (+33.0% CER) and €237 million in China (+197.3% CER).

Neurology and immunology

In 2022, the Neurology and Immunology franchise generated net sales of €2,450 million, up 5.4% on a reported basis and down 2.5% CER, mainly reflecting lower sales of Aubagio®.

Aubagio® posted net sales of €2,031 million in 2022 (-4.3% CER), due to negative price effects and to lower sales in the United States (-3.8% CER at €1,420 million, due to increased competition) and the Rest of the World region (-26.0% CER at €100 million). In the United States, Aubagio® generic competition will be able to enter the market on March 12, 2023, as agreed in 2017 with the generics manufacturers. In Europe, Aubagio® generic competition is expected in the fourth quarter of 2023.

In 2022, net sales of Lemtrada® amounted to €80 million, down 8.5% CER, on a decline in sales in the United States (-20.0% CER at €31 million) and Europe (-8.3% CER at €22 million).

Net sales of Kevzara® (developed in collaboration with Regeneron) in 2022 reached €339 million, up 11.8% CER.

Rare diseases

In 2022, net sales for the Rare Diseases franchise totaled €3,445 million, up 10.2% on a reported basis and 5.7% at constant exchange rates (CER), reflecting a rise in all three regions and franchises. The Rest of the World region is driving growth with net sales up 7.8% CER at €974 million, followed by the United States, where net sales advanced by 6.3% CER to €1,367 million. In Europe, net sales for the franchise rose by 3.3% CER to €1,104 million.

Net sales for the Gaucher disease franchise (Cerezyme® and Cerdelga®) reached €995 million in 2022, up 3.7% CER. Cerezyme® sales were up 2.6% CER at €707 million, helped by a solid performance in the Rest of the World region (+9.0% CER at €274 million), driven by new patients on therapy and benefiting from favorable pricing. In parallel, sales of Cerdelga® rose by 6.7% CER to €288 million, driven by the United States (+7.6% CER at €160 million), Europe (+5.7% CER at €111 million), and the Rest of the World region (+5.9% CER at €17 million) as new patients adopted the product or switched treatment.

Net sales of the Pompe disease franchise (Myozyme®/Lumizyme® and Nexviazyme®) were up 7.3% CER in 2022 at €1,154 million, driven by the Nexviazyme® launch in the United States, Europe and Japan. Nexviazyme® sales reached €196 million, including €158 million in the United States. Sales of Myozyme®/Lumizyme® were down year-on-year (-8.8% CER at €958 million) due to switches of eligible Pompe patients (advanced stage) to Nexviazyme®.

Net sales of the Fabry disease treatment Fabrazyme® in 2022 were €938 million (+5.2% CER), propelled by the United States (+5.8% CER at €471 million), the Rest of the World region (+7.1% CER at €239 million) and Europe (+2.2% CER at €228 million), due to more patients adopting the product and better observance of the treatment.

Xenpozyme® (olipudase alfa), the first and only treatment for non-neurological manifestations of Acid Sphingomyelinase Deficiency (ASMD) has been approved by the FDA and EMA, in Japan, and in Brazil. Xenpozyme® has been launched in six countries and reported sales of €15 million in Europe, €5 million in the US and €1 million in the Rest of the World region.

Oncology

In 2022, net sales for the Oncology franchise amounted to €952 million, up 4.4% on a reported basis and down 1.5% CER, reflecting the end of consolidation of Libtayo® sales from the beginning of July. Excluding Libtayo®, Oncology sales were up 3.8% CER, as strong growth for Sarclisa® more than offset the impact of declining Jevtana® sales due to generic competition in Europe and increased competition in the US.

Sanofi stopped consolidating non-US Libtayo® sales from the start of the third quarter of 2022 following the restructuring of its immuno-oncology collaboration with Regeneron, pursuant to which Regeneron obtained the worldwide exclusive licensing rights to Libtayo®. Previously, the companies had split Libtayo® worldwide operating profits equally and co-commercialized Libtayo® in the US, with Sanofi solely responsible for commercialization in the rest of the world.

In 2022, net sales of Sarclisa® reached €294 million, up 60.2% CER, driven by a very strong performance in the United States (+€127 million, up 68.7% CER), in Europe (€88 million, up 35.9% CER), and in Japan (€66 million, up 75.0% CER).

Jevtana® posted net sales of €391 million in 2022 (-20.0% CER), as sales decreased in Europe (-70.5% CER at €33 million) following the arrival of generic competition in some European markets at end March 2021. In the United States, Jevtana® is currently covered by four Orange Book listed patents: US 7,241,907, US 8,927,592, US 10,583,110 and US 10,716,777. Sanofi has filed patent infringement suits under Hatch-Waxman against generic filers asserting the '110 patent, the '777 patent and the '592 patent in the US District Court for the District of Delaware. Sanofi has since reached settlement agreements with most of the defendants, and the suit against the remaining defendant (Sandoz) is ongoing. In August 2022, the district court dismissed Sanofi's infringement claim related to the '592 patent. A three-day trial took place on January 11 through January 13, 2023, and Sandoz agreed not to launch any generic cabazitaxel product until the earlier of a district court decision in favor of Sandoz or four months after the completion of the post-trial briefing. Jevtana® sales in the United States were down 3.2% CER at €275 million.

Rare Blood Disorders

In 2022, the Rare Blood Disorders franchise generated net sales of €1,317 million, up 15.4% on a reported basis and 5.6% at constant exchange rates, mainly as a result of growth for Alprolix® and Cablivi® and the launch of Enjaymo®, more than offsetting lower sales of Eloctate®.

Eloctate®, indicated in the treatment of hemophilia A, generated net sales of €580 million in 2022, down 5.9% CER, due to competitive pressure and lower sales in the Rest of the World region (-3.0% CER).

In 2022, net sales of Alprolix®, indicated in the treatment of hemophilia B, were €504 million, up 10.4% CER. In the United States, sales of the product reached €406 million, up 8.7% CER, reflecting patient switching to prophylactic treatments.

Cablivi®, which treats acquired thrombotic thrombocytopenic purpura (aTTP) in adults, posted net sales of €211 million in 2022, up 20.7% CER, reflecting increased ATTP awareness and treatment in line with guidelines from the International Society on Thrombosis and Haemostasis (ISTH) recommending first line use of Cablivi® for all aTTP patients. Sales reached €110 million in the United States (+21.0% CER), while in Europe net sales were up 16.0% CER at €94 million mainly due to higher market penetration as a result of increased product awareness.

Net sales of Enjaymo®, the first-ever treatment for cold agglutinin disease, reached €22 million. The product was launched in the United States and Japan during 2022, and approved in Europe in November 2022.

General Medicines

In 2022, net sales for the General Medicines GBU decreased by 4.2%. Core assets accounted for 47% of total General Medicines sales in 2022, compared with 43% in 2021 (excluding industrial sales). Divestments of non-core assets had a negative impact of 0.8 ppt, and the deconsolidation of EUROAPI third party sales, a negative impact of 2.4 ppt. In 2022, Industrial sales were €620 million, down 26.2%, reflecting the impact of the deconsolidation of EUROAPI third party sales.

Core Assets

In 2022, global Core Assets sales were €6,389 million, up 10.8% on a reported basis and 5.2% at constant exchange rates, with double-digit growth for Praluent® and Thymoglobulin® and a strong contribution from Toujeo®, Multaq®, and Rezurock®, partly offset by lower sales of Lovenox®. Sales rose in all geographies during the period, with the strongest growth in China (+19.1% CER at €795 million).

Net sales of Lovenox® were €1,310 million in 2022, down 13.8% CER, reflecting lower COVID-19-related demand compared to 2021, which also led to a contraction in the Low Weight Molecular Heparins market. At the same time, penetration of biosimilars increased.

In 2022, Toujeo® posted net sales of €1,117 million, up 9.8% CER, driven by the Rest of the World region (+23.7% CER at €413 million. In China, there was increased demand and a favorable comparative base, reflecting price and inventory adjustments in the fourth quarter of 2021 in anticipation of the implementation of the Value Based Procurement program for insulins. Europe also reported growth (+7.1% CER at €421 million).

Net sales of Plavix® were up by 2.5% at €983 million in 2022, reflecting consistent volume growth in China (+10.3% CER at €462 million) more than offset lower sales in Europe (-12.2% CER) and in the US (-11.1% CER).

Net sales of Multaq® totaled €383 million in 2022, up 4.3% CER, mainly due to growth in US sales (+5.5% CER).

In 2022 net sales of Praluent® were €376 million, up 65.1% CER, reflecting a solid performance in Europe (+41.6% CER, at €229 million) and an accelerated ramp-up in China due to inclusion in the National Drug Reimbursement List (NDRL) effective January 2022.

Net sales of Soliqua® were up 1.5% CER at €215 million in 2022. Growth was driven by the Rest of the World region (+23.5% CER at €67 million), partly offset by a decrease in US sales to €119 million (-7.8% CER). Soliqua® was approved in China in January 2022, and Sanofi will work with the authorities with a view to the product being added to the NRDL.

Sales of Rezurock® were €207 million in 2022. Since its launch, more than 1,400 patients have been treated with Rezurock® (over 30% of the current potential patient population worldwide), with strong persistency rates.

Non-Core Assets

In 2022, net sales of Non-Core Assets amounted to €7,222 million, down 5.5% on a reported basis and 9.0% at constant exchange rates (and down 7.4% excluding the impact of divestments), reflecting the impact of VBP in China on sales of Lantus®, Eloxatin® and Taxotere®, along with lower sales of Lantus® in the United States.

Net sales of Lantus® in 2022 were down 14.4% CER at €2,259 million, reflecting lower sales in the United States (-22.1% CER), impacted by prior formulary losses and erosion of the basal insulin market. In Europe, Lantus® sales were down 10.1% at €426 million, due to biosimilar competition and switches to Toujeo®. In the Rest of the World region, sales were also down, by 10.4% CER at €1,076 million, mainly as a result of the rollout of the VBP program in China in May 2022.

In China, Sanofi participated in the VBP tender for basal insulin analogs in November 2021, and was among the bidding winners in Group A with Toujeo® and Lantus®. In 2022, sales of Toujeo® and Lantus® in China amounted to €447 million (-10.7%), reflecting high volumes but at significantly lower prices.

Net sales of Aprovel®/Avapro® were €478 million, up 7.6% CER, driven by regaining market share in the Rest of the World region following supply constraints in the previous year.

4/ Net sales – Vaccines segment/GBU

In 2022, the Vaccines segment posted net sales of €7,229 million, up 14.3% on a reported basis and 6.3% CER. The main drivers were the progressive recovery of travel vaccines (+57.8% CER, at €510 million), other vaccines (+86.9% CER at €167 million), and influenza vaccines (+2.4% CER at €2,977 million). At the same time, sales of meningitis vaccines decreased by 3.6% CER to €703 million.

Sales of influenza vaccines rose by 2.4 % CER in 2022 to €2,977 million, as new manufacturing capacity in the US took influenza vaccines sales to record levels. This perfrormance was once again driven by the ongoing conversion to differentiated premium priced vaccines, such as Fluzone® HD in the US and Efluelda® in Europe, that have demonstrated improved efficacy against a standard dose vaccine in randomized controlled trials.

Polio/Pertussis/Hib (PPH) vaccines generated net sales of €2,285 million in 2022, up 2.5% CER, sustained by growth in the Rest of the World region (+7.2% CER at €1,504 million), especially in China. In Europe, net sales of PPH vaccines were up 6.9% CER at €325 million, while in the United States sales were down 13.8% CER at €456 million. As a reminder, Vaxelis® US sales are not consolidated, and the profits are shared equally between Sanofi and Merck & co.

Net sales of Meningitis/Pneumonia vaccines for 2022 were €703 million, down 3.6% CER, mainly on lower sales in the United States (-4.9% CER at €531 million). Sales in the Rest of the World region were down 8.2% CER at €157 million.

In 2022, sales of Booster vaccines advanced by 11.3% CER to €587 million, driven by the Rest of the World region.

Net sales of travel and endemics vaccines in 2022 were €510 million, up 57.8% CER, reflecting growth across all geographies in a post-pandemic environment.

Net sales of other vaccines were €167 million (+86.9% CER), and include sales of the recently approved monovalent recombinant-protein COVID-19 booster vaccine VidPrevtyn® Beta.

5/ Net sales – Consumer Healthcare segment/GBU

In 2022, net sales for the Consumer Healthcare (CHC) segment increased by 13.7% on a reported basis and 8.6% at CER to €5,080 million, driven by double-digit growth in Europe and the Rest of the World region. In 2022, divestments of non-core products had a negative impact of 1.0 ppt. CHC therefore achieved organic growth of 9.6% in 2022 excluding divestments.

In the United States, CHC net sales amounted to €1,290 million in 2022, up 0.8% CER.

In Europe, CHC net sales were up 13.1% CER in 2022 at €1,501 million, reflecting a more intense Cough & Cold season.

In the Rest of the World region, CHC net sales were up 10.0% CER at €2,289 million in 2022, driven mainly by growth in Cough, Cold and Allergy products.

6/ Net sales by geographical region

The table below sets forth our net sales for 2022 and 2021 by geographical region:

(€ million)	2022	2021	Change on a reported basis	Change at constant exchange rates
United States	18,275	14,385	+27.0%	+12.2%
Europe	9,999	9,759	+2.5%	+2.4%
Rest of the World	14,723	13,617	+8.1%	+4.8%
of which China	*3,123*	*2,720*	*+14.8%*	*+6.2%*
of which Japan	*1,613*	*1,657*	*-2.7%*	*+3.1%*
of which Brazil	*927*	*815*	*+13.7%*	*-2.0%*
of which Russia	*674*	*575*	*+17.2%*	*+0.7%*
Total net sales	**42,997**	**37,761**	**+13.9%**	**+7.0%**

In 2022, net sales in the United States reached €18,275 million, up 27.0% on a reported basis and 12.2% at constant exchange rates, reflecting a strong performance from Dupixent® (+41.6 CER at €6,346 million) and the Core Assets franchise (€1,653 million, representing 11.6 % growth).

In Europe, net sales advanced by 2.5% on a reported basis and 2.4% at constant exchange rates in 2022 to €9,999 million. A substantial rise in sales for Dupixent® (+44.4% CER at €940 million) and sales growth for the CHC GBU (+13.1% CER at €1,501 million) more than offset lower sales for the Non Core Assets franchise (-10.9% CER).

In the Rest of the World region, net sales for 2022 increased by 8.1% on a reported basis and 4.8% at constant exchange rates to €14,723 million, due to exceptional performances from Dupixent® (+56.6% CER, at €1,007 million), Sarclisa® (+82.2% CER, at €79 million) and Booster and Travel Vaccines. China led the way in terms of growth, with net sales up 6.2% CER at €3,123 million, driven by an acceleration in sales of Dupixent®. In Japan, net sales rose by +3.1% CER to €1,613 million, also on higher sales of Dupixent®. Sales in Turkey also registered a very strong rise (+53.4% CER at €405 million). Dupixent® was also a growth driver in Russia, with sales of the product up 88.9%. Total sales in Russia increased by 0.7% CER. In March 2022, Sanofi suspended new spending not directly related to the supply of its essential medicines and vaccines in Russia. This includes advertising and promotional activities. Although the long-term repercussions of Russia's invasion of Ukraine are difficult to predict at this time, the financial impact of the conflict in 2022, including accounts receivable and inventory reserves, was not material. During the year ended December 31, 2022, the activities of our subsidiaries in Russia and Ukraine represented less than 1% of our consolidated assets and revenues.

A.2.2. Other income statement items

1/ Other revenues

Other revenues increased by 69.2% to €2,392 million in 2022 (versus €1,414 million in 2021). This line item mainly comprises VaxServe sales of non-Sanofi products (€1,567 million in 2022 versus €1,078 million in 2021, recorded within the Vaccines segment). The year-on-year increase also reflects higher revenues from manufacturing services contracts, including those related to the COVID-19 vaccine.

2/ Gross profit

Gross profit for 2022 amounted to €31,694 million compared with €26,920 million in 2021, an increase of 17.7%. Gross margin (the ratio of gross profit to net sales) also rose, reaching 73.7% in 2022, versus 71.3% in 2021. The year-on-year increase in gross margin reflects in particular stronger gross margin for the Pharmaceuticals segment, which reached 77.7% in 2022 versus 75.2% in 2021, driven largely by productivity gains in Manufacturing & Supply and a favorable portfolio mix. It also reflects an improvement in gross margin for the Vaccines segment to 66.3% in 2022 (versus 63.1% in 2021), largely due to growth in other revenues (23.0%, versus 17.3% in 2021).

3/ Research and development expenses

Research and development (R&D) expenses amounted to €6,706 million in 2022, versus €5,692 million in 2021, an increase of 17.8%. The increase was mainly due to additional expenditures in pharmaceuticals priority assets and early-stage projects, as well as the mRNA vaccines platform. R&D expenses represented 15.6% of net sales in 2022, versus 15.1% in 2021.

4/ Selling and general expenses

Selling and general expenses amounted to €10,492 million in 2022 (24.4% of net sales), versus €9,555 million in 2021 (25.3% of net sales); the 9.8% increase was a result of increased promotional expenditures, mainly in Specialty Care. The reduction in the ratio of selling and general expenses to net sales was due to operational excellence.

5/ Other operating income and expenses

Other operating income amounted to €1,969 million in 2022 (versus €859 million in 2021), and other operating expenses to €2,531 million, versus €1,805 million in 2021.

Overall, this represented a net expense of €562 million in 2022, compared with a net expense of €946 million in 2021.

(€ million)	2022	2021	Change
Other operating income	1,969	859	+1,110
Other operating expenses	(2,531)	(1,805)	-726
Other operating income/(expenses), net	**(562)**	**(946)**	**+384**

The increase of €384 million mainly reflects (i) an increase of €237 million in gains on asset disposals and (ii) a decrease of €142 million in the net expense relating to our pharmaceutical alliance partners, following the recognition of the proceeds derived from the restructuring of the Immuno-Oncology (IO) collaboration agreement between Sanofi and Regeneron applicable effective July 1, 2022 (see Note C.1. to our consolidated financial statements, included at Item 18 of this Annual Report on Form 20-F); those effects were partly offset by an increase in the share of profits/losses generated by the Regeneron alliance under the collaboration agreement (see Note C.1. to our consolidated financial statements due mainly to higher sales of Dupixent®.

For 2021, other operating income also includes a payment of €119 million received from Daiichi Sankyo relating to the ending of a vaccines collaboration agreement in Japan.

The contribution of our alliance with Regeneron to this line item is as follows:

(€ million)	2022	2021
Income & expense related to (profit)/loss sharing under the Monoclonal Antibody Alliance	(2,325)	(1,253)
Additional share of profit paid by Regeneron towards development costs [(b)]	434	127
Reimbursement to Regeneron of selling expenses incurred	(476)	(303)
Total: Monoclonal Antibody Alliance	**(2,367)**	**(1,429)**
Immuno-Oncology Alliance	**16**	**68**
Other (mainly Zaltrap® and Libtayo®)[(a)]	**1,120**	**(12)**
Other operating income/(expenses), net related to the Regeneron Alliance	**(1,231)**	**(1,373)**

(a) Following the restructuring of the Immuno-Oncology (IO) collaboration agreement between Sanofi and Regeneron effective July 1, 2022 (see Note C. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F).
(b) As of December 31, 2022, the commitment received by Sanofi in respect of the additional profit share payable by Regeneron towards development costs amounted

6/ Amortization of intangible assets

Amortization charged against intangible assets amounted to €2,053 million in 2022, compared with €1,580 million in 2021.

This €473 million increase was mainly due to (i) an accelerated amortization charge of €226 million taken against Libtayo® rights following the restructuring of the IO LCA with Regeneron (see Note C.1. to our consolidated financial statements, included at Item 18. of this Annual report on Form 20-F); and (ii) the impact of the acquisition of Kadmon in November 2021, which triggered the amortization of the intangible asset relating to Rezurock® as from that date (€159 million).

7/ Impairment of intangible assets, net of reversals

For 2022, this line shows a net gain of €454 million, mainly comprising:

- a reversal of €2,154 million relating to Eloctate franchise assets, following FDA approval of the marketing authorization request for ALTUVIIIO™ (the commercial name of efanesoctocog alpha, corresponding to the BIVV001 project); and
- an impairment loss of €1,586 million relating to the development project for SAR444245 (non-alpha interleukin-2), based on revised cash flow projections reflecting unfavorable developments in the launch schedule.

For 2021, this line item shows net impairment losses of €192 million taken against intangible assets, relating primarily to the discontinuation of the development of sutimlimab in Immune Thrombocytopenic Purpura (ITP) and the termination of various research projects in Vaccines.

8/ Fair value remeasurement of contingent consideration

Fair value remeasurements of contingent consideration recognized in acquisitions represented a net gain of €27 million in 2022, versus a net loss of €4 million in 2021.

9/ Restructuring costs and similar items

Restructuring costs and similar items represented a total charge of €1,336 million in 2022, versus a charge of €820 million in 2021.

The amount charged in 2022 includes employee-related expenses of €507 million and net expenses, gains and losses on assets (including asset write-downs and accelerated depreciation and amortization) of €261 million. The year-on-year increase mainly reflects provisions for separation costs associated with announcements made in 2022. Charges, gains and losses on assets mainly reflect a strategic decision to close an industrial facility outside France. The costs of Sanofi's transformation program (as defined in Note B.19. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F) amounted to €547 million in 2022.

In 2021, restructuring costs and similar items represented a total charge of €820 million, including employee-related expenses of €193 million, relating primarily to the creation of the new standalone Consumer Healthcare entity and of EUROAPI (the new

European market leader in active pharmaceutical ingredients), and to the implementation of Sanofi's new digital strategy. The 2021 figure also includes net expenses, gains and losses on assets (including asset write-downs and accelerated depreciation and amortization) of €110 million.

10/ Other gains and losses, and litigation

For 2022, this line item showed a net loss of €370 million, including the pre-tax loss arising on the deconsolidation of EUROAPI (see Note D.1. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F) and costs associated with major litigation (including estimated future defense costs to which Sanofi may be exposed in connection with the Zantac® litigation).

For 2021, this line item shows a net loss of €5 million.

11/ Operating income

Operating income amounted to €10,656 million in 2022, versus €8,126 million in 2021.

The year-on-year increase was largely due to the reversal of imparment losses totaling €2,154 million following the approval by the FDA on February 22, 2023 of the marketing authorization application for ALTUVIIIO™, part of the Eloctate franchise.

12/ Financial income and expenses

Net financial expenses were €234 million in 2022, versus €328 million in 2021, a decrease of €94 million.

The cost of our net debt (see the definition in "B. Liquidity and Capital Resources" below) was €124 million in 2022, compared with €259 million in 2021; the reduction of €135 million was largely due to an increased return on cash, cash equivalents and associated derivatives (€241 million in 2022 versus €54 million in 2021, an increase of €187 million).

A further factor was an increase in expenses arising from the unwinding of discounting of provisions and net interest costs on employee benefits and leases, which amounted to €107 million in 2022 compared with €90 million in 2021, a rise of €17 million (see Note D.29. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F).

13/ Income before tax and investments accounted for using the equity method

Income before tax and investments accounted for using the equity method reached €10,422 million in 2022, versus €7,798 million in 2021.

14/ Income tax expense

Income tax expense represented €2,006 million in 2022, versus €1,558 million in 2021, giving an effective tax rate based on consolidated net income of 19.2% in 2022, compared with 20.0% in 2021. The increase in income tax expense was mainly due to taxation of Libtayo® income from out-licensing (€246 million in 2022) and the reversal of impairment losses relating to ALTUVIIIO™ (€503 million in 2022) following FDA approval. The increase in tax expense is partly offset by the positive tax effect of the divestment of a 70% equity interest in EUROAPI recognized in the period (€111 million in 2022).

The effective tax rate on our business net income is a non-IFRS financial measure (see definition under "A.1.5. Segment information — 3. Business Net Income" above). 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, our effective tax rate was 19.3% in 2022, compared with 20.9% in 2021.

The table below reconciles our effective tax rate based on consolidated net income to our effective tax rate based on business net income:

(as a percentage)	2022	2021
Effective tax rate based on consolidated net income	**19.2%**	**20.0%**
Tax effects:		
Amortization and impairment of intangible assets	0.4	0.5
Restructuring costs and similar items	(0.3)	0.4
Other tax effects	0.8	—
Effective tax rate based on business net income	**19.3%**	**20.9%**

15/ Share of profit/(loss) from investments accounted for using the equity method

Investments accounted for using the equity method contributed net income of €68 million in 2022, versus €39 million in 2021.

16/ Net income

Net income amounted to €8,484 million in 2022, compared with €6,279 million in 2021.

17/ Net income attributable to non-controlling interests

Net income attributable to non-controlling interests was €113 million in 2022, versus €56 million in 2021.

18/ Net income attributable to equity holders of Sanofi

Net income attributable to equity holders of Sanofi amounted to €8,371 million in 2022, compared with €6,223 million in 2021.

Basic earnings per share for 2022 was €6.69 versus €4.97 for 2021, based on an average number of shares outstanding of 1,251.9 million in 2022 and 1,252.5 million in 2021. Diluted earnings per share for 2022 was €6.66 versus €4.95 for 2021, based on an average number of shares after dilution of 1,256.9 million in 2022 and 1,257.9 million in 2021.

A.2.3. Segment results

Our business operating income, as defined in Note D.35. ("Segment information") to our consolidated financial statements, amounted to €13,040 million in 2022, compared with €10,714 million in 2021, an increase of 21.7%. That represents 30.3% of our net sales, compared with 28.4% in 2021.

The table below sets forth our business operating income for the years ended December 31, 2022 and 2021:

(€ million)	December 31, 2022	December 31, 2021	Change
Pharmaceuticals	11,043	9,409	+17.4%
As percentage of sales	*36.0%*	*+34.9%*	
Vaccines	3,168	2,609	+21.4%
As percentage of sales	*43.8%*	*+41.3%*	
Consumer Healthcare	1,810	1,493	+21.2%
As percentage of sales	*35.6%*	*+33.4%*	
Other	(2,981)	(2,797)	+6.6%
Business operating income (non-IFRS Financial measure)	**13,040**	**10,714**	**+21.7%**

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.

"Net debt" is a non-IFRS financial indicator which is reviewed by our management, and which we believe provides useful information to measure our overall liquidity and capital resources. We define "net debt" as (i) the sum total of short term debt, long term debt, and interest rate derivatives and currency derivatives used to manage debt, minus (ii) the sum total of cash and cash equivalents and interest rate derivatives and currency derivatives used to manage cash and cash equivalents. Lease liabilities are not included in net debt.

As of December 31, 2022 our net debt was €6,437 million, compared with €9,983 million as of December 31, 2021 mainly reflecting the free cash flow generated in the year as described below.

In order to assess our financing risk, we also use the "gearing ratio", a non-IFRS financial measure (see table in section "B.2. Consolidated Balance Sheet and Debt" below). We define the gearing ratio as the ratio of net debt to total equity. As of December 31, 2022, our gearing ratio was 8.6%, compared with 14.5% as of December 31, 2021.

Because our net debt and gearing ratio are not standardized measures, they may not be directly comparable with the non-IFRS financial measures of other companies using the same or similar non-IFRS financial measures. Despite the use of non-IFRS measures by management in setting goals and measuring performance, these are non-IFRS measures that have no standardized meaning prescribed by IFRS.

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 vaccines. Receipts of royalty payments also contribute to cash from operations.

Summarized consolidated statements of cash flows

(€ million)	2022	2021
Net cash provided by/(used in) operating activities	10,526	10,522
Net cash provided by/(used in) investing activities	(2,075)	(7,298)
Net cash provided by/(used in) financing activities	(5,821)	(7,056)
Impact of exchange rates on cash and cash equivalents	8	15
Net change in cash and cash equivalents	**2,638**	**(3,817)**

Net cash provided by/used in operating activities represented a net cash inflow of €10,526 million in 2022, compared with €10,522 million in 2021. This increase mainly resulted from an improvement in operating cash flow before changes in working capital (which amounted to €11,233 million in 2022, versus €9,113 million in 2021) and a net reduction of €707 million in the working capital requirement in 2022, versus a net increase of €1,409 million in 2021.

Net cash provided by/used in investing activities represented a net cash outflow of €2,075 million in 2022, compared with a net outflow of €7,298 million in 2021. In 2022, the net cash outflow was mainly due to the acquisition of Amunix Pharmaceuticals, Inc (€852 million), partly offset by the proceeds of €150 million from the sale of a 12% equity interest in EUROAPI to EPIC Bpifrance. The net cash outflow in 2021 was attributable mainly to the acquisitions of Translate Bio (€2,333 million), Kadmon (€1,575 million), Kymab (€932 million), Kiadis (326 million), Tidal (€135 million) and Origimm (€50 million).

Acquisitions of property, plant and equipment and intangible assets amounted to €2,201 million, versus €2,043 million in 2021. There were €1,606 million of acquisitions of property, plant and equipment (versus €1,479 million in 2021), most of which (€1,025 million) related to the Pharmaceuticals segment, primarily in industrial facilities. The Vaccines segment accounted for €504 million of acquisitions of property, plant and equipment during 2022. Acquisitions of intangible assets (€595 million, versus €564 million in 2021) mainly comprised contractual payments for intangible rights under license and collaboration agreements.

After-tax proceeds from disposals (€1,488 million in 2022, €676 million in 2021) included divestments of assets and activities related to the streamlining of the portfolio, and disposals of equity and debt instruments.

Net cash provided by/used in financing activities represented a net cash outflow of €5,821 million in 2022, compared with a net cash outflow of €7,056 million in 2021. The 2022 figure includes the redemption of bond issues totaling €2,700 million, and a new bond issue of €1,500 million carried out in April 2022. Other movements included the dividend payout to our shareholders of €4,168 million (versus €4,008 million in 2021), and the effect of changes in our share capital (repurchases of our own shares, net of capital increases), representing a net cash outflow of €309 million in 2022 versus a net cash outflow of €196 million in 2021.

The ***net change in cash and cash equivalents*** in 2022 was an increase of €2,638 million, versus an increase of €3,817 million in 2021.

"Free cash flow" for the year ended December 31, 2022 was €8,483 million, an increase on the 2021 figure of €8,096 million. This reflects our operational performance (including the effect of cost containment measures), and proceeds from disposal made during the period (see the table below).

"Free cash flow" is a non-IFRS financial indicator which is reviewed by our management, and which we believe provides useful information to measure the net cash generated from our operations that is available for strategic investments[1] (net of divestments[1]), for debt repayment, and for payments to shareholders. "Free cash flow" is determined from our "Business net income"[2] after adding back (in the case of expenses and losses) or deducting (in the case of income and gains) the following items: depreciation, amortization and impairment, share of undistributed earnings from investments accounted for using the equity method, gains & losses on disposals, net change in provisions including pensions and other post-employment benefits, deferred taxes, share-based payment expense and other non-cash items. It also includes net changes in working capital, capital expenditures and other asset acquisitions[3] net of disposal proceeds[3], and payments related to restructuring and similar items. "Free cash flow" is not defined by IFRS, and is not a substitute for ***Net cash provided by operating activities*** as reported under IFRS. Management recognizes that the term "Free cash flow" may be interpreted differently by other companies and under different circumstances.

The table below sets forth a reconciliation between ***Net cash provided by operating activities*** and "Free cash flow":

(€ million)	2022	2021
Net cash provided by operating activities (IFRS)	**10,526**	**10,522**
Acquisitions of property, plant and equipment and software	(1,656)	(1,516)
Acquisitions of intangible assets, equity interests and other non-current financial assets[a]	(824)	(1,488)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax[a]	1,531	667
Repayments of lease liabilities[b]	(291)	(149)
Other items[c]	(803)	60
Free cash flow (non-IFRS Financial measure)	**8,483**	**8,096**

(a) Free cash flow includes investments and divestments not exceeding a cap of €500 million per transaction.
(b) Cash outflows relating to repayments of the principal portion of lease liabilities (IFRS 16) are included in free cash flow.
(c) In 2022, includes an upfront payment of $900 million and a regulatory milestone payment of $100 million related to the granting of the Libtayo® license.

[1] Above a cap of €500 million per transaction.
[2] Non-IFRS financial measure, as defined in "— A.1.5. — Segment Information — 3. Business Net income" above.
[3] Not exceeding a cap of €500 million per transaction.

B.2. Consolidated balance sheet and debt

Total assets were €126,722 million as of December 31, 2022, compared with €120,242 million as of December 31, 2021, an increase of €6,480 million.

Total equity was €75,152 million as of December 31, 2022, versus €69,031 million as of December 31, 2021. The year-on-year net change reflects the following principal factors:

- increases: our net income for 2022 (€8,484 million), and positive currency translation differences (€2,278 million); and
- decreases: the dividend paid to our shareholders in respect of the 2021 financial year (€4,168 million), and repurchases of our own shares (€497 million).

Net debt was €6,437 million as of December 31, 2022, versus €9,983 million as of December 31, 2021. The decrease in 2022 reflects the €8,483 million of free cash flow generated in the year, more than offsetting cash outflows that included €992 million on acquisitions of consolidated entities and the €4,168 million dividend payout to our shareholders.

"Net debt" is a non-IFRS financial measure which is reviewed by our management, and which we believe provides useful information to measure our overall liquidity and capital resources. We define "net debt" as (i) the sum total of short term debt, long term debt, and interest rate derivatives and currency derivatives used to manage debt, minus (ii) the sum total of cash and cash equivalents and interest rate derivatives and currency derivatives used to manage cash and cash equivalents.

(€ million)	2022	2021
Long-term debt	14,857	17,123
Short-term debt and current portion of long-term debt	4,174	3,183
Interest rate and currency derivatives used to manage debt	187	-56
Total debt	**19,218**	**20,250**
Cash and cash equivalents	-12,736	-10,098
Interest rate and currency derivatives used to manage cash and cash equivalents	-45	-169
Net debt[(a)] (IFRS)	**6,437**	**9,983**
Total equity	75,152	69,031
Gearing ratio (non-IFRS financial measure)	**8.6%**	**14.5%**

(a) Net debt does not include lease liabilities, which amounted to €2,181 million as of December 31, 2022 and €2,108 million as of December 31, 2021.

To assess our financing risk, we use the "gearing ratio", a non-IFRS financial measure. This ratio (which we define as the ratio of net debt to total equity) decreased from 14.5% as of December 31, 2021 to 8.6% as of December 31, 2022. Analyses of debt as of December 31, 2022 and December 31, 2021, by type, maturity, interest rate and currency, are provided in Note D.17.1. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F.

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, 2022 at the Sanofi parent company level are not subject to covenants regarding financial ratios and do not contain any clauses linking fees to Sanofi's credit rating.

As of December 31, 2022, we held 8.2 million of our own shares, recorded as a deduction from equity and representing 0.65% of our share capital.

Goodwill and Other intangible assets (€71,532 million in total) increased by €2,069 million year-on-year, the main factors being the acquisition of Amunix, partly offset by impairment losses net of impairment reversals recognized on certain intangible assets (in particular, an impairment loss against IL-2, and a reversal relating to Eloctate® franchise assets).

Investments accounted for using the equity method (€677 million) increased by €427 million, mainly reflecting the equity investment of EUROAPI from May 10, 2022 (see Note D.1. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F).

Other non-current assets amounted to €3,095 million, a year-on-year decrease of €32 million, with a reduction in funds held to cover pension obligations partly offset by an increase in prepaid expenses.

Net deferred tax assets amounted to €3,540 million as of December 31, 2022, versus €2,981 million as of December 31, 2021, a year-on-year increase of €559 million. This mainly reflects deferred taxes arising on the capitalization of R&D expenses, and consolidation adjustments for intragroup margin in inventory.

Non-current provisions and other non-current liabilities (€6,341 million) showed a decrease of €380 million, mainly related to actuarial gains on defined-benefit plans (recognized in Other comprehensive income).

Liabilities related to business combinations and to non-controlling interests (€779 million) were €65 million higher year-on-year. The main movement in this line item during 2022 was the recognition of the €156 million contingent consideration liability arising on the acquisition of Amunix.

B.3. Liquidity

We expect that our existing cash resources and cash from operations will be sufficient to finance our foreseeable working capital requirements, in both the short term (i.e. the 12 months following the year ended December 31, 2022) and the long term (i.e. beyond such additional 12-month period). At year-end 2022, we held cash and cash equivalents amounting to €12,736 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 on Form 20-F). As at December 31, 2022, €439 million of our cash and cash equivalents were held by 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 €56 million as of December 31, 2021 to €51 million as of December 31, 2022 (see Note D.10. to our consolidated financial statements).

At year-end 2022, 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 €8,000 million at December 31, 2022. 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."

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, 2022 are shown in Notes D.3., D.17., D.18., and D.21. 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 2022 consolidated financial statements.

Sanofi's contractual obligations and other commercial commitments are set forth in the table below

December 31, 2022		Payments due by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Future contractual cash flows relating to debt and debt hedging instruments[a]	**20,617**	**4,230**	**3,769**	**4,529**	**8,089**
Principal payments related to lease liabilities[b]	**2,400**	**320**	**515**	**436**	**1,129**
Other lease obligations (with a term of less than 12 months, low value asset leases and lease contracts committed but not yet commenced)[c]	**38**	**26**	**4**	**3**	**5**
Irrevocable purchase commitments[d]					
• given	**10,921**	**5,957**	**2,922**	**1,062**	**980**
• received	**(1,025)**	**(482)**	**(335)**	**(86)**	**(122)**
Research & development license agreements					
• Commitments related to R&D and other commitments	**259**	**197**	**39**	**10**	**13**
• Potential milestone payments[e]	**2,919**	**203**	**875**	**889**	**952**
Obligations relating to business combinations[f]	**604**	**104**	**145**	**—**	**355**
Estimated benefit payments on unfunded pensions and post employment benefits[g]	**1,188**	**74**	**116**	**139**	**859**
Total contractual obligations and other commitments	**37,921**	**10,629**	**8,050**	**6,982**	**12,260**
Undrawn general-purpose credit facilities	8,000	4,000	—	4,000	—

(a) See Note D.17.1. to our consolidated financial statements, included at Item 18. of this annual report.

(b) See Note D.17.2. to our consolidated financial statements, included at Item 18. of this annual report.

(c) See Note D.21.1. to our consolidated financial statements, included at Item 18. of this annual report.

(d) 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.

(e) This line includes all potential milestone payments on projects regarded as reasonably possible, i.e. on projects in the development phase.

(f) See Note D.18. 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 ongoing annual employer's contributions to plan assets, estimated at €38 million for 2023.

We may have payments due to our current or former research and development partners under collaboration 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 (€18.0 billion in 2022, and €6.7 billion in 2021) and payments contingent upon the attainment of sales targets once a product is on the market (€18.5 billion in 2022, and €8.1 billion in 2021).

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. Annual evaluations conducted since that date have indicated that this governance structure is appropriate to Sanofi's current configuration. With the term of office of the current Chairman, Serge Weinberg, coming to an end, the Board of Directors has decided to continue separating the offices of Chairman and Chief Executive Officer. The Board believes this governance structure is still appropriate to the current context in which Sanofi operates and its share ownership structure, as well as protecting the rights of all of its stakeholders.

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 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.

The Chairman carries out his duties during the entire period of his term of office, subject to the caveat that a director who is a natural person may not be appointed or reappointed once that director has reached the age of 70.

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) the 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 upon exercising a firm 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

Composition

As of December 31, 2022 our Board of Directors had 16 directors, including ten independent directors and two directors representing employees. It also has one non-voting member since September 2, 2022.

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 and a broad diversity of competencies, experiences, nationalities and ages, 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.

43% of the directors (excluding directors representing employees and the non-voting member, in accordance with regulations) are women, and 47% of the directors (including directors representing employees and the non-voting member) are non-French nationals.

Acting on proposals from the Chief Executive Officer and in liaison with the Appointments, Governance and CSR Committee, the Board sets objectives for gender balance on Sanofi's executive bodies, and more generally ensures that an inclusion (non-discrimination) and diversity policy is applied within the Company. That policy is fully embedded in our Play to Win strategy. As of December 31, 2022, 20% of the ten Executive Committee members were women, and 73% were non-French nationals. For more details on changes to our Executive Committee, see the section entitled "Executive Committee" below.

The Board of Directors is also kept informed, in particular on the occasion of its annual discussion on equal opportunity and equal pay policy, on how Sanofi's inclusion and diversity policy is cascaded down to "Senior Leaders" and "Executives" (the positions in Sanofi with the highest level of responsibility).

Mission

The Board of Directors establishes the orientation of the Company's activities and ensures that they are implemented, paying due consideration to social and environmental issues. Subject to those powers expressly attributed to Shareholders' General Meetings and within the limits set by the corporate purpose, it addresses any issue of relevance to the proper conduct of the Company's affairs and, through its deliberations, settles matters concerning the Company.

The Board monitors progress on our CSR strategy, as recalibrated in 2021, paying particularly close attention to tracking delivery on our CSR program including our climate commitments. Since 2020, 15% of the annual variable compensation of our CEO has been linked to CSR criteria, including an objective to cut our greenhouse gas emissions; and starting in 2023, our equity-based compensation plans will also include CSR criteria - see section B. below.

The Board committees are also involved in sustainable development issues – see section "— C. Board practices below" – and their members work together on specific topics. For example, discussions have taken place between the Compensation Committee and the Appointments, Governance & CSR Committee on determination of the extra-financial criteria applicable to the various elements of compensation awarded to the Chief Executive Officer and other beneficiaries of variable compensation (annual variable compensation, equity-based compensation).

The rules and operating procedures of our Board of Directors are defined by law, by our Articles of Association, and by our Board Charter (English language versions of which are reproduced in full as Exhibit 1.1 and 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.

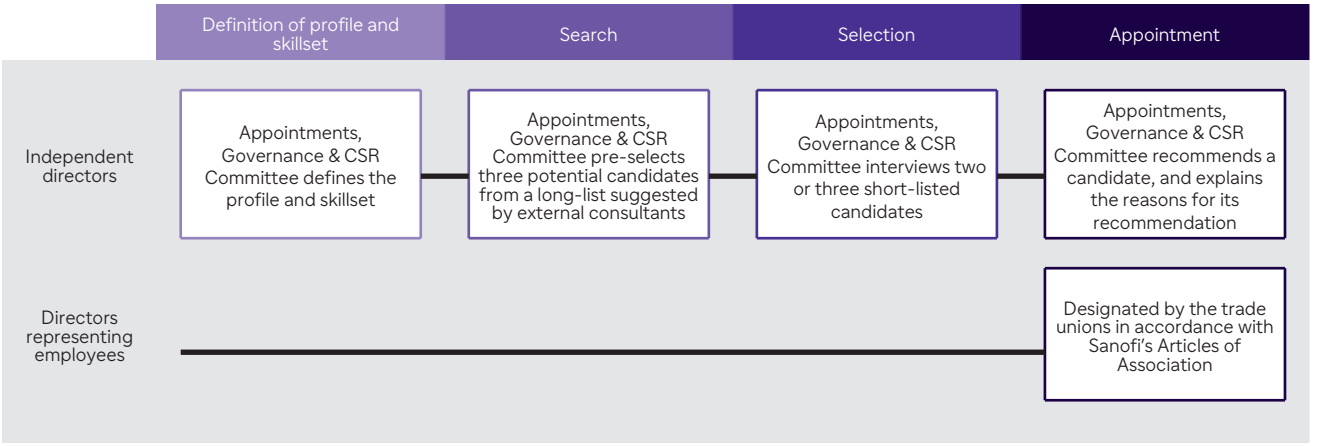
A natural person cannot be appointed or reappointed as a director once he or she reaches the age of 70. As soon as the number of directors aged over 70 represents more than one-third of the directors in office, the oldest director shall be deemed to have resigned; his or her term of office shall end at the date of the next Shareholders' Ordinary General Meeting.

Selection Process for Board members

The Appointments, Governance and CSR Committee has a remit to organize a procedure for selecting future independent directors. Once the desired profile and skillset for a new director has been defined, a search for potential candidates is conducted by external consultants.

Once a shortlist has been established, the Committee interviews two or three candidates. After completing the interviews, the Committee makes a recommendation to the Board on the candidate with the best fit for the profile, supporting that recommendation with an explanation of how the interviews were conducted and giving reasons why a candidate was selected.

Overview of selection process for Board members



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 an auditor for the Company over the course of the past five years (criterion 5);
- has not been a director of the Company for more than twelve years (criterion 6);
- 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); or
- does not represent a shareholder that has a significant or controlling interest in the Company (criterion 8).

The influence of other factors such as 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 accordance with our Board Charter and pursuant to the AFEP-MEDEF Code, the Board of Directors' meeting of February 22, 2023 discussed the independence of the current directors. Of the 16 directors in office on that date, 10 were deemed to be independent directors by reference to the independence criteria used by the Board of Directors pursuant to the AFEP-MEDEF Code: Rachel Duan, Carole Ferrand, Lise Kingo, Patrick Kron, Fabienne Lecorvaisier, Gilles Schnepp, Diane Souza, Thomas Südhof, Emile Voest and Antoine Yver.

In accordance with the rules described above, Paul Hudson (who is an executive director of Sanofi), Serge Weinberg (who has been a director for more than 12 years), and Barbara Lavernos and Christophe Babule (who were appointed on the recommendation of L'Oréal, a major shareholder of Sanofi), are not deemed independent.

Consequently, the proportion of independent directors is 71%. This complies with the AFEP-MEDEF recommendation of at least 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 and elected by trade unions are excluded when calculating the proportion of independent directors.

	Serge Weinberg	Paul Hudson	Christophe Babule	Rachel Duan	Carole Ferrand	Lise Kingo	Patrick Kron	Barbara Lavernos	Fabienne Lecorvaisier	Gilles Schnepp	Diane Souza	Thomas Südhof	Emile Voest	Antoine Yver
Criterion 1: not an employee/executive officer in past 5 years	YES	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Criterion 2: no cross-directorships	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Criterion 3: no significant business relationship	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Criterion 4: no close family ties	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Criterion 5: not an auditor	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Criterion 6: not held office for > 12 years	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Criterion 7: no variable or performance-linked compensation	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Criterion 8: not a significant shareholder	YES	YES	NO	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES
Deemed independent	NO	NO	NO	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES

Failure to fulfil one of the criteria does not automatically disqualify a director from being independent.

In assessing the criterion related to significant business relationships (criterion 3), 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 2022. 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 not at amounts that the Board regarded as undermining the independence of the directors in question.

Other information about Board members

As of December 31, 2022, 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.

As of December 31, 2022, the members of our Board of Directors collectively held (directly, or via the employee share ownership fund associated with the Group savings scheme) 23,831 of our shares, representing 0.0019% of our share capital.

Board evaluation

Under the terms of the Board Charter, a discussion of the operating procedures of the Board and its committees must be included on the agenda of one Board meeting every year. The Charter also requires a formal evaluation to be performed at least every three years under the direction of the Appointments, Governance and CSR Committee, with assistance from an independent consultant.

In 2021, a formal evaluation was conducted under the direction of the Appointments, Governance and CSR Committee, with the assistance of a specialist consulting firm (the same one as conducted the previous formal evaluation). Following this evaluation, a series of actions were taken in 2022 to address the areas of progress and vigilance summarized below:

Areas of progress and vigilance identified in the 2021 evaluation	Actions taken in 2022
The preparation of the Chairman's succession must be continued and accelerated, under the leadership of an independent director.	At the instigation of Serge Weinberg, and subsequently under the chairmanship of Giles Schnepp, the Appointments, Governance & CSR Committee carried out preparatory work with assistance from a consultancy firm, including consideration of the profile required for the new Chairman and discussions with Board members. That work was picked up and formalized by the Committee in 2022. Following the selection process, Frédéric Oudéa was appointed as non-voting member on September 2, 2022, with the intention of proposing that he be appointed as an independent director at the 2023 Annual General Meeting, and subsequently of appointing him to succeed Serge Weinberg as Chairman.
Implementation of the CSR strategy will have to be subject to tighter monitoring.	In 2022, the Appointments, Governance & CSR Committee held an extra meeting compared to previous years, giving it an opportunity to examine each of the four pillars of our CSR strategy as well as extra-financial ratings.
Strategic seminars should be more devoted to discussing strategy rather than reviewing activities.	The strategy seminars held in April and October 2022 each devoted half a day to Sanofi strategy.
The duration of the two executive sessions should be extended to allow for more in-depth discussion.	Executive sessions were extended from one hour to one and a half hours.
The induction program for new directors, made difficult due to the health crisis linked to COVID-19, will have to be reinforced.	Until 2021, the induction program for new directors was devised on an ad hoc basis. In 2022, Sanofi provided an induction session on risks for each new director.
Board members stated that COVID had not harmed the working of the Board but they expressed a desire for a rapid return to physical meetings as well as normal social activities.	The format of meetings returned to normal in 2022.

The Chairman provided feedback on each Board member's individual performance over the course of the year.

The 2022 evaluation was conducted internally, using a detailed questionnaire sent to directors by the Secretary to the Board. Each director was allowed a few weeks to complete the questionnaire using a secure digital platform. At the end of that period, the responses were analyzed by the Secretary to the Board, and supplemented by one-on-one interviews. The results were then presented to, and discussed by, a meeting of the Appointments, Governance and CSR Committee. The detailed report prepared for that meeting was then submitted to the Board meeting of February 22, 2023.

The results of this 2022 evaluation show continuous improvement in the functioning of the Board:

- the directors particularly emphasized the quality of relations with management, which have become more fluid, especially due to the return of physical meetings;
- the work of the Board gained in scientific expertise as well as in strategic vision;
- the further development and increased length of executive sessions mean that they are seen positively as a necessary space to discuss critical issues without management present;
- finance and compensation issues, and HR policy, are adequately covered, and the Board is properly involved in areas around strategy, business, operations and risks;
- the Chairman succession process has been very well received; and
- directors who followed the enhanced induction program expressed themselves satisfied.

The areas of improvement identified are:

- there is room for improvement in the information and documentation supplied to the Board, and in reports on the work of the Committees;
- some directors felt the Board should be more involved in research and development issues;
- the Board should be even more involved in CSR and research and development issues;
- delivery on CSR strategy should continue to be monitored;
- the focus on the global review of the strategy through strategic seminars should be continued; and
- field trips should be resumed, with directors keen to visit sites, especially research and development sites.

Succession planning

General principles

The remit of the Appointments, Governance and CSR Committee includes preparing for the future of the Company's executive bodies, in particular through the establishment of a succession plan for executive officers.

The succession plan, which is reviewed at meetings of the Appointments, Governance and CSR Committee, addresses various 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.

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, but which also builds in diversity – in all its facets – as a key factor.

To fulfill its remit, the Appointments, Governance and CSR Committee:

- provides the Board with progress reports, in particular at executive sessions;
- co-ordinates with the Compensation Committee. In that regard, having a director that sits on both Committees is a great advantage;
- works closely with the Chief Executive Officer to (i) ensure the succession 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;
- meets with key executives as needed; and
- involves the Chairman and the Chief Executive Officer insofar as each has a key role in planning for his own successor, though without them directing the process.

In fulfilling their remit, Committee members are acutely conscious of confidentiality issues.

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.

Succession of Serge Weinberg

Serge Weinberg's current term of office expires at the end of the Annual General Meeting of Sanofi shareholders called to approve the financial statements for the year ended December 31, 2022, and cannot be renewed as he will have reached the age limit stipulated in the Articles of Association. At the instigation of Serge Weinberg, and subsequently under the chairmanship of Gilles Schnepp, the Appointments, Governance & CSR Committee carried out preparatory work with assistance from a consultancy firm, including consideration of the profile required for the new Chairman and discussions with Board members. That work was formalized by the Appointments, Governance & CSR Committee as follows:

- a long-list of potential candidates was put forward by external consultants;
- three candidates were short-listed by the Appointments, Governance & CSR Committee;
- the three candidates were interviewed by members of the Appointments, Governance & CSR Committee, after which the Committee ranked the candidates; and
- the highest-ranked candidate was then interviewed by the Chair of each of the Board committees.

On completion of this process, and there being no vacancies on the Board, the Board decided to appoint Frédéric Oudéa as a non-voting member on a transitional basis, with the intention of proposing his appointment as a director at the Annual General Meeting of May 25, 2023, and to appoint him as Chairman of the Board of Directors after the close of that meeting.

Succession planning for the Chief Executive Officer is subject to regular review by the Appointments, Governance and CSR Committee.

Board Charter

Our Board Charter describes the rights and obligations of Board members; the composition, role and operating procedures of the Board of Directors and Board Committees; and the roles and powers of the Chairman and the Chief Executive Officer. It is prepared in accordance with the French Commercial Code and our Articles of Association.

Composition of the Board of Directors as of December 31, 2022

As of December 31, 2022, our Board of Directors comprised 16 directors and one non-voting member:

Director	Age	Gender	Nationality	Number of shares	Number of directorships in listed companies[a]	Independent	First appointed	Term expires	Years of Board service	AC	AGC	CC	SC	SciC
Serge Weinberg, Chairman of the Board	72	M	French	1,636	2	No	2009	2023 AGM	13		M		C	M
Paul Hudson, Chief Executive Officer	55	M	British	5,600	1	No	2019	2026 AGM	3				M	
Christophe Babule	57	M	French	1,000	1	No	2019	2026 AGM	3	M				
Rachel Duan	52	F	Chinese	1,000	4	Yes	2020	2024 AGM	2			M		
Carole Ferrand	52	F	French	1,000	1	Yes	2022	2025 AGM	—					
Lise Kingo	61	F	Danish	1,000	4	Yes	2020	2024 AGM	2		M			
Patrick Kron	69	M	French	1,000	4	Yes	2014	2026 AGM	8		M	C	M	
Wolfgang Laux[b]	55	M	German	3,482	1	No	2021	2025 AGM	1			M		
Barbara Lavernos	54	F	French	500	1	No	2021	2025 AGM	1		M			
Fabienne Lecorvaisier	60	F	French	1,000	3	Yes	2013	2025 AGM	9	C				
Gilles Schnepp	64	M	French	1,000	4	Yes	2020	2026 AGM	2		C		M	
Diane Souza	70	F	American	1,208	1	Yes	2016	2024 AGM	6	M		M		
Thomas Südhof	67	M	American/ German	1,170	1	Yes	2016	2024 AGM	6					C
Yann Tran[b]	57	M	French	1,235	1	No	2021	2025 AGM	1					
Emile Voest	62	M	Dutch	500	1	Yes	2022	2025 AGM	—					M
Antoine Yver	64	M	French/ American/ Swiss	1,000	2	Yes	2022	2025 AGM	—					M

Independent directors[c]	Female directors[c]	Non-French directors
71%	43%	40%

Non-voting member	Age	Gender	Nationality	Number of shares	Number of directorships in listed companies[a]	Independent	First appointed	Term expires	Years of Board service	AC	AGC	CC	SC	SciC
Frédéric Oudéa	59	M	French	500	3	Yes	2022	N/A	—					

AC: Audit Committee.
AGC: Appointments, Governance and CSR Committee.
CC: Compensation Committee.
SC: Strategy Committee.
SciC: Scientific Committee.
C: Chairman/Chairwoman.
M: Member.
(a) Includes all non-executive and executive (and equivalent) directorships held in listed companies. The office held within Sanofi is included in the calculation of this rate.
(b) Director representing employees.
(c) Directors representing employees are not taken into consideration for the calculation of these percentages.

Competencies of Board members

The Board of Directors, in liaison with the Appointments, Governance and CSR 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 new challenges facing Sanofi and the corporate strategy, and determines whether the qualities of serving directors are sufficient for the Board to deliver on its remit.

Over the past several years, the Board has adapted its composition in line with its roadmap by:

- bringing additional scientific expertise onto the Board;
- further raising the proportion of non-French directors, especially those with experience of the Chinese market;
- developing its knowledge of CSR issues; and
- maintaining the level of core competencies, especially in accounting and finance.

The Board has completed an overview of the competencies currently represented. The matrix below[(a)] 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)[(b)]:

Scientific training	3[(c)]
Healthcare/pharmaceutical industry experience	5[(d)]
Senior executive role in international group[(e)]	11[(f)]
Board membership in international group	7[(g)]
International experience[(h)]	11[(i)]
Mergers & acquisitions	7[(j)]
Finance/Accounting	5[(k)]

(a) Based on the composition of the Board as of February 22, 2023.
(b) The information shown excludes directors representing employees.
(c) Thomas Südhof, Emile Voest and Antoine Yver.
(d) Paul Hudson, Rachel Duan, Lise Kingo, Diane Souza and Antoine Yver.
(e) Executive Committee member within an international group.
(f) Serge Weinberg, Paul Hudson, Christophe Babule, Rachel Duan, Carole Ferrand, Lise KIngo, Patrick Kron, Barbara Lavernos, Fabienne Lecorvaisier, Gilles Schnepp and Antoine Yver.
(g) Serge Weinberg, Rachel Duan, Carole Ferrand, Patrick Kron, Fabienne Lecorvaisier, Lise Kingo and Gilles Schnepp.
(h) Operational role within an international group.
(i) Serge Weinberg, Paul Hudson, Christophe Babule, Rachel Duan, Lise Kingo, Patrick Kron, Barbara Lavernos, Fabienne Lecorvaisier, Gilles Schnepp, Diane Souza and Antoine Yver.
(j) Serge Weinberg, Paul Hudson, Christophe Babule, Patrick Kron, Fabienne Lecorvaisier, Gilles Schnepp and Diane Souza.
(k) Christophe Babule, Fabienne Lecorvaisier, Carole Ferrand, Gilles Schnepp and Diane Souza.

All members of our Board or Directors are engaged with CSR issues, and have complementary skills and experience in the field, for example (non-exhaustive list):

- Serge Weinberg founded Weinberg Capital Partners, a responsible investment fund that takes sustainability criteria into account in its investment decisions and measures the impact of its investments on society and the environment, in 2005;
- Christophe Babule, as CFO of L'Oréal, is in charge of financing the group's sustainable transition. He is also a director of the L'Oréal for Women endowment fund;
- Lise Kingo holds a Master degree in Responsibility & Business Practice from the University of Bath in the United Kingdom. She was Professor of Sustainability and Innovation at the Vrije Universiteit Amsterdam (The Netherlands) from 2006 to 2015, and in parallel held various CSR-related positions including Director of Environmental Affairs at Novozymes and Executive Vice President, Corporate Relations at Novo Nordisk, before becoming CEO & Executive Director of the United Nations Global Compact from 2015 to 2020 - a key tole at the Paris COP21 climate change conference in 2015;
- Fabienne Lecorvaisier has experience as Executive Vice President of Air Liquide with responsibiliy for sustainable development, public and international affairs, along with experience acquired through her involvement in societal programs such as the Air Liquide Foundation and Inclusive Business;
- Gilles Schnepp led Legrand's CSR policy as Chairman and CEO from 2006 to 2018, and since March 2021 has been Chairman of the Board of Directors of Danone, a *société à mission* (social purpose company). He also chaired the Ecological and Economic Transition Commission of MEDEF (the French employer's federation) from 2018 to 2021; and
- Carole Ferrand, as Chief Financial Officer of Capgemini, is an active member of the CFO Coalition for SDGs (Sustainable Development Goals).

Future appointments

The term of office of Serge Weinberg will expire at the Annual General Meeting to be held on May 25, 2023. Consequently, that meeting will be asked to appoint Frédéric Oudéa to succeed him. The appointment would bring to the Board of Directors the following competencies/experiences:

- experience as a senior executive in an international group;
- Board membership in an international group; and
- Finance/Accounting expertise.

For more information, refer to his career résumé below.

Detailed information about Board members

The following pages provide key information about each Board member individually:

- directorships and appointments held during 2022 (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;
- training and professional experience; and
- competencies (as identified in the Board competencies matrix above).

Serge Weinberg

Date of birth: February 10, 1951 (aged 72)
Nationality: French
First appointed: December 2009
Last reappointment: April 2019
Term expires: 2023
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 1,636 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Director and Chairman of the Board of Directors

- Chairman of the Strategy Committee
- Member of the Appointments, Governance and CSR Committee
- Member of the Scientific Committee

OUTSIDE THE SANOFI GROUP

In French companies

Director of Kering *
- Chairman of the Appointments and Governance Committee
- Member of the Audit Committee
- Member of the Remuneration Committee

Chairman of Weinberg Capital Partners:
- Chairman of Maremma
- Manager of Alret

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- Permanent representative of Weinberg Capital Partners on the Board of Directors of ADIT (ended October 4, 2019)
- Director of Madrigall (ended June 19, 2019)
- Chairman of the Supervisory Boards of Financière Climater SAS (ended October 31, 2018) and Financière Tess SAS (ended October 4, 2019)
- Chairman of Financière Piasa and Piasa Holding (ended October 5, 2018)

In foreign companies

- None

Education and professional experience

- Graduate in law, degree from the *Institut d'Études Politiques*
- Graduate of ENA (*École Nationale d'Administration*)

Since 2005	**Chairman of Weinberg Capital Partners**
2005-2010	Vice Chairman of the Supervisory Board of Schneider Electric*
2006-2009	Chairman of the Board of Accor*
1990-2005	Various positions at PPR* Group (now Kering *) including Chairman of the Management Board for 10 years
1987-1990	Chief Executive Officer of Pallas Finance
1982-1987	Deputy General Manager of FR3 (French television channel) and then Chief Executive Officer of Havas Tourisme
1976-1982	*Sous-préfet* and then Chief of Staff of the French Budget Minister (1981)

Competencies

Senior executive in international group, Board membership in international group, International experience, Mergers & acquisitions

Paul Hudson

Date of birth: October 14, 1967 (aged 55)
Nationality: British
First appointed: September 2019
Last reappointment: May 2022
Term expires: 2026
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 5,600 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Chief Executive Officer

- Chairman of the Executive Committee
- Director
- Member of the Strategy Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Education and professional experience

- Degree in economics from Manchester Metropolitan University, UK
- Diploma in marketing from the Chartered Institute of Marketing, UK
- Honorary Doctorate in Business Administration, Manchester Metropolitan University, UK

From September 1, 2019	**Chief Executive Officer of Sanofi***
2016-2019	CEO of Novartis Pharmaceuticals, member of Executive Committee
2006-2016	Various operational and managerial positions at AstraZeneca (including President, AstraZeneca US; Executive Vice President, North America; Representative Director & President, AstraZeneca KK, Japan; President of AstraZeneca Spain; and Vice-President and head of Primary Care United Kingdom)
Before 2006	Various operational and managerial positions at Schering-Plough, including Head of Global Marketing for biologicals. Various sales and marketing positions at GlaxoSmithKline UK and Sanofi-Synthélabo UK

Competencies

Healthcare/pharmaceutical industry experience, Senior executive role in international group, International experience, Mergers & acquisitions

Christophe Babule

Date of birth: September 20, 1965 (aged 57)
Nationality: French
First appointed: February 2019
Last reappointment: May 2022
Term expires: 2026
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Director

- Member of the Audit Committee

OUTSIDE THE SANOFI GROUP

In French companies

- Director of the "L'Oréal Fund for Women" charitable endowment fund

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

L'Oréal* Group:

- Director of L'Oréal US Inc. (United States)

Education and professional experience

- Education and professional experience

Since February 2019	**Chief Financial Officer at L'Oréal***
Since 1988	Various positions within the L'Oréal* Group, including as Director of Administration & Finance for China, then Mexico; Director of Internal Audit; and Administration & Financial Director for the Asia Pacific Zone

Competencies

Senior executive role in international groups, International experience, Mergers & acquisitions, Finance/Accounting, CSR

Rachel Duan

Date of birth: July 25, 1970 (aged 52)
Nationality: Chinese
First appointed: April 2020
Term expires: 2024
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Member of the Compensation Committee

OUTSIDE THE SANOFI GROUP

In French companies

- Independent director of AXA*

In foreign companies

- Independent director of HSBC*
- Independent director of Adecco Group*

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Education and professional experience

- MBA, University of Wisconsin-Madison (United States)
- Bachelor's degree in Economics and International Trade, Shanghai International Studies University (China)

Since September 2021	Independent Director, HSBC*
Since April 2020	Independent Director, Adecco Group*
Since April 2018	Independent Director, AXA*
1996-2020	Senior Vice President of General Electric* (United States) and President & CEO of GE Global Markets (China)

Competencies

Healthcare/pharmaceutical industry experience, Senior executive role in international groups, Board membership in international groups, International experience

Carole Ferrand

Date of birth: April 2, 1970 (aged 52)
Nationality: French
First appointed: May 2022
Term expires: 2025
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Member of the Audit Committee

OUTSIDE THE SANOFI GROUP

In French companies

- Honorary President and Director of Terra Nova (non-profit association)
- President of Capgemini Ventures SAS

In foreign companies

- Director of Capgemini Solutions Canada Inc. (Canada)
- Director of Capgemini UK plc. (United Kingdom)
- Director of CGS Holdings Ltd. (United Kingdom)
- Director of Capgemini Espana SL (Spain)
- Director of Altran Innovacion S.L.U (Spain)

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- Independent Director and Chair of the Audit Committee of Fnac Darty
- Member of the Executive Committee of June 21 SAS
- Director of Capgemini
- Director of Sebdo, Le Point
- Director of Archer Obligations (previously Artemis 21)
- Director of Editions Tallandier
- Member of the Audit Committee of Capgemini
- Director of Collection Pinault-Paris

In foreign companies

- Director of June 21 SAS
- Substitute of Alain de Marcellus, Capgemini Brasil SA (Brazil)
- Director of Pallazzo Grassi (Italy)

Education and professional experience

- HEC School of Management, Master's degree

Since 2018	**Chief Financial Officer of Capgemini**
2013-2018	Financing Operations Director of Groupe Artémis
2011-2012	Chief Financial Officer of EuropaCorp
2000-2011	Chief Financial Officer and General Counsel of Sony France
1992-2000	Audit and Transaction Services at PricewaterhouseCoopers (PwC)

Competencies

Senior executive role in international groups, Board membership in international groups, Finance/Accounting

Lise Kingo

Date of birth: August 3, 1961 (aged 61)

Nationality: Danish

First appointed: April 2020

Term expires: 2024

Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France

Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Member of the Appointments, Governance & CSR Committee

OUTSIDE THE SANOFI GROUP

In French companies

- Independent director of Danone*

In foreign companies

- Independent director of Covestro AG* (Germany)
- Independent director of Aker Horizons ASA* (Norway)

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Education and professional experience

- Bachelor's degree in Religions and Ancient Greek Art, University of Aarhus (Denmark)
- Bachelor's degree in Marketing and Economics, Copenhagen Business School (Denmark)
- Master's degree in Responsibility & Business, University of Bath (United Kingdom)
- Director Certification, INSEAD (France)

Since 2022	Independent Director, Danone*
Since 2021	Independent Director, Covestro AG* (Germany)
Since 2021	Independent Director, Aker Horizons ASA* (Norway)
Since 2020	Member of the Advisory Panel for Humanitarian and Development Coordination, Novo Nordisk Foundation (Denmark)
Since 2020	Chair of Blueprint for Denmark Initiative (Denmark)
2015-2020	Director of Principles for Responsible Investment, UN PRI (UK)
2015-2020	CEO & Executive Director of United Nations Global Compact (US)
2014-2015	Deputy chair of the Danish Foundation for Nature Preservation (Denmark)
2013-2015	Member of the "Scale for Good" Advisory Panel, Tesco Plc, (United Kingdom)
2012-2015	Chair of the Danish Council for Corporate Social Responsibility (Denmark)
2012-2015	Independent Director of Grieg Star Shipping (Norway)
2010-2014	Chair, Steno Diabetes Center (Denmark)
2006-2015	Professor of Sustainable Development and Innovation at Vrije Universiteit Amsterdam (Netherlands)
2005-2009	Independent Director and Deputy Chairwoman, GN Store Nord (Denmark)
2002-2014	Executive Vice President Corporate Relations & Chief of Staff at Novo Nordisk A/S (Denmark)
1999-2002	Senior Vice President, Stakeholder Relations at Novo Holding (Denmark)
1995-2006	Member of the HRH Prince of Wales Cambridge University Faculty for Sustainability Leadership (United Kingdom)
1988-1999	Various positions at the Bioindustrial Novo Industry Group, now Novozymes (Denmark), including Promotion Coordinator and Director, Corporate Environmental Affairs.

Competencies

Healthcare/pharmaceutical industry experience, Senior executive role in international groups, Board membership in international groups, International experience

Patrick Kron

Date of birth: September 26, 1953 (aged 69)
Nationality: French
First appointed: May 2014
Last reappointment: May 2022
Term expires: 2026
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Chairman of the Compensation Committee
- Member of the Appointments, Governance and CSR Committee
- Member of the Strategy Committee

OUTSIDE THE SANOFI GROUP

In French companies

- Chairman of Imerys*
- Chairman of Truffle Capital SAS
- Chairman of PKC&I SAS:
- Permanent representative of PKC&I on the Supervisory Board of Segula Technologies

In foreign companies

- Director of Holcim* (Switzerland)
- Director of Viohalco* (Belgium)

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- Interim Chief Executive Officer of Imerys*

In foreign companies

- ElvalHalcor* (Greece)

Education and professional experience

- Degree from *École Polytechnique* and *École Nationale Supérieure des Mines de Paris*

Since 2019	**Chairman of Imerys* (and Interim Chief Executive Officer from October 2019 to February 2020)**
Since 2016	**Chairman of Truffle Capital SAS**
Since 2016	**Chairman of PKC&I SAS**
2003-2016	Chief Executive Officer, then Chairman and Chief Executive Officer, of Alstom*
1998-2002	Chairman of the Managing Board of Imerys
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)
1993-1997	Chairman and Chief Executive Officer of Carbone Lorraine
1993	Member of the Executive Committee of the Pechiney Group
1988-1993	Various senior operational and financial positions within the Pechiney Group
1984-1988	Operational responsibilities in one of the Pechiney Group's biggest factories in Greece, then manager of the Greek subsidiary of Pechiney
1979-1984	Various positions at the French Ministry of Industry, including as project officer at the Direction régionale de l'Industrie, de la Recherche et de l'Environnement (DRIRE) and in the Ministry's general directorate

Competencies

Senior executive role in international groups, Board membership in international group, International experience, Mergers & acquisitions

Wolfgang Laux

Date of birth: January 24, 1968 (aged 55)
Nationality: German
First appointed: April 2021
Term expires: 2025
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 3,482 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Director representing the employees

- Member of the Compensation Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Education and professional experience

- Post-doctoral research fellow at the State University of New York at Stony Brook (1998-2000) and at the University of Montpellier (1996-1997)
- Ph.D. in organic chemistry from the University of Frankfurt am Main
- Corporate Director's Certificate from SciencesPo/IFA *(Certificat Administrateur de Sociétés)*
- European Board Diploma by ecoDa

Since 2006	**Industrialization Coordinator at Sanofi Chimie headquarters, Croix-de-Berny and Gentilly (France)**
Since 2014	Staff representative on the CFE-CGC ticket
2016-2021	Union delegate
2014-2021	Member of the Works Council, Sanofi Chimie headquarters
2016-2019	Member of the Committee on health, safety and working conditions (CHSCT)
2000-2006	Senior scientist in Process Development at the Frankfurt site of Höchst AG

Competencies

Scientific training, Healthcare/pharmaceutical industry experience, International experience.

Barbara Lavernos

Date of birth: April 22, 1968 (aged 54)
Nationality: French
First appointed: April 2021
Term expires: 2025
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 500 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Director

- Member of the Appointments, Governance and CSR Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- Director of Bpifrance Investment and Bpifrance Participations

In foreign companies

- None

Education and professional experience

- Graduate of the HEI chemical engineering school at Lille (HEI France)

Since May 2021	**Deputy CEO of L'Oréal* in charge of Research, Innovation and Technology**
February 2021-May 2021	President Research, Innovation and Technologies at L'Oréal*– Member of the Executive Committee at L'Oréal*
2018-2021	Chief Technology and Operations Officer at L'Oréal* – Member of the Executive Committee at L'Oréal*
2014-2018	Executive Vice-President Operations at L'Oréal* – Member of the Executive Committee at L'Oréal*
2011-2014	Managing Director of Travel Retail at L'Oréal*
2004-2011	Global Chief Procurement Officer at L'Oréal*

Competencies

Senior executive role in international groups, International experience, Scientific training

Fabienne Lecorvaisier

Date of birth: August 27, 1962 (aged 60)
Nationality: French
First appointed: May 2013
Last reappointment: April 2021
Term expires: 2025
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Chair of the Audit Committee

OUTSIDE THE SANOFI GROUP

In French companies

Air Liquide Group*:
- Director of Air Liquide International
- Director of The Hydrogen Company

Safran Group*:
- Independent Director
- Member of the Audit and Risk Committee

In foreign companies

Air Liquide Group*:
- Executive Vice President of Air Liquide International Corporation
- Director of American Air Liquide Holdings, Inc.

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

Air Liquide Group*:
- Director of Air Liquide Finance, Air Liquide Eastern Europe, Aqualung International, Air Liquide Welding SA and SOAEO
- Director of ANSA (Association Nationale des Sociétés par Actions)

In foreign companies

- Chairwoman of Air Liquide US LLC

Education and professional experience

- Civil engineer, graduate of *École Nationale des Ponts et Chaussées*

Since July 2021	**Executive Vice President in charge of Sustainable Development, Public and International Affairs, Social Programs and General Secretariat of Air Liquide***
July 2017-July 2021	Executive Vice President of Air Liquide*
Since 2008	Executive Committee member of Air Liquide*
2008-2021	Chief Financial Officer of Air Liquide*
1993-2008	Various positions within Essilor* including Group Chief Financial Officer (2001-2007) and Chief Strategy and Acquisitions Officer (2007-2008)
1990-1993	Assistant General Manager of Banque du Louvre, Taittinger Group
1989-1990	Senior Banking Executive in charge of the LBO Department (Paris)/Corporate Finance Department (Paris and London) at Barclays
1985-1989	Member of the Corporate Finance Department, then Mergers and Acquisitions Department of Société Générale*

Competencies

Senior executive role in international groups, Board membership in international groups, International experience, Mergers & acquisitions, Finance/ Accounting

Gilles Schnepp

Date of birth: October 16, 1958 (aged 64)
Nationality: French
First appointed: May 2020
Last reappointment: May 2022
Term expires: 2026
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Chairman of the Appointments, Governance and CSR Committee
- Member of the Strategy Committee

OUTSIDE THE SANOFI GROUP

In French companies

- Member of the Board of Directors of Saint Gobain*
- Chairman of the Board of Directors of Danone*
- Member of the Board of Directors of Socotec

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- Vice-Chairman of the Supervisory Board of PSA*
- Member of the Board of Directors of Legrand*

In foreign companies

- None

Education and professional experience

- Graduate of HEC business school

Since 2021	**Chairman of Danone***
2006-2018	Chairman & CEO of Legrand
2004-2006	CEO of Legrand
2001-2004	Deputy CEO of Legrand
1989-2001	Various positions within the Legrand Group
1983	Merrill Lynch

Competencies

Senior executive role in international groups, Board membership in international groups, International experience, Mergers & acquisitions, Finance/ Accounting

Diane Souza

Date of birth: July 3, 1952 (aged 70)
Nationality: American
First appointed: May 2016
Last reappointment: April 2020
Term expires: 2024
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 2,416 American Depositary Receipts, equivalent to 1,208 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Member of the Compensation Committee
- Member of the Audit Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

Amica Insurance Companies (United States):
- Member of the Board of Directors
- Member of the Compensation and Investment Committees

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

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

Farm Credit East (United States)
- Member of the Board of Directors

Education and professional experience

- Degree in Accounting from University of Massachusetts
- Honorary doctorate in Business Administration from University of Massachusetts Dartmouth
- Certified Public Accountant
- Diploma in Dental Hygiene from Northeastern University, Forsyth School for Dental Hygienists

2008-2014	Chief Operating Officer of OptumHealth Specialty Benefits (2008), then Chief Executive Officer of UnitedHealthcare Specialty Benefits (2009-2014) (United States)
2007-2008	Principal consultant at Strategic Business Solutions, LLC (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)
1988-1994	Various positions at Price Waterhouse from Senior Tax Manager to Head of the Northeast Insurance Tax Region (United States)
1980-1988	Various positions at Deloitte Haskins & Sells, from Audit Staff Accountant to Senior Tax Manager-in-Charge (United States)
1979	Audit Staff Accountant at Price Waterhouse (United States)

Competencies

Healthcare/pharmaceutical industry experience, International experience, Mergers & acquisitions, Finance/Accounting

Thomas Südhof

Date of birth: December 22, 1955 (aged 67)
Nationality: German and American
First appointed: May 2016
Last reappointment: April 2020
Term expires: 2024
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 2,485 American Depositary Receipts, equivalent to 1,242 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Chairman of the Scientific Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- Independent director of CytoDel Inc. (United States) (since 2021)
- Member of the Scientific Advisory Committee of NeuroCentria (United States) (since 2022)

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- Independent director of Abide Therapeutics (United States) (2019-2020)

Education and professional experience

- Degree in medicine from the Faculty of Medicine of the University of Göttingen (Germany)
- Elected member of the National Academy of Sciences of the US (2002)
- Elected member of the National Academy of Medicine (2007)
- Bernard Katz Prize of the Biophysical Society, jointly with Reinhard Jahn (2008)
- Elected member of the American Academy of Arts and Sciences (2010)
- Nobel Prize for Physiology or Medicine, jointly with James Rothman and Randy Schekman (2013)
- Albert Lasker Prize for Basic Medical Research, jointly with Richard Scheller (2013)
- Elected foreign member of the German Academy Leopoldina (2015)
- Elected foreign member of the Royal Society of London for Improving Natural Knowledge (2017)
- Elected member of the Norwegian Society of Sciences

Since 2008	Avram Goldstein Professor in the Molecular & Cellular Physiology, Neurosurgery, Psychiatry, and Neurology Department in the School of Medicine at Stanford University (United States)
Since 2020	Member of the Scientific Advisory Board of Danaher Corporation (United States)
Since 2020	Co-founder and member of the Scientific Advisory Board of Boost, Inc. and Recognify, Inc. (United States)
Since 2020	Member of the Scientific Advisory Board of NeuroCure, Charite, Berlin (Germany)
Since 2019	Member of the Scientific Advisory Board of the Neuroscience Department at the Institut Pasteur (France)
Since 2019	Member of the Scientific Advisory Board of the Chinese Institute for Brain Research, Beijing (China)
Since 2019	Advisor to Camden Venture Partners (United States)
Since 2018	Member of the Scientific Advisory Board of Jupiter, Inc. (United States)
Since 2018	Chairman of the Scientific Advisory Board of Capital Medical University, Beijing (China)
Since 2018	Member of the Scientific Advisory Board of Alector, Inc. (United States)
Since 2017	Member of the Scientific Advisory Board of Cytodel, Inc. (United States)
Since 2017	Member of the Scientific Advisory Board of the Chinese Academy of Sciences Institute of Guangzhou (China)
Since 2016	Member of the Scientific Advisory Board of the Picower Institute, MIT Boston (United States)
Since 2016	Member of the Scientific Advisory Board of Simcere, Inc. (China)
Since 2014	Member of the Scientific Advisory Board of Elysium, Inc. (United States)
Since 2013	Member of the Scientific Advisory Board of the Shemyakin-Ovchinnikov Institute of Bio-Organic Chemistry (Russia)
Since 2002	Co-founder and member of the Scientific Advisory Board of REATA Pharmaceuticals (United States)
Since 1986	Investigator at the Howard Hughes Medical Institute (United States)
2017-2019	Member of the Scientific Advisory Board of C-Bridge Everest Medical (China)

2017-2018	Member of the Scientific Advisory Board of Abide (United States)
2014-2018	Member of the Scientific Advisory Committee of the Institute of Cellular and Molecular Biology of A*Star (China)
2014-2018	Member of the Scientific Advisory Board of the Chinese Academy Institute of Biophysics (China)
2014-2018	Member of the Scientific Advisory Board of the Singapore National Research Foundation (Singapore)
2014-2017	Co-founder and member of the Scientific Advisory Board of Bluenobel, Inc. (China)
2013-2016	Member of the Review Board of Genentech Neuroscience (United States)
2011-2019	Co-founder and member of the Scientific Advisory Board of Circuit Therapeutics, Inc. (United States)
1986-2008	Professor and subsequently Chair of the Neuroscience Department at the University of Texas Southwestern Medical School (United States)
1983-1986	Postdoctoral Fellow, Dept. of Molecular Genetics, UT Southwestern Medical School (United States)
1981-1982	Intern at the University Hospital of Göttingen (Germany)
1979	Student on exchange clerkship program at Harvard Medical School (United States)
1978-1981	Research assistant at the Max Planck Institute for Biophysical Chemistry (Germany)

Competencies
Scientific training

Yann Tran

Date of birth: December 5, 1965 (aged 57)

Nationality: French

First appointed: May 2021

Term expires: 2025

Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France

Number of shares held: 1,235 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Director representing the employees

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- Coordinator for IndustriALL Europe on the Sanofi European Works

OUTSIDE THE SANOFI GROUP

In French companies

- Member of the French Strategy Committee for the Healthcare Industries and Technologies Sector

In foreign companies

- None

Education and professional experience

- DEA in Biochemistry: Integrative Protein Biology from the University of Paris VII (France)
- Master's degree in Biochemical and Biological Engineering Sciences and Techniques from the University of Paris XII (France)

Since 2010	**Head of Labor Relations, France at Sanofi**
2021	Coordinator for IndustriALL Europe on the Sanofi European Works Council
2014-2021	Federation delegate for the Pharmaceuticals industry, in charge of negotiating and monitoring of industry agreements and national collective agreements
2014-2021	FCE-CFDT federation delegate for social welfare
2010-2021	Trade union leader in labor relations in the Sanofi Group
2010-2014	Member of the Supervisory Board of Sanofi employee savings plans (PEG and PERCO) and member of the Sanofi Group Committee
2006-2010	Bioinformatics researcher at Sanofi R&D
1995-2006	Researcher in molecular biology at Sanofi and Aventis

Competencies

Scientific training, Healthcare/pharmaceutical industry experience

Emile Voest

Date of birth: August 20, 1959 (aged 63)
Nationality: Dutch
First appointed: May 2022
Term expires: 2025
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 500

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Member of the Scientific Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- Chairman of the Board of Cancer Core Europe
- Board Member of the Center for Personalized Cancer Treatment
- Member of the Supervisory Board of Hartwig Medical Foundation

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- **None**

Education and professional experience

- Ph.D. in Medicine, cum laude, University of Utrecht

Since 2021	**Founder of Mosaic Therapeutics and Strategic Advisor**
Since 2019	Senior Group Leader of the Oncode Institute
Since 2016	Director of Cancer Core Europe
Since 2015	Founder and Member of Supervisory Board of the Hartwig Medical Foundation
2015-2020	ESMO (European Society for Medical Oncology) • Chair of the Publications Committee (2016-2020) • Member of the Executive Board (2015-2020)
Since 2014	The Netherlands Cancer Institute • Medical Oncologist (since 2014) • Executive Medical Director (2014-2020) and senior group leader
2013-2016	Co-founder and Non-Executive Medical Director of Hubrecht Organoid Technology
Since 2010	Co-founder and Member of the Executive Board of the Center for Personalized Cancer Treatment (CPCT)
Since 1999	Professor of Medical Oncology at UMC Utrecht

Competencies

Scientific training

Antoine Yver

Date of birth: January 31, 1958 (aged 65)
Nationality: French, American, Swiss
First appointed: May 2022
Term expires: 2025
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 2,000 American Depositary Receipts, equivalent to 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Member of the Scientific Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

Board Member of Spotlight Therapeutics

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Education and professional experience

- Doctor of Medicine and Pediatrics, University of Paris-Sud 11

2021-2022	Chairman of Development of Centessa Pharmaceuticals
2016-2021	EVP Global Head Oncology R&D at Daiichi Sankyo, Inc.
2009-2016	AstraZeneca • SVP Head Oncology Global Medicines Development & Lead China GMD (2013-2016) • VP Head Oncology Global Medicines Development & Lead China GMD (2012-2013) • VP Clinical Oncology & New Opportunities (2011-2012) • VP Clinical Oncology & Infection (2009-2011)
2006-2009	Executive Director in Oncology at the Schering-Plough Research Institute
2005-2006	Senior Director Oncology at Johnson & Johnson
1990-2005	Senior Director Clinical Research at Aventis
1981-1990	Medical doctor at the Assistance Publique des Hôpitaux de Paris

Competencies

Scientific training, Healthcare/pharmaceutical industry experience, Senior executive role in international groups, International experience

Frédéric Oudéa - Non-voting Board member

Date of birth: July 3, 1963 (aged 59)
Nationality: French
First appointed as a non-voting Board member: September 2022
Appointment as a director proposed at the 2023 General Meeting
Business address: Sanofi - 46, avenue de la Grande Armée - 75017 Paris - France
Number of shares held: 500 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Non-voting Board member

OUTSIDE THE SANOFI GROUP

In French companies

- Chief Executive Officer of Société Générale*
- Board member of Capgemini*
- Board member of ALD*

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Education and professional experience

- Graduate of ENA (*École Nationale d'Administration*)
- Degree from *École Polytechnique*

Since 2015	**Chief Executive Officer of Société Générale**
Since 2010	Chairman of the Steering Committee on Regulatory Capital of the Institute of International Finance
2009-2015	Chief Executive Officer and Chairman of the Board of Société Générale
2008-2009	Chief Executive Officer of Société Générale
2003-2008	Group Chief Financial Officer of Société Générale
2002-2003	Deputy Group Chief Financial Officer of Société Générale
1998-2002	Head of global supervision and development of the Equity Department of Société Générale
1995-1998	Assistant Manager, then Manager of the Corporate Banking department in London at Société Générale

Competencies

Senior executive role in international groups, Board membership in international groups, Finance/Accounting

Changes in the composition of the Board of Directors

The table below shows changes in the composition of the Board of Directors during 2021 and 2022, and the changes that will be submitted for approval by our shareholders at the Annual General Meeting of May 25, 2023:

	Annual General Meeting of April 30, 2021	Annual General Meeting of May 3, 2022	Annual General Meeting of May 25, 2023
End of term of office	Marion Palme Christian Senectaire Laurent Attal Bernard Charlès	Melanie Lee[(a)] Carole Piwnica[(a)]	Serge Weinberg[(c)]
Renewal of term of office	Fabienne Lecorvaisier Melanie Lee	Paul Hudson Christophe Babule Patrick Kron Gilles Schnepp	None
Proposed new appointments	Barbara Lavernos	Carole Ferrand[(b)] Emile Voest[(b)] Antoine Yver[(b)]	Frédéric Oudéa[(c)]
Co-opted	Gilles Schnepp	None	None
Other	Wolfgang Laux Yann Tran	None	None

(a) Melanie Lee and Carole Piwnica left the Board of Directors ahead of the General Meeting of May 3, 2022.

(b) On a proposal from the Board of Directors, Carole Ferrand, Emile Voest and Antoine Yver were appointed as directors at the General Meeting held on May 3, 2022.

(c) The term of office of Serge Weinberg will expire at the Annual General Meeting held to approve the financial statements for the year ended December 31, 2022, and cannot be renewed (see below). Acting on a recommendation from the Appointments, Governance and CSR Committee, the Board of Directors appointed Frédéric Oudéa as a non-voting member of the Board on September 2, 2022. The Board meeting of February 22, 2023 decided to ask the Annual General Meeting of May 25, 2023 to approve the appointment of Frédéric Oudéa as an independent director, to replace Serge Weinberg. The Board then intends to appoint Frédéric Oudéa as Chairman on the conclusion of that meeting.

If the appointment of Frédéric Oudéa as an independent director were to be approved, the proportion of independent directors[(1)] would be increased from 71% to 79%.

Executive Committee

The Executive Committee is chaired by the Chief Executive Officer. The Committee meets at least twice a month.

There were changes in the composition of the Executive Committee in 2022 and early 2023. One new member, Roy Papatheodorou (Executive Vice President, General Counsel & Head of Legal, Ethics & Business Integrity), joined on February 1, 2022; and two members, Arnaud Robert (Executive Vice President, Chief Digital Officer) and John Reed (Executive Vice President, Global Head of Research and Development) respectively in December 2022 and February 2023, respectively. Arnaud Robert and John Reed's functions are being performed internally until the appointment of their respective successors.

As of February 24, 2023, the Executive Committee had nine members, two of whom are women. In accordance with our Board Charter, the Board of Directors – in liaison with the Compensation Committee and the Appointments, Governance and CSR Committee, and on a proposal from the Chief Executive Officer – has established a policy on gender balance within Sanofi's executive bodies. A key objective of this policy is to support the creation of a talent pool of both women and men who can potentially join the Executive Committee in future.

Paul Hudson

Chief Executive Officer

Date of birth: October 14, 1967.

Paul Hudson joined Sanofi as Chief Executive Officer on September 1, 2019.

Previously CEO of Novartis Pharmaceuticals (2016-2019), where he was a member of the Executive Committee, Paul has had an extensive international career in healthcare that spans the US, Japan and Europe.

Prior to Novartis, he worked for AstraZeneca, where he held several increasingly senior positions and most recently carried out the roles of President, AstraZeneca United States and Executive Vice President, North America.

He began his career in sales and marketing roles at GlaxoSmithKline UK and Sanofi-Synthélabo UK.

Paul holds a degree in economics from Manchester Metropolitan University in the UK and last year his alma mater awarded him an honorary Doctor of Business Administration for his achievements in industry. He also holds a diploma in marketing from the Chartered Institute of Marketing, also in the UK.

Paul Hudson is a citizen of the United Kingdom.

(1) Calculated in accordance with currently applicable rules.

Natalie Bickford

Executive Vice President, Chief People Officer

Date of birth: July 16, 1970.

Natalie Bickford joined Sanofi on August 1, 2020.

She holds a degree in French and International Politics from the University of Warwick in the UK.

She has worked in HR and HR leadership for more than 20 years and brings a wealth of experience in consumer-facing industries to Sanofi.

Prior to joining Sanofi, Natalie was Group HR Director at Merlin Entertainments, the world's second largest location-based entertainment business, where she was responsible for 30,000 employees across Europe, North America, and Asia Pacific. She also held senior HR positions at Sodexo, AstraZeneca and Kingfisher Plc.

Natalie has a solid track record of transforming organizations, with a strong focus on inclusion and diversity. She was awarded "HR Diversity Champion of the Year" at the European Diversity Awards in November 2019. Natalie is also Board member of the Kronos Workforce Institute, a reflection of her deep interest in understanding and shaping the future of work.

Natalie Bickford is a citizen of the United Kingdom.

Olivier Charmeil

Executive Vice President, General Medicines

Date of birth: February 19, 1963.

Olivier Charmeil is a graduate of HEC (*École des Hautes Études Commerciales*) and of the *Institut d'Études 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 Sanofi, 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.

From June 2016 to December 2018, Olivier Charmeil served as Executive Vice President of our General Medicines and Emerging Markets Global Business Unit.

He took up the position of Executive Vice President China & Emerging Markets in January 2019. In February 2020 he was appointed to lead the General Medicines GBU, created out of the former Primary Care and China & Emerging Markets GBUs. He also serves as sponsor for China. Also in 2020, Olivier became a Board Member of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Olivier Charmeil is a citizen of France.

Jean-Baptiste Chasseloup de Chatillon

Executive Vice President, Chief Financial Officer

Date of birth: March 19, 1965.

Jean-Baptiste Chasseloup de Chatillon joined Sanofi on October 1, 2018.

Jean-Baptiste Chasseloup de Chatillon holds a Masters from Paris Dauphine University and studied Finance in the United Kingdom at Lancaster University.

Until July 2018, he served as Chief Financial Officer and Executive Vice President of the PSA Group. In that capacity, he was also a member of the Managing Board and Executive Committee. He held various management positions within the PSA Group in finance (Treasurer in Spain, Chief Financial Officer in the United Kingdom) and in sales and marketing (Business units: Bank/Insurance, Spare parts, Used vehicles, Proprietary dealership network).

He was also Chairman of the Board of Banque PSA Finance (BPF) from 2012 to June 2016. He joined the Peugeot S.A. Managing Board in 2012.

He was appointed as Director and member of the Audit Committee of Sodexo (a French listed company) on December 14, 2021.

Jean-Baptiste Chasseloup de Chatillon is a citizen of France.

Brendan O'Callaghan

Executive Vice President, Global Manufacturing & Supply

Date of birth: July 16, 1961.

Brendan O'Callaghan joined Sanofi on January 1, 2015. He joined the Executive Committee on October 1, 2021.

Brendan graduated in chemical engineering from the University College of Dublin, where he currently serves as an honorary adjunct Professor of Chemical and Biochemical Engineering.

Brendan joined Sanofi in 2015 and was previously Global Head of Biologics and Industrial Affairs Head of the Specialty Care portfolio. He has played a key role in supporting our transformation to a fully integrated BioPharma company and advancing the digital transformation of our manufacturing network.

Prior to Sanofi, Brendan worked at Schering-Plough before moving to Merck/MSD as Head of Biologics and later Vice President of its Europe, Middle East and Africa Operations.

Brendan O'Callaghan is a citizen of Ireland.

Julie Van Ongevalle

Executive Vice President, Consumer Healthcare

Date of birth: November 22, 1974.

Julie Van Ongevalle joined Sanofi on September 1, 2020.

She graduated from the *Institut Catholique des Hautes Études Commerciales* (Belgium) with a Master of Science in Commercial and Financial Sciences.

With over 20 years of international experience, Julie has a deep knowledge of consumers and digital, as well as a proven track record in brand building, from identifying growth opportunities to building and implementing delivery strategies.

Prior to joining Sanofi, Julie worked at the Estée Lauder Companies, where she held roles of increasing responsibility across the company, starting in 2004. As Global Brand President of the Origins brand from 2016, she led a global organization of 4,000 people, growing the company's market share across geographies. Prior to Origins, she spent eight years in the M.A.C. Cosmetics division, first as General Manager Benelux, then of the EMEA Region and finally North America.

Julie started her career as a marketing manager at GSK Consumer Healthcare and Clinique.

Julie Van Ongevalle is a citizen of Belgium.

Roy Papatheodorou

Executive Vice President, General Counsel & Head of Legal, Ethics & Business Integrity

Date of birth: May 15, 1978.

Roy Papatheodorou joined Sanofi on February 1, 2022.

Prior to joining Sanofi, Roy was General Counsel of Novartis Pharmaceuticals. He has a wealth of experience in leading global and diverse teams, having also headed the Legal Transactions team at Novartis and having previously been the General Counsel of the Actavis Group, one of the largest generics companies at the time.

He started his career at international law firm Linklaters, where he specialized in international M&A, corporate and private equity based in London, with time also spent in Russia and Brazil.

Roy Papatheodorou is a citizen of Cyprus and Italy.

Bill Sibold

Executive Vice President, Specialty Care

Date of birth: October 29, 1966.

Bill Sibold holds an MBA from Harvard Business School and a B.A. in Molecular Biophysics and Biochemistry from the Yale University. He has more than thirty 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 to June 2017 he served as head of Specialty Care's Global Multiple Sclerosis, Oncology and Immunology organization, where he led preparation for the global launches of Dupixent® and Kevzara®.

Bill Sibold has headed up Specialty Care global business unit, since July 1, 2017. He has also served as President for North America since February 2020.

Bill Sibold is a citizen of Canada and of the United States of America.

Thomas Triomphe

Executive Vice President, Vaccines

Date of birth: August 6, 1974.

Thomas Triomphe earned his MSc in industrial engineering from École des Ponts ParisTech and the IFP School, and he also holds an MBA from INSEAD.

Thomas joined Vaccines in 2004 and has since advanced within the company in several roles of increasing responsibility in sales and marketing at country, regional and global levels. From 2015 to 2018, he was Head of the Asia-Pacific Region, based in Singapore. Before that, he served as Head of Vaccines Japan from 2012 to 2015. In 2010, he became Associate Vice President, Head of the Influenza-Pneumo Franchise after three years as Director for the same franchise, based in the United States. Earlier in his career, Thomas worked in banking and strategic consulting.

Thomas served as Vice President and Head of Franchise & Product Strategy for Vaccines from January 2018, in which position he implemented the strategy for our vaccine franchises, in close collaboration with Manufacturing & Supply and R&D.

He was appointed to his current position on June 15, 2020.

Thomas Triomphe is a citizen of France.

B. Compensation

Compensation and other arrangements for corporate officers

Compensation policy for corporate officers

This section describes the compensation policy for corporate officers of Sanofi, as established pursuant to Article L. 22-10-8 of the French Commercial Code. That policy describes all the components of compensation awarded to corporate officers of Sanofi as consideration for holding office, and explains the process by which it is determined, divided, reviewed and implemented.

Our compensation policy for corporate officers has three distinct elements: (i) the compensation policy for directors; (ii) the compensation policy for the Chairman of the Board; and (iii) the compensation policy for the Chief Executive Officer.

Each of those policies is submitted for approval by our shareholders at the Annual General Meeting, in accordance with Article L. 22-10-8 II of the French Commercial Code. The compensation policy approved in any given year applies to any person holding corporate office in that year. Moreover, when a corporate officer is appointed between two Annual General Meetings, their compensation is defined applying the terms of the compensation policy approved by the most recent Annual General Meeting of shareholders.

Process for determining the compensation policy for corporate officers

The compensation policy for corporate officers is established by the Board of Directors, acting on the recommendation of the Compensation Committee. The Board of Directors applies the AFEP-MEDEF Code when determining the compensation and benefits awarded to our executive and non-executive corporate officers.

All members of the Compensation Committee are independent, and were chosen for their technical competencies and their good understanding of current standards, emerging trends and Sanofi's practices.

To fulfill their remit, the Committee regularly invites the Chief People Officer and the Head of Reward and Performance of the Group to attend their meetings, although the latter absent themselves when the Committee deliberates. Committee members also work with the Chairman and the Secretary of the Board, who have contacts with our principal institutional 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, Governance and CSR Committee and the Strategy Committee (to both of which he belongs), thereby gaining assurance that the proposed performance criteria are consistent and appropriate in light of Sanofi's strategic ambitions.

The compensation policy is not subject to annual review, although some arrangements for implementing the policy – such as the performance criteria applicable to the Chief Executive Officer's annual variable compensation, for example – are defined by the Board of Directors on an annual basis.

After consulting the Compensation Committee and as the case may be the other Board Committees, the Board of Directors may, under the second paragraph of item III of Article L. 225-37-2 of the French Commercial Code, temporarily derogate from the approved compensation policy for the Chief Executive Officer in exceptional circumstances and to the extent that the changes are aligned with the corporate interest and necessary to safeguard the continuity or viability of Sanofi. Derogations from the approved policy are possible in respect of the performance conditions applied to the Chief Executive Officer's compensation, and may result in either an increase or a decrease in compensation. The circumstances in which it is possible to apply such a derogation are (i) a change in the structure of the Sanofi group or (ii) major events affecting the markets. Such derogation may only be temporary and must be properly substantiated. Moreover, it will remain subject to approval by the next General Meeting of Sanofi shareholders.

General principles and objectives

Our compensation policy is based on the following general principles:

- the policy must be simple;
- the policy must prioritize long-term performance;
- the level of compensation must be competitive, so that we can attract and retain talent; and
- there must be a fair balance between the corporate interest, the challenges of delivering on our strategy, and the expectations of our stakeholders.

The Compensation Committee must ensure that trends in the compensation of corporate officers over the medium term are not uncorrelated with trends in the compensation of all our employees. In terms of annual variable compensation and equity-based compensation, the Compensation Committee aims to achieve convergence between the performance criteria applied to our Senior Leaders and those applied to the Chief Executive Officer.

Our equity-based compensation policy, which aims to align employee and shareholder interests and reinforce loyalty to Sanofi, is a critical tool for our worldwide attractiveness as an employer.

With effect from June 2019, grantees of equity based compensation plans (including our Chief Executive Officer) can only be awarded performance shares. Awarding performance shares reduces the dilutive effect of equity based compensation plans while maintaining the same level of motivation for grantees.

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, thereby furthering the attainment of our objectives. Our equity-based compensation plan rules are made available to our shareholders on the governance page of our website *(www.sanofi.com)* in the same form as that distributed to our employees.

The Board of Directors makes any grant of performance shares contingent on multiple, exacting multi-year performance criteria in order to ensure that our equity-based compensation plans incentivize overall performance. Failure to achieve those criteria over the entire performance measurement period results in a reduction or loss of the initial grant.

In order to align equity-based compensation with our long-term performance, performance is measured over three financial years (the "vesting period"). Awards of performance shares are also contingent on continued employment in the Sanofi group during the vesting period, followed by stringent lock-up obligations in the case of the Chief Executive Officer (see below).

The terms of prior awards cannot be reset subsequently, for instance with less exacting performance conditions.

Compensation policy for directors

Directors hold office for a four-year term, as specified in our Articles of Association. They may be removed from office by a shareholders' meeting, at any time and without restriction.

The maximum annual amount of overall compensation allocated to the directors has been set at €2,000,000 since 2020. Given the increasing number of Board and committee meetings and in order to be able to compensate the Directors in accordance with the compensation policy, the forthcoming Annual General Meeting of Sanofi shareholders will be asked to amend this maximum annual amount to €2,500,000, with effect from the 2023 financial year. The fixed and variable compensation for directors will remain unchanged.

The arrangements for allocating the overall annual amount set by the Annual General Meeting between the directors are determined by the Board of Directors, acting on a recommendation from the Compensation Committee. Directors' compensation comprises (i) an annual fixed amount of €30,000, apportioned on a time basis for directors who assumed or left office during the year, and (ii) a variable amount, allocated by the Board according to actual attendance at Board and Committee meetings. As required by the AFEP-MEDEF Code, directors' compensation is allocated predominantly on a variable basis.

The table below shows how the variable amount payable to directors for attendance at Board and committee meetings is determined; the allocation was last changed in 2020.

	Compensation per meeting			
	Directors resident in France	Directors resident outside France but within Europe	Directors resident outside Europe	Chairman/Chairwoman
Board of Directors	€5,500	€8,250	€11,000	N/A
Audit Committee	€8,250	€8,250	€8,250	€11,000
Compensation Committee	€5,500	€8,250	€11,000	€8,250
Appointments, Governance and CSR Committee	€5,500	€8,250	€8,250	€8,250
Strategy Committee	€5,500	€8,250	€11,000	Determined by reference to place of residence
Scientific Committee	€5,500	€8,250	€11,000	Determined by reference to place of residence

Directors who take part via videoconference receive compensation equivalent to that paid to a director resident in France attending in person. Committee Chairs continue to receive the usual compensation in respect of the Committee they chair.

As an exception, in certain cases two meetings held on the same day give entitlement only to a single payment:

- if on the day of a Shareholders' General Meeting, the Board of Directors meets both before and after the Meeting, only one payment is made for the two Board meetings; and
- if on the same day a director participates in a meeting of the Compensation Committee and a meeting of the Appointments, Governance and CSR Committee, only the higher of the two payments is made to cover both meetings.

The introduction of a separate compensation 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.

Directors do not receive any exceptional compensation or equity-based compensation and have no entitlement to a top-up pension plan.

Neither the Chairman of the Board nor the Chief Executive Officer receives any compensation for serving as a director.

In accordance with Sanofi's Articles of Association, the Board may compensate non-voting members by allocating sums from the annual amount allotted by the Annual General Meeting to Board members (see above). Acting on a recommendation from the Compensation Committee, which took into account the time spent by the non-voting member on the induction process ahead of his future appointment as Chairman of the Board, the Board of Directors decided to allocate him the same compensation as is allocated to the other Board members.

Compensation policy for the Chairman of the Board of Directors

The term of office of the Chairman of the Board is the same as that of the other directors (four years), and the Chairman's term is aligned with his term of office as a director. He may be removed from office at any time by the Board of Directors.

The compensation policy for the Chairman of the Board of Directors is discussed by the Compensation Committee, which then makes a recommendation to the Board of Directors. The Chairman of the Board is not a member of the Committee, and does not attend meetings where his compensation is discussed.

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 compensation for serving as a director.

The annual fixed compensation awarded to the current Chairman of the Board of Directors is €800,000 gross, unchanged since 2021.

At its meeting of February 22, 2023, the Board of Directors considered the compensation of the future Chairman of the Board of Directors. Acting on a recommendation from the Compensation Committee, which took into account the practices of comparable CAC 40 companies, the Board set the compensation of the future Chairman of the Board of Directors at €880,000 gross with effect from May 26, 2023. That amount also takes account of the specific remit of the Chairman of the Board of Directors as described in the Sanofi Board Charter, and of the intention to propose that the future Chairman of the Board of Directors will sit on the same committees as the current Chairman of the Board of Directors.

The compensation of the Chairman of the Board of Directors is not subject to annual review.

Where the office of Chairman is separate from that of Chief Executive Officer, the Chairman of the Board is not entitled to the Sanofi top-up defined-contribution pension plan.

Nor is he entitled to a termination benefit or a non-compete indemnity.

The Chairman of the Board does not receive compensation for chairing Board meetings, or as a member of Board committees.

Compensation policy for the Chief Executive Officer

General principles

Our Chief Executive Officer is not appointed for a fixed term of office. He may be removed from office on legitimate grounds at any time by the Board of Directors.

The compensation policy for the Chief Executive Officer is established by the Board of Directors, acting on the recommendation of the Compensation Committee. The compensation structure is not subject to annual review and is applicable for as long as it remains unchanged. The arrangements for implementing the policy may vary from year to year; a table showing the changes made to those arrangements in 2023 and 2022 is provided at the end of the present section.

The compensation of the Chief Executive Officer is determined with reference to compensation awarded to the chief executive officers of the following 12 leading global pharmaceutical companies[(1)]: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd. This panel comprises companies that are comparable to Sanofi, with no limitation as to geographical region given that Sanofi operates in a particularly competitive international environment. Consistency with market practice is fundamental in order to attract and retain the talents necessary to our success. In 2022, on the basis of 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 twelve leading global pharmaceutical companies was in the region of €1,613,000; the median of the annual variable compensation awarded was in the region of €2,665,000; and the median of the long-term compensation awarded (whether equity-based or in cash) represented around 790% of fixed compensation. Within this peer group, Paul Hudson's overall compensation (fixed, variable and equity-based compensation) lies in the low range of the second quartile of the compensation paid by the panel companies. The practices of the main CAC 40 companies are also taken into account[(1)].

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 and maintaining 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 compensation policy for the Chief Executive Officer is designed to motivate and reward performance by ensuring that a significant portion of compensation is contingent on the attainment of financial, operational and extra-financial criteria that reflect Sanofi's objectives, and are 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, and are intended to align the interests of the Chief Executive Officer with those of our shareholders and stakeholders.

During the meeting that follows the Board meeting held to close off the financial statements for the previous year, the Compensation Committee examines the levels of attainment of variable compensation for that year. In advance of that meeting, the Chief Executive Officer presents the Committee with a report containing narrative and quantitative information necessary to measure attainment of the objectives. The members of the Compensation Committee then discuss the information provided and report to the Board on those discussions, giving an evaluation of the Chief Executive Officer's performance against each of the criteria (determining the level of attainment for quantitative objectives, and evaluating the level of attainment for qualitative objectives).

Annual fixed compensation

The annual fixed compensation of the Chief Executive Officer has been set at €1,400,000 gross since 2022. It had previously remained unchanged since 2019.

The amount of fixed compensation is not subject to annual review. It may however be changed, provided that such changes are not material:

- on the appointment of a new Chief Executive Officer, to reflect the new appointee's competencies and/or then current market practice; and
- in exceptional circumstances, to take account of changes in (i) the role or responsibilities of the Chief Executive Officer, for example in terms of market conditions or the size of the Sanofi group or (ii) the performance level of Sanofi over a given period.

(1) Surveys conducted on the basis of data communicated by Pay Governance and Boracay.

Annual variable compensation

Annual variable compensation is in a range between 0% and 250% of fixed compensation, with a target of 150%. It is subject to a range of varied and exacting performance criteria, both quantitative and qualitative. The criteria are reviewed annually in light of the strategic objectives determined by Sanofi. The Board of Directors sets the criteria for each year at the start of that year on the recommendation of the Compensation Committee. For 2023, the criteria are:

- 50% based on financial indicators published by the Company: sales growth, business net income (BNI), free cash flow (FCF) and business operating income (BOI) margin and growth in new assets, each accounting for 10%. FCF and BOI margin were chosen because they are in line with the Company's strategic roadmap; and
- 50% based on specific individual objectives, including criteria linked to CSR criteria for Sanofi (partly quantitative), underlining the Board's commitment to long-term value creation. The individual objectives set for variable remuneration for 2023 are described in "— Compensation and benefits of all kinds awarded to corporate officers in respect of 2023" below.

Overall, the quantitative element of the financial and individual objectives is in a range between 65% and 70%.

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.

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, which can only be in the form of performance shares, may not exceed 250% of his target short-term compensation (fixed plus variable).

The Chief Executive Officer's equity-based compensation is contingent upon attainment of exacting performance conditions, all of them quantitative, measured over a three-year-period. Such awards are contingent upon both:

- internal criteria based upon:
  - BNI and FCF – financial criteria, and
  - Affordable Access and Healthy Planet – extra-financial criteria; and
- an external criterion based upon total shareholder return (TSR) relative to a benchmark panel of twelve of the leading global pharmaceutical companies: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd.

The inclusion in equity-based compensation plans from 2023 of measurable, material extra-financial criteria aligned with Sanofi's strategy follows a recommendation from the Compensation Committee, which took the view that such a policy would embed a link in the long-term compensation of the Chief Executive Officer and all other beneficiaries of equity-based compensation plans.

The valuation of performance shares is calculated at the date of grant, weighted between (i) fair value determined using the Monte Carlo model and (ii) the market price of Sanofi shares at the date of grant, adjusted for dividends expected during the vesting period.

Each award to our Chief Executive Officer takes into account previous awards and his overall compensation. In any event, the maximum number of shares to be delivered may not be more than the number of performance shares initially awarded.

For details of the award to the Chief Executive Officer in respect of 2023, refer to "— Compensation and benefits of all kinds awarded to corporate officers in respect of 2023" below.

Share ownership and lock-up obligation of the Chief Executive Officer

The Chief Executive Officer is bound by the same obligations regarding share ownership specified in our Articles of Association and Board Charter as our 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 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, the Chief Executive Officer must undertake to refrain from entering into speculative or hedging transactions.

Multi-year variable compensation

The Chief Executive Officer does not receive multi-year variable compensation.

Compensation for serving as a director

Executive officers of Sanofi do not receive any compensation for serving as directors. Consequently, the Chief Executive Officer does not receive compensation 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-contribution pension plan, a termination benefit, and a non-compete indemnity.

Such arrangements are part of the overall compensation package generally awarded to executive officers; in line with recommendations of the AFEP-MEDEF code, there are very strict rules about how they are implemented. The termination benefit and non-compete indemnity are intended to compensate for the fact that the Chief Executive Officer may be dismissed at any time.

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 entitled to benefits under the top-up defined-contribution pension plan introduced within Sanofi on January 1, 2020. This is a collective plan falling within the scope of Article 82 of the French General Tax Code. It is also offered to members of our Executive Committee and all senior executives whose position is classified within the Sanofi grade scale as "Executive Level 1 or 2". The Chief Executive Officer's entitlement under this plan may be withdrawn by a decision of the Board of Directors, but not retroactively.

Under the terms of the plan, the Chief Executive Officer receives an annual contribution the amount of which (subject to attainment of a performance condition) may be up to 25% of his reference compensation (annual fixed and variable cash-based compensation only; all other compensation is excluded). The rights accruing under the plan are those that are generated by the capitalization contract taken out with the insurer, and vest even if the Chief Executive Officer does not remain with Sanofi until retirement. The Chief Executive Officer may elect for the rights to be transferable as a survivor's pension.

The performance condition is as follows:

- 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 contribution is paid;
- if the level of attainment for variable compensation is less than 100% of fixed compensation, no contribution is paid; and
- between those two limits, the contribution is calculated on a prorata basis.

Because this performance condition is linked to the attainment of the performance criteria for annual variable compensation (which itself is determined with reference to the strategic objectives of Sanofi), it ensures that no pension contributions could be made in the event that the Chief Executive Officer fails to deliver.

The plan is wholly funded by Sanofi, which pays the full amount of the gross contributions. Because it is treated as equivalent to compensation, the contribution is subject to payroll taxes and employer's social security charges, and to income tax in the hands of the Chief Executive Officer; all of the above are charged on the basis of the bands, rates and other conditions applicable to compensation, paid and declared on his payslips for the contribution period.

Subject to (i) formal confirmation by the Board of Directors that the performance condition for the previous year has been met and (ii) approval of the Chief Executive Officer's compensation package for that year by the Annual General Meeting of our shareholders, the annual gross contribution is paid as follows:

- 50% as a gross insurance premium to the fund manager; and
- 50% to the Chief Executive Officer, to indemnify him for the social security and tax charges for which he will become immediately liable.

In accordance with Article 39.5 bis of the French General Tax Code, deferred compensation as defined in section 4 of Article L. 22-10.9 of the French Commercial Code can be offset against corporate profits as a taxable expense up to a limit set at three times the annual social security ceiling per beneficiary.

The pension entitlement is not cumulative with (i) any termination benefit paid in the event of forced departure or (ii) any non-compete indemnity.

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 and the arrangement is deemed to have been rescinded in the following circumstances:

- removal from office for gross or serious misconduct *(faute grave ou lourde)*;
- if the Chief Executive Officer elects to leave Sanofi to take up another position;
- if the Chief Executive Officer is assigned to another position within Sanofi; or
- if the Chief Executive Officer takes his pension.

Payment of the termination benefit is contingent upon fulfillment of a performance condition, which is deemed to have been met if the attainment rate for the individual variable compensation objectives exceeded 90% of the target; that condition is assessed over the three financial years preceding the Chief Executive Officer leaving office.

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 condition.

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 Sanofi 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, based on his fixed compensation effective on the day he leaves office and on the last individual variable compensation he 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 that 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 Sanofi 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 in full), the overall allocation percentage is 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 the vesting period of his 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 performance shares regardless of any full or partial discharge by the Board of Directors of the non-compete undertaking relating to his office as Chief Executive Officer.

Since 2021, if the Chief Executive Officer retires at statutory retirement age prior to the expiration of the vesting period of his performance shares, the overall allocation rate will be apportioned on a prorata basis to reflect the amount of time for which the Chief Executive Officer remained in the employment of Sanofi during the vesting period.

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.

	Voluntary departure/Removal from office for gross or serious misconduct	Forced departure	Retirement
Termination benefit[(a)]	/	24 months of fixed compensation as of the date of leaving office + 24 months of most recent individual variable compensation received[(d)] – Amounts received as non-compete indemnity	/
Non-compete indemnity[(b)]	12 months of fixed compensation as of the date of leaving office + 12 months of most recent individual variable compensation received prior to leaving office	12 months of fixed compensation as of date of leaving office + 12 months of most recent individual variable compensation received prior to leaving office[(e)]	/
Top-up pension[(c)]	/	/	Annual contribution of up to 25% of reference compensation
Performance share plans not yet vested	Forfeited in full	Rights retained prorata to period of employment within Sanofi[(f)]	Rights retained prorata to period of employment within Sanofi[(f)]

(a) The amount of the termination benefit is reduced by any indemnity 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) Defined-contribution pension plan, within the scope of Article 82 of the French General Tax Code. Subject to fulfillment of the performance condition, assessed annually.

(d) Subject to fulfillment of the performance condition assessed over the three financial years preceding departure from office, as described above.

(e) Subject to the Board of Directors enforcing the non-compete undertaking, the amount of the termination benefit is reduced by any indemnity 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.

(f) In this case, the Chief Executive Officer remains subject to the terms of the plans, including the performance conditions and the non-compete clause.

Policy to recover erroneously-awarded compensation ("clawback")

On November 28, 2022, the SEC adopted rules, pursuant to Section 10D-1 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, requiring national securities exchanges and national securities associations, such as the NASDAQ, to amend their relevant listing standards no later than November 28, 2023 to require companies with listed securities to put in place a policy whereby listed companies will recover erroneously-awarded variable compensation from the Chief Executive Officer and certain other "executive officers" as defined in Section 10D-1(d). As of the date of publication of this Annual Report on Form 20-F, the NASDAQ listing standards have not yet been amended pursuant to Section 10D-1 of the Exchange Act. Consequently, Sanofi will adopt a clawback mechanism once the final rules are adopted. In particular, in accordance with Section 10D-1 of the Exchange Act and the requirements to be adopted by NASDAQ in its revised listing rules, the Board of Directors will adopt a clause requiring the recovery in full or in part of the components of the Chief Executive Officer's compensation that are wholly or partially contingent on the attainment of financial performance criteria based on financial information that has been determined to be erroneous and has required restatement of the financial statements for accounting purposes. The compensation policy of the Chief Executive Officer will be presented to our shareholders at our Annual General Meeting to be held on May 25, 2023.

Summary of changes made to the compensation policy for the Chief Executive Officer

The table below summarizes adjustments made to how the compensation policy for the Chief Executive Officer is implemented. Some of them been thoroughly discussed with our shareholders.

2023	2022
• Annual variable compensation: – To reflect shareholder expectations, Sanofi is from now on disclosing the content of the qualitative criteria. • Variable equity-based compensation: – In order to link share-based compensation (long-term compensation) to the execution of the Group's CSR strategy, measurable and material CSR criteria have been introduced into performance share plans awarded in or after 2023. • Clawback Policy: – Pursuant to Section 10D-1 of the Exchange Act, SEC regulations and NASDAQ listing rules, the Board of Directors will adopt a clause allowing for the recovery of some or all of the components of the Chief Executive Officer's compensation that are wholly or partially contingent on the attainment of financial performance criteria based on erroneous financial information (see above).	• Annual fixed compensation: – Annual fixed compensation is increased to €1,400,000 gross with effect from 2022. • Annual variable compensation: – Sanofi now publishes the content of the individual CSR performance objective (sub-criteria). • Variable equity-based compensation: – The external criterion based on Total Shareholder Return (TSR) will no longer be measured in absolute value (ranking) but in relative terms (variation from the previous ranking), with the caveat that for the Chief Executive Officer any TSR-linked payment will remain contingent on Sanofi achieving a rank greater than or equal to the median of the TSR panel.

Arrangements in favor of executive officers in office as of December 31, 2022 (table No. 11 of the AFEP-MEDEF Code)

Executive officer	Contract of employment	Top-up pension plan	Indemnities or benefits payable or potentially payable on cessation of office	Indemnities payable under non-compete clause
Chairman of the Board	No	No	No	No
Chief Executive Officer	No	Yes	Yes	Yes

Compensation and benefits of all kinds paid during 2022 or awarded in respect of 2022 to corporate officers

The section below constitutes the report on compensation of corporate officers required by Article L. 225-37 of the French Commercial Code. The arrangements described therein will be submitted for approval by our shareholders at the Annual General Meeting called to approve the financial statements for the year ended December 31, 2022 pursuant to Article L. 22-10-34 of the French Commercial Code.

Compensation elements and benefits of all kinds paid during 2022 or awarded in respect of 2022 to directors (table No. 3 of the AFEP-MEDEF Code)

The compensation policy for directors (as described above in the section entitled "— Compensation policy for directors") defines the fixed amount of compensation, and the principles for allocating the variable portion between directors, up to the limit of the overall amount approved by the Annual General Meeting.

Directors' compensation includes an annual fixed payment, apportioned on a time basis for directors who assumed or left office during the year; and a variable amount, allocated by the Board according to actual attendance at Board and Committee meetings. As required by the AFEP-MEDEF Code, directors' compensation is allocated predominantly on a variable basis.

For 2022, directors' compensation was determined in accordance with the compensation policy for directors as described above in the section entitled "— Compensation policy for directors".

The table below shows amounts paid in respect of 2022 and 2021 to each member of our Board of Directors, including those whose term of office ended during those years.

Directors' compensation for 2021, the amount of which was approved at the Board meeting of February 22, 2022, was partially paid in July 2021, with an additional payment in 2022.

Directors' compensation for 2022, the amount of which was approved at the Board meeting of February 22, 2023, was partially paid in July 2022, with an additional payment to be made in 2023.

The notional amount of compensation to which directors were entitled for 2022 exceeded the maximum annual amount set by the Annual General Meeting, due to more Board and committee meetings (eight extra meetings in total) being held in 2022; (ii) most of those meetings being face-to-face; and the international profile of two of the new directors. As a result, compensation was apportioned between the directors on a pro rata basis, such that directors had to be paid less than the agreed amount per meeting (variable portion).

Acting on a recommendation from the Compensation Committee, which took into account the time spent by the non-voting member on the induction process ahead of his future appointment as Chairman of the Board, the Board of Directors decided to allocate him the same compensation as is allocated to the other Board members.

(€)	Compensation in respect of 2022				Compensation in respect of 2021		
Name	Fixed portion	Variable portion	Total amount (variable + fixed portion)	Total gross compensation apportioned on a pro rata basis(*)	Fixed portion	Variable portion	Total gross compensation
Laurent Attal [(a)]	N/A	N/A	—	N/A	10,000	33,000	43,000
Christophe Babule	30,000	129,250	159,250	134,912	30,000	99,000	129,000
Bernard Charlès [(b)]	N/A	N/A	—	N/A	10,000	16,500	26,500
Rachel Duan [(c)]	30,000	115,500	145,500	123,263	30,000	88,000	118,000
Carole Ferrand	20,000	82,500	102,500	86,835	N/A	N/A	N/A
Lise Kingo [(d)]	30,000	140,250	170,250	144,231	30,000	68,750	98,750
Patrick Kron	30,000	134,750	164,750	139,571	30,000	118,250	148,250
Wofgang Laux [(e)(f)]	30,000	88,000	118,000	99,966	20,000	22,000	42,000
Barbara Lavernos	30,000	99,000	129,000	109,285	20,000	27,500	47,500
Fabienne Lecorvaisier	30,000	143,000	173,000	146,560	30,000	115,500	145,500
Melanie Lee [(g)]	10,000	46,750	56,750	56,750	30,000	107,250	137,250
Marion Palme [(h)]	N/A	N/A	—	N/A	10,000	N/A	10,000
Carole Piwnica [(g)]	10,000	35,750	45,750	45,750	30,000	85,250	115,250
Gilles Schnepp	30,000	154,000	184,000	155,879	30,000	121,000	151,000
Christian Senectaire	N/A	N/A	—	N/A	10,000	22,000	32,000
Diane Souza [(c)]	30,000	206,250	236,250	200,144	30,000	137,500	167,500
Thomas Südhof [(c)]	30,000	203,500	233,500	197,814	30,000	115,500	145,500
Yann Tran [(f)(i)(j)]	30,000	77,000	107,000	90,647	20,000	22,000	42,000
Emile Voest [(d)(k)]	20,000	101,750	121,750	103,143	N/A	N/A	N/A
Antoine Yver [(c)(k)]	20,000	137,500	157,500	133,429	N/A	N/A	N/A
Frédéric Oudéa [(l)]	10,000	27,500	37,500	31,769	N/A	N/A	N/A
Total	**420,000**	**1,922,250**	**2,342,250**	**1,999,948**	**400,000**	**1,199,000**	**1,599,000**
Total				**1,999,948**			

(*) Due to the high number of Board and committee meetings in 2022, the theoretical amount of compensation payable to directors exceeded the maximum amount set by the Annual General Meeting of our shareholders. Consequently, the amount payable to each director has been scaled down on a pro rata basis.

The amounts reported are gross amounts before taxes.

(a) Director who resigned from office in 2021.

(b) Director who left office on April 30, 2021.

(c) Director resident outside Europe.

(d) Director resident outside France but within Europe.

(e) Director appointed by the European Works Council.

(f) Director representing employees.

(g) Director who resigned from office on May 2, 2022.

(h) Director who left office on April 28, 2020.

(i) Compensation due to Yann Tran is paid directly to Fédération Chimie Énergie CFDT.

(j) Director appointed by the CFDT, the leading trade union organization with Sanofi in France.

(k) Director appointed by the General Meeting of May 3, 2022.

(l) Non-voting board member appointed by the Board on September 2, 2022.

Each of the two directors representing employees has 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.

Variable compensation allocated to directors in respect of 2022 represented 82% of their total compensation.

Compensation and benefits of all kinds paid during 2022 or awarded in respect of 2022 to Serge Weinberg, Chairman of the Board of Directors

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. He will leave office at the conclusion of the Annual General Meeting on May 25, 2023.

The Chairman of the Board is a member of the Appointments, Governance and CSR Committee (which he chaired until December 15, 2021), the Scientific Committee and the Strategy Committee.

The remit of the Chairman of the Board is specified in the Board Charter, which is reproduced in its entirety in Exhibit 1.2. to this Annual Report on Form 20-F.

During the course of 2022, the Chairman's activities included:

- chairing all the meetings of the Board of Directors (12 in 2022) and of the Committees of which he is a member (six meetings of the Appointments, Governance and CSR Committee, four meetings of the Strategy Committee and six meetings of the Scientific 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 appointment of Carole Ferrand, Emile Voest and Antoine Yver, to explain to them how the Board operates and answer their questions, (ii) in connection with the evaluation of the Board's operating procedures, and (iii) on matters relating to the projects presented to the Board;
- regular meetings with the members of the Executive Committee;
- meetings with Sanofi employees;
- visits to subsidiaries of Sanofi;
- meetings with biotechs and medtechs;
- organizing two strategy seminars, in April and October 2022; and
- representing Sanofi at events or official meetings (in France and abroad) 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 2022, to discuss what Sanofi had achieved in 2021 and answer questions about the Company's latest news, future prospects and dividend policy.

Those tasks were carried out in coordination with the Chief Executive Officer.

Compensation awarded in respect of the 2022 financial year

On February 22, 2022, acting on a recommendation from the Compensation Committee, the Board of Directors determined the components of Serge Weinberg's compensation for the 2022 financial year, taking into account the nature of his duties and the level of his involvement in the work of the Board and in broader corporate governance matters.

For the 2022 financial year, Serge Weinberg's annual fixed compensation was €800,000, unchanged from 2021.

In line with our compensation policy for the Chairman of the Board, as approved by our shareholders at the Annual General Meeting of May 3, 2022, he did not receive any variable compensation and was not awarded any stock options or performance shares. He received no compensation for serving as a director, and no compensation from any company included in Sanofi's scope of consolidation within the meaning of Article L. 233-16 of the French Commercial Code.

The amount reported for benefits in kind (€7,740 in 2022) relates to a company car with a driver.

Serge Weinberg is not covered by the Sanofi defined-contribution pension plan.

Compensation, options and shares awarded to Serge Weinberg (table No. 1 of the AFEP-MEDEF Code)

(€)	2,022	2,021
Compensation awarded for the year (details provided in the following table)	807,740	807,740
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
Total	**807,740**	**807,740**

Compensation awarded to Serge Weinberg (table No. 2 of the AFEP-MEDEF Code)

	2022		2021	
(€)	Amounts due	Amounts paid	Amounts due	Amounts paid
Fixed compensation[(a)]	800,000	800,000	800,000	800,000
Annual variable compensation	N/A	N/A	N/A	N/A
Exceptional compensation	N/A	N/A	N/A	N/A
Compensation for serving as a director	N/A	N/A	N/A	N/A
Benefits in kind	7,740	7,740	7,740	7,740
Total	**807,740**	**807,740**	**807,740**	**807,740**

The amounts reported are gross amounts before taxes.
(a) Fixed compensation due in respect of a given year is paid during that year.

Compensation and benefits of all kinds paid during 2022 or awarded in respect of 2022 to Paul Hudson, Chief Executive Officer

Paul Hudson has served as Chief Executive Officer of Sanofi since September 1, 2019, and holds office for an indeterminate period.

Paul Hudson does not have a contract of employment with Sanofi, and receives no compensation from any company included in Sanofi's scope of consolidation within the meaning of Article L. 233-16 of the French Commercial Code.

Compensation awarded to Paul Hudson (table No. 1 of the AFEP-MEDEF Code)

(€)	2022	2021
Compensation awarded for the year (details provided in the following table)	3,750,797	5,731,332
Valuation of performance shares awarded during the year[(a)]	6,967,950	5,347,500
Total	**10,718,747**	**11,078,832**

(a) Weighting between (i) fair value determined using the Monte Carlo model and (ii) market price of Sanofi shares at the date of grant, adjusted for dividends expected during the vesting period.

The parameters used to calculate the valuations are market parameters available in the financial press.

Fixed and variable compensation awarded to Paul Hudson (table No. 2 of the AFEP-MEDEF Code)

	2022		2021	
(€)	Amounts due	Amounts paid	Amounts due	Amounts paid
Fixed compensation[(a)]	1,400,000	1,400,000	1,300,000 [(a)]	1,300,000
Annual variable compensation[(b)]	2,337,300	2,308,800	2,308,800	2,213,250
Cash bonus (sign-on bonus)[(b)]	N/A	2,013,534 [(d)]	2,013,534 [(c)]	2,011,750
Exceptional compensation	N/A	N/A	N/A	N/A
Compensation for serving as a director	N/A	N/A	N/A	N/A
Benefits in kind	13,497	8,998	8,998	8,998
Total	**3,750,797**	**5,731,332**	**5,631,332**	**5,533,998**

The amounts reported are gross amounts before taxes.
(a) Fixed compensation due in respect of a given year is paid during that year.
(b) 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.
(c) Cash bonus in respect of the 2020 financial year (First Tranche of the Phantom Stock Units plan), vesting of which was subject to performance conditions (see separate section below). Paul Hudson was awarded 25,000 Phantom Stock Units in respect of 2020. The amount mentioned corresponds to the final valuation of the 25,000 Phantom Stock Units, determined as of March 30, 2021 (the vesting date of the First Tranche).
(d) Cash bonus in respect of the 2021 financial year (Second Tranche of the Phantom Stock Units plan), vesting of which was subject to performance conditions (see separate section below). The Board meeting of February 22, 2022 formally noted the attainment level of the performance conditions, and the overall allocation rate. Paul Hudson was awarded 21,775 Phantom Stock Units in respect of 2021. The amount disclosed in this table represents the final valuation of the 21,775 Phantom Stock Units in respect of 2021 determined as of March 31, 2022 (the vesting date of the Second Tranche).

Fixed and variable compensation

On February 22, 2023, acting on a recommendation from the Compensation Committee, the Board of Directors determined the components of Paul Hudson's compensation for the 2022 financial year.

The Chief Executive Officer's annual compensation for 2022 comprises (i) annual fixed gross compensation of €1,400,000; and (ii) in line with our compensation policy for the Chief Executive Officer as approved by our shareholders at the Annual General Meeting of May 3, 2022, annual variable compensation in a range from 0% to 250% of his annual fixed compensation, with a target of 150%, and subject to both quantitative and qualitative criteria.

The objectives applicable to annual variable compensation are:

- 50% based on financial indicators (sales growth, BNI, FCF, BOI margin and growth of new assets, each accounting for one-fifth); and
- 50% based on specific individual objectives. For 2022, the individual objectives set by the Board were:
  - business transformation (15%) – quantitative and qualitative objective;
  - development pipeline (12.5%) – quantitative objective;
  - people and culture (7.5%) – quantitative and qualitative objective; and
  - CSR (15%) – quantitative and qualitative objective.

Overall, the quantitative element of the financial and individual objectives is in a range between 65% and 70%.

At the start of 2022, the Board established a precise matrix for determining each individual objective. For confidentiality reasons, the level of attainment required (target) for the quantitative criteria cannot be disclosed. To reflect shareholder expectations, Sanofi is from now on disclosing the content of the qualitative criteria. Those criteria are always assessed by reference to the performances of the leading global pharmaceutical companies.

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of February 22, 2023 reviewed the attainment level of each criterion and sub-criterion. The Board's conclusions are summarized in the table below.

Criterion	Type	Weight	Target/Maximum (as % of fixed compensation)	Attainment level	Comments	Payout (as % of fixed compensation)
Financial objectives						
Sales growth	Quantitative	10%	15% / 25%	114.25%	Confidential target, Performance above budget	17.14%
Business net income [(a)]	Quantitative	10%	15% / 25%	132.49%	Confidential target, Performance above budget	19.87%
Free cash flow	Quantitative	10%	15% / 25%	118.49%	Confidential target, Performance above budget	17.77%
Business operating income margin	Quantitative	10%	15% / 25%	102.0 %	Confidential target, Performance equal to budget	15.30%
Growth in new key assets	Quantitative	10%	15% / 25%	108.98%	Dupixent® and vaccines over budget, China under budget	16.35%

Criterion	Type	Weight	Target/Maximum (as % of fixed compensation)	Attainment level	Comments	Payout (as % of fixed compensation)
				Individual objectives		
Business Transformation	Quantitative/ Qualitative	15%	22.5% / 37.5%	100.50%	Specialty Care: • Dupixent® sales: performance above target (quantitative) • Market leadership achieved in the US for Dupixent® • On track to achieve pre-launch awareness goal on tolebrutinib • Strong external engagement with key stakeholders, including Key Opinion Leaders (KOLs)	22.61%
					Vaccines: • Completion of critical activities to finalize the creation of the mRNA Center of Excellence (CoE) and advance mRNA + lipid nanoparticle (LNP) technology and pipeline across vaccines and specialty care • Translate Bio integration completed with high retention rate of Translate Bio employees • Prelaunch of Beyfortus® (Nirsevimab) on track with key regulatory and commercial milestones achieved	
					General Medicines: • Drive growth of core assets almost at budget (quantitative), • Successful launch of Rezurock® in the US • New business models implemented in Europe, Eurasia, Africa and Indonesia in 2022 • Portfolio simplification, reaching 122 Product Families at year end, exceeding the 2022 target	
					CHC: • Acceleration on digital, e-commerce sales below budget (quantitative) • Carve-in: Deployment of standalone CHC with minimal business disruption (quantitative) • Shift in timelines for Cialis® and Tamiflu® switches due to ongoing discussions with FDA	
					Industrial Affairs: • IA transformation executed on plan • Dupixent® 2022 growth enabled by supply (quantitative) • Global launches: Enjaymo® successfully approved and launched, Olipudase successfully approved and launched, Rezurock® growth, ALTUVIIIO™ (Efanesoctocog alpha): US submission completed and on track to launch • Acceleration of IA performance through Digital: 4 pilot sites successfully launched for Sanofi Manufacturing System (SMS) 2.0	
					Digital: • Contribution to BOI above budget target due to value creation (quantitative) • Increase Health Care Provider engagement from digital: target met in all markets where digital solutions have been deployed • Completion of all major digital, data and technology foundations (harmonized enterprise governance / single source of truth) • Commercial deployments slightly ahead of schedule	

Criterion		Type	Weight	Target/Maximum (as % of fixed compensation)	Attainment level	Comments	Payout (as % of fixed compensation)
People & Culture		Quantitative/ Qualitative	7.5%	11.25% / 18.75%	98.00%	• Number of women recruited to positions at Level 5 and above - slightly below target (quantitative) • Strong progress in embedding Play to Win culture (engagement score increased) (quantitative) • Great progress in strengthening the succession pipeline for Key Value Driving Roles • New Employee Value Proposition built and launched in line with overall rebrand initiative in Q1 • Acceleration of the processes' simplification (above the original goal)	11.03%
CSR	Further reinforce and expand on the CSR agenda	Quantitative/ Qualitative	15%	22.5% / 37.5%	110.00%	• CO_2 emissions reduced by 3.8% above target (Scopes 1&2) (quantitative) • Leaders to citizens launched with completion of eLearning by senior leaders (quantitative) • Successful launch of the Global Health Unit (GHU) in July 2022: Launch of non-profit Impact brand for 30 medicines in low-income countries, first concrete investment in Dec 2022 • Reached 185K patients with Non-Communicable Diseases (NCDs) over target (quantitative)	24.75%
	Image and Reputation & Compliance					• Successful launch of Sanofi's ambition, purpose and brand identity (adoption of a single company ambition and a unifying purpose for all 4 GBUs, adoption of a single brand integrating Genzyme and Pasteur under One Sanofi)	
	Compliance / Ethics & Business Integrity					• Development of the new Code of Conduct	
Development pipeline		Quantitative	12.5%	18.75% / 31.25%	118.0%	• R&D (Pharma + Vaccines) has achieved above execution focused KPI : 22 entries into M1, 12 development candidates M2, 9 assets entered clinical trials (FIH), 6 Ph 3 studies have been initiated, 7 submissions have been completed • 14 approvals (vs 11 in 2021), among which are 2 NMEs (pharma) and 3 vaccines • Progress in R&D productivity • Reinforcement of the pipeline through Business Development or Acquisitions: 16 pharma and 6 vaccines partnerships signed, Acquisition and full integration of Amunix (pharma) and Origimm Bio (vaccines) • Modernization of our portfolio management solutions for long-term portfolio projections and simulations to support strategic decision and workforce planning	22.13%
Total			**100%**	**150% / 250%**	**111.30%**		**166.95%**

(a) For a definition, see "Item 5. Operating and Financial Review and Prospects – A.1.5. Business net income" in Sanofi's 2022 Annual Report on Form 20-F.

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of February 22, 2023 set Paul Hudson's variable compensation for 2022 at €2,337,300, equivalent to 166.95% of his fixed compensation.

Payment of Paul Hudson's variable compensation in respect of the 2022 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. 22-10-34 II of the French Commercial Code.

Phantom stock units

Having waived all equity-based compensation not yet vested when he left his previous employer, upon joining Sanofi, Paul Hudson was awarded on joining Sanofi a medium-term incentive plan providing for a cash bonus subject to continuous presence and performance conditions. Under the terms of the plan, which compensated for approximately 50% of the incentive plans that Paul Hudson waived, he was awarded Phantom Stock Units, the vesting of which was contingent on (i) his continuous presence and (ii) attainment of performance conditions, with the attainment level of those conditions to be determined for half of the award, i.e. 25,000 phantom stock units, as of March 30, 2021 (the "First Tranche") and for the other half of the award, i.e. 25,000 phantom stock units, as of March 31, 2022 (the "Second Tranche"). The cash bonuses corresponding to the 50,000 Phantom Stock Units were paid in 2021 (First Tranche) and 2022 (Second Tranche); the bonus for the Second Tranche amounted to €2,013,534. The main terms of the plan, including the performance conditions applicable to the Phantom Stock Units, are described on pages 114 to 116 of our 2021 Annual Report on Form 20-F.

Equity-based compensation

Using the authorizations granted by our shareholders via the 24th resolution at the Annual General Meeting of April 30, 2021, and acting on the recommendations of the Compensation Committee, the Board of Directors meeting of May 3, 2022 decided to award Paul Hudson 82,500 performance shares in respect of 2022. The valuation of that award as of May 3, 2022, determined in accordance with IFRS and incorporating a market-related condition, was €6,967,950, equivalent to 4.97 times his fixed compensation.

The entire amount of the award is contingent upon both internal criteria based upon BNI and FCF, and upon an external criterion based on improvement in TSR relative to that of a benchmark panel of twelve leading global pharmaceutical companies (plus Sanofi): Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd.

To align equity-based compensation on our medium-term performance, a three-year period (2022-2024) is used to measure performance.

The above criteria were selected because they align medium-term equity-based compensation on the strategy adopted by Sanofi.

The arrangements relating to these awards are as follows:

- the performance criterion based on BNI accounts for 50% of the award. That criterion corresponds to the ratio, at constant exchange rates, of actual BNI to budgeted BNI. It represents the average actual-to-budget ratio attained over the entire period. Budgeted BNI is derived from the budget as approved by the Board of Directors at the beginning of each financial year. The BNI 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 attainment level is less than 95%, the corresponding performance shares are forfeited.

BNI actual-to-budget attainment level ("B")	BNI allocation rate
If B < 95%	0%
If B = 95%	50%
If B is > 95% but < 98%	(50 + [(B - 95) x 16])%
If B is ≥ 98% but ≤ 105%	B%
If B is > 105% but < 110%	(105 + [(B - 105) x 3])%
If B is ≥ 110%	120%

- the FCF criterion accounts for 30% of the award. This criterion was selected because it is aligned with Sanofi's current strategic objectives, and is transparent both within and outside the company.

  The FCF criterion represents the average actual-to-budget FCF ratio attained over the entire period. The award is based on a target FCF, below which some or all of the performance shares are forfeited.

FCF actual-to-budget attainment level ("F")	FCF allocation rate
If F is ≤ 70%	0%
If F is > 70% but < 80%	[(F - 70) x 5]%
If F = 80%	50%
If F is > 80% but < 100%	(50 + [(F – 80) x 2.5])%
If F = 100%	100%
If F is > 100% but < 120%	F%
If F is ≥ 120%	120%

- The criterion based on the Total Shareholder Return ("TSR") Rank Improvement accounts for 20% of the award. It corresponds to the evolution in rank of Sanofi's TSR when compared to the TSR of peer companies included in a panel. The TSR corresponds to the trading price of Sanofi shares increased by the dividends per share during the measurement periods, without reinvestment. Sanofi TSR Rank Improvement is determined by comparing the Endpoint Sanofi TSR rank to the Baseline Sanofi TSR rank.
  - The Baseline Sanofi TSR is equal to the following formula: (average prices of 2021 – average prices of 2020 + dividends per share 2021) / average prices of 2020.
  - The Endpoint Sanofi TSR is equal to the following formula: (average prices of 2024 – average prices of 2021 + dividends per share 2022 to 2024) / average prices of 2021.

Our TSR is compared with the benchmark panel of twelve companies listed above, so as to determine the ranking of Sanofi within the panel. The number of performance shares vesting depends upon the improvement in our TSR ranking, as follows:

Sanofi's improvement in the rankings	TSR allocation rate
+3 or more	150%
+2	100%
+1	50%
No improvement	—%

Even if there is an improvement in Sanofi's TSR ranking based on the principles set out above, no TSR allocation can be made if Sanofi's ranking is below median TSR, defined as the performance of the company ranked 7th in the panel.

Paul Hudson is under an obligation to retain, until he ceases to hold office, a quantity of Sanofi shares equivalent to 50% of any gain (net of taxes and social contributions) arising on the vesting of his performance shares, calculated as of the date on which those shares vest.

In compliance with the AFEP-MEDEF Code and our Board Charter, Paul Hudson has undertaken to refrain from entering into speculative or hedging transactions, and so far as Sanofi is aware no hedging instruments have been contracted.

In the interests of transparency, we disclose below attainment levels and allocation rates for the most recent performance-linked equity-based compensation plans awarded to our Chief Executive Officer (bearing in mind that only the April 28, 2020 Plan applies to Paul Hudson, since this was the first plan he was awarded following his appointment in 2019):

	Attainment level			Allocation rate
	BNI	**ROA**	**TSR**	
May 2, 2018 plans	2018-2020: 100.7%	2018-2020: 87.9%	2018-2020: 0% (8th of 11)	2018-2020: 76.72% i.e. 168,784 stock options and 38,360 performance shares
	BNI	**FCF**	**TSR**	
April 30, 2019 plans	2019-2021: 101.99%	2019-2021: 127.67%	2018-2020: 50% (6th of 11)	2019-2021: 97.00% i.e. 213,400 stock options and 48,500 performance shares
April 28, 2020 plans	2020-2022: 103.27%	2020-2022: 117.67%	2020-2022: 0%	2020-2022: 86.94% i.e. 65,205 performance shares

Performance shares awarded to Paul Hudson in 2022 (table No. 6 of the AFEP-MEDEF Code)

Source	Plan date	Valuation of performance shares (€)	Number of performance shares awarded during the period	Vesting date	Availability date[a]	Performance conditions
Sanofi	05/03/2022	6,967,950	82,500	05/03/2025	05/03/2025	Yes

(a) Under the terms of our Board Charter, Paul Hudson is required to retain a quantity of shares corresponding to 50% of the capital gain arising on the vesting of the shares, net of the associated taxes and social contributions.

Each performance share awarded on May 3, 2022, was valued at €84.46, valuing the total benefit at €6,967,950.

The General Meeting of May 3, 2022 decided to restrict the number of performance shares that can be awarded to executive officers to 5% of the overall limit (1.5% of the share capital). The number of shares awarded to Paul Hudson in 2022 represents 0.43% of the total limit approved by that Meeting and 0.006% of our share capital at the date of grant.

Performance shares awarded to Paul Hudson which became available in 2022 (table No. 7 of the AFEP-MEDEF Code)

Because Paul Hudson took office on September 1, 2019, he was not awarded any performance shares prior to the 2020 financial year. Consequently, no performance shares became available to him in 2022.

Source	Plan date	Valuation of performance shares (€)	Number of performance shares awarded during the period	Vesting date	Availability date	Performance conditions
Sanofi	—	—	None	—	—	–

Because awards of stock options to our Chief Executive Officer are not permitted under our compensation policy, tables No.4 and No. 5 of the AFEP-MEDEF Code are not applicable.

Pension rights

Paul Hudson is entitled to benefits under the top-up defined-contribution pension plan introduced within Sanofi on January 1, 2020. Under the terms of the plan, the Chief Executive Officer receives (subject to attainment of a performance condition) an annual contribution of up to 25% of his reference compensation (annual fixed and variable compensation).

The performance condition for the vesting of pension rights is linked to the attainment of the performance criteria for 2022 variable compensation. The Board of Directors, at its meeting of February 22, 2023, ascertained whether that performance condition had been met, noting that the attainment level for the variable portion of Paul Hudson's compensation for the 2022 financial year was 111.30%, i.e. 166.95% of his fixed compensation.

The annual gross contribution is paid as follows:

- 50% as a gross insurance premium to the fund manager – the amount due to the fund manager with respect to 2022 is €467,162.50; and
- 50% to Paul Hudson, to indemnify him for the social security and tax charges for which he will become immediately liable. The amount due to Paul Hudson with respect to 2022 was set by the Board of Directors at its meeting of February 22, 2023 at €467,162.50.

Payment of those amounts is contingent on approval of the Chief Executive Officer's compensation package by the shareholders in an Ordinary General Meeting, on the terms stipulated in Article L. 22-10-34 II of the French Commercial Code.

Social welfare and health insurance

Paul Hudson 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 also benefits from an unemployment insurance scheme.

Benefits in kind

The benefits in kind received by Paul Hudson in 2022 were valued at €13,497, and correspond to a company car with a driver.

Pay ratio between compensation of executive officers and average/median compensation of Sanofi employees – changes in compensation of executive officers and employees relative to the performance of Sanofi

This information is disclosed in accordance with Article L. 22-10-9 6° of the French Commercial Code, further to the enactment of the "Pacte" law.

Explanations of calculation methods and of year-on-year changes in the executive pay ratio:

- the scope includes Sanofi SA (the parent company) and all of its direct and indirect subsidiaries located in France, and hence covers more than 80% of total payroll of permanent employees in France. No separate ratios are published for Sanofi SA (the parent company), as the low headcount at Sanofi SA means that such ratios would not be representative of our total headcount in France;
- the employee compensation used in the calculation is the full time equivalent (FTE) compensation of permanent employees with at least two financial years of uninterrupted employment;
- compensation includes fixed compensation awarded during the reference year, and variable compensation related to the previous year and paid during the reference year. All compensation amounts are gross amounts;
- in order to maintain consistency, we have excluded from the numerator (i) compensation items not included in the denominator and (ii) non-recurring compensation items. This applies in particular to accommodation expenses related to the relocation to France of the Chief Executive Officer (Paul Hudson) in 2020, and to expenses related to unemployment insurance;
- long term variable compensation: performance shares and stock options awarded during each reference year are valued at the date of grant in accordance with international financial reporting standards. The valuation of performance shares that include the Total Shareholder Return (TSR) performance condition incorporates market conditions where applicable. Awards are subject to a continuing employment condition (three years minimum) and to performance conditions. Consequently, the valuation at the date of grant is not necessarily indicative of the value of stock options and performance shares at the end of the vesting period, especially if the performance conditions are not met;

- since Olivier Brandicourt (our previous Chief Executive Officer) received the same number of stock options and performance shares each year from 2016 to 2019, fluctuations in the Sanofi share price had a significant impact on the pay ratio during this period;
- 2018 and 2019 figures have been restated for comparative purposes, to (i) exclude Sanofi's equity-accounted share of Regeneron's net profits (see note D.2. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F) and (ii) include the effects of IFRS 16;
- regular benchmarking reviews are conducted to ensure that the level of compensation awarded to our employees and CEO is competitive and consistent with pharmaceutical industry levels.

Comparison of compensation of Sanofi executive officers with employee compensation (parent company and all direct and indirect subsidiaries located in France)

Chief Executive Officer[(a)]	2018	2019	2020	2021	2022
Ratio versus average compensation	93.8	106.6	110.6	111.4	124.6
Change in %		13.6%	3.8%	0.7%	11.8%
Ratio versus median compensation	120.3	135.4	142.8	142.1	159.2
Change in %		12.5%	5.5%	-0.5%	12.0%

Chairman of the Board (Serge Weinberg)	2018	2019	2020	2021	2022
Ratio versus average compensation	9.2	9.2	10.0	10.1	9.4
Change in %		-0.1%	8.4%	1.7%	-7.3%
Ratio versus median compensation	11.8	11.7	12.9	12.9	12.0
Change in %		-1.1%	10.1%	0.5%	-7.1%

(a) 2019: Olivier Brandicourt left office on August 31. Paul Hudson was appointed as CEO on September 1, 2019.
2020: The 2020 CEO compensation includes Paul Hudson's 2020 fixed compensation (€1.3 million), his 2019 variable compensation as paid in 2020 and annualized (€1.95 million), and 75,000 performance shares awarded in 2020.

Based on full-time equivalent permanent employees of all Sanofi legal entities worldwide with at least two years of uninterrupted employment, the ratios for 2022 were as follows:

- CEO:
  - ratio versus average compensation: 136.9, and
  - ratio versus median compensation: 200.5;
- Chairman of the Board of Directors:
  - ratio versus average compensation: 10.34, and
  - ratio versus median compensation: 115.1.

These ratios were calculated on the basis of annualized basic compensation, variable compensation in respect of the previous year, and performance shares awarded during 2022, applying 2022 average exchange rates.

Annual change in compensation, company performance and average employee compensation (parent company and all direct and indirect subsidiaries located in France)

	2017	2018 vs 2017	2019 vs 2018 [a]	2020 vs 2019 [b]	2021 2020[c]	FY 2022 vs 2021
Chief Executive Officer (in € thousand)						
Compensation	9,916	7,213	8,200	8,958	8,870	10,690
Change in € thousand		(2,703)	987	758	(89)	1,820
Change in %		-27.26%	13.69%	9.25%	-0.99%	20.52%
Chairman of the Board (in € thousand)						
Compensation	708.35	708.36	708.19	807.72	807.74	807.74
Change in € thousand		0.01	(0.17)	99.52	0.02	—
Change in %		—%	-0.02%	14.05%	—%	—%
Average employee compensation on FTE basis (in € thousand)						
Compensation	77.40	76.87	76.93	80.97	79.59	85.83
Change in € thousand		(0.53)	0.06	4.03	(1.37)	6.23
Change in %		-0.69%	0.08%	5.24%	-1.69%	7.83 (c)
Business net income (in € million)						
Business net income	6,943	6,411	7,050	7,346	8,213	10,341
Change in € thousand		(532)	639	296	867	2,128
Change in %		-7.66%	9.97%	4.20%	11.80%	25.91%

(a) 2019: Olivier Brandicourt left office on August 31. Paul Hudson was appointed as CEO on September 1, 2019. His 2019 variable compensation, paid in 2020, has been annualized for the purpose of calculating the ratios.

(b) 2020: Paul Hudson took office on September 1, 2019. The 2020 CEO compensation includes Paul Hudson's 2020 fixed compensation (€1.3 million), his 2019 variable compensation paid in 2020 and annualized (€1,950 million), and 75,000 performance shares awarded in 2020.

(c) The change in average employee compensation in France between 2020 and 2021 was driven primarily by differences in the average compensation levels of employees who left the company versus those who joined.

Compensation and benefits of all kinds awarded to corporate officers in respect of 2023

Compensation and benefits of all kinds awarded to directors in respect of 2023

The amounts awarded to directors in respect of 2023 will be determined in accordance with the principles described above in "Compensation policy for directors", within the section entitled "Compensation policy for corporate officers".

Compensation and benefits of all kinds awarded in respect of 2023 to the Chairman of the Board of Directors

The components of the compensation awarded to the Chairman of the Board of Directors are described above in "Compensation policy for the Chairman of the Board of Directors", within the section entitled "Compensation policy for corporate officers".

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of February 22, 2023 determined the following components of compensation (i) for Serge Weinberg, for the period from January 1, 2023 to May 25, 2023, when his term of office will expire and (ii) for his successor, with effect from May 26, 2023:

- Serge Weinberg: annual fixed compensation of €800,000 (the same amount as for 2022); and
- his successor: annual fixed compensation of €880,000; see the explanations provided above in "Compensation policy for the the Board of Directors", within the section entitled "Compensation policy for corporate officers".

The Chairman of the Board of Directors does not receive any variable compensation, stock options or performance shares. In accordance with AMF recommendations, he does not receive any compensation (i) for serving as a director or (ii) from any company included in Sanofi's scope of consolidation within the meaning of Article L. 233-16 of the French Commercial Code.

Benefits in kind for 2023 comprise a company car with a driver.

Compensation and benefits of all kinds awarded in respect of 2023 to Paul Hudson, Chief Executive Officer

Fixed and variable compensation

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of February 22, 2023 determined the components of Paul Hudson's compensation for the 2023 financial year.

Paul Hudson's annual compensation comprises (i) annual fixed gross compensation of €1,400,000 (see the explanations provided under "Compensation policy for the Chief Executive Officer" in the section entitled "Compensation policy for corporate officers" above) and (ii) annual variable compensation in a range from 0% to 250% of his annual fixed compensation, with a target of 150%, and subject to both quantitative and qualitative criteria.

Those objectives are 50% based on financial indicators (sales growth, BNI, FCF, BOI margin, and growth of new assets, each accounting for 10%), and 50% based on specific individual objectives. The individual objectives for 2023 are shown below:

2023 individual objectives		**2022 individual objectives ***	
Business transformation *(CHC, Vaccines, General Medicines, Manufacturing & Supply, Digital & Information Systems, Specialty Care)*	15%	Business transformation	15%
People and Culture *(Diversity, Culture, Succession Pipeline, Simplification)*	7.5%	Organization and people	7.5%
Development pipeline *M1 (Lead selection), M2 (Candidate selection), First in Human, Pivotal Studies, Submissions, Approvals*	12.5%	Development pipeline	12.5%
CSR – *Enhancement and progress on CSR program: CO_2 emissions, Affordable Access, Development of Sanofi Global Health Unit (GHU)* – *Image & Reputation: ongoing rollout of new corporate branding),* – *Compliance/ Ethics & Business Integrity: launch of new Code of Conduct*	15%	CSR	15%

(*) For details of individual objectives for 2022 refer to "— Compensation and benefits of all kinds paid during 2022 or awarded in respect of 2022 to Paul Hudson, Chief Executive Officer" above.

Equity-based compensation

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of February 22, 2023 proposes awarding 82,500 performance shares to Paul Hudson in respect of 2023. In accordance with the AFEP-MEDEF Code, the entire award will be subject to criteria that are both internal (based on our BNI, FCF and CSR) and external (based on the improvement in TSR as compared with that of a panel of the 12 leading global pharmaceutical companies: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd.).

For the plan applicable to Executive Committee members, the TSR criterion is measured in relative terms (variation from the previous ranking). That variation (the "Sanofi TSR Rank Improvement") is determined by comparing the Endpoint Sanofi TSR Rank (established over a 3-year measurement period) to the Baseline Sanofi TSR Rank (established over a 1-year measurement period). TSR-linked awards would be 50% if the ranking improved by 1; 100% if it improved by 2; and 150% if it improved by 3. For the Chief Executive Officer, any TSR-linked payment will remain contingent on Sanofi achieving an Endpoint Rank greater than or equal to the median of the TSR panel.

With effect from the 2023 awards, the plan applicable to the Chief Executive Officer and top executives includes the following extra-financial criteria, both of which are quantitative and which count for 10% of the award:

1. Affordable Access: providing essential medicines to non-communicable disease patients through Sanofi Global Health.
2. Planet Care: Carbon Footprint Reduction, scope 1&2 (CO_2 emissions reduction vs 2019).

Following the introduction of the CSR criteria, the business net income criterion counts for 45%; the free cash flow criterion for 25%; and the TSR Rank Improvement criterion for 10% (unchanged). We will make details of the terms of the plan available to shareholders on the governance page of our corporate website (www.sanofi.com) in advance of the Annual General Meeting of May 25, 2023.

In accordance with the AFEP-MEDEF Code, Paul Hudson is bound by rules on insider trading that impose blackout periods, as contained in our Board Charter.

In accordance with the AFEP-MEDEF Code and with our Board Charter, Paul Hudson has undertaken not to engage in speculative or hedging transactions, and as far as the company as aware no hedging instruments have been contracted.

Service contracts

Neither we nor our subsidiaries have entered into service contracts with members of our Board of Directors or executive officers providing for any benefits.

Compensation and arrangements for other Executive Committee members

Compensation

The compensation of Executive Committee members other than the Chief Executive Officer is reviewed by the Compensation Committee, taking into consideration the practices of leading global pharmaceutical companies.

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 joint contribution of all Executive Committee members to Sanofi's performance.

For 2022, the variable component consisted of two elements:

- attainment of quantitative objectives (accounting for 50%) which are measured at consolidated level: sales growth 30%, ratio of BOI to net sales ("BOI margin") 35%, research and development outcomes 20%, and FCF 15%; 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 Sanofi's annual performance objectives; individual objectives; and the attainment of people objectives like gender parity in senior executive roles, individual career development plans, and transformation of the corporate culture to align with the "Play to Win" strategy.

In addition, Executive Committee members may be awarded performance shares.

For 2022, the total gross compensation paid and accrued in respect of members of the Executive Committee (excluding the Chief Executive Officer) was €17 million, including €8 million in fixed compensation.

A total of 189,887 performance shares were awarded in 2022 to members of the Executive Committee (excluding the award to the Chief Executive Officer). No stock options were awarded in 2022 to members of the Executive Committee or the Chief Executive Officer.

In compliance with the AFEP-MEDEF Code, these entire awards are contingent upon two internal criteria, based on BNI[(1)], FCF; and on an external criterion, based on TSR. Those criteria were selected because they align medium-term equity-based compensation with the strategy adopted by Sanofi. The Board believes that the performance conditions applied are good indicators of shareholder value creation in terms of the quality of investment decision and the commitment to deliver exacting financial results in a difficult economic environment.

The arrangements relating to these awards are as follows:

- the BNI performance criterion accounts for 50% of the award. This criterion corresponds to the ratio, at constant exchange rates, of actual BNI to budgeted BNI. It represents the average actual-to-budget ratio attained over the entire period. Budgeted BNI is derived from the budget as approved by the Board of Directors at the beginning of each financial year. The BNI 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 performance shares are forfeited.

BNI actual-to-budget attainment level ("B")	BNI allocation rate
If B is < 95%	0%
If B = 95%	50%
If B is > 95% but < 98%	(50 + [(B –95) x 16])%
If B is ≥ 98% but ≤ 105%	B%
If B is > 105% but < 110%	(105 + [(B –105) x 3])%
If B is ≥ 110%	120%

- the FCF criterion accounts for 30% of the award. It represents the average actual-to-budget ratio of FCF attained over the entire period. The award is based on a target FCF, below which some or all of our performance shares are forfeited.

FCF actual-to-budget attainment level ("F")	FCF allocation rate
If F is ≤ 70%	0%
If F is > 70% but < 80%	[(F – 70) x 5]%
If F = 80%	50%
If F is > 80% but < 100%	(50 + [(F – 80) x 2.5])%
If F = 100%	100%
If F is > 100% but < 120%	F%
If F is > 120%	120%

- The criterion based on the Total Shareholder Return ("TSR") Rank Improvement accounts for 20% of the award. It corresponds to the evolution in rank of Sanofi's TSR when compared to the TSR of peer companies included in a panel. The TSR corresponds to the trading price of Sanofi shares increased by the dividends per share during the measurement periods,

(1) Non-IFRS financial measure. For a definition, see "Item 5. – Operating and Financial Review and Prospects – Business Net Income".

without reinvestment. Sanofi TSR Rank Improvement is determined by comparing the Endpoint Sanofi TSR rank to the Baseline Sanofi TSR rank.

- The Baseline Sanofi TSR is equal to the following formula: (average prices of 2021 – average prices of 2020 + dividends per share 2021) / average prices of 2020
- The Endpoint Sanofi TSR is equal to the following formula: (average prices of 2024 – average prices of 2021 + dividends per share 2022 to 2024) / average prices of 2021

The TSR obtained will be compared with that of each of the companies in a panel of peers to generate a ranking that includes Sanofi and the 12 companies in the panel: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd;

- definitions:
  - median TSR ("M") is the performance of the company ranked seventh in the panel,
  - the upper bound ("H") is the arithmetical average of the performances of the panel companies ranked first, second and third, and
  - the intermediate level is calculated as M + [(H–M)/2];
- the TSR allocation rate will be calculated as follows based on Sanofi's ranking within the panel:
  - if Sanofi's TSR is below M, the TSR allocation rate will be 0%,
  - if Sanofi's TSR is M, the TSR allocation rate will be 50%,
  - if Sanofi's TSR is equal to the intermediate level, the TSR allocation rate will be 100%,
  - if Sanofi's TSR is ≥ H, the TSR allocation rate will be 150%, and
  - if Sanofi's TSR is above M but below H, the TSR allocation rate will be calculated using linear interpolation;
- with effect from the 2022 awards, for the plan applicable to members of the Executive Committee, the mechanism of the TSR criterion was modified as follows:
  - the TSR criterion is no longer measured in absolute value (ranking) but in relative terms (variation from the previous ranking). That variation (the "Sanofi TSR Rank Improvement") will be determined by comparing the Endpoint Sanofi TSR Rank (established over a 3-year measurement period) to the Baseline Sanofi TSR Rank (established over a 1-year measurement period). TSR-linked awards would be 50% if the ranking improved by 1, 100% if it improved by 2, and 150% if it improved by 3, and
  - a multiplier is applied that will uplift the number of performance shares vesting by 10% if (i) the maximum TSR allocation rate is attained and (ii) Sanofi ranks greater than or equal to the median for the TSR benchmark panel;
- the number of performance shares actually vesting depends on the overall allocation rate, which for the vesting period is the weighted average of the BNI allocation rate (50%), the FCF allocation rate (30%) and the TSR allocation rate for the vesting period (20%);
- 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 collective plan negotiated and approved by the Chief Executive Officer of Sanofi; (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; or (iv) death of the beneficiary.

Pension arrangements

The total amount accrued as of December 31, 2022 in respect of corporate pension plans for persons who have held an executive position during the year 2021 was €10 million. That amount includes an expense of €1 million recognized in profit or loss during 2022.

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 the Chief Executive Officer, see also "— B. Compensation — Compensation and arrangements for corporate officers" above.

Application of the AFEP-MEDEF Code

The AFEP-MEDEF Code requires us to report specifically on the application of its recommendations and if any of them have not been applied, explain why.

At the close of the Annual General Meeting of Sanofi shareholders held on May 3, 2022, a director representing employees was appointed as a member if the Compensation Committee. Consequently, Sanofi no longer diverges from the AFEP-MEDEF code on that point.

Currently, our departures from this Code are as follows:

Paragraph of the AFEP-MEDEF Code	Recommendation of the AFEP-MEDEF Code	Application by Sanofi
10.2 Evaluation of the Board of Directors	The evaluation has three objectives: • .../...; • measure the actual contribution of each director to the Board's work.	Actual individual contributions are assessed during formal evaluations conducted every three years with the help of a specialist consulting firm, the most recent of which took place at the end of 2021. More generally, 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 member or appointment as a Committee member. The Appointments, Governance and CSR Committee examined this point during its meeting of February 15, 2023 and plans to change the practice from 2023 towards an assessment of the individual contribution of directors.
24.4 Non-competition agreement	In any event, no benefit can be paid over the age of 65.	Under the compensation policy for our Chief Executive Officer, he undertakes in the event he leaves the Company 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 based on his fixed compensation effective on the day he ceases to hold office and the last individual variable compensation received prior to that date. The indemnity is payable in 12 monthly installments. However, the Board of Directors may decide at the time the Chief Executive Officer leaves office (regardless of his age) to release him from the non-compete undertaking for some or all of the 12-month period. In such a case, the non-compete indemnity would not be due for the period of time waived by the Company. The Board of Directors, acting on a recommendation of the Compensation Committee, decided not to alter the compensation policy and non-compete undertaking of the Chief Executive Officer such that his indemnity would not be payable after he reaches the age of 65, on the basis that this is out of line with the actual situation. In practice, many executive officers continue to work after they leave office, often in a consultancy role. Consequently, enforcing such a rule could deprive Sanofi of legal protection in the event that the Chief Executive Officer were to engage in a competing activity immediately after leaving the Company.

Activities of the Board of Directors in 2022

During 2022, the Board of Directors met 14 times (including strategy seminars), with an overall attendance rate among Board members of 95%. Individual attendance rates of serving directors varied between 86% 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: the statutory auditors, managers of our global support functions, and other company employees.

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; those issues are then submitted for a decision by the Board of Directors.

Since 2016, acting on a recommendation from the Appointments, Governance and CSR Committee, the Board has held at least two executive sessions (i.e. meetings held without the Chief Executive Officer present) per year. If the Chairman of the Board so decides, such sessions may also be held without the directors representing employees (or any other Sanofi employee) being present. The primary purpose of such sessions is to evaluate the way the Board and its Committees operate, discuss the performance of the Chief Executive Officer, and to debate succession planning. Two executive sessions each lasting an hour and a half were held in 2022, in February and December.

In 2022, the main activities of the Board of Directors related to the following issues:

Financial statements and financial management	• Review of the individual company and consolidated financial statements for the 2021 financial year and for the first half of 2022, review of the consolidated financial statements for the first three quarters of 2022, and review of draft press releases and presentations to analysts relating to the publication of those financial statements. • Review of forward-looking management documents. • Projected 2022 accounting close, presentation of 2023 budget, 2023-2025 financial forecasts. • Proposed dividend for 2021, in particular the proposal to distribute a dividend in kind in connection with the EUROAPI carve-out. • Delegation of authority to the Chief Executive Officer to issue bonds and guarantees. • Renewal of the share repurchase program. • Recording the amount of share capital, reducing the share capital through cancellation of treasury
Operations, strategy and risk management	• Drafting a new chapter in the Play to Win strategy. • Situation in Ukraine. • Alliances (Innovent, IGM). • EUROAPI project and the spin-off of EUROAPI. • Updates on Zantac® litigation. • Update on the agreement to transfer worldwide exclusive license rights for Libtayo® to Regeneron. • Update on Industrial Affairs (now Manufacturing and Supply). • Update on Digital. • Review of the minutes of the Strategy Committee and the Scientific Committee. • Update on risks, review of Sanofi's 2022 risk management activity report and risk profile analysis. • Review of acquisition projects. • Relocation of Sanofi's headquarters to 46, avenue de la Grande Armée, Paris 17th.
Appointments and governance	• Composition of the Board and its Committees: – proposal to renew the terms of office of Paul Hudson, Christophe Babule, Patrick Kron and Gilles Schnepp, and to appoint Carole Ferrand, Emile Voest and Antoine Yver as directors; at the 2022 Annual General Meeting; – appointment of Carole Ferrand to the Audit Committee, Barbara Lavernos to the Appointments, Governance and CSR Committee, Wolfgang Laux to the Compensation Committee, and Emile Voest and Antoine Yver to the Scientific Committee; and – implementation of the succession plan for the Chairman of the Board, and appointment of Frédéric Oudéa as a non-voting member of the Board. • Review of succession planning for the Chief Executive Officer. • Review of director independence. • Reviews of the Board of Directors' Management Report, the report on corporate governance, and the reports of the statutory auditors. • Adoption of the draft resolutions, the report of the Board of Directors on the resolutions, and the special reports on the awards of stock options and performance shares. • Annual evaluation of the work of the Board and its Committees. • Review of previously-approved related party agreements. • Update on the Action 2022 employee share ownership plan.

Compensation	• Determination of the compensation of corporate officers (note that the Board deliberates in executive session without the corporate officers present: the situation of the Chairman of the Board of Directors is dealt with first in his absence, and then the Chief Executive Officer's compensation is dealt with in the presence of the Chairman but with the Chief Executive Officer absent): – review of Paul Hudson's fixed compensation and determination of the objectives of his variable compensation for 2022; and – determination of the 2022 compensation of the Chairman of the Board of Directors. • Allocation of the amount of directors' compensation for 2021, and principles for allocating directors' compensation for 2022. • Review of the fixed and variable compensation of the Executive Committee for 2021 and 2022. • Adoption of the performance share plans for 2022, and determination of the fulfilment of performance conditions of previous equity-based compensation plans.
CSR	• Monitoring of progress on Sanofi's CSR strategy. • Monitoring of objectives for gender balance on executive bodies, and more generally of Sanofi's diversity policy. • Monitoring of Sanofi's equal pay and equal opportunity policy.

In addition, two strategy seminars were held, in April and October 2022, in which all members of the Executive Committee took part. The seminar gave directors an opportunity to address issues including:

- preparing the 2nd phase of the Play to Win strategy;
- research platforms;
- use of data and AI in decision-making;
- leadership in immunology and inflammation;
- update on oncology and alliance strategies;
- Play to Win culture within Sanofi;
- strategic planning and ambitions for each GBU; and
- our financial roadmap.

Activities of the Board Committees in 2022

Our Board of Directors is assisted in its deliberations and decisions by five specialist Committees (for a description of the remit of each Committee, refer to our Board Charter, provided as Exhibit 1.2 to this Annual Report on Form 20-F). Chairs 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 Chair of the Committee having a casting vote. Minutes are drafted, and approved by the Committee members.

The Chair 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.

Composition of the committees during the 2022 financial year:

Audit Committee

	Composition as of January 1, 2022	Composition as of December 31, 2022
Chair	Fabienne Lecorvaisier (independent director)	Fabienne Lecorvaisier (independent director)
Members	Diane Souza (independent director) Christophe Babule	Diane Souza (independent director) Christophe Babule Carole Ferrand (independent director)[(a)]
	Proportion of independent directors: 66% (2/3)	Proportion of independent directors: 75% (3/4)

(a) Carole Ferrand was appointed a member of the Audit Committee by decision of the Board of Directors on May 3, 2022.

Appointments, Governance and CSR Committee

	Composition as of January 1, 2022	Composition as of December 31, 2022
Chair	Gilles Schnepp (independent director)	Gilles Schnepp (independent director)
Members	Serge Weinberg Patrick Kron (independent director) Melanie Lee (independent director) Lise Kingo (independent director)	Serge Weinberg Patrick Kron (independent director) Lise Kingo (independent director) Barbara Lavernos[(a)]
	Proportion of independent directors: 80% (4/5)	Proportion of independent directors: 60% (3/5)

(a) Barbara Lavernos was appointed a member of the Appointments, Governance and CSR Committee by decision of the Board of Directors on May 3, 2022.

Compensation Committee

	Composition as of January 1, 2022	Composition as of December 31, 2022
Chair	Patrick Kron (independent director)	Patrick Kron (independent director)
Members	Carole Piwnica (independent director) Diane Souza (independent director) Rachel Duan (independent director)	Wolfgang Laux[(a)] Diane Souza (independent director) Rachel Duan (independent director)
	Proportion of independent directors: 100% (4/4)	Proportion of independent directors: 75% (3/4)

(a) Wolfgang Laux was appointed a member of the Compensation Committee by decision of the Board of Directors on May 3, 2022.

Strategy Committee

	Composition as of January 1, 2022	Composition as of December 31, 2022
Chair	Serge Weinberg	Serge Weinberg
Members	Paul Hudson Patrick Kron (independent director) Gilles Schnepp (independent director)	Paul Hudson Patrick Kron (independent director) Gilles Schnepp (independent director)
	Proportion of independent directors: 50% (2/4)	Proportion of independent directors: 50% (2/4)

Scientific Committee

	Composition as of January 1, 2022	Composition as of December 31, 2022
Chair	Thomas Südhof (independent director)	Thomas Südhof (independent director)
Members	Melanie Lee (independent director) Serge Weinberg	Emile Voest (independent director)[(a)] Antoine Yver (independent director)[(a)] Serge Weinberg
	Proportion of independent directors: 66% (2/3)	Proportion of independent directors: 75% (3/4)

(a) Emile Voest and Antoine Yver were appointed as members of the Scientific Committee by decision of the Board of Directors on May 3, 2022.

Audit Committee

Three of the four members of the Audit Committee (Fabienne Lecorvaisier, Diane Souza and Carole Ferrand) qualify as independent pursuant to the criteria adopted by the Board of Directors. All three members have financial or accounting expertise as a consequence of their training and professional experience, and all are deemed to be financial experts as defined by the Sarbanes-Oxley Act and by Article L. 823-19 of the French Commercial Code. See "Item 16A. Audit Committee Financial Expert".

The Audit Committee met seven times in 2022, 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.

The Committee members had an exemplary attendance record, with an overall attendance rate of 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 1 and July 26, 2022, respectively. The Committee meets regularly with the statutory auditors without management present.

The Chairman of the Committee also meets regularly with certain members of management, in particular the heads of Internal Audit, Risk Management and Ethics/Compliance.

In 2021, the main activities of the Audit Committee related to:

Financial position	• Preliminary review of the individual company and consolidated financial statements for the 2021 financial year, review of the individual company and consolidated financial statements for the first half of 2022, review of the consolidated financial statements for the first three quarters of 2022, and review of draft press releases. • Analysis of gross sales relative to net sales, and contribution to improving gross margin. • Update on the EUROAPI project. • Sanofi's financial position, indebtedness and liquidity.
Internal audit, internal control and risk management	• Review of the work of the Internal Control function and evaluation of that work for 2021 as certified by the statutory auditors pursuant to Section 404 of the Sarbanes-Oxley Act, and examination of the 2021 Annual Report on Form 20-F. • Principal risks (risk management and risk profiles) facing Sanofi; Risk Committee report; review of whistleblowing and material compliance investigations; review of geopolitical risks arising from the conflict between Russia and Ukraine; review of tax risks and deferred tax assets, and changes in tax legislation; review of material litigation. • Conclusions of Sanofi senior management on internal control procedures and review of the Board of Directors' 2021 Management Report, in particular the description of risk factors in the Universal Registration Document. • Internal audit report and audit program for 2022. • Update on digital, including cybersecurity. • Update on the process for supervising outsourced activities. • Reporting on guarantees and endorsements.
Strategy and compensation	• Presentation of the 2023 budget. • Assessment of fulfilment of performance conditions of the 2019 equity-based compensation plans.
Compliance, ethics and business integrity, and CSR	• Update on the data protection compliance program. • Presentation of the new 2026 Ethics & Business Integrity strategy. • Review of the European Green Taxonomy indicators.
Relations with the statutory auditors	• Tendering process for a new statutory auditor from 2024, when the term of office of Ernst & Young expires. • Audit engagement and fees.

The Committee did not use external consultants in 2022.

Compensation Committee

Three of the four members of the Compensation Committee (i.e. 75%) are deemed to be independent.

The Compensation Committee met three times in 2021, 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 2022, the Compensation Committee dealt with the following issues:

Compensation of corporate officers	• Components of the compensation of corporate officers (Chief Executive Officer and Chairman of the Board). • Review of performance criteria applicable to the compensation of the Chief Executive Officer, in particular CSR criteria. • Consideration of potential CSR criteria to be applied to equity-based compensation starting from 2023, in conjunction with the Appointments, Governance and CSR Committee. • Allocation of the amount of directors' compensation for 2021, and review of the compensation policy applicable to directors. • Review of the disclosures about compensation contained in the corporate governance section of the 2021 French-language *Document d'enregistrement universel* and the Annual Report on Form 20-F, and of equal pay ratios. • Review of the draft resolutions to be submitted to the Annual General Meeting of May 13, 2022. • Governance roadshow campaign arranged for the main investors in Sanofi, and an analysis of the policies adopted by proxy advisors. • Compensation for the non-voting member of the Board.
Equity-based compensation	• Review of the equity-based compensation policy consisting of performance shares, including consideration of the introduction of a CSR-based criterion. • Implementation of share-based compensation plans awarded in previous years (level of attainment of performance conditions for 2019 plans. • Status report on awards of performance shares, and proposal for off-cycle awards.
Employee share ownership plan	• Status report and analysis on 2022 employee share ownership plan. • Consideration of next employee share ownership plan, and implementation of Plan Action 2023.
Compensation of Executive Committee members	• Monitoring of fixed and variable remuneration of Executive Committee members in 2021 and 2022. • New SEC rules on clawback clauses.

The Committee did not use external consultants in 2022.

Appointments, Governance and CSR Committee

Three of the five members of the Committee are deemed to be independent.

The Committee met six times in 2022, with an overall attendance rate of 97%.

In 2022, the Appointments, Governance and CSR Committee dealt with the following issues:

Appointments	• Succession planning for the Chairman, the Chief Executive Officer and the Executive Committee. • Changes in the composition of the Board and its Committees. • Review of expiring terms of office, and appointment of directors. • Implementation of the process for onboarding the future Chairman, short-listing of candidates, and recommendation to appoint Frédéric Oudéa as a non-voting member of the Board.
Corporate governance	• Annual evaluation of the work of the Board and its Committees. • Review of director independence. • Review of the Management Report and the corporate governance section of the 2021 French-language *Document d'enregistrement universel* and the Annual Report on Form 20-F. • The governance roadshow campaign arranged for the main investors in Sanofi, and an analysis of the policies adopted by proxy advisors.
CSR	• Update on the four pillars of Sanofi's CSR strategy: – Ensuring Affordable Access to Healthcare; – Innovating for Unmet Needs; – Planet Care; and – Building an Inclusive Workplace. • Update on extra-financial ratings. • Equity-based compensation plans (consideration of potential CSR criteria to be applied to equity-based compensation from 2023, in conjunction with the Compensation Committee).

The Committee used external consultants in 2022.

Strategy Committee

Two of the four members of the Strategy Committee are deemed to be independent: Patrick Kron and Gilles Schnepp.

The Strategy Committee met four times in 2022.

The Committee members had an exemplary attendance record, with an overall attendance rate of 100%.

In 2022, the main activities of the Strategy Committee related to:

- report on the Bioverativ and Ablynx acquisitions;
- transfer to Regeneron of the exclusive license rights to Libtayo®;
- divestment and acquisition proposals, and business development priorities;
- opening of the next chapter in the the Play to Win strategy; and
- opportunities for alliances.

The Committee did not use external consultants in 2022.

Scientific Committee

Three of the four members of the Scientific Committee are deemed to be independent. The Committee's main roles are to:

- assist the Board in scrutinizing the strategic orientation and investments proposed by senior management from a scientific standpoint;
- identify and discuss emerging trends and new challenges in science and technology, and ensure that Sanofi is as well prepared as possible to meet those challenges;
- ensure that processes are in place to enable optimal decision-making on investments in R&D, consistent with the strategy determined by the Board; and
- review and evaluate the quality of Sanofi's scientific expertise, and advise the Board accordingly.

The Committee met six times in 2022, with a 100% attendance rate.

In 2022, the Committee dealt with the following issues:

- third-party analysis of the development portfolio and its key assets;
- Immunology and Inflammation;
- oncology;
- chemistry, manufacturing, and controls (CMC);
- neurology; and
- organization of R&D.

The Committee used external consultants in 2022.

Attendance rate of Board members

Director	Attendance rate at Board meetings	Attendance rate at Committee meetings	
Serge Weinberg, Chairman of the Board	100%	100%	
Paul Hudson, Chief Executive Officer	100%	100%	
Christophe Babule	93%	100%	
Rachel Duan	100%	100%	
Carole Ferrand [(a)]	100%	100%	[(b)]
Lise Kingo	100%	100%	
Patrick Kron	93%	92%	
Wolfgang Laux	100%	100%	[(c)]
Barbara Lavernos	93%	100%	[(d)]
Fabienne Lecorvaisier	86%	100%	
Melanie Lee [(e)]	60%	100%	
Carole Piwnica [(e)]	80%	100%	
Gilles Schnepp	100%	100%	
Diane Souza	100%	100%	
Thomas Südhof	100%	100%	
Yann Tran	100%	—%	
Emile Voest [(a)]	100%	100%	[(f)]
Antoine Yver [(a)]	100%	100%	[(f)]
Frédéric Oudéa [(g)]	100%	100%	

Average attendance rate at Board meetings	Average attendance rate at Committee meetings
95 %	**99.5 %**

(a) Carole Ferrand, Emile Voest and Antoine Yver joined the Board during 2022.
(b) Carole Ferrand joined the Audit Committee in May 2022 and attended all three meetings held after her appointment.
(c) Wolfgang Laux joined the Compensation Committee in May 2022 and attended both of the meetings held after his appointment.
(d) Barbara Lavernos joined the Appointments, Governance and CSR Committee in May 2022 and attended all five meetings meetings held after her appointment.
(e) Melanie Lee and Carole Piwnica left the Board during 2022.
(f) Emile Voest and Antoine Yver joined the Scientific Committee in May 2022 and attended both of the meetings held after their appointment.
(g) Frédéric Oudéa joined the Board of Directors as a non-voting Board member in September 2022.

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).

D. Employees

Number of Employees

In 2022, Sanofi employed 91,573,442 people worldwide, 3,869 fewer than in 2021. The tables below give a breakdown of employees by geographical area and function as of December 31, 2022, 2021 and 2020.

Employees by Geographical Area

	As of December 31,					
	2022	%	2021	%	2020	%
Europe	35,815	39.1%	47,039	49.3%	46,761	47.0%
United States	12,444	13.6%	13,030	13.7%	12,972	13.0%
Rest of the World	43,314	47.3%	35,373	37.1%	39,679	39.9%
Total	**91,573**	**100.0%**	**95,442**	**100.0%**	**99,412**	**100.0%**

Employees by Function

	As of December 31,			
	2022	2021	2020	2019
Sales Force	19,613	21,113	25,203	26,178
Research and Development	16,487	16,223	15,446	15,538
Production	34,310	37,431	37,935	37,873
Marketing and Support Functions	21,163	20,675	20,828	20,820
Total	**91,573**	**95,442**	**99,412**	**100,409**

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 conventions 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 schemes

Voluntary schemes *(intéressement des salariés)* 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 2022 in respect of the voluntary scheme for the year ended December 31, 2021 represented 2.53% of total payroll.

Sanofi did not distribute any profit-sharing in 2021 under voluntary schemes in respect of the 2020 financial year, as the special profit-sharing reserve exceeded the maximum amount, as determined by application of the criteria defined by the profit-sharing agreement.

In April 2020, we entered into a new fixed-term statutory profit-sharing agreement for the 2020, 2021 and 2022 financial years, which 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) BOI margin. For each of those criteria, a matrix determines what percentage of total payroll is to be allocated to the scheme. An additional sum may be distributed, based on a CSR-related performance condition reflecting progress in environmental matters (reduction in greenhouse gas emissions) and capped at 0.5% of total payroll.

This overall allocation is 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 equals or exceeds the maximum amount determined under the specified criteria, in which case no profit share is paid to the employees.

Statutory scheme

The statutory scheme *(participation des salariés aux résultats de l'entreprise)* is a French legal obligation for companies with more than 50 employees that made a profit in the previous financial year.

The amount distributed by our French companies during 2022 in respect of the statutory scheme for the year ended December 31, 2021 represented 8.52% 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 received 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 2022, 89.1% of the employees who benefited from the profit-sharing schemes opted to invest in the collective savings scheme, and nearly 80.3% 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 2022, €143.4 million and €60.1 million were invested in the collective savings scheme and the collective retirement savings scheme respectively through the voluntary and statutory schemes for 2021, and through top-up contributions.

Employee share ownership

As of December 31, 2022, shares held under the collective savings scheme or in registered form by employees of Sanofi, employees of related companies and former employees amounted to 2.05% 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.

Existing Option Plans as of December 31, 2022

In 2019, the Board of Directors reviewed Sanofi's compensation policy and decided that stock options would no longer be awarded from 2020 onwards. That decision was taken to standardize the terms of equity-based compensation awards within Sanofi, and in response to feedback from some shareholders and proxy advisors who had concerns about stock options given their dilutive effect and potential unintended consequences.

Share Purchase Option Plans

As of December 31, 2022 there were no stock purchase option plans outstanding.

Share Subscription Option Plans

Source	Date of shareholder authorization	Date of grant	Total number of options granted	to corporate officers[a]	to the 10 employees awarded the most options[b]	Start date of exercise period	Expiry date	Exercise price (€)	Number of shares subscribed as of 12/31/2022	Number of options canceled as of 12/31/2022[c]	Number of options outstanding
Sanofi	May 6, 2011	March 5, 2012	574,050	—	274,500	March 6, 2016	March 5, 2022	56.44	478,107	95,943	—
Sanofi	May 6, 2011	March 5, 2012	240,000	240,000	—	March 6, 2016	March 5, 2022	56.44	204,720	35,280	—
Sanofi	May 6, 2011	March 5, 2013	548,725	—	261,000	March 6, 2017	March 5, 2023	72.19	361,571	109,065	78,089
Sanofi	May 6, 2011	March 5, 2013	240,000	240,000	—	March 6, 2017	March 5, 2023	72.19	175,920	64,080	—
Sanofi	May 3, 2013	March 5, 2014	769,250	—	364,500	March 6, 2018	March 5, 2024	73.48	354,023	102,625	312,602
Sanofi	May 3, 2013	March 5, 2014	240,000	240,000	—	March 6, 2018	March 5, 2024	73.48	—	46,560	193,440
Sanofi	May 3, 2013	June 24, 2015	12,500	—	12,500	June 25, 2019	June 24, 2025	89.38	1,500	8,500	2,500
Sanofi	May 3, 2013	June 24, 2015	202,500	—	202,500	June 25, 2019	June 24, 2025	89.38	45,000	—	157,500
Sanofi	May 3, 2013	June 24, 2015	220,000	220,000	—	June 25, 2019	June 24, 2025	89.38	—	41,536	178,464
Sanofi	May 4, 2016	May 4, 2016	17,750	—	17,750	May 5, 2020	May 4, 2026	75.9	4,500	9,750	3,500
Sanofi	May 4, 2016	May 4, 2016	165,000	—	165,000	May 5, 2020	May 4, 2026	75.9	82,500	—	82,500
Sanofi	May 4, 2016	May 4, 2016	220,000	220,000	—	May 5, 2020	May 4, 2026	75.9	—	41,250	178,750
Sanofi	May 10, 2017	May 10, 2017	158,040	—	157,140	May 11, 2021	May 10, 2027	88.97	22,754	44,276	91,010
Sanofi	May 10, 2017	May 10, 2017	220,000	220,000	—	May 11, 2021	May 10, 2027	88.97	—	42,570	177,430
Sanofi	May 2, 2018	May 2, 2018	220,000	220,000	—	May 3, 2022	May 2, 2028	65.84	—	51,216	168,784
Sanofi	April 30, 2019	April 30, 2019	220,000	220,000	—	May 2, 2023	April 30, 2029	76.71	—	6,600	213,400

(a) Comprises the Chief Executive Officer, and any Deputy Chief Executive Officers or members of the Management Board in office at the date of grant.
(b) In office at the date of grant.
(c) Includes 234,856 options cancelled due to partial non-fulfilment of performance conditions.

In 2022, 19,362 stock options were exercised by individuals who were Executive Committee members as of December 31, 2022. All of the plans involved post-date the creation of the Executive Committee: Sanofi plan of March 5, 2012, exercise price €56.44; and Sanofi plan of March 5, 2013, exercise price €72.19.

As of December 31, 2022, a total of 1,837,969 stock subscription options remained outstanding. As of the same date, 1,624,569 options were immediately exercisable.

Existing Performance Share Plans as of December 31, 2022

The Board of Directors awards 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 by the Board of Directors on the basis of a list submitted to the Compensation Committee. The Board of Directors sets terms of the awards, including continuing employment conditions and performance conditions (measured over three financial years).

The employee plans have a three-year vesting period, with no lock-up period.

At its meeting of May 3, 2022, the Board of Directors awarded a share performance plan, cascaded down into three sub-plans:

- a plan under which 459 beneficiaries classified as “Senior Executives” were awarded a total of 1,146,431 shares;
- a plan under which 1,869 beneficiaries not classified as “Senior Executives” were awarded a total of 2,000,627 shares;
- a plan under which 82,500 performance shares were awarded to the Chief Executive Officer.

Of the 7,277 beneficiaries, 48% were women.

At its meeting of December 14, 2022, the Board of Directors awarded a share performance plan, cascaded down into two sub-plans:

- a plan under which 16 beneficiaries classified as "Senior Executives" were awarded a total of 90,580 performance shares;
- a plan under which 6 beneficiaries not classified as "Senior Executives" were awarded a total of 10,335 performance shares.

Of those 22 beneficiaries, 55% were women.

The entirety of those awards is contingent upon criteria based on business net income (BNI) and free cash flow (FCF); in the case of employees classified as "Senior Executives", an additional criterion based on total shareholder return (TSR) is added, accounting for 20% of the total. Vesting is subject to a non-compete clause.

The number of shares awarded to the Chief Executive Officer in 2022 represents 0.4% of the total limit approved by our shareholders at the Annual General Meeting of April 30, 2021 (1.5% of our share capital) and 2.48% of the total amount awarded to all beneficiaries in 2022.

The 2022 awards represent a dilution of approximately 0.26% of our undiluted share capital as of December 31, 2022.

Not all of our employees were awarded performance shares, but a new voluntary profit-sharing agreement was signed in April 2020 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).

Performance Share Plans

Source	Date of shareholder authorization	Date of award	Total number of shares awarded	to corporate officers[a]	to the 10 employees awarded the most shares[b]	Start date of vesting period[c]	Vesting date	End of lock-up period	Number of shares vested as of 12/31/2022	Number of rights canceled as of 12/31/2022[d]	Number of shares not yet vested
Sanofi	April 30, 2019	April 30, 2019	50,000	50,000	—	April 30, 2019	May 1, 2022	May 2, 2022	48,500	1,500	0
Sanofi	April 30, 2019	April 30, 2019	1,243,434	—	142,541	April 30, 2019	May 1, 2022	May 2, 2022	1,176,358	67,076	—
Sanofi	April 30, 2019	April 30, 2019	2,504,148	—	219,990	April 30, 2019	May 1, 2022	May 2, 2022	1,841,498	662,650	—
Sanofi	April 30, 2019	April 28, 2020	75,000	75,000	—	April 28, 2020	May 1, 2023	May 2, 2023	—	—	75,000
Sanofi	April 30, 2019	April 28, 2020	328,113	—	120,951	April 28, 2020	May 1, 2023	May 2, 2023	0	45 118	282,995
Sanofi	April 30, 2019	April 28, 2020	400,495	—	151,761	April 28, 2020	May 1, 2023	May 2, 2023	—	116,832	283,663
Sanofi	April 30, 2019	April 28, 2020	753,720	—	19,027	April 28, 2020	May 1, 2023	May 2, 2023	285	32,820	720,615
Sanofi	April 30, 2019	April 28, 2020	1,783,173	—	26,542	April 28, 2020	May 1, 2023	May 2, 2023	559	394,855	1,387,759
Sanofi	April 30, 2019	October 28, 2020	73,027	—	73,027	October 28, 2020	October 29, 2023	October 30, 2023	—	5,878	67,149
Sanofi	April 30, 2021	April 30, 2021	1,614,023	—	19,407	April 30, 2021	May 1, 2024	May 1, 2024	447	233,035	1,380,541
Sanofi	April 30, 2021	April 30, 2021	701,824	—	163,877	April 30, 2021	May 1, 2024	May 1, 2024	—	108,906	592,918
Sanofi	April 30, 2021	April 30, 2021	595,878	—	10,918	April 30, 2021	May 1, 2024	May 1, 2024	—	27,090	568,788
Sanofi	April 30, 2021	April 30, 2021	497,695	—	150,339	April 30, 2021	May 1, 2024	May 1, 2024	—	30,932	466,763
Sanofi	April 30, 2021	April 30, 2021	75,000	75,000	—	April 30, 2021	May 1, 2024	May 1, 2024	—	—	75,000
Sanofi	April 30, 2021	October 27, 2021	13,521	—	13,521	October 27, 2021	October 28, 2024	October 28, 2024	—	—	13,521
Sanofi	April 30, 2021	May 3, 2022	2,000,627	—	25,882	May 3, 2022	May 3, 2025	May 4, 2025	—	70,060	1,930,567
Sanofi	April 30, 2021	May 3, 2022	1,146,431	—	192,542	May 3, 2022	May 3, 2025	May 4, 2025	—	53,552	1,092,879
Sanofi	April 30, 2021	May 3, 2022	82,500	82,500	—	May 3, 2022	May 3, 2025	May 4, 2025	—	—	82,500
Sanofi	April 30, 2021	Dec. 14, 2022	90,580	—	77,111	Dec. 14, 2022	Dec. 14, 2025	Dec. 15, 2025	—	—	90,580
Sanofi	April 30, 2021	Dec. 14, 2022	10,335	—	10,335	Dec. 14, 2022	Dec. 14, 2025	Dec. 15, 2025	—	—	10,335

(a) Comprises the Chairman & Chief Executive Officer, the Chief Executive Officer, and any Deputy Chief Executive Officers or members of the Management Board in office at the date of grant.

(b) In office at the date of grant.

(c) Subject to the conditions set.

(d) No rights were cancelled due to partial non-fulfilment of performance conditions.

As of December 31, 2021, 9,121,573 shares had not yet vested pending fulfilment of performance conditions.

During the year ended December 31, 2022, the ten employees (other than corporate officers) awarded the most shares were collectively awarded a total of 192,542 shares.

Shares Owned by Members of the Board of Directors

As of December 31, 2022, members of our Board of Directors held in the aggregate 23,831 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 Barbara Lavernos or Christophe Babule (who disclaim beneficial ownership of such shares).

Transactions in Shares by Members of the Board of Directors and Equivalent Persons in 2022

As far as Sanofi is aware, transactions in our securities carried out during 2022 by (i) Board members, (ii) executives with the power to make management decisions affecting our future development and corporate strategy and (iii) persons with close personal ties to such individuals (as per Article L. 621-18-2 of the French Monetary and Financial Code), were as follows:

- June 14, 2022: Wolfgang Laux, a director representing employees, sold 52 shares at a price of €94.54 per share;
- June 16, 2022: Wolfgang Laux acquired 10.71 units in the FCPE (employee share ownership fund) at a price of €93.33 per unit;
- June 23, 2022: Antoine Yver, director, acquired 1,000 American Depositary Receipts (ADRs) at a price of $50.34 per ADR;
- July 26, 2022: Wolfgang Laux subscribed 250 units in the FCPE at a price of €80.21 per unit;
- September 6, 2022: Carole Ferrand, director, acquired 1,000 shares at a price of €80.62 per share; and
- September 23, 2022: Frédéric Oudéa, non-voting Board member, acquired 320 shares at a price of €79.51 per share and 180 shares at a price of €78.59 per share.

F. Disclosure of action to recover erroneously awarded compensation

N/A

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The table below shows the ownership of our shares as of January 31, 2023, 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)[d]		Theoretical number of voting rights (including treasury shares)[e]	
	Number	%	Number	%	Number	%
L'Oréal	118,227,307	9.38	236,454,614	16.81	236,454,614	16.67
BlackRock[a]	89,036,452	7.06	89,036,452	6.33	89,036,452	6.28
Employees[b]	25,384,441	2.01	55,766,082	3.97	55,766,082	3.93
Public	1,015,992,138	80.58	1,025,036,142	72.89	1,025,036,142	72.26
Treasury shares[c]	12,195,470	0.97	—	—	12,195,470	0.86
Total	**1,260,835,808**	**100**	**1,406,293,290**	**100**	**1,418,488,760**	**100**

(a) Based on BlackRock's declaration dated January 31, 2023.
(b) Shares held through the Group Saving Plan and shares held directly by present employees.
(c) Number of shares repurchased as of January 31, 2023 under the share repurchase program in force.
(d) Based on the total number of voting rights as of January 31, 2023.
(e) Based on the total number of voting rights as of January 31, 2023 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, 2022 we received several share ownership declarations informing us that a legal threshold had been passed, as required under Article L. 233-7 of the French Commercial Code.

Dodge & Cox, acting on behalf of its clients and funds under its management, declared that on June 22, 2022 it had passed below the 5% threshold in terms of share capital, and holds, on behalf of its clients and funds, 4.96% of the share capital and 4.42% of the voting rights.

Dodge & Cox, acting on behalf of its clients and funds under its management, declared that on October 14, 2022 it had passed above the 5% threshold in terms of voting rights, and holds, on behalf of its clients and funds, 5.01% of the share capital and 4.45% of the voting rights.

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 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 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 specified threshold, if their direct or indirect holding passes below any of the aforementioned thresholds.

Since January 1, 2023 Sanofi has only received share ownership declarations of statutory threshold.

As of December 31, 2022, 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 7.85% of our share capital. Institutional shareholders (excluding L'Oréal) held approximately 77.35% of our share capital. Such shareholders are primarily American (32.44%), French (11.19%) and British (13.75%). German institutions held 4.18% of our share capital, Swiss institutions held 2.17%, institutions from other European countries held 2.04% and Canadian institutions held 1.63% of our share capital. Other international institutional investors (excluding those from Europe and North America) held approximately 1.19% of our share capital. In France, our home country, we have 10,440 identified shareholders of record. In the United States, our host country, we have 54 identified shareholders of record and 18,471 identified ADS holders of record.

(Source: analysis performed by NASDAQ as of December 31, 2022, 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

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, 2022, 2021 and 2020 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, 2018, 2019, 2020 and 2021 and our shareholders will be asked to approve the payment of an annual dividend of 3.56 per share for the 2022 fiscal year at our next annual shareholders' meeting. If approved, this dividend will be paid on June 1, 2023.

We expect that we will continue to pay regular dividends based on our financial condition and results of operations. The proposed 2022 dividend equates to a distribution of 43.1% of our business net income. For information on the non-IFRS 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 2018, 2019, 2020 and 2021 fiscal years and the dividend that will be proposed for approval by our shareholders in respect of the 2022 fiscal year at our May 25, 2023 shareholders' meeting.

	2022 [(a)]	2021	2020	2019	2018
Dividend per Share (€)	3.56	3.33 [(c)]	3.2	3.15	2.96
Dividend per Share ($)[(b)]	3.91	3.53	3.52	3.63	3.12

(a) Proposal, subject to shareholder approval.
(b) Based on the relevant year-end exchange rate.
(c) And a dividend in kind of EUROAPI shares, at a ratio of one EUROAPI share per 23 Sanofi shares.

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 engages in limited business activities with Iran related to human health products – namely, sales of bulk and branded pharmaceuticals and vaccines. These activities, which are disclosed pursuant to Section 13(r) of the United States Exchange Act of 1934, as amended, are not financially material to Sanofi and contributed well under 1% of Sanofi's consolidated net sales in 2022.

Sanofi's US affiliates and non-US affiliates owned or controlled by Sanofi's US affiliates either do not engage in Iran-related activities or act under licenses issued by the US Department of the Treasury's Office of Foreign Assets Control (OFAC).

Sanofi and certain non-US Sanofi affiliates engage in limited business activities that neither are expressly authorized by OFAC nor require such authorization.

In 2016, Sanofi and the Iran Food and Drug Administration (IFDA), an entity affiliated with the Iranian Ministry of Health and Medical Education, 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 and Medical Education 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. In 2022, activities conducted under the MOC did not generate any revenue or net profits.

Certain non-US Sanofi affiliates engage in limited business with Iranian counterparties associated with the Iranian Ministry of Health, such as public hospitals or distributors. In 2022, those business activities generated approximately €28.2 million in gross revenue and contributed no more than €7.6 million in net profits.

Finally, a representative office in Tehran incurs incidental expenses from state-owned utilities.

Sanofi believes that it and its affiliates' activities are compliant with applicable law, and in light of the nature of the activities concerned, Sanofi and its affiliates intend to continue their ongoing 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 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.

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.

From 2017 through 2022, several government agencies issued Civil Investigative Demands (CIDs) or other discovery requests calling for the production of documents and information relating to Sanofi's trade and pricing practices for its insulin products and/or Lantus®-related litigation. Sanofi US is cooperating with each of the previously reported investigations, (including those by the State Attorney General's offices in Washington, California, New York, Colorado and Vermont); none of which has been closed. In addition, Sanofi US is cooperating with investigations initiated by the US Federal Trade Commission in June of 2022, by the Texas State Attorney General's office in August 2022, and by the Ohio Attorney General's office in October 2022.

In September 2019, Sanofi US received a Civil Investigative Demand (CID) from the US Department of Justice concerning Dupixent®, Kevzara®, Praluent® and Zaltrap®. In June 2021, the government declined to intervene in the underlying complaint which was filed in November 2018. The government investigation into this matter is now closed. Relators, however, filed their First Amended Complaint in October 2021 and Defendants filed motions to dismiss in January 2022.

In February 2020, Genzyme Corporation received a CID from the US Department of Justice. The CID requests documents and information relating to Genzyme Corporation's payments made to vendors or developers of electronic health record technology. Genzyme Corporation is cooperating with this investigation.

In October 2022, Sanofi US received a CID from the Ohio State Attorney General's office, seeking documents and information about the pricing, sale, and distribution of pharmaceuticals and pharmacy benefit manager services in the State of Ohio. Sanofi US is cooperating with this investigation.

Insulin Related Litigation

In December 2016 and January 2017, two putative class actions were filed against Sanofi US and Sanofi GmbH in the US Federal Court in Massachusetts on behalf of direct purchasers of Lantus® alleging certain antitrust violations. Sanofi GmbH was later dismissed from the actions. In January 2018, the Court dismissed Plaintiffs' consolidated amended complaint against Sanofi US. Plaintiffs appealed that order to the Court of Appeals for the First Circuit, which issued its decision on February 13, 2020 reversing and remanding to the district court. In January 2021, Sanofi-Aventis Puerto Rico, Inc. ("Sanofi PR") was added as a defendant. In October 2022, Plaintiffs informed Sanofi US and Sanofi PR that they would proceed via joinder rather than move for class certification. Consistent with the Court's joinder deadline, new plaintiffs moved to intervene on January 3, 2023.

There are a number of insulin-related litigation matters pending in the US federal and state courts. These include cases brought on behalf of putative classes of consumers, wholesale purchasers of insulin, and state and local governments. The cases, which have been filed against Sanofi US along with other insulin manufacturers and, in some cases, pharmacy benefit managers, challenge those entities' insulin pricing practices (including Sanofi's pricing practices for Lantus®, Apidra®, Toujeo® and/or Soliqua®). The suits allege some combination of: violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO Act"); violations of various state unfair/deceptive trade practices statutes, unjust enrichment, common-law fraud, and civil conspiracy. The status of these matters varies from initial motions to dismiss the complaints to active discovery.

B. Significant Changes

Updates to Note D.22.

N/A

Other Changes

On January 5, 2023, Sanofi announced that the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) has accepted the Biologics License Application (BLA) for nirsevimab for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in newborns and infants entering or during their first RSV season and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

On January 11, 2023, Sanofi Ventures announced an additional multi-year commitment from Sanofi, with an increase in capital to more than $750 million to the evergreen venture fund. In addition to serving as a financial partner to top-tier early-to-mid-stage portfolio companies, the fund supports future efforts for business development and M&A opportunities within Sanofi. The additional capital, confirmed by the executive committee, will also fuel the expansion and investment capacity of the Sanofi Ventures investment team on a global scale.

On January 30, 2023, the European Commission (EC) expanded the marketing authorization for Dupixent® (dupilumab) in the European Union (EU) to treat eosinophilic esophagitis (EoE) in adults and adolescents 12 years and older, weighing at least 40 kg, who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy. With this approval, Dupixent is the first and only targeted medicine specifically indicated to treat EoE in Europe and the U.S.

On February 13, 2023, Sanofi announced that Dr. John Reed, its Global Head of R&D, will be leaving the company to pursue a new opportunity outside Sanofi. The company warmly thanks Dr. Reed for his leadership over these last years. Since joining Sanofi in 2018, John has laid the foundation for the company's R&D transformation. He helped reshape Sanofi's discovery and development of therapeutics, focusing efforts on first and best in class medicines that have the potential to transform the practice of medicine and improve the lives of people with serious diseases, whilst managing the integration and development of new technology platforms and partnerships, and driving R&D productivity.

On February 23, 2023, the U.S. Food and Drug Administration (FDA) has approved ALTUVIIIO™ [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl], previously referred to as efanesoctocog alfa, a first-in-class, high-sustained factor VIII replacement therapy. ALTUVIIIO™ is indicated for routine prophylaxis and on-demand treatment to control bleeding episodes, as well as perioperative management (surgery) for adults and children with hemophilia A. ALTUVIIIO™ is the first and only hemophilia A treatment that delivers normal to near-normal factor activity levels (over 40%) for most of the week with once-weekly dosing, and significantly reduces bleeds compared to prior factor VIII prophylaxis.

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 Nasdaq Global Select Market, or Nasdaq.

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 Nasdaq under the symbol "SNY".

As of the date of this annual report, our shares are included in a large number of indexes, 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 included in European indexes, such as the EURO STOXX 50, STOXX Europe 600 index, FTSE Eurofirst 300, MSCI Europe, MSCI Pan Euro, Euronext 100, and STOXX Europe 600 Health Care. They are also included in American and international indexes, such as the NASDAQ Composite, NASDAQ Health Care, S&P Global 100, MSCI World, and MSCI World Pharmaceuticals, Biotechnology and Life Sciences.

Our shares are also part of the main extra-financial rating indices, taking into account environmental, social, and governance criteria (FTSE4Good, ATM index, STOXX® Global ESG Leaders, and EURO STOXX 50 Low Carbon).

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

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. The LEI number of the Company is 549300E9PC51EN656011.

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 approve 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 accordance with Article L. 22-10-8 of the French Commercial Code. Each such undertaking must be included in our compensation policy for corporate officers, which is submitted for approval by our shareholders at the Annual General Meeting in accordance with Article L. 22-10-8 II of the French Commercial Code. No such compensation or undertaking may be determined, awarded or paid unless in accordance with such compensation policy.

See "Item 6. Directors, Senior Management and Employees — B. Compensation" for a description of the process for establishing and authorizing such compensation policy.

Directors' compensation

The aggregate amount of compensation 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." Furthermore, under our Articles of Association, the Board of Directors may compensate any observers *(censeurs)* to the Board of Directors, which would reduce by the same amount the total annual compensation available for allocation to the Board of Directors.

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' Extraordinary 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 – A. Directors and Senior Management".

Directors' share ownership requirements

Pursuant to our Articles of Association, each director appointed by a Shareholders' Ordinary General Meeting must own at least 500 shares throughout their term of office. In addition, pursuant to the Board Charter, our Directors must within no more than two years from their appointment hold at least 1,000 Sanofi shares in their own name, which must be retained until they cease to hold office.

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;
- 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.

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.

Under our Articles of Association, the Board of Directors may take decisions by written consultation under the conditions permitted by law and as specified in the Board Charter (an English language version of which is reproduced in full as Exhibit 1.2 to this Annual Report on Form 20-F), including the possibility to convene an ordinary or extraordinary general meeting,

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;
- 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, 12:00 a.m. (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, the French Civil Code and our Articles of Association.

An attendance sheet and written minutes are established for each shareholders' meeting; failure to do so could lead to cancellation of the decisions at the shareholders' meeting.

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.

A proxy is only valid for one meeting (or by way of exception for two meetings, one being ordinary and the other extraordinary, held on the same day or within a single 15-day period); it remains valid in the event such meeting is convened multiple times for the same agenda, and may be revoked by written statement of the shareholder granting the proxy.

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.

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.

C. Material Contracts

N/A

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 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.*

No advance ruling has been obtained with respect to the tax consequences of the acquisition, ownership or disposition of the Securities from either the French or US tax authorities. Thus, there can no assurances that either or both of such authorities will not take a position concerning said tax consequences different from that set out herein or that such a position would not be sustained by a court.

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 created or organized in or under the laws of the United States or any state thereof, including the District of Columbia, or (iii) certain estates or trusts that are subject to US tax jurisdiction. 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 an estate or trust or 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, although our depositary has indicated that such transactions have been halted) 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 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 as of December 1 of the year preceding the taxation year. A list of companies whose market capitalization exceeds €1 billion 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-ANNX-000467-21/12/2022 issued on December 21, 2022, purchases of Sanofi's Securities in 2022 should be subject to the FTFF as the market capitalization of Sanofi exceeded €1 billion as of December 1, 2022. In accordance with Article 726-II-d 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 (i) 25% for payments benefiting legal persons who are not French tax residents (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-30-30-10-70-24/12/2019, No. 130), and (ii) 12.8% for payments benefiting individuals who are not French tax residents. 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 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 25% 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 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 2021 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 2022 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 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 depositary, 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

Item 11. Quantitative and Qualitative Disclosures about Market Risk[(1)]

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.

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 the notional amounts of the investments and the fair value of the hedging instruments, is monitored on a daily basis.

The table below shows our total exposure as of December 31, 2022 by rating and in terms of our percentage exposure to the dominant counterparty.

(€ million)	Cash and cash equivalents (excluding mutual funds) [(a)]	Notional amounts of currency hedges [(b)]	Fair value of currency hedges	Notional amounts of interest rate hedges [(b)]	Fair value of interest rate hedges	General corporate purpose credit facilities
AA	319	1,280	5	—	—	500
AA-	707	5,668	26	880	(65)	1,000
A+	655	9,237	57	774	(76)	3,500
A	290	4,585	20	437	(52)	2,000
A-	42	638	4	343	(38)	1,000
BBB+	—	—	—	—	—	—
Unallocated	166	—	—	—	—	—
Total	**2,179**	**21,408**	**113**	**2,434**	**(232)**	**8,000**
% / rating of dominant counterparty	30.0%/AA-	16.8%/A+		20.3%/A+		6%/A

(a) Cash equivalents include mutual fund investments of €9,537 million.
(b) The notional amounts are translated into euros at the relevant closing exchange rate as of December 31, 2022.

As of December 31, 2022, we held investments in euro and US dollar denominated money-market mutual funds. Those instruments have low volatility, low sensitivity to interest rate risk, and a very low probability of loss of principal. The depositary 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.

[(1)] *The disclosures in this section supplement those provided in Note B.8.7. 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.*

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 2022, for example, 42.5% of our net sales were generated in the United States; 23.3% in Europe; and 34.2% in the Rest of the World region (see the definition in "Item 5. Operating and Financial Review and Prospects — A/ Operating results), including countries that are, or may in the future become, subject to exchange controls, of which 7.3% was generated in China and 3.8% 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. Sanofi operates a foreign exchange risk hedging policy to reduce the exposure of operating income to exchange rate movements. That policy involves regular assessments of Sanofi's 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, Sanofi contracts hedges using liquid derivative instruments, mainly forward currency purchases and sales, and also foreign exchange swaps.

The table below shows operating currency hedging instruments in place as of December 31, 2022, 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, 2022).

Operating foreign exchange derivatives as of December 31, 2022

(€ million)	Notional amount	Fair value
Forward currency sales	**5,403**	**49**
of which US dollar	2,732	56
of which Chinese yuan renminbi	576	2
of which Japanese yen	240	(5)
of which Singapore dollar	180	1
of which Korean won	179	(14)
Forward currency purchases	**3,459**	**(27)**
of which US dollar	2,047	(21)
of which Singapore dollar	375	(7)
of which Chinese yuan renminbi	142	—
of which Korean won	130	4
of which Taiwan dollar	84	—
Total	**8,862**	**22**

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, 2022 and recognized in the balance sheet at that date. Gains and losses on hedging instruments (forward contracts) are 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 profit or loss on these items (hedging instruments and hedged transactions) will be immaterial in 2022.

B. Financial foreign exchange risk

The cash pooling arrangements for foreign subsidiaries outside the euro zone, and some of Sanofi's financing activities, expose certain Sanofi 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 using derivative instruments (foreign exchange swaps, forward contracts or currency swaps) that alter the currency split of Sanofi's net debt once those instruments are taken into account.

The table below shows financial currency hedging instruments in place as of December 31, 2022, 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, 2022).

Financial foreign exchange derivatives as of December 31, 2022

(€ million)	Notional amount		Fair value	Expiry
Forward currency sales	**7,559**		**66**	
of which US dollar	*6,114*	(a)	*59*	*2023*
of which Pound sterling	*384*		*7*	*2023*
of which Chinese yuan renminbi	*203*		*2*	*2023*
Forward currency purchases	**4,997**		**24**	
of which US dollar	*2,011*	(b) (c)	*(4)*	*2023*
of which Singapore dollar	*2,154*	(d)	*22*	*2023*
of which Japanese yen	*205*		*4*	*2023*
Total	**12,556**		**90**	

(a) Includes forward sales with a notional amount of $3,615 million expiring in 2023, designated as a hedge of Sanofi's net investment in Bioverativ. As of December 31, 2022, the fair value of these forward contracts represented an asset of €38 million; the opposite entry was recognized in "Other comprehensive income", with the impact on financial income and expense being immaterial.

(b) Includes forward purchases with a notional amount of $1,000 million expiring in 2023, designated as a fair value hedge of the exposure of $1,000 million of bond issues to fluctuations in the EUR/USD spot rate. As of December 31, 2022, the fair value of the contracts was an asset of €3 million, the opposite entry for €0.6 million of which was debited to "Other comprehensive income" under the cost of hedging accounting treatment.

(c) Includes receiver currency swaps with a notional amount of $1,000 million expiring in 2023, designated as a fair value hedge of the exposure of an equivalent amount of intragroup current accounts to fluctuations in the EUR/USD spot rate. As of December 31, 2022, the fair value of the swaps was a liability of €2 million, the opposite entry for €1.4 million of which was credited to "Other comprehensive income" under the cost of hedging accounting treatment.

(d) Includes forward purchases with a notional amount of SGD1,500 million expiring in 2023, designated as a fair value hedge of the exposure of an equivalent amount of intragroup current accounts to fluctuations in the EUR/SGD spot rate. As of December 31, 2022, the fair value of the contracts was an asset of €33 million, the opposite entry for €2.5 million of which was credited to "Other comprehensive income" under the cost of hedging accounting.

These hedging instruments generate a net financial 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. The interest rate differential is recognized within cost of net debt (see Note D.29. to our consolidated financial statements). 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.

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.

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.17.1.c. and D.17.1.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, 2022, cash and cash equivalents amounted to €12,736 million, and short-term investments predominantly comprised:

- collective investments in euro and US dollar denominated money-market mutual funds. 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.

In addition, to optimize the liquidity/return profile of our short-term investments, we had €196 million invested in term deposits as of December 31, 2022, expiring in June 2023 and presented within "Other current financial assets" (see Note D.11.).

As of December 31, 2022 we also had €8 billion of undrawn general corporate purpose confirmed credit facilities, half of which expires in December 2023 and half in December 2027. 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 Negotiable European Commercial Paper programs in France. The average maturity of our total debt was 4.71 years as of December 31, 2022, compared with 5.5 years as of December 31, 2021. During 2022, we did not draw down on our Negotiable European Commercial Paper programs in France. Average drawdowns under the US commercial paper program during 2022 were €2.2 billion (with a maximum of €3.8 billion); the average maturity of those drawdowns was two months. As of December 31, 2022, 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

Sanofi issues debt in two currencies, the euro and the US dollar, and also invests its cash and cash equivalents in those currencies. Sanofi also operates cash pooling arrangements to manage the surplus cash and short-term liquidity needs of foreign subsidiaries located outside the euro zone.

To optimize the cost of debt or reduce the volatility of debt and manage its exposure to financial foreign exchange risk, Sanofi uses derivative instruments (interest rate swaps, currency swaps, foreign exchange swaps and forward contracts) that alter the fixed/floating rate split and the currency split of its net debt.

The projected full-year sensitivity to interest rate fluctuations of our debt, net of cash and cash equivalents for 2023 is as follows:

Change in short-term interest rates	Impact on pre-tax net income (€ million)	Impact on pre-tax income/(expense) recognized directly in equity (€ million)
+100 bp	98	—
+25 bp	25	—
-25 bp	(25)	—
-100 bp	(98)	—

Stock market risk

It is our policy not to trade on the stock market for speculative purposes.

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 Second Amended and Restated Deposit Agreement between Sanofi and JPMorgan dated February 13, 2015, as amended by Amendment No. 1 dated July 23, 2020 ("Amendment No. 1"), and as may be further amended from time to time (together, the "deposit agreement"). The depositary's principal executive office is located at 383 Madison Avenue, 11th Floor, New York, New York 10179.

For additional information on our ADSs, please refer to Exhibit 2.2 "Description of Securities" of this Annual Report.

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	Depositary Action
$5.00 or less per 100 ADSs (or portion thereof)	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.
$0.05 or less per ADS (or portion thereof)	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.
$0.05 or less per ADS per calendar year (or portion thereof)	Services performed in administering the ADRs (which fee may be charged on a periodic basis during each calendar year)
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 US 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 that Sanofi incurs relating to the establishment and maintenance of the ADR program, as agreed from time to time. Pursuant to a letter agreement dated October 4, 2022 (the "letter agreement"), JPMorgan as our ADS depositary has agreed to make (i) an initial contribution to Sanofi, within 30 days of the commencement date of the letter agreement and (ii) with respect to each 12-month period beginning on the anniversary of the effective date of the agreement (each such 12-month period, a "Contract Year"), a contribution, paid at the end of such Contract Year quarter, equal to the aggregate of the program share (equal to 100% of routine program revenues and 50% of non-routine program revenues) of any program revenues, less the aggregate of any program costs for the applicable Contract Year and any invoiced supplementary costs not paid within 60 days of the date of the applicable invoice.

To the extent in any given Contract Year the depositary does not collect/recoup the entirety of the program costs and unpaid supplementary costs, no contribution shall be payable to Sanofi and such excess will, at the discretion of the depositary, either be deducted from future contributions or be payable to the depositary by Sanofi promptly upon invoicing as supplementary costs under the letter agreement.

JPMorgan has further agreed to waive the $0.05 per ADS issuance fees that would normally be owed by Sanofi in connection with our deposits of shares as part of our employee stock purchase plans. Sanofi is responsible for reimbursing JPMorgan for all taxes and governmental charges in connection with payments to JPMorgan under the letter agreement.

From January 1, 2022 to December 31, 2022, we received a total amount of $26,104,126.68 from JPMorgan pursuant to the letter agreement.

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, 2022 based on the framework in "Internal Control — Integrated Framework" (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

   Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2022 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 (PCAOB ID 1347) and Ernst & Young et Autres (PCAOB ID 1704) independent registered public accounting firms, as stated in their report on the Company's internal control over financial reporting as of December 31, 2022, 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 F-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.

Item 16A. Audit Committee Financial Expert

The Audit Committee is composed of Fabienne Lecorvaisier, Christophe Babule, Carole Ferrand and Diane Souza.

Our Board of Directors has determined that all directors are independent financial experts within the meaning of Section 407 of the Sarbanes-Oxley Act of 2002.

The Board of Directors deemed Fabienne Lecorvaisier to be a financial expert based on her education and 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 Sustainable Development, Public and International Affairs as well as the supervision of the Social Programs and the General Secretariat of Air Liquide Group.

The Board of Directors deemed Christophe Babule to be a financial expert based on his education and experience in audit and corporate finance in major corporations and as Executive Vice President and Chief Financial Officer of L'Oréal. He has also served as a director of L'Oréal US Inc.

The Board of Directors deemed Carole Ferrand to be a financial expert based on her education and experience in audit at PriceWaterhouseCoopers and as Chief Financial Officer of Sony France, EuropaCorp and Groupe Artémis. She is now Chief Financial Officer of Capgemini.

The Board of Directors deemed Diane Souza to be a financial expert based on her education (she is a certified public accountant) and experience in audit and tax in major international corporations, as Chief Financial Officer of Aetna's Guaranteed Products business, and as Chief Executive Officer of the UnitedHealthcare Specialty Benefits.

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 Fabienne Lecorvaisier, Carole Ferrand and Diane Souza 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 code of ethics (hereafter the "Code of conduct"), as defined in Item 16B. of Form 20-F under the Exchange Act, containing specific rules relating to financial ethics. Our Code of conduct 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 Code of conduct is available on our website at www.sanofi.com (information on our website is not incorporated by reference in this annual report). A copy of our Code of conduct 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 conduct 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

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In 2022, Sanofi made the following purchases of its ordinary shares.

Period	(A) Total Number of Shares Purchased	(B) Average Price Paid per Share	(C) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs[a]	(D) Approximate Value of Shares that May Yet Be Purchased Under the Plans or Programs[b]
January 2022	3,976,992	90.21	3,976,992	18,285
December 2022	1,510,000	90.62	1,510,000	18,817
Total	**5,486,992**			

(a) The Company was authorized to repurchase up to €18,884,575,950 of shares for a period of eighteen months (i.e., through October 30, 2022) by the Annual Shareholders' Meeting held on April 30, 2021. Then, the Company was authorized to repurchase up to €18,953,410,350 of shares for a period of eighteen months (i.e., through November 3, 2023) by the Annual Shareholders' Meeting held on May 3, 2022.

(b) Millions of euros.

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

The terms of office of Ernst & Young et Autres, joint statutory auditor of the Company since 1986, will expire expire at the end of the Annual Shareholders' Meeting called in 2024. Ernst & Young et Autres' terms of office could not be legally extended as they had reached the maximum legal duration.

The selection procedure of the auditors to be appointed by the Annual Shareholders' Meeting in 2024 was overseen by the Audit Committee, following which a recommendation to the Board of Directors was issued.

The Board of Directors, at its meeting of October 27, 2022 approved the Audit Committee's recommendation and decided to propose the appointment of Mazars as statutory auditor. Consequently, the Board of Directors will propose to the Annual Shareholders' Meeting to be held in 2024 to appoint Mazars as new joint statutory auditor for a 6-year term, i.e. until the Annual Shareholders' Meeting to be held in 2030, which will approve the financial statements for the year 2029.

The report of Ernst & Young et Autres on the consolidated financial statements for each of the years ended December 31, 2022 and 2021 did not contain an adverse opinion or a disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles. During each of the years ended December 31, 2022 and 2021:

- there were no "disagreements" (as that term is described in Item 16F.(a)(1)(iv) of the Instructions to Form 20-F and the instructions to Item 16F.) between Sanofi and Ernst & Young et Autres on any matters of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreement(s), if not resolved to Ernst & Young et Autres' satisfaction, would have caused Ernst & Young et Autres to make reference to the subject matter of the disagreement(s) in connection with its report; and
- there were no "reportable events" (as that term is defined in Item 16F.(a)(1)(v) of the Instructions to Form 20-F).

A copy of Ernst & Young et Autres' letter, dated February 24, 2023, is filed as Exhibit 23.1 to this Annual Report on Form 20-F.

Item 16G. Corporate Governance

Sanofi is incorporated under the laws of France, with securities listed on regulated public markets in the United States (Nasdaq Global Select Market - NASDAQ) and France (Euronext Paris). Consequently, as described further in this Annual Report on Form 20-F, 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.

As a "foreign private issuer," as defined in the rules promulgated under the US Securities Exchange Act of 1934, as amended, (the "Exchange Act"), Sanofi is permitted, pursuant to NASDAQ Listing Rule 5615(a)(3), to follow its home country practice in lieu of certain NASDAQ corporate governance requirements applicable to US corporations listed on the NASDAQ. Sanofi has informed NASDAQ that it intends to follow corporate governance standards under French law to the extent permitted by the NASDAQ listing rules and US securities laws, as further discussed below.

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 NASDAQ. Nevertheless, there are certain important differences.

In line with NASDAQ listing rules applicable to domestic issuers, a majority of Sanofi's Board of Directors is comprised of independent directors. Sanofi evaluates 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 – that Board members have no relationship of any kind whatsoever with the Company, its group or the management of either such as to color a Board member's judgment – is on the whole consistent with the goals of the NASDAQ's listing rules; however, the specific tests proposed under the two standards may vary on some points. Our Audit Committee complies with the independence and other requirements of Rule 10A-3 under the Exchange Act, adopted pursuant to the Sarbanes-Oxley Act of 2002. Our Audit Committee includes one member, Christophe Babule, who is considered non-independent under the AFEP-MEDEF Code, and which is permitted under the AFEP-MEDEF Code, although this would not be permitted under the listing rules of the NASDAQ for domestic issuers. Three out of the four members of our Compensation Committee meet the independence standards of the AFEP-MEDEF Code (the Director representing employees is not considered as independent) and the independence requirements of NASDAQ's listing rules.

Sanofi follows the recommendation of the AFEP-MEDEF Code that at least one meeting of the Board of Directors not attended by the company's executive officers be organized each year. Accordingly, Sanofi's Board Charter provides that the Board of Directors shall organize at least two meetings a year without its executive officers, thereby providing the Chairman with the option of whether to include directors representing employees or any other Group employee, as the case may require, depending on the agenda of the meeting. Sanofi's practice in that respect departs from NASDAQ Listing Rule 5605(b)(2), which provides that independent directors must have regularly scheduled meetings at which only independent directors are present.

Under French law, the committees of our Board of Directors are advisory only, and where the NASDAQ Listing Rule 5600 series would vest certain decision-making powers with specific committees by delegation (e.g. the appointment of Sanofi's auditors by the Audit Committee), 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 of Sanofi voting at the Shareholders' General Meeting that have the authority to appoint our auditors upon consideration of 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, is in line with the NASDAQ'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. While NASDAQ rules require shareholder approval when a plan or other equity compensation arrangement is established or materially amended, under French law our shareholders must decide any issuance of equity, as a general matter. We intend to follow our French home country practice and ask our shareholders to delegate their authority to issue incentive equity and define the final terms of any equity compensation plan or arrangements to our Board of Directors. We may, from time to time, ask for our shareholders' subsequent approval on an equity compensation arrangement in order to obtain advantageous tax treatment or otherwise. In addition, under French law, our Board of Directors must obtain the prior approval of our shareholders before establishing or amending a plan or arrangement that would exceed the limits of the granted delegation.

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.

Because we are a "foreign private issuer" as described above, our Chief Executive Officer and our Chief Financial Officer issue the certifications required by Section 302 and Section 906 of the Sarbanes-Oxley Act of 2002 on an annual basis (with the filing of our Annual Report on Form 20-F) rather than on a quarterly basis as would be the case of a US corporation filing quarterly reports on 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 operates in place of certain provisions of the NASDAQ listing rules.

Sanofi is governed by the French Commercial Code, which provides that an ordinary general meeting of the shareholders may validly deliberate when first convened if the shareholders present or represented hold at least one-fifth of the voting shares. If it is reconvened, no quorum is required. The French Commercial Code further provides that the shareholders at an extraordinary general meeting may validly deliberate when first convened only if the shareholders present or represented hold at least one-quarter of the voting shares and, if reconvened, one-fifth of the voting shares. Therefore, Sanofi will not follow NASDAQ's Listing Rule 5620(c), which provides that the minimum quorum requirement for a meeting of shareholders is $33^{1}/_{3}$% of the outstanding common voting shares of the company. In accordance with the provisions of the French Commercial Code, the required majority for the adoption of a decision is a simple majority (for an ordinary general meeting of the shareholders) or a two-thirds majority (for an extraordinary general meeting) of the votes cast by the shareholders present or represented.

The Company intends, in accordance with Section 10D-1 of the Exchange Act, to introduce a recovery policy for compensation erroneously paid to "executive officers" (as defined in Section 10D-1(d) of the Exchange Act) based in whole or in part on any financial reporting measures, at such time as required by the applicable NASDAQ listing rules, Section 10D-1 of the Exchange Act and applicable interpretive guidance.

Item 16H. Mine Safety Disclosure

N/A

Item 16I. Disclosure regarding foreign jurisdictions that prevent inspections

N/A

Part III

Item 17. Financial Statements

See Item 18.

Item 18. Financial Statements

See pages F-1 through F-102 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).
2.1.	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.
2.2.	Description of securities registered under section 12 of the Exchange Act
8.1.	List of significant subsidiaries, see "Item 4. Information on the Company — C. Organizational Structure" of this 20-F.
12.1.	Certification by Paul Hudson, Chief Executive Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002.
12.2.	Certification by Jean-Baptiste Chasseloup de Chatillon, Principal Financial Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002.
13.1.	Certification by Paul Hudson, Chief Executive Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002.
13.2.	Certification by Jean-Baptiste Chasseloup de Chatillon, Principal Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002.
23.1.	Consent of Ernst & Young et Autres dated February 24, 2023.
23.2.	Consent of PricewaterhouseCoopers Audit dated February 24, 2023.
23.3	EY change in auditors 16F item letter.

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/ PAUL HUDSON
Name:	Paul Hudson
Title:	Chief Executive Officer

Date: February 24, 2023.

Report of Independent Registered Public Accounting Firms

To the Shareholders and the Board of Directors 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, 2022, 2021, and 2020, the related consolidated income statements, statements of comprehensive income, statements of changes in equity and statements of cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 2021, and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 24, 2023 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 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Recoverable amount of other intangible assets

Description of the Matter	Other intangible assets amounted to €21,640 million at December 31, 2022. Management recognized a net gain of €454 million relating to impairment charges and reversals for the year ended December 31, 2022. As described in Notes B.6.1., D.4. and D.5. to the consolidated financial statements, other intangible assets not yet available for use are tested for impairment annually and whenever events or circumstances indicate that impairment might exist. Other intangible 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. Management 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. Value in use is determined by management using estimated future cash flows generated by the asset or CGU which are discounted and prepared using the same methods as those used in the initial measurement of the assets and on the basis of medium-term strategic plans. Management cash flow projections include significant assumptions related to mid and long-term sales forecasts; perpetual growth or attrition rate, where applicable; discount rate; and probability of success of current research and development projects. The principal considerations for our determination that auditing the recoverable amount of other intangible assets is especially challenging, subjective, and required complex auditor judgment related to the significant judgments made by management when developing the significant assumptions utilized in the future cash flow projections as described above.
How We Addressed the Matter in Our Audit	Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to management's other intangible assets impairment assessment, including controls over the significant assumptions used in the impairment testing of the other intangible assets. These audit procedures also included, among others, evaluating the appropriateness of the discounted cash flow model; testing the completeness, accuracy, and relevance of underlying data used in the model; and evaluating the significant assumptions used by management as described above. Evaluating management's assumptions involved evaluating whether the assumptions used by management were reasonable by considering the current and past performance of other intangible assets in comparison to management's previous forecasts and current trends, the consistency of certain assumptions with external market and industry data, and whether these assumptions were consistent with evidence obtained in other areas of the audit such as internal company communications and presentations and external communications. We involved our professionals with specialized skills and knowledge to assist us notably in the assessment of the discount rate used by management.

Valuation of the provisions for rebates relating to Sanofi's business in the United States – Medicaid, Medicare and Managed Care

Description of the Matter	As described in Notes B.13.1. and D.23. to the consolidated financial statements, products sold in the United States are covered by various Government and State programs (of which Medicaid and Medicare are the most significant) and are subject to commercial agreements with healthcare authorities and certain customers and distributors. Estimates of discounts and rebates incentives (hereinafter the "Rebates") to be provided to customers under those arrangements are recognized as a reduction of gross sales in the period in which the underlying sales are recognized. Provisions for the Medicaid, Medicare and Managed Care Rebates amounted to €1,307 million, €775 million and €934 million, respectively, at December 31, 2022. The Rebates estimated by management are based on 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; 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; market trends including competition, pricing and demand. The principal considerations for our determination that auditing the provisions for Rebates relating to the Company's business in the United States is especially challenging and required complex auditor judgment related to the significant judgment by management due to significant measurement uncertainty involved in developing these provisions. These provisions are estimated based on multiple factors as described above.
How We Addressed the Matter in Our Audit	Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to management's estimates of the provisions for Rebates relating to the Company's business in the United States, including controls over the assumptions used to estimate these Rebates. These procedures also included, among others, developing an independent estimate of the provisions for Rebates by utilizing third party data on inventory levels in distribution channels, volume, changes to price, the terms of the specific rebate programs, and the historical trend of actual rebate claims paid. The independent estimate was compared to the provisions recorded by the Company. Additionally, these procedures included testing actual rebate claims paid and evaluating the contractual terms of the Company's rebate agreements.

Provisions for product liability risks, litigation and other and contingent liabilities

Description of the Matter	Provisions for product liability risks, litigation and other risks were recorded in an amount of €1,652 million at December 31, 2022. As described in Notes B.12., D.19.3. and D.22. to the consolidated financial statements, the Company records such provisions when an outflow of resources is probable and the amount of the outflow can be reliably estimated. The Company also discloses the contingent liabilities in circumstances where management is unable to make a reasonable estimate of the expected financial effect that will result from ultimate resolution of the proceeding, or a cash outflow is not probable. The pharmaceutical industry is highly regulated, which increases the inherent risk of litigation and arbitration. The Company is involved in litigation, arbitration and other legal proceedings. These proceedings are typically related to litigation concerning product liability claims, intellectual property rights, competition law and trade practices, as well as claims under warranties or indemnification arrangements relating to business divestments. The issues raised by these claims are highly complex and subject to substantial uncertainties; therefore, the probability of loss and an estimation of damages are difficult to ascertain. The principal considerations for our determination that auditing the provision for product liability risks, litigation and other, and auditing the contingent liabilities is especially challenging, subjective and required complex auditor judgment resulted from the determination that the measurement of the provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions by management. There is inherent uncertainty related to these cases and in estimating the likelihood and outcome of the cases.
How We Addressed the Matter in Our Audit	Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to management's evaluation of the provisions for product liability risks, litigation and other, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as the need for and the level of financial statement disclosures. These procedures also included, among others, obtaining and evaluating the letters of audit inquiry with internal and external legal counsels, evaluating management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable through the evaluation of the legal letters and summaries of the proceedings and lawsuit correspondence. We also evaluated the Company's disclosures for contingent liabilities.

Uncertain tax positions

Description of the Matter	As described in Notes B.22. and D.19.4. to the consolidated financial statements, the Company has recorded liabilities pertaining to uncertain tax positions of €1,520 million at December 31, 2022. The Company operates in multiple tax jurisdictions, carrying out potentially complex transactions that require management to make judgments and estimates as to the tax impact of those transactions. The positions adopted by the Company 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, the Company 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 liability is regarded as probable, it is measured on the basis of the Company's best estimate. The principal considerations for our determination that auditing uncertain tax positions is especially challenging, subjective and required complex auditor judgment related to the significant judgment by management when determining the liability for uncertain tax positions, including a high degree of estimation uncertainty of certain assumptions and interpretations of the tax laws and regulations underlying the positions.
How We Addressed the Matter in Our Audit	Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to the identification and recognition of the liability for uncertain tax positions, management's assessment and interpretation of tax laws and its evaluation of which tax positions may not be sustained upon audit and controls over measurement of the liability. These procedures also included, among others, testing the completeness and accuracy of the underlying data used in the calculation of the liability for uncertain tax positions and evaluating the assumptions used by management when determining its tax positions, the status of tax audits and investigations, and the potential impact of past claims. Our tax professionals assisted in evaluating management's assessments by comparing the positions taken by management with tax regulations and past decisions from tax authorities and where applicable, evaluating opinions from the Company's external tax advisors. We also evaluated the disclosures provided in the notes to the consolidated financial statements concerning uncertain tax positions.

/s/ PricewaterhouseCoopers Audit

/s/ Ernst & Young et Autres

Ernst & Young et Autres and PricewaterhouseCoopers Audit have served as the Company's auditors since 1986 and 1999, respectively.

Neuilly-sur-Seine and Paris-La Défense, France, February 24, 2023

Report of Independent Registered Public Accounting Firms

To the Shareholders and the Board of Directors 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, 2022, 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, 2022, based on the COSO criteria.

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, 2022, 2021, and 2020, the related consolidated income statements, statements of comprehensive income, statements of changes in equity and statements of cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). Our report dated February 24, 2023 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 or procedures may deteriorate.

/s/ PricewaterhouseCoopers Audit

/s/ Ernst & Young et Autres

Neuilly-sur-Seine and Paris-La Défense, France, February 24, 2023

2022 Consolidated financial statements

The financial statements are presented in accordance with International Financial Reporting Standards (IFRS).

Consolidated balance sheets - assets

(€ million)	Note	December 31, 2022	December 31, 2021	December 31, 2020 [(a)]
Property, plant and equipment	D.3.1.	9,869	10,028	9,365
Right-of-use assets	D.3.2.	1,815	1,948	1,198
Goodwill	D.4.	49,892	48,056	44,364
Other intangible assets	D.4.	21,640	21,407	18,341
Investments accounted for using the equity method	D.6.	677	250	201
Other non-current assets	D.7.	3,095	3,127	2,734
Non-current income tax assets		242	175	248
Deferred tax assets	D.14.	5,381	4,598	4,176
Non-current assets		**92,611**	**89,589**	**80,627**
Inventories	D.9.	8,960	8,715	8,352
Accounts receivable	D.10.	8,424	7,568	7,491
Other current assets	D.11.	3,532	3,571	2,737
Current income tax assets		374	612	1,208
Cash and cash equivalents	D.13. - D.17.1.	12,736	10,098	13,915
Current assets		**34,026**	**30,564**	**33,703**
Assets held for sale or exchange	D.8.	85	89	83
Total assets		**126,722**	**120,242**	**114,413**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

Consolidated balance sheets – equity and liabilities

(€ million)	Note	December 31, 2022	December 31, 2021	December 31, 2020 [(a)]
Equity attributable to equity holders of Sanofi	D.15.	74,784	68,681	63,106
Equity attributable to non-controlling interests	D.16.	368	350	146
Total equity		**75,152**	**69,031**	**63,252**
Long-term debt	D.17.1.	14,857	17,123	19,745
Non-current lease liabilities	D.17.2.	1,904	1,839	931
Non-current liabilities related to business combinations and to non-controlling interests	D.18.	674	577	387
Non-current provisions and other non-current liabilities	D.19.	6,341	6,721	7,315
Non-current income tax liabilities	D.19.4.	1,979	2,039	1,733
Deferred tax liabilities	D.14.	1,841	1,617	1,770
Non-current liabilities		**27,596**	**29,916**	**31,881**
Accounts payable		6,813	6,180	5,295
Current liabilities related to business combinations and to non-controlling interests	D.18.	105	137	218
Current provisions and other current liabilities	D.19.5.	12,021	11,217	10,132
Current income tax liabilities		574	309	604
Current lease liabilities	D.17.2.	277	269	232
Short-term debt and current portion of long-term debt	D.17.1.	4,174	3,183	2,767
Current liabilities		**23,964**	**21,295**	**19,248**
Liabilities related to assets held for sale or exchange	D.8.	10	—	32
Total equity and liabilities		**126,722**	**120,242**	**114,413**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

Consolidated income statements

(€ million)	Note	2022	2021	2020 [(a)]
Net sales	**D.35.1.**	**42,997**	**37,761**	**36,041**
Other revenues		2,392	1,414	1,328
Cost of sales		(13,695)	(12,255)	(12,159)
Gross profit		**31,694**	**26,920**	**25,210**
Research and development expenses		(6,706)	(5,692)	(5,530)
Selling and general expenses		(10,492)	(9,555)	(9,391)
Other operating income	D.25.	1,969	859	697
Other operating expenses	D.26.	(2,531)	(1,805)	(1,415)
Amortization of intangible assets	D.4.	(2,053)	(1,580)	(1,681)
Impairment of intangible assets	D.5.	454	(192)	(330)
Fair value remeasurement of contingent consideration	D.12. - D.18.	27	(4)	124
Restructuring costs and similar items	D.27.	(1,336)	(820)	(1,089)
Other gains and losses, and litigation	D.28.	(370)	(5)	136
Gain on Regeneron investment arising from transaction of May 29, 2020	D.2.	—	—	7,382
Operating income		**10,656**	**8,126**	**14,113**
Financial expenses	D.29.	(440)	(368)	(388)
Financial income	D.29.	206	40	53
Income before tax and investments accounted for using the equity method	**D.35.1.**	**10,422**	**7,798**	**13,778**
Income tax expense	D.30.	(2,006)	(1,558)	(1,807)
Share of profit/(loss) from investments accounted for using the equity method	D.31.	68	39	359
Net income		**8,484**	**6,279**	**12,330**
Net income attributable to non-controlling interests	D.32.	113	56	36
Net income attributable to equity holders of Sanofi		**8,371**	**6,223**	**12,294**
Average number of shares outstanding (million)	D.15.9.	1,251.9	1,252.5	1,253.6
Average number of shares after dilution (million)	D.15.9.	1,256.9	1,257.9	1,260.1
• Basic earnings per share (in euros)		6.69	4.97	9.81
• Diluted earnings per share (in euros)		6.66	4.95	9.76

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

Consolidated statements of comprehensive income

(€ million)		2022	2021	2020 [(a)]
Net income		**8,484**	**6,279**	**12,330**
Attributable to equity holders of Sanofi		*8,371*	*6,223*	*12,294*
Attributable to non-controlling interests		*113*	*56*	*36*
Other comprehensive income:				
• Actuarial gains/(losses)	D.15.7.	654	686	(267)
• Change in fair value of equity instruments included in financial assets and financial liabilities	D.15.7.	13	165	320
• Tax effects	D.15.7.	(216)	(54)	(39)
Sub-total: items not subsequently reclassifiable to profit or loss (A)		**451**	**797**	**14**
• Change in fair value of debt instruments included in financial assets	D.15.7.	(77)	(21)	15
• Change in fair value of cash flow hedges	D.15.7.	7	(6)	4
• Change in currency translation differences	D.15.7.	2,278	2,459	(3,976)
• Tax effects	D.15.7.	105	78	(64)
Sub-total: items subsequently reclassifiable to profit or loss (B)		**2,313**	**2,510**	**(4,021)**
Other comprehensive income for the period, net of taxes (A+B)		**2,764**	**3,307**	**(4,007)**
Comprehensive income		**11,248**	**9,586**	**8,323**
Attributable to equity holders of Sanofi		*11,130*	*9,519*	*8,307*
Attributable to non-controlling interests		*118*	*67*	*16*

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

Consolidated statements of changes in equity

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi [a]	Attributable to non-controlling interests	Total equity
Balance at January 1, 2020[a]	**2,508**	**147**	**(9)**	**51,902**	**3,863**	**645**	**59,056**	**174**	**59,230**
Other comprehensive income for the period[a]	—	—	—	14	—	(4,001)	(3,987)	(20)	(4,007)
Net income for the period[a]	—	—	—	12,294	—	—	12,294	36	12,330
Comprehensive income for the period[a]	**—**	**—**	**—**	**12,308**	**—**	**(4,001)**	**8,307**	**16**	**8,323**
Dividend paid out of 2019 earnings (€3.15 per share)	—	—	—	(3,937)	—	—	(3,937)	—	(3,937)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(44)	(44)
Share repurchase program[b]	—	—	(822)	—	—	—	(822)	—	(822)
Share-based payment plans:									
• Exercise of stock options[b]	2	49	—	—	—	—	51	—	51
• Issuance of restricted shares and vesting of existing restricted shares[b]/[d]	3	(3)	126	(126)	—	—	—	—	—
• Employee share ownership plan[b]	5	169	—	—	—	—	174	—	174
• Value of services obtained from employees	—	—	—	—	274	—	274	—	274
• Tax effects of the exercise of stock options	—	—	—	—	1	—	1	—	1
Other changes arising from issuance of restricted shares[c]	—	—	—	2	—	—	2	—	2
Balance at December 31, 2020	**2,518**	**362**	**(705)**	**60,149**	**4,138**	**(3,356)**	**63,106**	**146**	**63,252**

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi	Attributable to non-controlling interests	Total equity
Balance at January 1, 2021[a]	**2,518**	**362**	**(705)**	**60,149**	**4,138**	**(3,356)**	**63,106**	**146**	**63,252**
Other comprehensive income for the period	—	—	—	797	—	2,499	3,296	11	3,307
Net income for the period	—	—	—	6,223	—	—	6,223	56	6,279
Comprehensive income for the period	**—**	**—**	**—**	**7,020**	**—**	**2,499**	**9,519**	**67**	**9,586**
Dividend paid out of 2020 earnings (€3.20 per share)	—	—	—	(4,008)	—	—	(4,008)	—	(4,008)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(49)	(49)
Share repurchase program[b]	—	—	(382)	—	—	—	(382)	—	(382)
Share-based payment plans:									
• Exercise of stock options[b]	—	11	—	—	—	—	11	—	11
• Issuance of restricted shares and vesting of existing restricted shares[b]/[d]	4	(4)	148	(148)	—	—	—	—	—
• Employee share ownership plan[b]	5	163	—	—	—	—	168	—	168
• Value of services obtained from employees	—	—	—	—	244	—	244	—	244
• Tax effects of the exercise of stock options	—	—	—	—	23	—	23	—	23
Other changes in non-controlling interests[e]	—	—	—	—	—	—	—	186	186
Balance at December 31, 2021	**2,527**	**532**	**(939)**	**63,013**	**4,405**	**(857)**	**68,681**	**350**	**69,031**

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi	Attributable to non-controlling interests	Total equity
Balance at January 1, 2022	**2,527**	**532**	**(939)**	**63,013**	**4,405**	**(857)**	**68,681**	**350**	**69,031**
Other comprehensive income for the period	—	—	—	451	—	2,308	2,759	5	2,764
Net income for the period	—	—	—	8,371	—	—	8,371	113	8,484
Comprehensive income for the period	**—**	**—**	**—**	**8,822**	**—**	**2,308**	**11,130**	**118**	**11,248**
Dividend paid out of 2021 earnings (€3.33 per share)	—	—	—	(4,168)	—	—	(4,168)	—	(4,168)
Effect of the distribution of an exceptional supplementary dividend of 58% of the shares of EUROAPI to the equity holders of Sanofi[f]	—	—	—	(793)	—	—	(793)	—	(793)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(100)	(100)
Share repurchase program[b]	—	—	(497)	—	—	—	(497)	—	(497)
Reduction in share capital[b]	(13)	(587)	600	—	—	—	—	—	—
Share-based payment plans:									
• Exercise of stock options[b]	1	34	—	—	—	—	35	—	35
• Issuance of restricted shares and vesting of existing restricted shares[b]/[d]	3	(3)	130	(130)	—	—	—	—	—
• Employee share ownership plan[b]	4	149	—	—	—	—	153	—	153
• Value of services obtained from employees	—	—	—	—	245	—	245	—	245
• Tax effects of the exercise of stock options	—	—	—	—	8	—	8	—	8
Other changes	—	—	—	(10)	—	—	(10)	—	(10)
Balance at December 31, 2022	**2,522**	**125**	**(706)**	**66,734**	**4,658**	**1,451**	**74,784**	**368**	**75,152**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

(b) See Notes D.15.1., D.15.3., D.15.4. and D.15.5.

(c) Issuance of restricted shares to former employees of the European Generics business subsequent to the date of divestment.

(d) This line includes the use of existing shares to fulfill vested rights under restricted share plans.

(e) This line includes changes in non-controlling interests arising from divestments and acquisitions.

(f) This amount includes the valuation of the shares distributed as a dividend in kind, at a price of €14.58 per share, as of May 10, 2022 (see note D.1.).

Consolidated statements of cash flows

(€ million)	Note	2022	2021	2020 [j]
Net income attributable to equity holders of Sanofi		**8,371**	**6,223**	**12,294**
Non-controlling interests	D.32.	113	56	36
Share of undistributed earnings from investments accounted for using the equity method		(48)	(15)	(339)
Depreciation, amortization and impairment of property, plant and equipment, right-of-use assets and intangible assets		3,420	3,351	3,671
Gains and losses on disposals of non-current assets, net of tax[a]		(711)	(300)	(301)
Gain on Regeneron investment arising from transaction of May 29, 2020, net of tax[b]	D.2.	—	—	(6,880)
Net change in deferred taxes		(578)	(356)	(221)
Net change in non-current provisions and other non-current liabilities[c]		280	(37)	(133)
Cost of employee benefits (stock options and other share-based payments)	D.15.2. - D.15.3. - D.15.8.	245	244	274
Impact of the workdown of acquired inventories remeasured at fair value	D.35.1.	3	4	53
Other profit or loss items with no cash effect on cash flows generated by operating activities[d]		138	(57)	(711)
Operating cash flow before changes in working capital		**11,233**	**9,113**	**7,743**
(Increase)/decrease in inventories		(927)	(357)	(593)
(Increase)/decrease in accounts receivable		(777)	185	(134)
Increase/(decrease) in accounts payable		452	451	86
Net change in other current assets and other current liabilities		545	1,130	316
Net cash provided by/(used in) operating activities[e]		**10,526**	**10,522**	**7,418**
Acquisitions of property, plant and equipment and intangible assets	D.3. - D.4.	(2,201)	(2,043)	(2,083)
Acquisitions of consolidated undertakings and investments accounted for using the equity method[f]	D.1. - D.18.	(992)	(5,594)	(5,336)
Acquisitions of other equity investments	D.7.	(488)	(311)	(137)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax[g]		1,488	676	918
Disposal of consolidated undertakings and investments accounted for using the equity method, net of tax[h]		134	42	—
Net proceeds from sale of Regeneron shares on May 29, 2020	D.2.	—	—	10,370
Net change in other non-current assets		(16)	(68)	(113)
Net cash provided by/(used in) investing activities		**(2,075)**	**(7,298)**	**3,619**
Issuance of Sanofi shares	D.15.1.	188	186	203
Dividends paid:				
• to shareholders of Sanofi		(4,168)	(4,008)	(3,937)
• to non-controlling interests		(99)	(48)	(44)
Additional long-term debt contracted	D.17.1.	1,549	—	2,019
Repayments of long-term debt	D.17.1.	(2,718)	(2,241)	(3,952)
Repayments of lease liabilities		(291)	(149)	(234)
Net change in short-term debt and other financial instruments[i]		215	(414)	282
Acquisitions of treasury shares	D.15.4.	(497)	(382)	(822)
Net cash provided by/(used in) financing activities		**(5,821)**	**(7,056)**	**(6,485)**
Impact of exchange rates on cash and cash equivalents		**8**	**15**	**(64)**
Net change in cash and cash equivalents		**2,638**	**(3,817)**	**4,488**
Cash and cash equivalents, beginning of period		**10,098**	**13,915**	**9,427**
Cash and cash equivalents, end of period	**D.13.**	**12,736**	**10,098**	**13,915**

(a) Includes non-current financial assets.
(b) The gain on the sale of Regeneron shares is presented net of taxes, including deferred taxes of €115 million.
(c) This line item includes contributions paid to pension funds (see Note D.19.1.).
(d) This line item mainly comprises unrealized foreign exchange gains and losses arising on the remeasurement of monetary items in non-functional currencies and on instruments used to hedge such items.

(e) Including:

	2022	2021	2020
• Income tax paid	(2,452)	(1,280)	(2,051)
• Interest paid	(380)	(334)	(315)
• Interest received	173	3	37
• Dividends received from non-consolidated entities	1	2	—

(f) This line item includes payments made in respect of contingent consideration identified and recognized as a liability in business combinations. For 2022, it includes the net cash outflow on the acquisition of Amunix (see Note D.1.). For 2021, it includes the net cash outflows on the acquisitions of Kymab, Kiadis, Tidal, Translate Bio, Kadmon and Origimm (see Note D.2.1.). For 2020, it includes the net cash outflows on the acquisitions of Synthorx and Principia (see Note D.2.2.).

(g) For 2022, 2021 and 2020, this line item mainly comprises disposals of assets and activities related to portfolio streamlining and disposals of equity and debt instruments. For 2020, it also includes the sale to Baxter of operations relating to Seprafilm® for a selling price (before taxes) of €311 million. (see Note D.7.1.).

(h) For 2022, this line item includes the net cash inflows (before taxes) of €101 million on the divestment of EUROAPI (see Note D.1).

(i) This line item includes realized foreign exchange differences on (i) cash and cash equivalents in non-functional currencies (primarily the US dollar) and (ii) derivative instruments used to manage such cash and cash equivalents.

(j) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

Notes to the Consolidated Financial Statements

Introduction

Sanofi, together with its subsidiaries (collectively "Sanofi", "the Group" 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 (Nasdaq: SNY).

The consolidated financial statements for the year ended December 31, 2022, and the notes thereto, were signed off by the Sanofi Board of Directors on February 23, 2023.

A/ Basis of preparation

A.1. International financial reporting standards (IFRS)

The consolidated financial statements cover the twelve-month periods ended December 31, 2022, 2021 and 2020.

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, 2022.

The consolidated financial statements of Sanofi as of December 31, 2022 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, 2022.

IFRS as endorsed by the European Union as of December 31, 2022 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 applicable from January 1, 2022

The following amendments are applicable from January 1, 2022, and have had no material impact: "Reference to the Conceptual Framework" (amendment to IFRS 3); "Proceeds before Intended Use" (amendment to IAS 16); "Onerous Contracts — Cost of Fulfilling a Contract" (amendment to IAS 37); and "Annual Improvements to IFRS standards 2018-2020".

As a reminder, Sanofi adopted in its consolidated financial statements for the year ended December 31, 2021 the IFRS IC final agenda decision (published in the March 2021 IFRS IC update) clarifying how to account for costs of configuring or customising a supplier's application software in a Software as a Service (SaaS) arrangement, which requires such costs to be recognized as an expense.

A.2.2. New pronouncements issued by the IASB and applicable from 2023 or later

This note describes standards, amendments and interpretations issued by the IASB that will have mandatory application in 2023 or subsequent years, and Sanofi's position regarding future application.

On February 12, 2021, the IASB issued "Disclosure of Accounting Policies", an amendment to IAS 1, and "Definition of Accounting Estimates", an amendment to IAS 8. On May 7, 2021, the IASB issued an amendment to IAS 12, relating to deferred tax assets and liabilities arising from a single transaction. Sanofi does not expect a material impact from those amendments, which are applicable at the earliest from January 1, 2023, and will not early adopt them.

On September 22, 2022, the IASB issued an amendment to IFRS 16 (Leases), relating to lease liabilities in a sale-and-leaseback arrangement, which is applicable at the earliest from January 1, 2024 (subject to endorsement by the European Union); it will not have a material impact on the Sanofi financial statements, and Sanofi will not early adopt it.

On January 23, 2020, the IASB issued "Classification of Liabilities as Current or Non-current", an amendment to IAS 1, and then on October 31, 2022 issued "Non-current Liabilities with Covenants", a further amendment to IAS 1. The amendments are applicable at the earliest from January 1, 2024 (subject to endorsement by the European Union); they will not have a material impact on the Sanofi financial statements, and Sanofi will not early adopt them.

IFRS 17 (Insurance Contracts), issued on May 18, 2017 and applicable on or after January 1, 2023, will not apply to the Sanofi consolidated financial statements because the insurance activities carried on by Sanofi's captive insurance companies are internal within the Sanofi group (the sole policyholders being subsidiaries of Sanofi), and hence are eliminated on consolidation.

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. and D.23.);
- impairment of property, plant and equipment and intangible assets (see Notes B.6. and D.5.);
- the valuation of goodwill and the valuation and estimated useful life of acquired intangible assets (see Notes B.3.2., B.4., D.4. and D.5.);
- the measurement of contingent consideration receivable in connection with asset divestments (see Notes B.8.5. and D.12.) and of contingent consideration payable (see Notes B.3. and D.18.);
- the measurement of financial assets at amortized cost (see Note B.8.5.);
- the amount of post-employment benefit obligations (see Notes B.23. and D.19.1.);
- the amount of liabilities or provisions for restructuring, litigation, tax risks relating to corporate income taxes, and environmental risks (see Notes B.12., B.19., B.20., D.19. and D.22.); and
- 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.).

Actual results could differ from these estimates.

A.4. Hyperinflation

In 2022, Sanofi continued 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. In 2018, following changes to the Venezuelan foreign exchange system, the "DICOM" rate was replaced by the "PETRO" rate (with a floating US dollar/bolivar parity) and the strong bolivar ("VEF") was replaced by the sovereign bolivar ("VES"), reflecting a 1-for-100,000 devaluation. Finally, in October 2021 a new currency called the "Digital Bolivar" (VED) was introduced at a rate of 1 VED to 1,000,000 sovereign bolivars. Consequently, the contribution of the Venezuelan subsidiaries to the consolidated financial statements is immaterial.

In Argentina, the cumulative rate of inflation over the last three years is in excess of 100%, based on a combination of indices used to measure inflation in that country. Consequently, Sanofi has since July 1, 2018 treated Argentina as a hyperinflationary economy and has applied IAS 29. The impact of the resulting restatements is immaterial at Sanofi group level.

Since the beginning of 2022, inflation in Turkey has increased significantly and the cumulative inflation rate over the past three years has been above 100% since the end of February 2022. Qualitative indicators following the deterioration of the economic situation and exchange controls also support the consensus conclusion that Turkey is a hyperinflationary country from 2022. Consequently, Sanofi has since January 1, 2022 treated Turkey as a hyperinflationary economy and has applied IAS 29. The impact of the resulting restatements is immaterial at Sanofi group level.

A.5. Agreements relating to the recombinant COVID-19 vaccine candidate developed by Sanofi in collaboration with GSK

On February 18, 2020, Sanofi and the US Department of Health and Human Services extended their research and development partnership to leverage Sanofi's previous development work on a SARS vaccine to attempt to unlock a fast path forward for developing a COVID-19 vaccine. Under the terms of the collaboration, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the US Department of Health and Human Services, is helping to fund the research and development undertaken by Sanofi.

On April 14, 2020, Sanofi and GlaxoSmithKline (GSK) entered into a collaboration agreement to develop a recombinant COVID-19 vaccine candidate, with Sanofi contributing its S-protein COVID-19 antigen (based on recombinant DNA technology) and GSK contributing its pandemic adjuvant technology. Sanofi is leading clinical development and the registration process for the vaccine.

On July 31, 2020, the recombinant COVID-19 vaccine candidate developed by Sanofi in collaboration with GSK was selected by the US government's Operation Warp Speed (OWS) program. Under the OWS, the US government is providing funds to support further development of the vaccine, including clinical trials and scaling-up of manufacturing capacity. Initially, the agreement also provided for the supply of 100 million doses of the vaccine, with payment due at the time vaccine doses are provided.

Sanofi has recognized the funding received from the US government as a deduction from the development expenses incurred, in accordance with IAS 20 (Accounting for Government Grants and Disclosure of Government Assistance).

The amount of government aid received from the US federal government and BARDA and recognized as a deduction from development expenses and other operating expenses was €265 million in 2022, compared with €147 million in 2021 and an immaterial amount in 2020.

In September 2020, Sanofi and GSK signed pre-order contracts with the Canadian and UK governments and with the European Union for doses of the vaccine candidate. During 2021, Sanofi and GSK contractualized with the Canadian and UK governments and with the European Union on the number of doses ordered.

On December 15, 2021, Sanofi and GSK announced positive preliminary data on their COVID-19 booster vaccine candidate and indicated that their Phase III trial was to continue, based on recommendations from an independent monitoring board.

On November 10, 2022, in line with the positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency, the European Commission approved VidPrevtyn® Beta vaccine as booster for the prevention of COVID-19 in adults aged 18 years and older. Designed to provide broad protection against multiple variants, this protein-based COVID-19 booster vaccine is based on the Beta variant antigen and includes GSK's pandemic adjuvant. VidPrevtyn® Beta is indicated as a booster for active immunization against SARS-CoV-2 in adults who have previously received an mRNA or adenoviral COVID-19 vaccine.

On December 21, 2022, following the European Commission approval, the Medicines and Healthcare Products Regulatory Agency (MHRA) approved VidPrevtyn® Beta vaccine for the prevention of COVID-19 in adults aged 18 and over within the UK.

As of December 31, 2022, there had been no material change in the commitments entered into by the United States in 2020, or in the pre-order arrangements with Canada, the United Kingdom and the European Union.

In accordance with IFRS 15 (see Note B.13.1.), Sanofi recognizes revenue when control over the product is transferred to the customer (for vaccines, transfer of control is determined by reference to the terms of release and acceptance of batches of vaccine). Payments received subsequent to signature of vaccine pre-order contracts relating to doses not yet delivered are customer contract liabilities (i.e. an obligation for the entity to supply goods to a customer, for which consideration has been received from the customer). They are presented within "Customer contract liabilities" in the balance sheet (see Note D.19.5.), and within "Net change in other current assets and other current liabilities" in the statement of cash flows.

As of December 31, 2022, customer contract liabilities amounted to €264 million, compared with €319 million as of December 31, 2021 (see Note D.19.5., "Current provisions and other current liabilities"). The portion of the December 31, 2021 balance recognized in profit or loss during 2022 was €85 million (no amounts were recognized in profit or loss during 2021).

A.6. Effects of climate change

Risks associated with climate change as assessed to date, and the commitments made by Sanofi on carbon neutrality and cutting greenhouse gas emissions, do not have a material impact on the financial statements.

Risks associated with trends in carbon costs, raw material shortages, supply chain disruption, etc. have been taken into account in the measurement of assets and liabilities.

A.7. War in Ukraine

The conflict triggered by the Russian invasion of Ukraine on February 24, 2022 led to the imposition of sanctions by the European Union and other countries. While complying with those sanctions inherent to its operations, Sanofi continues to carry on commercial and industrial activities in Russia under its direct control so as to meet patient needs. In 2022, Sanofi generated net sales of €674 million in Russia (compared with €575 million in 2021 and €641 million in 2020), representing 1.6% of consolidated net sales.

The conflict had no material direct or indirect impact on the financial statements ended December 31, 2022. Sanofi will continue to monitor the situation, and will update its estimates and assumptions accordingly.

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 (in which case, Sanofi recognizes the assets and liabilities of the operation in proportion to its rights and obligations relating to those assets and liabilities) or as a joint venture.

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 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 2022 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 acquiree's identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 (Business Combinations) are measured initially at their fair values 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, 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;
- 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 is elected for each acquisition individually.

Purchase price allocations are performed under the responsibility of management, with assistance from an independent valuer in the case of major acquisitions. 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.

Finally, management may where it deems fit elect to apply the optional test to identify concentration of fair value permitted under IFRS 3 in order to determine whether a transaction is a business combination within the meaning of IFRS 3, or merely the acquisition of an asset or of a group of similar assets.

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, 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 (in-process research and development, technology platforms, and currently marketed products) that 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 technology platforms and to products currently marketed by Sanofi are amortized on a straight line basis over their useful lives, determined (in particular for marketed products) 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 owned and leased

B.5.1. Property, plant and equipment owned

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.

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.

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.5.2. Property, plant and equipment leased

Effective from January 1, 2019 leases contracted by Sanofi have been accounted for in accordance with IFRS 16 (Leases). Sanofi recognizes a right-of-use asset and a lease liability for all of its lease contracts, except for (i) leases relating to low-value assets and (ii) short-term leases (12 months or less). Payments made in respect of leases not recognized on the balance sheet are recognized as an operating expense on a straight line basis over the lease term.

On commencement of a lease, the liability for future lease payments is discounted at the incremental borrowing rate, which is a risk-free rate adjusted to reflect the specific risk profile of each Sanofi entity. Because lease payments are spread over the lease term, Sanofi applies a discount rate based on the duration of those payments.

The payments used to determine the liability for future lease payments exclude non-lease components, but include fixed payments that Sanofi expects to make to the lessor over the estimated lease term.

After commencement of the lease, the liability for future lease payments is reduced by the amount of the lease payments made, and increased to reflect interest on the liability. In the event of a reassessment or modification of future lease payments, the lease liability is remeasured. The right-of-use asset – which is initially measured at cost including direct costs of the lessee, prepayments made at or prior to the commencement date, less lease incentives received and restoration costs – is depreciated on a straight line basis over the lease term, and tested for impairment as required.

Sanofi recognizes deferred taxes in respect of right-of-use assets and lease liabilities.

Leasehold improvements are depreciated over their economic life, which is capped at the lease term as determined under IFRS 16.

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 or group of CGUs 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 or groups of 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 six-year strategic plan and a terminal value. In the case of other intrangible 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 determines whether investments accounted for using the equity method may be impaired based on indicators such as default in contractual payments, significant financial difficulties, probability of bankruptcy, or a prolonged or significant decline in quoted market price. 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.

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 requires 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***;
- 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.

B.8. Financial instruments

B.8.1. Non-derivative financial assets

In accordance with IFRS 9 (Financial Instruments) and IAS 32 (Financial Instruments: Presentation), Sanofi has adopted the classification of non-derivative financial assets described below. The classification used depends on (i) the characteristics of the contractual cash flows (i.e. whether they represent interest or principal) and (ii) the business model for managing the asset applied at the time of initial recognition.

Financial assets at fair value through other comprehensive income

These mainly comprise:

- quoted and unquoted equity investments that Sanofi does not hold for trading purposes and that management has designated at "fair value through other comprehensive income" on initial recognition. Gains and losses arising from changes in fair value are recognized in equity within the statement of comprehensive income in the period in which they occur. When such instruments are derecognized, the previously-recognized changes in fair value remain within ***Other comprehensive income***, as does the gain or loss on divestment. Dividends received are recognized in profit or loss for the period, within the line item ***Financial income***; and
- debt instruments whose contractual cash flows represent payments of interest or repayments of principal, and which are managed with a view to collecting cash flows and selling the asset. Gains and losses arising from changes in fair value are recognized in equity within the statement of comprehensive income in the period in which they occur. When such assets are derecognized, the cumulative gains and losses previously recognized in equity are reclassified to profit or loss for the period within the line items ***Financial income*** or ***Financial expenses***.

Financial assets at fair value through profit or loss

These mainly comprise:

- contingent consideration already carried in the books of an acquired entity or granted in connection with a business combination;
- instruments whose contractual cash flows represent payments of interest and repayments of principal, which are managed with a view to selling the asset;
- instruments that management has designated at "fair value through profit or loss" on initial recognition; and
- quoted and unquoted equity investments: equity instruments that are not held for trading and which management did not designate at "fair value through other comprehensive income" on initial recognition, and instruments that do not meet the IFRS definition of "equity instruments".

Gains and losses arising from changes in fair value are recognized in profit or loss within the line items ***Financial income*** or ***Financial expenses***. Dividends received are recognized in profit or loss for the period, within the line item ***Financial income***.

Fair value of equity investments in unquoted entities

On initial recognition of an equity investment in an entity not quoted in an active market, the fair value of the investment is the acquisition cost. Cost ceases to be a representative measure of the fair value of an unquoted equity investment when Sanofi identifies significant changes in the investee, or in the environment in which it operates. In such cases, an internal valuation is carried out, based mainly on growth forecasts or by reference to similar transactions contracted with third parties.

Financial assets measured at amortized cost

Financial assets at amortized cost comprise instruments whose contractual cash flows represent payments of interest and repayments of principal and which are managed with a view to collecting cash flows. The main assets in this category are loans and receivables. They are presented within the line items ***Other non-current assets***, ***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***. These financial assets are measured at amortized cost using the effective interest method.

Impairment of financial assets measured at amortized cost

The main assets involved are accounts receivable. Accounts receivable are initially recognized at the amount invoiced to the customer. Impairment losses on trade accounts receivable are estimated using the expected loss method, in order to take account of the risk of payment default throughout the lifetime of the receivables. The expected credit loss is estimated collectively for all accounts receivable at each reporting date using an average expected loss rate, determined primarily on the basis of historical credit loss rates. However, that average expected loss rate may be adjusted if there are indications of a likely significant increase in credit risk. If a receivable is subject to a known credit risk, a specific impairment loss is recognized for that receivable. The amount of expected losses is recognized in the balance sheet as a reduction in the gross amount of accounts receivable. Impairment losses on accounts receivable are recognized within ***Selling and general expenses*** in the income statement.

B.8.2. 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 using the policies described in Note B.8.3. below.

IFRS 13 (Fair Value Measurement) requires counterparty credit risk to be taken into account when measuring the fair value of financial instruments. That 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.

B.8.3. Hedging

As part of its overall market risk management policy, Sanofi enters into various hedging transactions involving derivative or non-derivative instruments; these may include forward contracts, currency swaps or options, interest rate swaps or options, cross-currency swaps, and debt placings or issues.

Such financial instruments are designated as hedging instruments and recognized using the hedge accounting principles of IFRS 9 when (a) there is formal designation and documentation of the hedging relationship, of how the effectiveness of the hedging relationship will be assessed, and of the underlying market risk management objective and strategy; (b) the hedged item and the hedging instrument are eligible for hedge accounting; and (c) there is an economic relationship between the hedged item and the hedging instrument, defined on the basis of a hedge ratio that is consistent with the underlying market risk management strategy, and the residual credit risk does not dominate the value changes that result from that economic relationship.

Fair value hedge

A fair value hedge is a hedge of the exposure to changes in fair value of an asset, liability or firm commitment that is attributable to one or more risk components and could affect profit or loss.

Changes in fair value of the hedging instrument and changes in fair value of the hedged item attributable to the hedged risk components are generally 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 from an asset, liability or highly probable forecast transaction that is attributable to one or more risk components and 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 related to operating activities, and within ***Financial income*** or ***Financial expenses*** for hedges related to 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. Those reclassified gains and losses are recognized within ***Other operating income*** for hedges related to operating activities, and 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 incorporated in the initial carrying amount 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, or recognized as an adjustment to the initial cost of the related non-financial asset or liability, 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***.

Cost of hedging

As part of its market risk management policy, Sanofi may designate currency options or interest rate options as hedging instruments, the effectiveness of which is measured on the basis of changes in intrinsic value. In such cases, the time value of the option is treated as a hedging cost and accounted for as follows:

- if the option includes a component that is not aligned on the critical features of the hedged item, the corresponding change in the time value is taken to profit or loss;
- otherwise, the change in the time value is taken to equity within the statement of comprehensive income, and then:
  - if the hedged item is linked to a transaction that results in the recognition of a financial asset or liability, the change in the time value is reclassified to profit or loss symmetrically with the hedged item, or
  - if the hedged item is linked to a transaction that results in the recognition of a non-financial asset or liability, the change in the time value is incorporated in the initial carrying amount of that asset or liability, or
  - if the hedged item is linked to a period of time, the change in time value is reclassified to profit or loss on a straight line basis over the life of the hedging relationship.

In the case of forward contracts and foreign exchange swaps, and of cross-currency swaps that qualify for hedge accounting on the basis of changes in spot rates, Sanofi may elect for each transaction to use the option whereby the premium/discount or foreign currency basis spread are treated in the same way as the time value of an option.

Discontinuation of hedge accounting

Hedge accounting is discontinued when the eligibility criteria are no longer met (in particular, when the hedging instrument expires or is sold, terminated or exercised), or if there is a change in the market risk management objective of the hedging relationship.

B.8.4. 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 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.8.5. Fair value of financial instruments

Under IFRS 13 (Fair Value Measurement) and IFRS 7 (Financial Instruments: Disclosures), fair value measurements must be classified using a hierarchy based on the inputs used to measure the fair value of the instrument. This hierarchy has three levels:

a. level 1: quoted prices in active markets for identical assets or liabilities (without modification or repackaging);
b. level 2: quoted prices in active markets for similar assets and liabilities, or valuation techniques in which all important inputs are derived from observable market data; and
c. level 3: valuation techniques in which not all important inputs are derived from observable market data.

The table below shows the disclosures required under IFRS 7 relating to the measurement principles applied to financial instruments.

					Method used to determine fair value		
						Market data	
Note	Type of financial instrument	Measurement principle	Level in fair value hierarchy	Valuation technique	Valuation model	Exchange rate	Interest rate
D.7.	Financial assets measured at fair value (quoted equity instruments)	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets measured at fair value (quoted debt instruments)	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets measured at fair value (unquoted equity instruments)	Fair value	3	Cost/ Approach based on comparables	If cost ceases to be a representative measure of fair value, an internal valuation is carried out, based mainly on comparables.		
D.7.	Financial assets measured at fair value (contingent consideration receivable)	Fair value	3	Revenue-based approach	The fair value of contingent consideration receivable is determined by adjusting the contingent consideration at the end of the reporting period using the method described in Note D.7.3.		
D.7.	Financial assets measured at fair value held to meet obligations under post-employment benefit plans	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets designated at fair value held to meet obligations under deferred compensation plans	Fair value	1	Market value	Quoted market price		N/A
D.7.	Long-term loans and advances and other non-current receivables	Amortized cost	N/A	N/A	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.13.	Investments in mutual funds	Fair value	1	Market value	Net asset value		N/A
D.13.	Negotiable debt instruments, commercial paper, instant access deposits and term deposits	Amortized cost	N/A	N/A	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.		
D.17.1.	Debt	Amortized cost[(a)]	N/A	N/A	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. 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.17.2.	Lease liabilities	Amortized cost	N/A	N/A	The liability for future lease payments is discounted using the incremental borrowing rate.		
D.20.	Forward currency contracts	Fair value	2		Present value of future cash flows	Mid Market	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon
D.20.	Interest rate swaps	Fair value	2	Revenue-based approach	Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon
D.20.	Cross-currency swaps	Fair value	2		Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon
D.18.	Liabilities related to business combinations and to non-controlling interests (CVRs)	Fair value	1	Market value	Quoted market price		
D.18.	Liabilities related to business combinations and to non-controlling interests (other than CVRs)	Fair value	3	Revenue-based approach	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 B.8.4.		

(a) 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).

B.8.6. 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 the 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.8.7. 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. of Sanofi's Annual Report on Form 20-F for 2022.

Credit risk is the risk that customers may fail to pay their debts. For a description of credit risk, refer to "We are subject to the risk of non-payment by our customers" within Item 3.D. and Item 11. of Sanofi's Annual Report on Form 20-F for 2022.

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, other than in specific circumstances which make it possible to estimate that there is a high probability at the end of the reporting period that the carrying amount of the inventories will be recoverable. 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.

No provisions are recorded for future operating losses.

Sanofi records non-current provisions for certain obligations, such as legal or constructive obligations, where an outflow of resources is probable and the amount of the outflow can be reliably estimated.

In the case of environmental risks, including at sites where operations are ongoing, Sanofi recognizes a provision where there is a violation of integrity in respect of human health or the environment resulting from past contamination at a site that requires remediation. The amount of the provision is a best estimate of the future expenditures to be incurred on the remediation plan.

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, consumer healthcare 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. Analyses of net sales are provided in Note D.35.1. "Segment Information".

In accordance with IFRS 15 (Revenue from Contracts with Customers), such revenue is recognized when Sanofi transfers control over the product to the customer; control of an asset refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from that asset. For the vast majority of contracts, revenue is recognized when the product is physically transferred, in accordance with the delivery and acceptance terms agreed with the customer.

For contracts entered into by Sanofi Pasteur, transfer of control is usually determined by reference to the terms of release (immediate or deferred) and acceptance of batches of vaccine.

In the case of contracts with distributors, Sanofi does not recognize revenue when the product is physically transferred to the distributor if the products are sold on consignment, or if the distributor acts as agent. In such cases, revenue is recognized when control is transferred to the end customer, and the distributor's commission is presented within the line item ***Selling and general expenses*** in the income statement.

The amount of revenue recognized reflects the various types of price reductions or rights of return offered by Sanofi to its customers on certain products. Such price reductions and rights of return qualify as variable consideration under IFRS 15.

In particular, products sold in the United States are covered by various Government and State 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:

- the amount of chargeback incentives is 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;
- the amount of rebates based on attainment of sales targets is estimated and accrued as each of the underlying sales transactions is recognized;
- the amount of price reductions under Government and State programs, largely in the United States, is 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;
- the amount of sales returns is 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 amount recognized for returns 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. Most product return clauses relate solely to date-expired products, which cannot be resold and are destroyed. Sanofi does not recognize a right of return asset in the balance sheet for contracts that allow for the return of time-expired products, since those products have no value.

The estimated amounts described above are recognized in the income statement within ***Net sales*** as a reduction of gross sales, and within ***Other current liabilities*** in the balance sheet. They are subject to regular 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 amounts 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.

An analysis of provisions for discounts, rebates and sales returns is provided in Note D.23.

B.13.2. Other revenues

The line item ***Other revenues*** is used to recognize all revenue that falls within the scope of IFRS 15 but does not relate to sales of Sanofi products.

It mainly comprises (i) royalties received from licensing intellectual property rights to third parties; (ii) VaxServe sales of products sourced from third-party manufacturers; and (iii) revenue received under agreements for Sanofi to provide manufacturing services to third parties.

Royalties received under licensing arrangements are recognized over the period during which the underlying sales are recognized.

VaxServe is a Vaccines segment entity whose operations include the distribution within the United States of vaccines and other products manufactured by third parties. VaxServe sales of products sourced from third-party manufacturers are presented within ***Other revenues***.

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 agreements, which may include partnership, co-promotion arrangements and licenses not included in Other revenues.

This line item also includes realized and unrealized foreign exchange gains and losses on operating activities (see Note B.8.3.), 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 and other intangible assets (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 IFRS 3, are reported in profit or loss. 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 receivable in connection with a divestment and classified as a financial asset at fair value through profit or loss.

Finally, it 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 (including closures of leased sites), 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 December 2019 (and previously in November 2015), and intended primarily to (i) deliver a global information systems solution, further supported by the implementation in 2021 of Sanofi's new digital strategy; (ii) create a standalone Consumer Healthcare entity; and (iii) as announced on February 24, 2020, create a European leader in the production and marketing to third parties of active pharmaceutical ingredients (API).

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 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;
- costs 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 certain 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 provisions, 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 certain 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 on disposals of financial assets at fair value through profit or loss.

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. In addition, Sanofi has elected not to discount current taxes payable or receivable where the amounts in question are payable or receivable in the long term;
- 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 IFRS 3 as regards the recognition of deferred tax assets after the initial accounting period. Consequently, any deferred tax assets recognized by the acquiree after the end of that 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 liability is regarded as probable, it is measured on the basis of Sanofi's best estimate and recognized as a liability; uncertain tax assets are not recognized. 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"). Tax exposures relating to corporate income taxes are presented separately within ***Non-current income tax liabilities*** (see Note D.19.4.).

No deferred taxation is recognized on temporary differences that are liable to be subject to US global intangible low taxed income (GILTI) provisions. The related tax expense is recognized in the year in which it is declared in the tax return to the extent that it arises from the existence of non-US profits that exceed the theoretical return on investment specified in the GILTI provisions and are taxed at a rate lower than the applicable US tax rate.

In accordance with IAS 1 (Presentation of Financial Statements), current income tax assets and liabilities are presented as separate line items in the consolidated balance sheet.

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. 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 in profit or loss on a straight line basis over the vesting period of the plan, with the opposite entry recognized in equity. The vesting period is three years.

The fair value of restricted share plans is based on the quoted market price of Sanofi shares at the date of grant, adjusted for expected dividends during the vesting period; it also takes account of any vesting conditions contingent on stock market performance, measured using the Monte-Carlo valuation model. Other vesting conditions are taken into account in the estimate of the number of shares awarded during the vesting period; that number is then definitively adjusted based on the actual number of shares awarded on the vesting date.

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 (i) all outstanding dilutive options and warrants are exercised, and (ii) 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. Disclosures about operating segments required under IFRS 8 are presented in Note D.35. "Segment information" to the consolidated financial statements.

Sanofi has three operating segments: Pharmaceuticals, Vaccines, and Consumer Healthcare.

The Pharmaceuticals segment comprises, for all geographical territories, the commercial operations of the following global franchises: Specialty Care (Dupixent®, Neurology & Immunology, Rare Diseases, Oncology, and Rare Blood Disorders) and General Medicines (Core and Non-Core Assets), together with research, development and production activities dedicated to the Pharmaceuticals segment. This segment also includes associates whose activities are related to pharmaceuticals. Following the transaction of May 29, 2020, Regeneron is no longer an associate of Sanofi (see Note D.2.). Consequently, the Pharmaceuticals segment no longer includes Sanofi's equity-accounted share of Regeneron's profits for all the periods presented.

The Vaccines segment comprises, for all geographical territories, the commercial operations of Vaccines, together with research, development and production activities dedicated to vaccines.

The Consumer Healthcare segment comprises, for all geographical territories, the commercial operations for Sanofi's Consumer Healthcare products, together with research, development and production activities dedicated to those products.

Inter-segment transactions are not material.

The costs of Sanofi's global functions (Corporate Affairs, Finance, People & Culture, Legal, Ethics & Business Integrity, Information Solutions & Technologies, Sanofi Business Services, etc.) are managed centrally at group-wide level, and are presented within the "Other" category. That category also includes other reconciling items such as retained commitments in respect of divested activities.

Information about operating segments for the years ended December 31, 2022, 2021 and 2020 is presented in Note D.35., "Segment information".

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;
- 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 "Net debt" 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 agreements on human therapeutic antibodies

In November 2007, Sanofi and Regeneron signed two agreements (amended in November 2009) relating to human therapeutic antibodies: (i) the Discovery and Preclinical Development Agreement, and (ii) the License and Collaboration Agreement, relating to clinical development and commercialization. Under the License and Collaboration Agreement, Sanofi had an option to develop and commercialize antibodies discovered by Regeneron under the Discovery and Preclinical Development Agreement.

Discovery and development

Because Sanofi decided not to exercise its option to extend the Discovery and Preclinical Development Agreement, that agreement expired on December 31, 2017.

As a result of Sanofi's exercise of an option with respect to an antibody under the Discovery and Preclinical Development Agreement, such antibody became a "Licensed Product" under the License and Collaboration Agreement, pursuant to which Sanofi and Regeneron co-develop the antibody with Sanofi initially being wholly responsible for funding the development program. On receipt of the first positive Phase III trial results for any antibody being developed under the License and Collaboration Agreement, the subsequent development costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under the License and Collaboration Agreement are recognized by Sanofi as a reduction in the line item ***Research and development expenses***. Co-development with Regeneron of the antibodies Dupixent®, Kevzara® and REGN3500 (SAR440340 - itepekimab) is ongoing under the License and Collaboration Agreement as of December 31, 2022.

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 portion of Regeneron's profit-share (capped at 20% of Regeneron's share of quarterly profits since April 1, 2022, and at 10% until March 31, 2022) until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration (see Note D.21.1.).

On the later 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 and Collaboration Agreement.

Commercialization

Sanofi is the lead party with respect to the commercialization of all co-developed antibodies, and Regeneron has certain option rights to co-promote the antibodies. Regeneron has exercised its co-promotion rights in the United States and in certain other countries. Sanofi recognizes all sales of the 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 due to or from Regeneron under the agreement is recognized within the line items ***Other operating income or Other operating expenses***, which are components of ***Operating income***.

In addition, Regeneron is entitled to receive payments contingent on the attainment of specified levels of aggregate sales on all antibodies outside the United States, on a rolling twelve-month basis. A liability for those payments is recognized on the balance sheet when it is probable that the specified level of aggregate sales will be met. The opposite entry for that liability is capitalized within ***Other intangible assets*** on the balance sheet. Two payments of $50 million each were made in 2022, following attainment first of $2.0 billion and then of $2.5 billion in sales of all antibodies outside the United States on a rolling twelve-month basis. In the event that $3.0 billion in sales on a rolling twelve-month basis is attained, Regeneron is entitled to a final milestone payment of $50 million.

Amendments to the collaboration agreements

In January 2018, Sanofi and Regeneron signed a set of amendments to their collaboration agreements, including an amendment that allowed for the funding of additional programs on Dupixent® and REGN3500 (SAR440340 – itepekimab) with an intended focus on extending the current range of indications, finding new indications, and improving co-morbidity between multiple pathologies.

Effective April 1, 2020, Sanofi and Regeneron signed a Cross License and Commercialization Agreement for Praluent®, whereby Sanofi obtained sole ex-US rights to Praluent®, and Regeneron obtained sole US rights to Praluent® along with a right to 5% royalties on Sanofi's sales of Praluent® outside the United States. Each party is solely responsible for funding the development, manufacturing and commercialization of Praluent® in their respective territories. Although each party has responsibility for supplying Praluent® in its respective territory, Sanofi and Regeneron have entered into agreements to support manufacturing needs for each other.

Effective September 30, 2021, Sanofi and Regeneron signed an amendment to their collaboration agreement in order to specify allocations of responsibilities and associated resources between the two parties in connection with the co-promotion of Dupixent® in certain countries. The terms of the collaboration relating to REGN3500 (SAR440340 – itepekimab) are unchanged.

Effective July 1, 2022, Sanofi and Regeneron signed an amendment to their collaboration agreement in order to increase the additional portion of Regeneron's share of quarterly profits attributable to Sanofi from 10% to 20% with retroactive impact as of April 1, 2022.

Immuno-oncology (IO) collaboration agreements

On July 1, 2015, Sanofi and Regeneron signed two agreements – the IO Discovery and Development Agreement and the IO License and Collaboration Agreement (IO LCA) – relating to new antibody cancer treatments in the field of immuno-oncology.

The Amended IO Discovery Agreement, effective from December 31, 2018, was terminated through a Letter Amendment dated March 16, 2021 in which Sanofi formalized its opt-out from the BCMAxCD3 and MUC16xCD3 programs.

Libtayo® (cemiplimab)

Under the 2015 IO LCA as amended in January 2018, Sanofi and Regeneron committed funding of no more than $1,640 million, split on a 50/50 basis ($820 million per company), for the development of REGN2810 (cemiplimab, trademark Libtayo®), a PD-1 inhibitor antibody. The funding was raised to $1,840 million by way of amendment effective on September 30, 2021. Regeneron was responsible for the commercialization of Libtayo® in the United States, and Sanofi in all other territories. Sanofi has exercised its option to co-promote Libtayo® in the United States. In 2021, Regeneron exercised its option to co-promote Libtayo® in certain other countries.

The IO LCA also provided for a one-time milestone payment of $375 million by Sanofi to Regeneron in the event that sales of a PD-1 product were to exceed, in the aggregate, $2 billion in any consecutive 12-month period.

Under the IO LCA Sanofi and Regeneron shared equally in profits and losses generated by the commercialization of collaboration products, except that Sanofi was entitled to an additional portion of Regeneron's profit-share (capped at 10% of Regeneron's share of quarterly profits) until Regeneron had paid 50% of the cumulative development costs incurred by the parties under the IO Discovery Agreement, as amended.

Libtayo® is approved in the United States and Europe for the treatment of two types of locally advanced or metastatic skin cancer (cutaneous squamous cell carcinoma and basal cell carcinoma) and non-small cell lung cancer (NSCLC). It is also approved in Brazil and Canada as a second line treatment for recurring or metastatic cervical cancer. In the fourth quarter of 2022, it was approved in the United States in association with chemotherapy for the treatment of NSCLC, and in Europe and Japan as a second line treatment for recurring or metastatic cervical cancer. Libtayo® is currently approved in more than 30 countries.

In June 2022, Sanofi and Regeneron restructured their IO LCA. Under the terms of the Amended and Restated IO LCA, Regeneron holds exclusive worldwide licensing rights to Libtayo® with effect from July 1, 2022.

In July 2022, Sanofi received as consideration an upfront payment of $900 million (€856 million), which was recognized within ***Other operating income*** on the date of receipt. The same line item also includes a regulatory milestone payment of $100 million (€96 million) following the US FDA approval in November 2022 of Libtayo® in combination with chemotherapy as a first line treatment for NSCLC. In addition, Sanofi is entitled to royalties of 11% and to milestone payments (€111 million in 2022) linked to global net sales of Libtayo® which are recognized within ***Other operating income*** in line with the pattern of sales . All of the cash inflows relating to the above items (€967 million for the year ended December 31, 2022) are presented within ***Net cash provided by/(used in) operating activities*** in the consolidated statement of cash flows.

The amendment to the terms of the IO LCA resulted in Sanofi recognizing an accelerated amortization charge of €226 million; this was allocated to the Libtayo® product rights included within the residual carrying amount of the intangible asset recognized in July 2015 to reflect rights to an antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1) under the Sanofi/Regeneron alliance.

The transaction also includes a time-limited transitional services agreement with Regeneron which includes manufacturing, distribution (for which Sanofi acts as agent), and promotion.

Investor agreement

In 2014 and 2020, Sanofi and Regeneron amended the investor agreement entered into by the two companies in 2007. Under the terms of the amendments, Sanofi accepted various restrictions, including "standstill" provisions that 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 remains 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 agreements on human therapeutic antibodies" above), each as amended and (ii) other specified events.

Starting in 2018 Sanofi began to sell shares of Regeneron stock and announced on May 29, 2020 the closing of its sale of 13 million shares of Regeneron common stock in a registered offering and a private sale to Regeneron (see Note D.2.).

Pursuant to subsequent sales, as of December 31, 2022 Sanofi no longer holds any shares of Regeneron stock.

C.2. Alliance arrangements with Bristol-Myers Squibb (BMS)

Two of Sanofi's 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, effective 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 ("Territory B"), giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS received royalty payments on Sanofi's sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in Territory B) until 2018, and also received a payment of $200 million from Sanofi in December 2018, part of which is for buying out the non-controlling interests. Rights to Plavix® in Territory B remained unchanged and continued to be governed by the terms of the original agreement until February 28, 2020.

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 recognized in its consolidated financial statements the revenue and expenses generated by its own operations. Since January 2019 onwards, there has no longer been any share of profits reverting to BMS (previously presented within ***Net income attributable to non-controlling interests*** in the income statement).

In Territory B for Plavix®, which was managed by BMS, the Plavix® business was conducted through the Territory B partnerships, which were jointly owned by BMS and Sanofi. Sanofi recognized its share of profits and losses within the line item ***Share of profit/(loss) from investments accounted for using the equity method***.

On February 28, 2020, Sanofi purchased all BMS's interests (50.1%) in each of the Territory B partnerships for a cumulative purchase price of $12 million. Following a transition period, Sanofi has been commercializing Plavix® under its own label since July 1, 2020.

D/ Presentation of the financial statements

D.1. Principal changes in the scope of consolidation in 2022

Acquisition of Amunix Pharmaceuticals, Inc.

On February 8, 2022, Sanofi acquired the entire share capital of the immuno-oncology company Amunix Pharmaceuticals, Inc. (Amunix), thereby gaining access to Amunix's innovative Pro-XTEN™ technology and a promising pipeline of immunotherapies.

The acquisition price of Amunix comprises a fixed cash payment of €970 million, plus contingent consideration in the form of milestone payments based on attainment of certain future development objectives of up to $225 million, the fair value of which as of the acquisition date was €156 million. In accordance with IFRS 3, this contingent purchase consideration was recognized in ***Liabilities related to business combinations and non-controlling interests*** (see Note D.18.).

The final purchase price allocation led to the recognition of €609 million of goodwill, determined as follows:

(€ million)	Fair value at acquisition date
Other intangible assets	493
Other current and non-current assets and liabilities	(13)
Cash and cash equivalents	118
Deferred taxes, net	(81)
Net assets of Amunix	**517**
Goodwill	609
Purchase price	**1,126**

"Other intangible assets" comprise Pro-XTEN™, an innovative universal protease-releasable masking technology platform for the discovery and development of transformative cytokine therapies and T-cell engager (TCE) immunotherapies for patients with cancer.

Goodwill mainly represents the value of Amunix's upstream research and development pipeline of immuno-oncology therapies based on next-generation conditionally activated biologics, especially when combined with Sanofi's existing oncology portfolio.

The goodwill generated on this acquisition does not give rise to any deduction for income tax purposes.

Amunix has no commercial operations, and has made a negative contribution of €56 million to Sanofi's consolidated net income since the acquisition date.

Acquisition-related costs were recognized in profit or loss during 2021, primarily within the line item ***Other operating expenses***; the amount involved was immaterial.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a cash outflow of €852 million.

EUROAPI - Loss of control and accounting implications

On March 17, 2022, the Sanofi Board of Directors approved a decision to put to a shareholder vote the proposed distribution in kind of approximately 58% of the share capital of EUROAPI, thereby confirming Sanofi's commitment (announced in February 2020) to discontinue its active pharmaceutical ingredient operations. As part of the same corporate action and on the same date, Sanofi entered into an investment agreement with EPIC Bpifrance, which undertook to acquire from Sanofi – via the French Tech Souveraineté fund – a 12% equity interest in EUROAPI at a price not exceeding €150 million and to be determined on the basis of the volume weighted average price (VWAP) of EUROAPI shares on the Euronext Paris regulated market over the thirty-day period starting from the date of initial listing, i.e. May 6, 2022. On completion of those transactions, Sanofi holds an equity interest of 30.1% in EUROAPI, which it has undertaken to retain for at least two years from the date of the distribution, subject to the customary exceptions. With effect from that date, Sanofi exercises significant influence over EUROAPI as a result of (i) its equity interest, and (ii) having one representative on the EUROAPI Board of Directors.

On May 3, 2022, the General Meeting of Sanofi shareholders approved the decision of the Board of Directors to distribute approximately 58% of the share capital of EUROAPI in the form of an exceptional dividend in kind.

On May 10, 2022, the payment date of the dividend in kind in the days following the admission to listing of EUROAPI shares, those Sanofi shareholders who had retained their Sanofi shares received 1 EUROAPI share per 23 Sanofi shares, representing in total 57.88% of the share capital of EUROAPI. As of that date, Sanofi lost control over the EUROAPI entities, based on an assessment of the criteria specified in IFRS 10 (Consolidated financial statements). The assets and liabilities of EUROAPI, which since March 17, 2022 had been presented as assets and liabilities held for sale within the Sanofi statement of financial position in accordance with IFRS 5 (Non-Current Assets Held for Sale), were deconsolidated. In addition, because EUROAPI operations do not constitute a discontinued operation under IFRS 5, the contribution from EUROAPI has not been presented within separate line items in the income statement and statement of cash flows or in information for prior comparative periods. The contribution of EUROAPI operations to the consolidated net sales of Sanofi in the year ended December 31, 2021 was €486 million.

The principal consequences of the deconsolidation of EUROAPI are described below:

- the derecognition of the carrying amount of all the assets and liabilities of EUROAPI, representing a net amount of €1,227 million as of May 10, 2022. This includes goodwill of €164 million, determined in accordance with IAS 36 ("Impairment of Assets"), which was historically allocated to the Pharmaceuticals cash generating unit (CGU), and which for the purposes of the deconsolidation was allocated using an alternative method based on the relative values of goodwill as of the date of consolidation (the "notional goodwill method"). That method was considered more appropriate to the capital-intensive nature of EUROAPI operations than the method based on the relative values of EUROAPI operations and the retained portion of the CGU;
- a reduction in ***Equity attributable to equity holders*** of Sanofi reflecting the distribution in kind, measured at €793 million based on the weighted average price of €14.58 per share as of the date of delivery of the EUROAPI shares to Sanofi shareholders and corresponding to the fair value of the distribution in accordance with IFRIC 17 (Distribution of Non-Cash Assets to Owners);
- a cash inflow of €150 million from the divestment of 12% of the share capital of EUROAPI to EPIC Bpifrance as of the settlement date of the shares, i.e. June 17, 2022;
- the recognition in the statement of financial position, within the line item ***Investments accounted for using the equity method***, of the retained 30.1% equity interest in EUROAPI at an amount of €413 million, determined on the basis of the weighted average price of €14.58 per share and representing the fair value of the equity interest in accordance with IFRS 10;
- the reclassification within the net gain/loss on deconsolidation of unrealized foreign exchange losses amounting to €35 million arising on EUROAPI subsidiaries, in accordance with IAS 21 (The Effects of Changes in Foreign Exchange Rates);
- the recognition of transaction-related costs and of the effects of undertakings made under agreements entered into with EUROAPI setting out the principles and terms of the legal reorganization carried out ahead of the date of deconsolidation. The principal undertakings made to EUROAPI relate to compensation for:
  - environmental remediation obligations on non-operational chemical sites in France transferred to EUROAPI, amounting to €14 million, and
  - regulatory compliance costs relating to certain state-of-the-art active pharmaceutical ingredients of EUROAPI, capped at €15 million.

These elements collectively resulted in a pre-tax loss on deconsolidation of €3 million, presented within the line item ***Other gains and losses, and litigation*** in the income statement. The tax effect of the deconsolidation was a net gain of €111 million, presented within the line item ***Income tax expense*** in the income statement.

The cash impact of the deconsolidation of EUROAPI, presented within the line item ***Disposals of consolidated undertakings and investments accounted for using the equity method*** in the statement of cash flows, was a net cash inflow of €101 million.

Sanofi has entered into an agreement with EUROAPI for the manufacture and supply of active pharmaceutical ingredients, intermediates and other substances, which took effect on October 1, 2021 and expires five years after the loss of control. Under the terms of the agreement, Sanofi committed to target annual net sales of approximately €300 million for a list of specified active ingredients until the agreement expires in 2026. As of December 31, 2022, that commitment amounted to €1.1 billion.

With effect from the date of deconsolidation, the 30.1% equity interest in EUROAPI is accounted for using the equity method in accordance with IAS 28 (Investments in Associates and Joint Ventures), and the share of EUROAPI profits or losses arising from application of the equity method is excluded from "Business operating income", the non-IFRS financial indicator used internally by Sanofi to measure the performance of its operating segments.

D.2. Principal changes in the scope of consolidation in 2021 and 2020

D.2.1. Principal changes in the scope of consolidation in 2021

Acquisition of Kymab

On April 8, 2021, Sanofi acquired the entire share capital of Kymab for an upfront payment of $1.1 billion (€973 million) and up to $350 million contingent upon reaching certain development milestones.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was accounted for as an asset acquisition given that the principal asset (the KY1005 project, currently in Phase II clinical development, and relating to the human monoclonal antibody OX40L, an essential regulator of the immune system) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €965 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €932 million.

Acquisition of Kiadis

On November 2, 2020, Sanofi and Kiadis, a biopharmaceutical company developing novel "off-the-shelf" natural killer (NK) cell therapies for patients with life-threatening diseases, entered into a definitive agreement whereby Sanofi was to make a public offer to acquire the entire share capital of Kiadis, i.e. 61 million shares, at a cash price of €5.45 per share.

The acquisition was approved unanimously by the Boards of Directors of Sanofi and Kiadis, and 95.03% of the share capital of Kiadis had been tendered into the offer as of April 16, 2021. As of the end of the post-closing acceptance period on April 29, 2021, Sanofi held 97.39% of the share capital of Kiadis, and proceeded to buy out the remaining non-controlling shareholders. As of December 31, 2022, Sanofi held 100% of the share capital of Kiadis.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was accounted for as an asset acquisition given that the principal asset (the K-NK technology platform) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €339 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €326 million.

Acquisition of Tidal

On April 9, 2021, Sanofi acquired Tidal Therapeutics, a privately owned, pre-clinical stage biotech company with a unique mRNA-based approach for in vivo reprogramming of immune cells. The new technology platform will expand Sanofi's research capabilities in immuno-oncology and inflammatory diseases, and may have applicability to other disease areas as well.

Tidal Therapeutics was acquired for an upfront payment of $160 million (€136 million), and up to $310 million contingent upon reaching certain development milestones.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was accounted for as an asset acquisition given that the principal asset (the unique mRNA-based in vivo reprogramming technology) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €130 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €135 million.

Acquisition of Translate Bio

On August 3, 2021, Sanofi entered into a definitive agreement with Translate Bio, a clinical-stage mRNA therapeutics company, under which Sanofi was to acquire all outstanding shares of Translate Bio for $38 per share. The Sanofi and Translate Bio Boards of Directors unanimously approved the transaction.

The acquisition of Translate Bio by Sanofi was completed on September 14, 2021, with Sanofi holding the entire share capital of Translate Bio upon expiration of the squeeze-out procedure.

The final purchase price allocation, as presented in the table below, led to the recognition of goodwill of €2,118 million:

(€ million)	Fair value at acquisition date
Other intangible assets	396
Deferred tax liabilities	(93)
Other current and non-current assets and liabilities	235
Cash and cash equivalents	247
Shire contingent consideration liability (see Note D.18.)	(323)
Net assets of Translate Bio	**462**
Goodwill	2,118
Purchase price	**2,580**

The other intangible assets mainly comprise a messenger RNA technological platform applied to the development of vaccines and therapeutic agents.

Goodwill mainly represents the effects of expected future synergies and other benefits to be derived from the integration of Translate Bio into the Sanofi group, in particular by accelerating the delivery of development programs.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

Translate Bio has no commercial operations.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €2,333 million.

Under the terms of the collaboration agreement between Sanofi and Translate Bio as announced on June 23, 2020, Sanofi held an equity interest of approximately 5% in Translate Bio. As of the date when Sanofi obtained control of Translate Bio, that interest was remeasured at the purchase price of $38 per share. The change in fair value was recognized within ***Other comprehensive income***, in accordance with paragraph 42 of IFRS 3 (see Note D.7.).

Acquisition of Kadmon

On September 8, 2021, Sanofi entered into a definitive merger agreement with Kadmon, a biopharmaceutical company that discovers, develops and markets transformative therapies for disease areas with significant unmet medical needs. Shareholders of Kadmon common stock received $9.50 per share in cash, representing a transaction valued at $1.9 billion on a fully-diluted basis. The Sanofi and Kadmon Boards of Directors unanimously approved the transaction.

The acquisition of Kadmon by Sanofi was completed on November 9, 2021, with Sanofi holding the entire share capital of Kadmon upon expiration of the squeeze-out procedure.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was therefore accounted for as an asset acquisition given that the principal asset (belumosudil, commercialized in the United States under the brand name Rezurock®) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €1,739 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings*** *and* ***investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €1,575 million.

Acquisition of Origimm

On December 3, 2021, Sanofi acquired the entire share capital of Origimm Biotechnology GmbH, a privately owned Austrian biotechnology company specializing in the discovery of virulent skin microbiome components and antigens from bacteria that cause skin diseases such as acne, for an upfront payment of €55 million and up to €95 million contingent upon reaching certain development and regulatory milestones.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was therefore accounted for as an asset acquisition given that the principal asset (the group of Propionibacterium acnes antigens) concentrates substantially all of the fair value of the acquired set of activities and assets.

Nearly €55 million of the acquisition price paid was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows for the year ended December 31, 2021 is a net cash outflow of €50 million.

D.2.2. Principal changes in the scope of consolidation in 2020

Acquisition of Principia

On August 17, 2020, Sanofi and Principia Biopharma Inc. ("Principia"), a late-stage biopharmaceutical company focused on developing treatments for autoimmune diseases, entered into a definitive agreement under which Sanofi was to acquire all the outstanding shares of Principia for $100 per share. The transaction was approved unanimously by the Boards of Directors of Sanofi and Principia. Sanofi's acquisition of Principia was completed on September 28, 2020, with Sanofi holding the entire share capital of Principia upon expiration of the squeeze-out procedure. The final purchase price allocation, as presented in the table below, led to the recognition of goodwill of €912 million:

(€ million)	Fair value at acquisition date
Other intangible assets	2,534
Other current and non-current assets and liabilities	(38)
Cash and cash equivalents	186
Net deferred tax position	(436)
Net assets of Principia	**2,246**
Goodwill	912
Purchase price	**3,158**

The other intangible assets mainly comprise:

- rilzabrutinib (PRN 1008), a molecule undergoing clinical trials for various indications in immuno-inflammatory diseases and rare blood disorders; and
- tolebrutinib (PRN 2246/SAR442168), a molecule currently undergoing clinical trials for the treatment of multiple sclerosis and other diseases of the central nervous system.

Goodwill represents (i) the pipeline of future products in pre-clinical research and development; (ii) the capacity to draw on a specialized structure to refresh the existing product portfolio; and (iii) the competencies of Principia staff.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

No material adjustment was required on completion of the final purchase price allocation.

Acquisition of Synthorx

On December 9, 2019, Sanofi and Synthorx Inc. ("Synthorx"), a clinical-stage biotechnology company focused on prolonging and improving the lives of people suffering from cancer and autoimmune disorders, entered into a definitive agreement under which Sanofi was to acquire all of the outstanding shares of Synthorx for $68 per share. The transaction was unanimously approved by both the Sanofi and Synthorx Boards of Directors. On December 23, 2019, Sanofi launched a public tender offer to acquire all of the outstanding ordinary shares of Synthorx for $68 per share in cash, without interest and net of any applicable withholding taxes. The acquisition of Synthorx was completed on January 23, 2020, with Sanofi holding the entire share capital of Synthorx upon expiration of the squeeze-out procedure. The final purchase price allocation, as presented in the table below, led to the recognition of goodwill of €930 million:

(€ million)	Fair value at acquisition date
Other intangible assets	1,549
Other current and non-current assets and liabilities	36
Net deferred tax position	(269)
Net assets of Synthorx	**1,316**
Goodwill	930
Purchase price	**2,246**

The other intangible assets mainly comprise THOR-707, a molecule currently in Phase I clinical trials that stimulates T lymphocytes, and as such has potential as a cancer immunotherapy.

Goodwill represents (i) the pipeline of future products in pre-clinical research and development; (ii) the capacity to draw on a specialized structure to refresh the existing product portfolio; (iii) the competencies of Synthorx staff; (iv) benefits derived from the creation of new growth platforms; and (v) expected future synergies and other benefits from the combination of Synthorx and Sanofi.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

No material adjustment was required on completion of the final purchase price allocation.

Transaction related to the equity-accounted investment in Regeneron

From the beginning of April 2014, Sanofi accounted for its investment in Regeneron using the equity method. As from that date, in accordance with the Investor Agreement as amended in early 2014, Sanofi had the right to designate a member of the Regeneron Board of Directors.

On May 29, 2020, Sanofi closed the transaction announced on May 25, 2020 involving the sale of its equity investment in Regeneron (with the exception of 400,000 shares), through (i) a registered public offering in the United States and internationally and (ii) a share repurchase by Regeneron. Sanofi divested 13 million shares of Regeneron common stock (of which 10.6 million were sold by Sanofi) through the public offering at a price of $515 per share, raising a total amount of $6,703 million; and Regeneron repurchased 9.8 million of its own shares of common stock directly from Sanofi for $5,000 million, at the offer price less a subscription discount ($509.85 per share). The total sale proceeds (before transaction-related costs) amounted to €10,575 million. At the same time, Sanofi as a result of this transaction lost the right to designate a member of the Regeneron Board of Directors under the amended Investor Agreement. Finally, as of May 29, 2020 Sanofi retained ownership of 400,000 Regeneron shares in order to continue to partially fund its commitments to invest in the development programs for cemiplimab (REGN2810) and dupilumab, in line with the 2018 Letter Agreement under which Sanofi is permitted to sell up to 1.4 million shares through the end of 2020. As of December 31, 2022, Sanofi had sold 779,320 Regeneron shares under that agreement. The number of Regeneron shares retained by Sanofi is 279,766 as of December 31, 2021 (see Note C.1.).

Sanofi's equity investment in Regeneron was accounted for by the equity method until May 29, 2020. As of that date, the carrying amount of the investment was €3,668 million; that amount was reversed out on closing of the transaction. Before tax effects, the gain on the divestment amounted to €7,382 million, including (i) a gain of €318 million arising on the currency translation reserve associated with Regeneron, which was taken to profit or loss in accordance with IAS 21; (ii) the deduction of transaction-related costs of €64 million; and (iii) a gain of €157 million on the remeasurement of the 400,000 retained shares at their quoted market price as of May 29, 2020 ($612.81). In accordance with IFRS 9 (Financial Instruments), the retained shares were classified in the *"Equity instruments at fair value through other comprehensive income"* category on the transaction date, at a value of €221 million (see Note D.7.).

The tax charge arising on the transaction was €502 million.

Given the material impact of this transaction, and to facilitate users' understanding of the financial statements, the pre-tax gain on this transaction is presented as a separate line item in the consolidated income statement, "Gain on Regeneron investment arising from the transaction of May 29, 2020".

The net cash inflow from the transaction was €10,370 million, which (for the reason cited above) is presented as a separate line item in the consolidated statement of cash flows, "Net proceeds from sale of Regeneron shares on May 29, 2020".

Sale of Seprafilm®

On November 27, 2019, Sanofi entered into a definitive agreement to sell Seprafilm® to Baxter. The sale was completed on February 14, 2020. Sanofi recognized a pre-tax gain of €129 million.

The impact of this sale, reflected in the line item ***Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax*** within the consolidated statement of cash flows, was a net cash inflow before tax of €311 million.

D.3. Property, plant and equipment

D.3.1. Property, plant and equipment owned

Property, plant and equipment owned by Sanofi is comprised of the following items:

(€ million)	Land	Buildings	Machinery and equipment	Fixtures, fittings and other	Property, plant and equipment in process	Total
Gross value at January 1, 2020	**255**	**7,282**	**11,053**	**2,587**	**2,391**	**23,568**
Changes in scope of consolidation	—	6	3	1	—	10
Acquisitions and other increases	—	16	40	46	1,208	1,310
Disposals and other decreases	(11)	(173)	(177)	(123)	(3)	(487)
Currency translation differences	(13)	(264)	(276)	(67)	(91)	(711)
Transfers[(a)]	5	(39)	484	80	(1,051)	(521)
Gross value at December 31, 2020	**236**	**6,828**	**11,127**	**2,524**	**2,454**	**23,169**
Changes in scope of consolidation	—	11	15	2	2	30
Acquisitions and other increases	—	10	51	39	1,404	1,504
Disposals and other decreases	(3)	(75)	(153)	(80)	(3)	(314)
Currency translation differences	6	169	155	34	79	443
Transfers[(a)]	1	227	453	136	(839)	(22)
Gross value at December 31, 2021	**240**	**7,170**	**11,648**	**2,655**	**3,097**	**24,810**
Changes in scope of consolidation	(17)	(294)	(1,480)	(163)	(150)	(2,104)
Acquisitions and other increases	—	11	54	41	1,642	1,748
Disposals and other decreases	(1)	(161)	(240)	(155)	(2)	(559)
Currency translation differences	17	122	144	29	35	347
Transfers[(a)]	(2)	480	722	108	(1,626)	(318)
Gross value at December 31, 2022	**237**	**7,328**	**10,848**	**2,515**	**2,996**	**23,924**
Accumulated depreciation & impairment at January 1, 2020	**(11)**	**(4,065)**	**(7,660)**	**(1,984)**	**(131)**	**(13,851)**
Depreciation expense	—	(356)	(605)	(182)	—	(1,143)
Impairment losses, net of reversals	—	(24)	(12)	(7)	—	(43)
Disposals and other decreases	1	168	166	117	8	460
Currency translation differences	—	127	169	49	—	345
Transfers[(a)]	—	252	150	26	—	428
Accumulated depreciation & impairment at December 31, 2020	**(10)**	**(3,898)**	**(7,792)**	**(1,981)**	**(123)**	**(13,804)**
Depreciation expense	—	(306)	(592)	(167)	—	(1,065)
Impairment losses, net of reversals	—	(3)	(22)	(2)	(12)	(39)
Disposals and other decreases	—	74	149	75	1	299
Currency translation differences	—	(80)	(99)	(29)	—	(208)
Transfers[(a)]	1	23	16	(11)	6	35
Accumulated depreciation & impairment at December 31, 2021	**(9)**	**(4,190)**	**(8,340)**	**(2,115)**	**(128)**	**(14,782)**
Changes in scope of consolidation	—	201	1,202	130	—	1,533
Depreciation expense	—	(356)	(622)	(164)	—	(1,142)
Impairment losses, net of reversals	(1)	(50)	(58)	(2)	(75)	(186)
Disposals and other decreases	—	133	201	153	31	518
Currency translation differences	—	(52)	(69)	(22)	5	(138)
Transfers[(a)]	—	89	49	5	(1)	142
Accumulated depreciation & impairment at December 31, 2022	**(10)**	**(4,225)**	**(7,637)**	**(2,015)**	**(168)**	**(14,055)**
Carrying amount at December 31, 2020	226	2,930	3,335	543	2,331	9,365
Carrying amount at December 31, 2021	231	2,980	3,308	540	2,969	10,028
Carrying amount at December 31, 2022	**227**	**3,103**	**3,211**	**500**	**2,828**	**9,869**

(a) This line includes in particular property, plant and equipment in process brought into service during the period, but also includes the effect of the reclassification of assets to Assets held for sale or exchange.

The table below sets forth acquisitions and capitalized interest by operating segment for the years ended December 31, 2022, 2021 and 2020:

(€ million)	2022	2021	2020
Acquisitions	**1,748**	**1,504**	**1,310**
Pharmaceuticals	1,049	1,007	831
Industrial facilities	*597*	*534*	*634*
Research sites	*153*	*277*	*152*
Other	*299*	*199*	*45*
Vaccines	629	421	384
Consumer Healthcare	70	73	95
Capitalized interest	**17**	**14**	**11**

Off balance sheet commitments relating to property, plant and equipment as of December 31, 2022, 2021 and 2020 are set forth below:

(€ million)	2022	2021	2020
Firm orders of property, plant and equipment	861	769	708
Property, plant and equipment pledged as security for liabilities	—	9	—

The table below sets forth the net impairment losses recognized in each of the last three financial periods:

(€ million)	2022	2021	2020
Net impairment losses on property, plant and equipment[(a)]	**186**	**39**	**43**

(a) For 2022, the amount mainly comprises an impairment loss arising from a decision to discontinue operations at an industrial facility located outside France.

D.3.2. Property, plant and equipment leased – right-of-use assets

Right-of-use assets relating to property, plant and equipment leased by Sanofi are analyzed in the table below:

(€ million)	Right-of-use assets
Gross value at January 1, 2020	**1,583**
Changes in scope of consolidation	15
Acquisitions and other increases	340
Disposals and other decreases	(121)
Currency translation differences	(85)
Transfers[a]	(21)
Gross value at December 31, 2020	**1,711**
Changes in scope of consolidation	93
Acquisitions and other increases[b]	963
Disposals and other decreases	(91)
Currency translation differences	76
Transfers[a]	(7)
Gross value at December 31, 2021	**2,745**
Changes in scope of consolidation	(26)
Acquisitions and other increases	292
Disposals and other decreases	(232)
Currency translation differences	101
Transfers[a]	(8)
Gross value at December 31, 2022	**2,872**
Accumulated depreciation & impairment at January 1, 2020	**(283)**
Depreciation and impairment charged in the period	(299)
Disposals and other decreases	44
Currency translation differences	22
Transfers[a]	3
Accumulated depreciation & impairment at December 31, 2020	**(513)**
Depreciation and impairment charged in the period	(315)
Disposals and other decreases	40
Currency translation differences	(15)
Transfers[a]	6
Accumulated depreciation & impairment at December 31, 2021	**(797)**
Changes in scope of consolidation	14
Depreciation and impairment charged in the period	(341)
Disposals and other decreases	82
Currency translation differences	(17)
Transfers[a]	2
Accumulated depreciation & impairment at December 31, 2022	**(1,057)**
Carrying amount at December 31, 2020	**1,198**
Carrying amount at December 31, 2021	**1,948**
Carrying amount at December 31, 2022	**1,815**

(a) This line also includes the effect of the reclassification of assets to "Assets held for sale or exchange".

(b) In December 2018, Sanofi signed two leases on real estate assets in the United States (at Cambridge, Massachusetts) for an initial lease term of 15 years. The first lease, relating to office space, began in April 2021; Sanofi recognized a right-of-use asset of €320 million, as well as the lease liability. The second lease, relating to laboratory facilities, began on July 1, 2021; Sanofi recognized a right-of-use asset of €424 million, as well as the lease liability.

Leased assets are mainly comprised of office and industrial premises (93%) and the vehicle fleet (7%) as of December 31, 2022.

Annual lease costs on short term leases and low value asset leases amounted to €26 million in the year ended December 31, 2022, €25 million in the year ended December 31, 2021, and €27 million in the year ended December 31, 2020. Variable lease payments, sub-leasing activities, and sale-and-leaseback transactions were immaterial.

Total cash outflows on leases (excluding annual lease costs on short term leases and low value asset leases) were €389 million in the year ended December 31, 2022, €302 million in the year ended December 31, 2021, and €269 million in the year ended December 31, 2020.

A maturity analysis of the lease liability is disclosed in Note D.17.2.

Commitments related to short-term leases and low value asset leases, including future payments for lease contracts committed but not yet commenced, are disclosed in Note D.21.

D.4. Goodwill and other intangible assets

Movements in goodwill comprise:

(€ million)	Goodwill
Balance at January 1, 2020	**44,519**
Acquisitions during the period	1,843
Other movements during the period[(a)]	(75)
Currency translation differences	(1,923)
Balance at December 31, 2020	**44,364**
Acquisitions during the period	2,179
Other movements during the period[(a)]	(89)
Currency translation differences	1,602
Balance at December 31, 2021	**48,056**
Acquisitions during the period	609
Other movements during the period[(a)]	(258)
Currency translation differences	1,485
Balance at December 31, 2022	**49,892**

(a) This line mainly comprises the amount of goodwill allocated to divested operations in accordance with paragraph 86 of IAS 36, and in 2022 the sale of EUROAPI (see note D.1.).

Acquisition of Amunix Pharmaceuticals, Inc. (2022)

The final purchase price allocation for Amunix Pharmaceuticals, Inc. resulted in the recognition of intangible assets (other than goodwill) of €493 million as of the acquisition date (February 8, 2022), and of goodwill provisionally measured at €609 million as of the acquisition date (see Note D.1.).

Acquisition of Translate Bio (2021)

The final purchase price allocation for Translate Bio resulted in the recognition of intangible assets (other than goodwill) of €396 million as of the acquisition date (September 14, 2021), and of goodwill measured at €2,118 million as of the acquisition date (see Note D.2.1.).

Acquisition of Principia (2020)

The final purchase price allocation for Principia resulted in the recognition of intangible assets (other than goodwill) of €2,534 million as of the acquisition date (September 28, 2020), and of goodwill measured at €912 million as of the acquisition date (see Note D.2.2.).

Acquisition of Synthorx (2020)

The final purchase price allocation for Synthorx resulted in the recognition of intangible assets (other than goodwill) totaling €1,549 million as of the acquisition date (January 23, 2020), and of goodwill measured at €930 million as of the acquisition date (see Note D.2.2.).

Movements in other intangible assets comprise:

(€ million)	Acquired R&D	Products, trademarks and other rights	Software	Total other intangible assets
Gross value at January 1, 2020[a]	**5,730**	**63,953**	**1,613**	**71,296**
Changes in scope of consolidation	3,951	132	—	4,083
Acquisitions and other increases[a]	654	58	106	818
Disposals and other decreases	(44)	(243)	(46)	(333)
Currency translation differences[a]	(593)	(2,926)	(38)	(3,557)
Transfers[b]	(98)	100	(2)	—
Gross value at December 31, 2020[a]	**9,600**	**61,074**	**1,633**	**72,307**
Changes in scope of consolidation[c]	1,805	1,821	—	3,626
Acquisitions and other increases	339	159	118	616
Disposals and other decreases	(313)	(173)	(16)	(502)
Currency translation differences	560	2,234	24	2,818
Transfers[b]	(784)	791	(7)	—
Gross value at December 31, 2021	**11,207**	**65,906**	**1,752**	**78,865**
Changes in scope of consolidation[c]	—	499	(35)	464
Acquisitions and other increases	277	195	99	571
Disposals and other decreases	(72)	(423)	(48)	(543)
Currency translation differences	518	1,994	21	2,533
Transfers[b]	(1,576)	1,408	(6)	(174)
Gross value at December 31, 2022	**10,354**	**69,579**	**1,783**	**81,716**
Accumulated amortization & impairment at January 1, 2020[a]	**(3,396)**	**(50,314)**	**(1,077)**	**(54,787)**
Amortization expense[a]	—	(1,707)	(112)	(1,819)
Impairment losses, net of reversals[d]	(328)	(2)	—	(330)
Disposals and other decreases	44	232	45	321
Currency translation differences	158	2,460	31	2,649
Transfers[b]	14	(14)	—	—
Accumulated amortization & impairment at December 31, 2020[a]	**(3,508)**	**(49,345)**	**(1,113)**	**(53,966)**
Amortization expense	—	(1,621)	(119)	(1,740)
Impairment losses, net of reversals[d]	(150)	(42)	—	(192)
Disposals and other decreases	313	133	16	462
Currency translation differences	(132)	(1,869)	(21)	(2,022)
Accumulated amortization & impairment at December 31, 2021	**(3,477)**	**(52,744)**	**(1,237)**	**(57,458)**
Changes in scope of consolidation	—	—	11	11
Amortization expense[e]	—	(2,099)	(97)	(2,196)
Impairment losses, net of reversals[d]	(1,107)	1,561	—	454
Disposals and other decreases	75	411	39	525
Currency translation differences	(7)	(1,567)	(17)	(1,591)
Transfers[a]	388	(214)	5	179
Accumulated amortization & impairment at December 31, 2022	**(4,128)**	**(54,652)**	**(1,296)**	**(60,076)**
Carrying amount at December 31, 2020	6,092	11,729	520	18,341
Carrying amount at December 31, 2021	7,730	13,162	515	21,407
Carrying amount at December 31, 2022	**6,226**	**14,927**	**487**	**21,640**

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement (see Note A.2.1.).

(b) The "Transfers" line mainly comprises (i) acquired R&D that came into commercial use during the period and (ii) reclassifications of assets as held for sale or exchange.

(c) The "Changes in scope of consolidation" line corresponds to the fair value of intangible assets recognized in connection with acquisitions made during the period (see Notes D.1. and D.2.).

(d) See Note D.5.

(e) The amendment to the terms of the IO License and Collaboration Agreement resulted in the recognition of an amortization charge of €226 million (see Note C.1.).

"Products, trademarks and other rights" mainly comprise:

- "marketed products", with a carrying amount of €12.7 billion as of December 31, 2022 (versus €11.7 billion as of December 31, 2021 and €11.4 billion as of December 31, 2020) and a weighted average amortization period of approximately 10 years; and
- "technological platforms", with a carrying amount of €2.2 billion as of December 31, 2022 (versus €1.2 billion as of December 31, 2021 and €0.2 billion as of December 31, 2020) and a weighted average amortization period of approximately 18 years.

The table below provides information about the principal "marketed products", which were recognized in connection with major acquisitions made by Sanofi and represented 92% of the carrying amount of that item as of December 31, 2022:

(€ million)	Gross value	Accumulated amortization & impairment	Carrying amount at December 31, 2022	Amortization period (years)[a]	Residual amortization period (years)[b]	Carrying amount at December 31, 2021	Carrying amount at December 31, 2020
Genzyme	10,490	(9,869)	621	10	2	1,032	1,485
Boehringer Ingelheim Consumer Healthcare	3,633	(1,596)	2,037	17	12	2,213	2,489
Aventis	34,684	(34,626)	58	9	10	73	110
Chattem	1,360	(786)	574	23	11	593	602
Protein Sciences	857	(359)	498	13	8	532	554
Ablynx	1,966	(609)	1,357	14	10	1,494	1,861
Bioverativ	7,955	(3,119)	4,836	13	9	3,065	3,240
Kadmon	1,882	(180)	1,702	12	11	1,750	—
Total: principal marketed products	**62,827**	**(51,144)**	**11,683**			**10,752**	**10,341**

(a) Weighted averages. The amortization periods for these products vary between 1 and 25 years.
(b) Weighted averages.

Acquisitions of other intangible assets (excluding software) during 2022 amounted to €472 million. The main items were upfront and milestone payments within the Specialty Care GBU.

The principal intangible assets brought into service during 2022 were:

- Enjaymo® (sutimlimab-jome), a treatment for cold agglutinin disease (gross value €854 million net of impairment of €363 million), with effect from the date of marketing approval (February 2022); and
- technology platforms (€525 million).

The main asset brought into service during 2021 was the Translate Bio mRNA technology platform.

During 2020, some of the acquired research and development came into commercial use, and started being amortized from the date of marketing approval; the main items involved were Sarclisa®, indicated for the treatment of relapsed refractory multiple myeloma, and the meningococcal vaccine MenQuadfi®.

Amortization of other intangible assets is recognized in the income statement within the line item ***Amortization of intangible assets***, except for amortization of software and other rights of an industrial or operational nature which is recognized in the relevant classification of expense by function. An analysis of amortization of software is shown in the table below:

(€ million)	2022	2021	2020 [a]
Cost of sales	10	18	19
Research and development expenses	1	3	2
Selling and general expenses	82	98	87
Other operating expenses	4	—	4
Total	**97**	**119**	**112**

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement (see Note A.2.1.).

D.5. Impairment of intangible assets and property, plant and equipment

Goodwill

In accordance with IAS 36, goodwill is allocated to groups of cash generating units (CGUs) at a level corresponding to the Pharmaceuticals, Consumer Healthcare and Vaccines segments. When testing goodwill annually for impairment, the recoverable amount is determined for each segment on the basis of value in use, determined using discounted estimates of the future cash flows in accordance with the policies described in Note B.6.1.

The allocation of goodwill as of December 31, 2022 is shown below:

(€ million)	Pharmaceuticals	Consumer Healthcare	Vaccines	Total
Goodwill	39,421	6,690	3,781	49,892

The value in use of each segment was determined by applying an after-tax discount rate to estimated future after-tax cash flows.

A separate discount rate is used for each segment to reflect the specific economic conditions of that segment.

The rates used for impairment testing in 2022 were 7.25% for the Pharmaceuticals segment, 7.00% for the Consumer Healthcare segment and 7.25% for the Vaccines segment; an identical value in use for Sanofi as a whole would be obtained by applying a uniform 7.2% rate to all three segments.

The pre-tax discount rates applied to estimated pre-tax cash flows are calculated by iteration from the previously-determined value in use. Those pre-tax discount rates were 9.9% for the Pharmaceuticals segment, 9.4% for the Consumer Healthcare segment and 9.9% for the Vaccines segment, and equate to a uniform rate of 9.8% for Sanofi as a whole.

The assumptions used in testing goodwill for impairment are reviewed annually. Apart from the discount rate, the principal assumptions used in 2022 were as follows:

- the perpetual growth rates applied to future cash flows were zero for the Pharmaceuticals and Vaccines segments, and 1% for the Consumer Healthcare segment;
- Sanofi also applies assumptions on the probability of success of current research and development projects, and more generally on its ability to renew the product portfolio in the longer term.

Value in use (determined as described above) is compared with the carrying amount, and this comparison is then subjected to sensitivity analyses by reference to the principal parameters, including:

- changes in the discount rate;
- changes in the perpetual growth rate; and
- fluctuations in operating margin.

No impairment of goodwill would need to be recognized in the event of a reasonably possible change in the assumptions used in 2022.

A value in use calculation for each of the segments would not result in an impairment loss using:

- a discount rate up to 2.6 percentage points above the rates actually used; or
- a perpetual growth rate up to 4.3 percentage points below the rates actually used; or
- an operating margin up to 6.7 percentage points below the rates actually used.

No impairment losses were recognized against goodwill in the years ended December 31, 2022, 2021 or 2020.

Other intangible assets

When there is evidence that an asset may have become impaired, the asset's value in use is calculated by applying an after-tax discount rate to the estimated future after-tax cash flows from that asset. For the purposes of impairment testing, the tax cash flows relating to the asset are determined using a notional tax rate incorporating the notional tax benefit that would result from amortizing the asset if its value in use were regarded as its depreciable amount for tax purposes. Applying after-tax discount rates to after-tax cash flows gives the same values in use as would be obtained by applying pre-tax discount rates to pre-tax cash flows.

The after-tax discount rates used in 2022 for impairment testing of other intangible assets in the Pharmaceuticals, Consumer Healthcare and Vaccines segments were obtained by adjusting Sanofi's weighted average cost of capital to reflect specific country and business risks, giving after-tax discount rates in a range from 7.25% to 8.25%.

In most instances, there are no market data that would enable fair value less costs to sell to be determined other than by means of developing a similar estimate based on future cash flows. Consequently, recoverable amount is in substance equal to value in use. The estimates used to determine value in use are sensitive to assumptions specific to the nature of the asset and to Sanofi's activities. Apart from the discount rate, the principal assumptions used in 2022 were as follows:

- mid-term and long-term forecasts;
- perpetual growth or attrition rates, when applicable; and
- probability of success of current research and development projects.

The assumptions used in testing intangible assets for impairment are reviewed at least annually.

In 2022, 2021 and 2020, impairment testing of other intangible assets (excluding software) resulted in the recognition of net impairment losses as shown below:

(€ million)	2022	2021	2020
Impairment of other intangible assets, net of reversals (excluding software)	**(454)**	**192**	**330**
Marketed products	(1,561)	42	2
Pharmaceuticals [(a)]	*(1,542)*	*1*	*2*
Vaccines	*16*	—	—
Consumer Healthcare	*(35)*	*41*	—
Research and development projects [(a) / (b)]	1,107	150	328

(a) For 2022, these amounts mainly comprise a reversal of €2,154 million of impairment losses taken against Eloctate® and BIVV001 (assets belonging to the Eloctate franchise), consisting of €1,554 million for marketed products and €600 million for research and development projects respectively. In 2019, the launch of competing products for Eloctate® led Sanofi to update its sales forecasts for products belonging to the franchise, as a result of which impairment losses of €2.8 billion were recognized against the assets in question. The reversal reflects the approval by the FDA on February 22, 2023 of the marketing authorization application for ALTUVIIIO™ (the commercial name of efanesoctocog alpha, corresponding to the BIVV001 project), which was submitted in 2022.

(b) For 2022, this amount mainly comprises:

- *an impairment loss of €1,586 million taken against the development project for SAR444245 (non-alpha interleukin-2), recognized following revised cash flow projections reflecting unfavorable developments in the launch schedule;*
- *the €600m reversal relating to the BIVV001 project (see above).*

For 2021, this line relates to the discontinuation of the development of sutimlimab in the treatment of Immune Thrombocytopenic Purpura (ITP), and to the termination of various research projects in Vaccines. For 2020, this line mainly comprises impairment losses taken against R&D programs within the Specialty Care GBU, and the discontinuation of certain R&D programs and collaboration agreements in Diabetes.

Property, plant and equipment

Impairment losses taken against property, plant and equipment are disclosed in Note D.3.

D.6. Investments accounted for using the equity method

Investments accounted for using the equity method comprise associates and joint ventures (see Note B.1.), and are set forth below.

(€ million)	% interest	2022	2021	2020
EUROAPI[(a)]	30.1	392	—	—
Infraserv GmbH & Co. Höchst KG[(b)]	31.2	97	80	72
MSP Vaccine Company[(c)]	50.0	104	88	44
Other investments	—	84	82	85
Total		**677**	**250**	**201**

(a) Following the distribution in kind and the acquisition of an equity interest by EPIC Bpifrance, Sanofi holds 30.1% of the capital of EUROAPI (see Note B.1.).
(b) Joint venture.
(c) Joint venture. MSP Vaccine Company owns 100% of MCM Vaccine B.V.

The table below shows Sanofi's overall share of (i) profit or loss and (ii) other comprehensive income from investments accounted for using the equity method, showing the split between associates and joint ventures in accordance with IFRS 12 (the amounts for each individual associate or joint venture are not material):

	2022		2021		2020	
(€ million)	Joint ventures	Associates	Joint ventures	Associates	Joint ventures	Associates
Share of profit/(loss) from investments accounted for using the equity method	74	(6)	26	13	4	355 [(a)]
Share of other comprehensive income from investments accounted for using the equity method	(2)	(3)	(6)	—	8	(311)
Total	**72**	**(9)**	**20**	**13**	**12**	**44**

(a) Includes €343 million for Sanofi's share of the net income of Regeneron up to and including May 29, 2020 (see Note D.2.2.).

The financial statements include arm's length commercial transactions between Sanofi and some equity-accounted investments that are classified as related parties. The principal transactions and balances with related parties are summarized below:

(€ million)	2022 [(b)]	2021	2020
Sales	131	70	75
Royalties and other income[(a)]	81	66	97
Accounts receivable and other receivables	174	116	50
Purchases and other expenses (including research expenses)[(a)]	477	178	747
Accounts payable and other payables	132	28	15

(a) For 2020, these amounts include transactions between Sanofi and Regeneron for the period from January 1 through May 29, 2020. The table above does not include the repurchase by Regeneron of its own shares from Sanofi (see Note D.2.2.).
(b) In 2022, these items include Sanofi's transactions with EUROAPI from May 10, 2022 (see Note D.1.).

There were no funding commitments to associates and joint ventures as of December 31, 2022, December 31, 2021 or December 31, 2020.

For off balance sheet commitments of an operational nature involving joint ventures, see Note D.21.1.

D.7. Other non-current assets

Other non-current assets comprise:

(€ million)	2022	2021	2020
Equity instruments at fair value through other comprehensive income (D.7.1.)	936	823	588
Debt instruments at fair value through other comprehensive income (D.7.2.)	329	447	426
Other financial assets at fair value through profit or loss (D.7.3.)	823	902	890
Pre-funded pension obligations (Note D.19.1.)	269	408	177
Long-term prepaid expenses[(a)]	286	59	92
Long-term loans and advances and other non-current receivables[(b)]	452	485	537
Derivative financial instruments (Note D.20.)	—	3	24
Total	**3,095**	**3,127**	**2,734**

(a) The movement in this item mainly comprises (i) the non-current portion of a $100 million upfront payment made on signature of a research agreement with Exscientia on January 7, 2022 to develop a portfolio of precision-engineered medicines using artificial intelligence; and (ii) the non-current portion of a $150 million upfront payment made as part of a strategic partnership with IGM Biosciences signed on March 29, 2022, with a view to developing targets in oncology, immunology and inflammation
(b) As of December 31, 2022, this item includes a receivable under a sub-lease amounting to €164 million, or €227 million before discounting.

D.7.1. Equity instruments at fair value through other comprehensive income

Quoted equity investments

The line "Equity instruments at fair value through other comprehensive income" includes equity investments quoted in an active market with a carrying amount of €387 million as of December 31, 2022, €396 million as of December 31, 2021 and €439 million as of December 31, 2020.

The main changes in quoted equity investments included in the "Equity instruments at fair value through other comprehensive income" category in the year ended December 31, 2022 are described below:

- the sale in June 2022 of the residual equity interest in Regeneron (see Note C.1.). for $174 million, the entire loss on which was recorded within ***Other comprehensive income***; and
- the acquisition of an equity interest in Innovent Biologics, in connection with a strategic collaboration agreement to intensify development in oncology medicines signed in August 2022, which had a fair value of €250 million as of that date and €228 million as of December 31, 2022.

The main changes in quoted equity investments included in this category in previous years are described below:

- in 2021, following completion of the acquisition of Translate Bio on September 14, 2021 (see Note D.2.1.), the equity interest of approximately 5% in Translate Bio previously held by Sanofi ceased to be accounted for as an ***equity instrument at fair value through other comprehensive income***;
- in 2020:
  - following the sale of 22.8 million shares of Regeneron common stock on May 29, 2020 (see Note D.2.2.), Sanofi ceased to exercise significant influence over Regeneron, and this investment ceased to be accounted for using the equity method (see Note D.6.). In accordance with IFRS 9 (Financial Instruments), the 400,000 shares retained by Sanofi were classified in the "Equity instruments at fair value through other comprehensive income" category as of May 29, 2020, at a carrying amount of €221 million. As of December 31, 2020, Sanofi held 279,766 Regeneron shares with a carrying amount of €111 million,
  - an equity injection was made into Translate Bio under the terms of the collaboration and license agreement announced on June 23, 2020, which had a carrying amount of €74 million as of December 31, 2021 and represented an equity interest of approximately 8% of Translate Bio as of that date,
  - Sanofi owns equity interests in quoted biotechnology companies. Movements in the quoted market prices of the shares held in those companies generated a net gain of €357 million, recognized in "Equity instruments at fair value through other comprehensive income".

A 10% decline in stock prices of the quoted equity investments included within "Equity instruments at fair value through other comprehensive income" would have had a pre-tax impact of €39 million on ***Other comprehensive income*** as of December 31, 2022.

Unquoted equity investments

The line item "Equity instruments at fair value through other comprehensive income" also includes equity investments not quoted in an active market with a carrying amount of €549 million as of December 31, 2022, €427 million as of December 31, 2021 and €149 million as of December 31, 2020.

The change in unquoted equity investments included in the "Equity instruments at fair value through other comprehensive income" category during the year ended December 31, 2022 was mainly due to various equity stakes acquired through the Sanofi Ventures fund, partly offset by the sale in October 2022 of the 19% non-controlling interest in Onduo for $175 million; the entire gain on the disposal was recognised in ***Other comprehensive income***.

D.7.2. Debt instruments at fair value through other comprehensive income

The "Debt instruments at fair value through other comprehensive income" category includes quoted euro-denominated senior bonds amounting to €329 million as of December 31, 2022, including €104 million of securities obtained in exchange for financial assets held to meet obligations to employees under post-employment benefit plans.

Sanofi held €447 million of quoted senior bonds as of December 31, 2021 and €426 million as of December 31, 2020.

As regards debt instruments held to meet obligations to employees under post-employment benefit plans, an increase of 10 basis points in market interest rates as of December 31, 2022 would have had a pre-tax impact of €1 million on ***Other comprehensive income***.

As regards other quoted debt instruments, an increase of 10 basis points in market interest rates as of December 31, 2022 would have had a pre-tax impact of €1 million on ***Other comprehensive income***.

Other comprehensive income recognized in respect of "Equity instruments at fair value through other comprehensive income" and "Debt instruments at fair value through other comprehensive income" represented unrealized after-tax gains of €256 million for the year ended December 31, 2022, versus unrealized after-tax gains of €322 million for the year ended December 31, 2021 and unrealized after-tax losses of €200 million for the year ended December 31, 2020.

An analysis of the change in gains and losses recognized in ***Other comprehensive income***, and of items reclassified to profit or loss, is presented in Note D.15.7.

D.7.3. Other financial assets at fair value through profit or loss

The "Other financial assets at fair value through profit or loss" category includes:

- contingent consideration receivable by Sanofi following the dissolution of the Sanofi Pasteur MSD (SPMSD) joint venture, based on a percentage of MSD's future sales during the 2017-2024 period of specified products previously distributed by SPMSD (see Note D.12.).

  The fair value of the MSD contingent consideration was determined by applying the royalty percentage stipulated in the contract to discounted sales projections. A reduction of one percentage point in the discount rate would increase the fair value of the MSD contingent consideration by approximately 1%.

  Changes in the fair value of this contingent consideration are recognized in the income statement within the line item ***Fair value remeasurement of contingent consideration*** (see Note B.18.). As of December 31, 2022, the contingent consideration asset amounted to €303 million (including a non-current portion of €196 million), versus €378 million (non-current portion: €275 million) as of December 31, 2021 and €483 million (non current portion: €374 million) as of December 31, 2020;
- a portfolio of financial investments (amounting to €512 million as of December 31, 2022) held to fund a deferred compensation plan provided to certain employees (versus €549 million as of December 31, 2021 and €453 million as of December 31, 2020);
- unquoted securities not meeting the definition of equity instruments amounting to €115 million as of December 31, 2022 (versus €78 million as of December 31, 2021 and €63 million as of December 31, 2020).

D.8. Assets held for sale or exchange and liabilities related to assets held for sale or exchange

Assets held for sale or exchange, and liabilities related to assets held for sale or exchange, comprise:

(€ million)	December 31, 2022	December 31, 2021	December 31, 2020
Assets held for sale or exchange	**85**	**89**	**83**
Liabilities related to assets held for sale or exchange	**10**	**—**	**32**

As of December 31, 2022, assets held for sale mainly related to items of property, plant and equipment.

As of December 31, 2021, assets held for sale mainly related to the divestment of a listed equity investments.

As of December 31, 2020, assets held for sale mainly related to the planned divestment of an industrial facility in North America.

D.9. Inventories

Inventories comprise the following:

	2022			2021			2020		
(€ million)	Gross value	Allowances	Carrying amount	Gross value	Allowances	Carrying amount	Gross value	Allowances	Carrying amount
Raw materials	1,613	(139)	1,474	1,344	(66)	1,278	1,051	(76)	975
Work in process	5,663	(678)	4,985	5,579	(554)	5,025	5,398	(542)	4,856
Finished goods	2,748	(247)	2,501	2,696	(284)	2,412	2,739	(218)	2,521
Total	**10,024**	**(1,064)**	**8,960**	**9,619**	**(904)**	**8,715**	**9,188**	**(836)**	**8,352**

Allowances include write-downs of products on hand pending marketing approval, except in specific circumstances where it is possible to estimate that recovery of the value of inventories as of the end of the reporting period is highly probable.

Inventories pledged as security for liabilities amounted to €3 million as of December 31, 2022 (versus €20 million as of December 31, 2021 and €17 million as of December 31, 2020).

D.10. Accounts receivable

Accounts receivable break down as follows:

(€ million)	December 31, 2022	December 31, 2021	December 31, 2020
Gross value	8,537	7,705	7,633
Allowances	(113)	(137)	(142)
Carrying amount	**8,424**	**7,568**	**7,491**

The impact of allowances against accounts receivable in 2022 was a net amount of less than €1 million (versus a net expense of €12 million in 2021 and a net expense of €30 million in 2020).

The gross value of overdue receivables was €452 million as of December 31, 2022, versus €455 million as of December 31, 2021 and €549 million as of December 31, 2020.

(€ million)	Overdue accounts gross value	Overdue by <1 month	Overdue by 1 to 3 months	Overdue by 3 to 6 months	Overdue by 6 to 12 months	Overdue by > 12 months
December 31, 2022	**452**	**118**	**161**	**87**	**35**	**51**
December 31, 2021	455	169	151	67	12	56
December 31, 2020	549	271	97	52	34	95

Amounts overdue by more than one month relate mainly to public-sector customers.

Some Sanofi subsidiaries have assigned receivables to factoring companies or banks without recourse. The amount of receivables derecognized was €131 million as of December 31, 2022 (€3 million as of December 31, 2021 and €18 million as of December 31, 2020). The residual guarantees relating to such transfers were immaterial as of December 31, 2022.

D.11. Other current assets

An analysis of ***Other current assets*** is set forth below:

(€ million)	2022	2021	2020
Tax receivables, other than corporate income taxes	658	802	687
Prepaid expenses	714	615	525
Other receivables[(a)]	1,290	805	567
Interest rate derivatives measured at fair value (see Note D.20.)	—	11	—
Currency derivatives measured at fair value (see Note D.20.)	206	284	58
Other current financial assets[(b)]	664	1,054	900
Total	**3,532**	**3,571**	**2,737**

(a) This line mainly comprises advance payments to suppliers, and receivables relating to Sanofi's activities as agent under a transitional services agreement.

(b) This item includes bank loans and receivables maturing in less than one year with high-grade counterparties. For 2021, this item also includes debt instruments derived from the acquisitions of Translate Bio and Kadmon (carried out in 2021) with maturities of more than 3 months at inception and less than 12 months at December 31, 2021.

D.12. Financial assets and liabilities measured at fair value

Under IFRS 7 (Financial Instruments: Disclosures), fair value measurements must be classified using a fair value hierarchy with the following levels:

- level 1: quoted prices in active markets for identical assets or liabilities (without modification or repackaging);
- level 2: quoted prices in active markets for similar assets and liabilities, or valuation techniques in which all important inputs are derived from observable market data;
- level 3: valuation techniques in which not all important inputs are derived from observable market data.

The valuation techniques used are described in Note B.8.5.

The table below shows the balance sheet amounts of assets and liabilities measured at fair value.

		2022			2021			2020		
		Level in the fair value hierarchy			Level in the fair value hierarchy			Level in the fair value hierarchy		
(€ million)	Note	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Financial assets measured at fair value										
Quoted equity investments	D.7.1.	387	—	—	396	—	—	439	—	—
Unquoted equity investments	D.7.1.	—	—	549	—	—	427	—	—	149
Quoted debt securities	D.7.2.	329	—	—	447	—	—	426	—	—
Unquoted debt securities not meeting the definition of equity instruments	D.7.3.	—	—	115	—	—	78	—	—	63
Contingent consideration relating to divestments	D.7.3.	—	—	303	—	—	378	—	—	483
Financial assets held to meet obligations under deferred compensation plans	D.7.3. and D.11.	512	—	—	549	—	—	454	—	—
Non-current derivatives	D.7.	—	—	—	—	3	—	—	24	—
Current derivatives	D.11.	—	206	—	—	295	—	—	58	—
Mutual fund investments	D.13.	9,537	—	—	5,057	—	—	8,703	—	—
Total financial assets measured at fair value		**10,765**	**206**	**967**	**6,449**	**298**	**883**	**10,022**	**82**	**695**
Financial liabilities measured at fair value										
Bayer contingent purchase consideration arising from the acquisition of Genzyme	D.18.	—	—	26	—	—	59	—	—	104
MSD contingent consideration (European vaccines business)	D.18.	—	—	204	—	—	269	—	—	312
Shire contingent consideration arising from the acquisition of Translate Bio	D.18.	—	—	380	—	—	354	—	—	—
Contingent consideration arising from acquisition of Amunix	D.18.	—	—	165	—	—	—	—	—	—
Other contingent consideration arising from business combinations and acquisitions	D.18.	—	—	4	—	—	32	—	—	189
Non-current derivatives	D.19.	—	232	—	—	6	—	—	92	—
Current derivatives	D.19.5	—	94	—	—	79	—	—	205	—
Total financial liabilities measured at fair value		**—**	**326**	**779**	**—**	**85**	**714**	**—**	**297**	**605**

No transfers between the different levels of the fair value hierarchy occurred during 2022.

D.13. Cash and cash equivalents

(€ million)	2022	2021	2020
Cash	1,385	1,358	1,144
Cash equivalents[(a)]	11,351	8,740	12,771
Cash and cash equivalents	**12,736**	**10,098**	**13,915**

(a) As of December 31, 2022, cash equivalents mainly comprised the following: (i) €9,537 million invested in euro and US dollar denominated money-market mutual funds (December 31, 2021: €5,057 million; December 31, 2020: €8,703 million); (ii) €1,167 million of term deposits (December 31, 2021: €2,768 million; December 31, 2020: €3,259 million) and (iii) nil commercial paper (December 31, 2021: €179 million; December 31, 2020: €74 million). Cash equivalents also include €439 million held by captive insurance and reinsurance companies in accordance with insurance regulations (December 31, 2021: €427 million; December 31, 2020: €425 million).

D.14. Net deferred tax position

An analysis of the net deferred tax position is set forth below:

(€ million)	2022	2021	2020 [(d)]
Deferred taxes on:			
Consolidation adjustments (intragroup margin in inventory)	1,388	1,292	1,142
Provision for pensions and other employee benefits	850	1,117	1,156
Remeasurement of other acquired intangible assets	(3,269) [(a)]	(3,079)	(3,083)
Recognition of acquired property, plant and equipment at fair value	(24)	(26)	(27)
Equity interests in subsidiaries and investments in other entities[(b)]	(617)	(590)	(522)
Tax losses available for carry-forward	1,506	1,516	1,327
Stock options and other share-based payments	92	88	89
Accrued expenses and provisions deductible at the time of payment[(c)]	1,859	1,585	1,399
Other	1,755	1,078	925
Net deferred tax asset/(liability)	**3,540**	**2,981**	**2,406**

(a) As of December 31, 2022, includes remeasurements of the acquired intangible assets of Bioverativ (€1,429 million), Principia (€625 million), Ablynx (€229 million), Genzyme (€150 million) and Amunix (€118 million).

(b) In some countries, Sanofi is liable for withholding taxes and other tax charges when dividends are distributed. Consequently, Sanofi recognizes a deferred tax liability on the reserves of French and foreign subsidiaries (approximately €59.1 billion) which it regards as likely to be distributed in the foreseeable future. In determining the amount of the deferred tax liability as of December 31, 2022, Sanofi took into account changes in the ownership structure of certain subsidiaries, and the effects of changes in the taxation of dividends in France, following the ruling of the Court of Justice of the European Union in the Steria case and the resulting amendments to the 2015 Finance Act.

(c) Includes deferred tax assets related to restructuring provisions, amounting to €256 million as of December 31, 2022, €307 million as of December 31, 2021, and €259 million as of December 31, 2020.

(d) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

The reserves of Sanofi subsidiaries that would be taxable if distributed but for which no distribution is planned, and for which no deferred tax liability has therefore been recognized, totaled €10.6 billion as of December 31, 2022, compared with €10.0 billion as of December 31, 2021 and €11.5 billion as of December 31, 2020.

Most of Sanofi's tax loss carry-forwards are available indefinitely. For a description of policies on the recognition of deferred tax assets, refer to Note B.22. For each tax consolidation, the recognition of deferred tax assets is determined on the basis of profit forecasts that are consistent with Sanofi's medium-term strategic plan, and taking into consideration the tax consequences of the strategic opportunities available to Sanofi within the period of availability of tax loss carry-forwards and the specific circumstances of each tax consolidation. Deferred tax assets relating to tax loss carry-forwards as of December 31, 2022 amounted to €2,650 million, of which €1,144 million were not recognized (including €488 million in respect of capital losses). This compares with €2,391 million as of December 31, 2021 (of which €875 million were not recognized) and €1,658 million as of December 31, 2020 (of which €331 million were not recognized).

The table below shows when tax losses available for carry-forward are due to expire:

(€ million)	Tax losses available for carry-forward[(a)]
2023	—
2024	3
2025	21
2026	28
2027	102
2028 and later	8,349
Total as of December 31, 2022	**8,503**
Total as of December 31, 2021	**7,644**
Total as of December 31, 2020	**6,515**

(a) Excluding tax loss carry-forwards on asset disposals. Such carry-forwards amounted to €5 million as of December 31, 2022, €5 million as of December 31, 2021 and €6 million as of December 31, 2020.

Use of tax loss carry-forwards is limited to the entity in which they arose. In jurisdictions where tax consolidations are in place, tax losses can be netted against taxable income generated by entities in the same tax consolidation.

Deferred tax assets not recognized (primarily because their future recovery was not regarded as probable given the expected results of the entities in question) amounted to €995 million in 2022, €615 million in 2021 and €346 million in 2020.

D.15. Consolidated shareholders' equity

D.15.1. Share capital

As of December 31, 2022, the share capital was €2,521,671,464, consisting of 1,260,835,732 shares with a par value of €2. Treasury shares held by Sanofi are as follows:

	Number of shares (million)	% of share capital for the period
December 31, 2022	**8.20**	**0.650%**
December 31, 2021	11.02	0.872%
December 31, 2020	8.28	0.658%
January 1, 2020	0.02	0.002%

Treasury shares are deducted from shareholders' equity. Gains and losses on disposals of treasury shares are recorded directly in equity and are not recognized in net income for the period.

Movements in the share capital of the Sanofi parent company over the last three years are set forth below:

Date	Transaction	Number of shares
December 31, 2019		**1,253,846,111**
During 2020	Capital increase by exercise of stock subscription options[(a)]	868,655
During 2020	Capital increase by issuance of restricted shares[(b)]	1,666,256
Board meeting of July 28, 2020	Capital increase reserved for employees	**2,590,716**
December 31, 2020		**1,258,971,738**
During 2021	Capital increase by exercise of stock subscription options[(a)]	190,076
During 2021	Capital increase by issuance of restricted shares[(b)]	1,836,179
Board meeting of July 28, 2021	Capital increase reserved for employees	2,562,702
December 31, 2021		**1,263,560,695**
During 2022	Capital increase by exercise of stock subscription options[(a)]	490,373
During 2022	Capital increase by issuance of restricted shares[(b)]	1,499,987
Board meeting of July 27, 2022	Capital increase reserved for employees	2,027,057
Board meeting of December 14, 2022	Reduction in share capital by cancellation of treasury shares	(6,742,380)
December 31, 2022		**1,260,835,732**

(a) Shares issued on exercise of Sanofi stock subscription options.
(b) Shares vesting under restricted share plans and issued in the period.

For the disclosures about the management of capital required under IFRS 7, refer to Note B.27.

D.15.2. Restricted share plans

Restricted share plans are accounted for in accordance with the policies described in Note B.24.3. The principal characteristics of those plans are as follows:

	2022		2021		2020	
Type of plan	**Performance share plans**	**Performance share plans**	**Performance share plans**	**Performance share plans**	**Performance share plans**	**Performance share plans**
Date of Board meeting approving the plan	May 3, 2022	December 14, 2022	April 30, 2021	October 27, 2021	April 28, 2020	October 28, 2020
Service period	3 years	3 years	3 years	3 years	3 years	3 years
Total number of shares awarded	3,344,432	109,981	3,484,420	13,521	3,340,501	73,027
Of which with no market condition	2,000,627	10,335	2,209,901	—	2,536,893	—
Fair value per share awarded[(a)]	€91.19	€79.17	€77.27	—	€82.36	—
Of which with market condition	1,343,805	99,646	1,274,519	13,521	803,608	73,027
Fair value per share awarded other than to the Chief Executive Officer[(b)]	€86.65	€69.60	€71.30	€68.45	€76.11	€63.18
Fair value per share awarded other than to the Chief Executive Officer - additional shares[(c)]	€49.00	€54.70	—	—	—	—
Fair value per share awarded to the Chief Executive Officer[(b)]	€84.46	—	€71.30	—	€76.11	—
Fair value of plan at the date of grant (€ million)	**294**	**8**	**262**	**1**	**270**	**5**

(a) Market price of Sanofi shares at the date of grant, adjusted for dividends expected during the vesting period.

(b) Weighting between (i) fair value determined using the Monte Carlo model and (ii) market price of Sanofi shares at the date of grant, adjusted for dividends expected during the vesting period.

(c) Additional tranche subject to a higher level of market conditions: 114,874 additional shares were awarded in May 2022, and 9,066 additional shares were awarded in December 2022.

The total expense recognized for all restricted share plans, and the number of restricted shares not yet fully vested, are shown in the table below:

	2022	2021	2020
Total expense for restricted share plans (€ million)	206	193	222
Number of shares not yet fully vested	9,121,573	9,507,849	10,546,612
Under 2022 plans	*3,206,861*	—	—
Under 2021 plans	*3,097,531*	*3,364,895*	—
Under 2020 plans	*2,817,181*	*3,014,496*	*3,284,558*
Under 2019 plans	—	*3,128,458*	*3,375,717*
Under 2018 plans	—	—	*3,886,337*

D.15.3. Capital increases

The characteristics of the employee share ownership plans awarded in the form of a capital increase reserved for employees in 2022, 2021 and 2020 are summarized in the table below:

	2022	2021	2020
Date of Board meeting approving the plan	February 3, 2022	February 4, 2021	February 5, 2020
Subscription price (€)[(a)]	80.21	69.38	70.67
Subscription period	June 9-29, 2022	June 7-25, 2021	June 8-26, 2020
Number of shares subscribed	1,909,008	2,438,590	2,467,101
Number of shares issued immediately as employer's contribution	118,049	124,112	123,615

(a) Subscription price representing 80% of the average of the opening quoted market prices of Sanofi shares during the 20 trading days preceding June 6, 2022, June 3, 2021 and June 2, 2020, respectively.

The table below sets forth the expense recognized for each plan:

(€ million)	2022	2021	2020
Expense recognized	39	51	52
of which employer's contribution	*11*	*11*	*11*

D.15.4. Repurchase of Sanofi shares

The Annual General Meetings of Sanofi shareholders held on May 3, 2022, April 30, 2021 and April 28, 2020 each authorized a share repurchase program for a period of 18 months. The following repurchases have been made under those programs:

(in number of shares and € million)	2022		2021		2020	
Year of authorization	Number of shares	Value	Number of shares	Value	Number of shares	Value
2022 program	1,510,000	137	—	—	—	—
2021 program	3,976,992	360	2,765,388	242	—	—
2020 program	—	—	1,758,569	140	5,685,426	461
2019 program	—	—	—	—	3,982,939	361

D.15.5. Reductions in share capital

Reductions in share capital for the accounting periods presented are described in the table included at Note D.15.1. above.

Those reductions have no impact on shareholders' equity.

D.15.6. Currency translation differences

Currency translation differences comprise the following:

(€ million)	2022	2021	2020 [(a)]
Attributable to equity holders of Sanofi	1,499	(865)	(3,384)
Attributable to non-controlling interests	(37)	(42)	(55)
Total	**1,462**	**(907)**	**(3,439)**

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement, as described in Note A.2.1. to the financial statements for the year ended December 31, 2021.

The balance as of December 31, 2022 includes an after-tax amount of €(580) million relating to hedges of net investments in foreign operations (refer to Note B.8.3. for a description of the relevant accounting policy), compared with €(317) million as of December 31, 2021 and €(136) million as of December 31, 2020.

The movement in ***Currency translation differences*** is mainly attributable to the US dollar.

D.15.7. Other comprehensive income

Movements within other comprehensive income are shown below:

(€ million)	2022	2021	2020 [a]
Actuarial gains/(losses):			
• Actuarial gains/(losses) excluding investments accounted for using the equity method (see Note D.19.1.)	650	685	(266)
• Actuarial gains/(losses) of investments accounted for using the equity method, net of taxes	4	1	(1)
• Tax effects	(212)	(36)	45
Equity instruments included in financial assets and financial liabilities:			
• Change in fair value (excluding investments accounted for using the equity method)	(4)	154	358
• Change in fair value (investments accounted for using the equity method, net of taxes)	—	—	(14)
• Equity risk hedging instruments designated as fair value hedges	17	11	(24)
• Tax effects	(4)	(18)	(84)
Items not subsequently reclassifiable to profit or loss	**451**	**797**	**14**
Debt instruments included in financial assets:			
• Change in fair value (excluding investments accounted for using the equity method)[b]	(77)	(21)	15
• Tax effects	15	5	(3)
Cash flow and fair value hedges:			
• Change in fair value (excluding investments accounted for using the equity method)[c]	5	(6)	4
• Change in fair value (investments accounted for using the equity method, net of taxes)	2	—	—
• Tax effects	(1)	2	(2)
Change in currency translation differences:			
• Currency translation differences on foreign subsidiaries (excluding investments accounted for using the equity method)[d]	2,643	2,719	(3,870)
• Currency translation differences (investments accounted for using the equity method)[d]	(11)	(6)	32
• Currency translation differences related to the investment in Regeneron and reclassified to profit or loss[e]	—	—	(318)
• Hedges of net investments in foreign operations[d]	(354)	(254)	180
• Tax effects[e]	91	71	(59)
Items subsequently reclassifiable to profit or loss	**2,313**	**2,510**	**(4,021)**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

(b) Amounts reclassified to profit or loss: immaterial amount in 2022, €4 million in 2021 and €5 million in 2020.

(c) Amounts reclassified to profit or loss: €2 million in 2022, €12 million in 2021 and €1 million in 2020.

(d) Amounts reclassified to profit or loss: €40 million in 2022, including €35 million relating to the deconsolidation of EUROAPI (see note D.1.). The amounts reclassified to profit and loss were immaterial in 2021 and 2020. Currency translation differences arise from the translation into euros of the financial statements of foreign subsidiaries, and are mainly due to the appreciation of the dollar against the euro.

(e) The amount recorded for 2020 relates to the translation reserve arising on the investment in Regeneron; the reserve was reclassified to profit or loss in accordance with IAS 21 (The Effects of Changes in Foreign Exchange Rates), including €2 million (net of tax) relating to hedges of net investments in foreign operations.

D.15.8. Stock options

Stock option plans awarded and measurement of stock option plans

No stock options were awarded during 2022, 2021 or 2020.

Stock subscription option plans

Details of the terms of exercise of stock subscription options granted under the various plans are presented below in Sanofi share equivalents. These plans were awarded to certain corporate officers and employees of Sanofi companies.

The table shows all Sanofi stock subscription option plans still outstanding or under which options were exercised in the year ended December 31, 2022:

Source	Date of grant	Number of options granted	Start date of exercise period	Expiry date	Exercise price (€)	Number of options outstanding as of 12/31/2022
Sanofi-Aventis	03/05/2012	814,050	03/06/2016	03/05/2022	56.44	—
Sanofi	03/05/2013	788,725	03/06/2017	03/05/2023	72.19	78,089
Sanofi	03/05/2014	1,009,250	03/06/2018	03/05/2024	73.48	506,042
Sanofi	06/24/2015	435,000	06/25/2019	06/24/2025	89.38	338,464
Sanofi	05/04/2016	402,750	05/05/2020	05/04/2026	75.90	264,750
Sanofi	05/10/2017	378,040	05/11/2021	05/10/2027	88.97	268,440
Sanofi	05/02/2018	220,000	05/03/2022	05/02/2028	65.84	168,784
Sanofi	04/30/2019	220,000	05/02/2023	04/30/2029	76.71	213,400
Total						**1,837,969**

The exercise of all outstanding stock subscription options would increase shareholders' equity by approximately €145 million. The exercise of each option results in the issuance of one share.

Summary of stock option plans

A summary of stock options outstanding at each balance sheet date, and of movements during the relevant periods, is presented below:

	Number of options	Weighted average exercise price per share (€)	Total (€ million)
Options outstanding at January 1, 2020	**3,822,020**	**70.58**	**270**
Options exercisable	*2,650,375*	*67.14*	*178*
Options exercised	(868,655)	59.20	(52)
Options cancelled[(a)]	(91,305)	87.73	(8)
Options forfeited	(282,790)	54.12	(15)
Options outstanding at December 31, 2020	**2,579,270**	**75.61**	**195**
Options exercisable	*1,845,050*	*74.51*	*137*
Options exercised	(190,076)	59.53	(11)
Options cancelled[(a)]	(51,216)	65.84	(3)
Options forfeited	(10)	50.48	—
Options outstanding at December 31, 2021	**2,337,968**	**77.13**	**180**
Options exercisable	*1,949,184*	*78.15*	*152*
Options exercised	(490,373)	71.39	(35)
Options cancelled[(a)]	(9,626)	80.56	(1)
Options outstanding at December 31, 2022	**1,837,969**	**78.64**	**145**
Options exercisable	*1,624,569*	*78.89*	*128*

(a) Mainly due to the grantees leaving Sanofi.

The table below provides summary information about options outstanding and exercisable as of December 31, 2022:

	Outstanding			Exercisable	
Range of exercise prices per share	Number of options	Weighted average residual life (years)	Weighted average exercise price per share (€)	Number of options	Weighted average exercise price per share (€)
From €60.00 to €70.00 per share	168,784	5.34	65.84	168,784	65.84
From €70.00 to €80.00 per share	1,062,281	2.68	74.64	848,881	74.12
From €80.00 to €90.00 per share	606,904	3.31	89.20	606,904	89.20
Total	**1,837,969**			**1,624,569**	

D.15.9. Number of shares used to compute diluted earnings per share

Diluted earnings per share is computed using the number of shares outstanding plus stock options with dilutive effect and restricted shares.

(million)	2022	2021	2020
Average number of shares outstanding	1,251.9	1,252.5	1,253.6
Adjustment for stock options with dilutive effect	0.3	0.3	0.4
Adjustment for restricted shares	4.7	5.1	6.1
Average number of shares used to compute diluted earnings per share	**1,256.9**	**1,257.9**	**1,260.1**

In 2022, all stock options were taken into account in computing diluted earnings per share because they all had a dilutive effect. In both 2021 and 2020, 0.6 million stock options were not taken into account in computing diluted earnings per share because they had no dilutive effect.

D.16. Non-controlling interests

Non-controlling interests did not represent a material component of Sanofi's consolidated financial statements in the years ended December 31, 2022, 2021 and 2020.

D.17. Debt, cash and cash equivalents and lease liabilities

D.17.1. Debt, cash and cash equivalents

Changes in Sanofi's financial position during the period were as follows:

(€ million)	2022	2021	2020
Long-term debt	14,857	17,123	19,745
Short-term debt and current portion of long-term debt	4,174	3,183	2,767
Interest rate and currency derivatives used to manage debt	187	(56)	119
Total debt	**19,218**	**20,250**	**22,631**
Cash and cash equivalents	(12,736)	(10,098)	(13,915)
Interest rate and currency derivatives used to manage cash and cash equivalents	(45)	(169)	74
Net debt[(a)]	**6,437**	**9,983**	**8,790**

(a) Net debt does not include lease liabilities, which amounted to €2,181 million as of December 31, 2022, €2,108 million as of December 31, 2021, and €1,163 million as of December 31, 2020 (see the maturity analysis at Note D.17.2.).

"Net debt" is a non-IFRS financial measure used by management and investors to measure Sanofi's overall net indebtedness.

Reconciliation of carrying amount to value on redemption

				Value on redemption		
(€ million)	Carrying amount at December 31, 2022	Amortized cost	Adjustment to debt measured at fair value	December 31, 2022	December 31, 2021	December 31, 2020
Long-term debt	14,857	51	235	15,143	17,176	19,794
Short-term debt and current portion of long-term debt	4,174	—	4	4,178	3,183	2,767
Interest rate and currency derivatives used to manage debt	187	—	(235)	(48)	(45)	142
Total debt	**19,218**	**51**	**4**	**19,273**	**20,314**	**22,703**
Cash and cash equivalents	(12,736)	—	—	(12,736)	(10,098)	(13,915)
Interest rate and currency derivatives used to manage cash and cash equivalents	(45)	—	—	(45)	(169)	74
Net debt	**6,437**	**51**	**4**	**6,492**	**10,047**	**8,862**

a) Principal financing transactions during the year

The table below shows the movement in total debt during the period:

		Cash flows from financing activities			Non-cash items			
(€ million)	December 31, 2021	Repayments	New borrowings	Other cash flows	Currency translation differences[a]	Reclassification from non-current to current	Other items[b]	December 31, 2022
Long-term debt	17,123	(11)	1,549	—	56	(3,632)	(228)	14,857
Short-term debt and current portion of long-term debt	3,183	(2,707)	—	43	20	3,632	3	4,174
Interest rate and currency derivatives used to manage debt	(56)	—	—	(373)	366	7	243	187
Total debt	**20,250**	**(2,718)**	**1,549**	**(330)**	**442**	**7**	**18**	**19,218**

(a) These amounts include unrealized gains and losses, and the impact of foreign currency translation of the financial statements of subsidiaries outside the Euro zone.

(b) These amounts include changes in accrued interest balances, and fair value adjustments.

During 2022, Sanofi carried out a bond issue of €1.5 billion in April as part of its EMTN (Euro Medium Term Note) program, in two tranches:

i. €850 million bearing interest at a fixed annual rate of 0.875% and maturing April 2025; and

ii. €650 million bearing interest at a fixed annual rate of 1.250% and maturing April 2029; the amount of interest applicable is contingent on the attainment of a sustainability performance objective, i.e.: the cumulative number of patients (subject to a minimum of 1.5 million) to which Sanofi Global Health has provided essential medicines to treat non-communicable diseases in the 40 poorest countries on the planet between 2022 and 2026.

Three bond issues were redeemed in 2022:

i. €1,000 million issued September 2014 and maturing March 2022, early redeemed on January 10, 2022;

ii. €850 million issued March 2019 and maturing March 2022, early redeemed on February 21, 2022; and

iii. €850 million issued September 2016 and maturing September 2022, early redeemed on June 13, 2022.

As of December 31, 2022 Sanofi had two syndicated credit facilities of €4 billion each to provide liquidity for the purposes of current operations, each of them linked to environmental and social indicators. The maturity of one facility has been extended to December 3, 2023 following the exercise of an extension option in June 2022, and the maturity of the other has been extended to December 6, 2027 following the exercise of an extension option in September 2022. Sanofi does not have any further extension options available for either facility.

In line with Sanofi's commitment to embed sustainable development in the "Play to Win" strategy, the two revolving credit facilities build in an adjustment mechanism that links the credit spread to the attainment of two sustainable development performance indicators: Sanofi's contribution to polio eradication, and the reduction in Sanofi's carbon footprint.

The tables below show the movement in total debt during prior periods:

		Cash flows from financing activities			Non-cash items			
(€ million)	December 31, 2020	Repayments	New borrowings	Other cash flows	Currency translation differences[a]	Reclassification from non-current to current	Other items[b]	December 31, 2021
Long-term debt	19,745	(38)	—	—	124	(2,704)	(4)	17,123
Short-term debt and current portion of long-term debt	2,767	(2,203)	—	(615)	248	2,704	282	3,183
Interest rate and currency derivatives used to manage debt	119	—	—	(197)	9	—	13	(56)
Total debt	**22,631**	**(2,241)**	**—**	**(812)**	**381**	**—**	**291**	**20,250**

(€ million)	December 31, 2019	Cash flows from financing activities: Repayments	Cash flows from financing activities: New borrowings	Non-cash items: Other cash flows	Non-cash items: Currency translation differences [a]	Non-cash items: Reclassification from non-current to current	Non-cash items: Other items[b]	December 31, 2020
Long-term debt	20,131	—	2,019	—	(152)	(2,285)	32	19,745
Short-term debt and current portion of long-term debt	4,554	(3,952)	—	86	(219)	2,285	13	2,767
Interest rate and currency derivatives used to manage debt	(117)	—	—	196	(14)	—	54	119
Total debt	**24,568**	**(3,952)**	**2,019**	**282**	**(385)**	**—**	**99**	**22,631**

(a) These amounts include unrealized gains and losses, and the impact of foreign currency translation of the financial statements of subsidiaries outside the Euro zone.

(b) These amounts include movements in accrued interest and fair value remeasurements.

b) Net debt by type, at value on redemption

(€ million)	2022 Non-current	2022 Current	2022 Total	2021 Non-current	2021 Current	2021 Total	2020 Non-current	2020 Current	2020 Total
Bond issues	15,044	3,817	18,861	17,118	2,828	19,946	19,698	2,280	21,978
Other bank borrowings	99	187	286	21	163	184	96	200	296
Other borrowings	—	6	6	37	3	40	–	2	2
Bank credit balances	—	168	168	–	189	189	–	285	285
Interest rate and currency derivatives used to manage debt	—	(48)	(48)	–	(45)	(45)	57	85	142
Total debt	**15,143**	**4,130**	**19,273**	**17,176**	**3,138**	**20,314**	**19,851**	**2,852**	**22,703**
Cash and cash equivalents	—	(12,736)	(12,736)	–	(10,098)	(10,098)	–	(13,915)	(13,915)
Interest rate and currency derivatives used to manage cash and cash equivalents	—	(45)	(45)	–	(169)	(169)	6	68	74
Net debt[a]	**15,143**	**(8,651)**	**6,492**	**17,176**	**(7,129)**	**10,047**	**19,857**	**(10,995)**	**8,862**

(a) Net debt does not include lease liabilities (see the maturity schedule in Note D.17.2.).

Bond issues carried out by Sanofi under the Euro Medium Term Note (EMTN) program are as follows:

Issuer	ISIN code	Issue date	Maturity	Annual interest rate	Amount (€ million)
Sanofi	FR0011625433	November 2013	November 2023	2.5%	1,000
Sanofi	FR0014009KS6	April 2022	April 2025	0.875%	850
Sanofi	FR0012146801	September 2014	September 2026	1.75%	1,510
Sanofi	FR0014009KQ0	April 2022	April 2029	1.25%	650
Sanofi	FR0012969038	September 2015	September 2025	1.5%	750
Sanofi	FR0013143997	April 2016	April 2024	0.625%	600
Sanofi	FR0013144003	April 2016	April 2028	1.125%	700
Sanofi	FR0013201639	September 2016	January 2027	0.5%	1,150
Sanofi	FR0013505104	March 2020	April 2025	1%	1,000
Sanofi	FR0013505112	March 2020	April 2030	1.5%	1,000
Sanofi	FR0013324332	March 2018	March 2023	0.5%	1,750
Sanofi	FR0013324340	March 2018	March 2026	1%	1,500
Sanofi	FR0013324357	March 2018	March 2030	1.375%	2,000
Sanofi	FR0013324373	March 2018	March 2038	1.875%	1,250
Sanofi	FR0013409844	March 2019	March 2029	0.875%	650
Sanofi	FR0013409851	March 2019	March 2034	1.25%	500

Bond issues carried out by Sanofi under the public bond issue program (shelf registration statement) registered with the US Securities and Exchange Commission (SEC) comprise:

Issuer	ISIN code	Issue date	Maturity	Annual interest rate	Amount ($ million)
Sanofi	US801060AC87	June 2018	June 2023	3.375%	1,000
Sanofi	US801060AD60	June 2018	June 2028	3.625%	1,000

The "Other borrowings" line mainly comprises participating shares issued between 1983 and 1987, of which 74,996 remain outstanding, with a nominal amount of €11 million.

In order to manage its liquidity needs for current operations, as of December 31, 2022 Sanofi has:

- a syndicated credit facility of €4 billion, drawable in euros and in US dollars, maturing December 3, 2023 following the exercise of the second extension option in June 2022; and
- a syndicated credit facility of €4 billion, drawable in euros and in US dollars, maturing December 6, 2027 following the exercise of the second extension option in September 2022.

Sanofi also has a €6 billion Negotiable European Commercial Paper program in France and a $10 billion Commercial Paper program in the United States. During 2022 only the US program was used, with an average drawdown of $2.3 billion (versus a maximum of $4.0 billion). As of December 31, 2022, there were no drawdowns under any of those programs.

The financing in place as of December 31, 2022 at the level of the holding company (which manages most of Sanofi's financing needs centrally) is not subject to any financial covenants, and contains no clauses linking spreads or fees to the credit rating.

c) Debt by maturity, at value on redemption

December 31, 2022		Current	Non-current				
(€ million)	Total	2023	2024	2025	2026	2027	2028 and later
Bond issues	18,861	3,817	600	2,600	4,160	—	7,684
Other bank borrowings	286	187	61	—	—	—	38
Other borrowings	6	6	—	—	—	—	—
Bank credit balances	168	168	—	—	—	—	—
Interest rate and currency derivatives used to manage debt	(48)	(48)	—	—	—	—	—
Total debt	**19,273**	**4,130**	**661**	**2,600**	**4,160**	**—**	**7,722**
Cash and cash equivalents	(12,736)	(12,736)	—	—	—	—	—
Interest rate and currency derivatives used to manage cash and cash equivalents	(45)	(45)	—	—	—	—	—
Net debt[(a)]	**6,492**	**(8,651)**	**661**	**2,600**	**4,160**	**—**	**7,722**

(a) Net debt does not include lease liabilities, which amounted to €2,181 million as of December 31, 2022; €2,108 million as of December 31, 2021; and €1,163 million as of December 31, 2020 (see the maturity analysis at Note D.17.2.).

As of December 31, 2022, the main undrawn confirmed general-purpose credit facilities at holding company level amounted to €8 billion, half of which expires in 2023 and the other half of which expires in 2027.

As of December 31, 2022, no single counterparty represented more than 6% of Sanofi's undrawn confirmed credit facilities.

December 31, 2021		Current	Non-current				
(€ million)	Total	2022	2023	2024	2025	2026	2027 and later
Bond issues	19,946	2,828	3,629	600	1,750	4,160	6,979
Other bank borrowings	184	163	18	2	1	–	—
Finance lease obligations	–	–	–	–	–	–	–
Other borrowings	40	3	–	–	–	–	37
Bank credit balances	189	189	–	–	–	–	–
Interest rate and currency derivatives used to manage debt	(45)	(45)	–	–	–	–	–
Total debt	**20,314**	**3,138**	**3,647**	**602**	**1,751**	**4,160**	**7,016**
Cash and cash equivalents	(10,098)	(10,098)	–	–	–	–	–
Interest rate and currency derivatives used to manage cash and cash equivalents	(169)	(169)	–	–	–	–	–
Net debt	**10,047**	**(7,129)**	**3,647**	**602**	**1,751**	**4,160**	**7,016**

December 31, 2020		Current	Non-current				
(€ million)	Total	2021	2022	2023	2024	2025	2026 and later
Bond issues	21,978	2,280	2,700	3,569	600	1,750	11,079
Other bank borrowings	296	200	73	6	2	6	9
Finance lease obligations	–	–	–	–	–	–	–
Other borrowings	2	2	–	–	–	–	–
Bank credit balances	285	285	–	–	–	–	–
Interest rate and currency derivatives used to manage debt	142	85	57	–	–	–	–
Total debt	**22,703**	**2,852**	**2,830**	**3,575**	**602**	**1,756**	**11,088**
Cash and cash equivalents	(13,915)	(13,915)	–	–	–	–	–
Interest rate and currency derivatives used to manage cash and cash equivalents	74	68	6	–	–	–	–
Net debt	**8,862**	**(10,995)**	**2,836**	**3,575**	**602**	**1,756**	**11,088**

d) Debt by interest rate, at value on redemption

The table below splits net debt between fixed and floating rate, and by maturity, as of December 31, 2022. The figures shown are values on redemption, before the effects of derivative instruments:

(€ million)	Total	2023	2024	2025	2026	2027	2028 and later
Fixed-rate debt	18,861	3,817	600	2,600	4,160	—	7,684
of which euro	*16,993*						
of which US dollar	*1,868*						
% fixed-rate	**98 %**						
Floating-rate debt	460	361	61	—	—	—	38
of which euro	*60*						
of which US dollar	*15*						
% floating-rate	**2 %**						
Debt	**19,321**	**4,178**	**661**	**2,600**	**4,160**	**—**	**7,722**
Cash and cash equivalents	(12,736)	(12,736)	—	—	—	—	—
of which euro	*(3,908)*						
of which US dollar	*(8,391)*						
% floating-rate	**100 %**						
Net debt	**6,585**	**(8,558)**	**661**	**2,600**	**4,160**	**—**	**7,722**

Sanofi issues debt in two currencies, the euro and the US dollar, and also invests its cash and cash equivalents in those currencies. Sanofi also operates cash pooling arrangements to manage the surplus cash and short-term liquidity needs of foreign subsidiaries located outside the euro zone.

To optimize the cost of debt or reduce the volatility of debt and manage its exposure to financial foreign exchange risk, Sanofi uses derivative instruments (interest rate swaps, currency swaps, foreign exchange swaps and forward contracts) that alter the fixed/floating rate split and the currency split of its net debt:

(€ million)	Total	2023	2024	2025	2026	2027	2028 and later
Fixed-rate debt	16,386	1,342	600	2,600	4,160	—	7,684
of which euro	*13,944*						
of which US dollar	*2,443*						
% fixed-rate	**85%**						
Floating-rate debt	2,886	2,787	61	—	—	—	38
of which euro	*592*						
of which US dollar	*950*						
% floating-rate	**15%**						
Debt	**19,273**	**4,130**	**661**	**2,600**	**4,160**	**—**	**7,722**
Cash and cash equivalents	(12,781)	(12,781)	—	—	—	—	—
of which euro	*(4,046)*						
of which US dollar	*(5,797)*						
of which Singapore dollar	*(2,155)*						
% floating-rate	**100%**						
Net debt	**6,492**	**(8,651)**	**661**	**2,600**	**4,160**	**—**	**7,722**

The table below shows the fixed/floating rate split of net debt at value on redemption after taking account of derivative instruments as of December 31, 2021 and December 31, 2020:

(€ million)	2021	%	2020	%
Fixed-rate debt	17,612	87%	20,713	91%
Floating-rate debt	2,702	13%	1,990	9%
Debt	**20,314**	**100%**	**22,703**	**100%**
Cash and cash equivalents	(10,267)		(13,841)	
Net debt	**10,047**		**8,862**	

The weighted average interest rate on debt as of December 31, 2022 was 1.6% before derivative instruments and 2.5% after derivative instruments. Cash and cash equivalents were invested as of December 31, 2022 at an average rate of 3.9% before derivative instruments and 4.0% after derivative instruments.

The projected full-year sensitivity of net debt to interest rate fluctuations for 2023 is as follows:

Change in short-term interest rates	Impact on pre-tax net income (€ million)	Impact on pre-tax income/(expense) recognized directly in equity (€ million)
+100 bp	98	—
+25 bp	25	—
-25 bp	(25)	—
-100 bp	(98)	—

e) Debt by currency, at value on redemption

The table below shows net debt by currency at December 31, 2022, before and after derivative instruments contracted to convert the foreign-currency net debt of exposed entities into their functional currency:

(€ million)	Before derivative instruments	After derivative instruments
Euro	13,145	10,489
US dollar	(6,508)	(2,404)
Singapore dollar	—	(2,155)
Pound sterling	—	359
Mexican peso	—	98
Other currencies	(52)	105
Net debt	**6,585**	**6,492**

The table below shows net debt by currency at December 31, 2021 and 2020, after derivative instruments contracted to convert the foreign currency net debt of exposed entities into their functional currency:

(€ million)	2021	2020
Euro	13,129	13,725
US dollar	(669)	(3,304)
Other currencies	(2,413)	(1,559)
Net debt	**10,047**	**8,862**

f) Market value of net debt

The market value of Sanofi's debt, net of cash and cash equivalents and derivatives and excluding accrued interest, is as follows:

(€ million)	2022	2021	2020
Market value	5,227	11,024	10,500
Value on redemption	6,492	10,047	8,862

The fair value of debt is determined by reference to quoted market prices at the balance sheet date in the case of quoted instruments (level 1 in the IFRS 7 hierarchy, see Note D.12.), and by reference to the fair value of interest rate and currency derivatives used to manage net debt (level 2 in the IFRS 7 hierarchy, see Note D.12.).

g) Future contractual cash flows relating to debt and related derivatives

The table below shows the amount of future undiscounted contractual cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt:

December 31, 2022		**Payments due by period**					
(€ million)	**Total**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028 and later**
Debt	**20,408**	**4,206**	**868**	**2,803**	**3,184**	**1,283**	**8,064**
Principal	18,932	3,928	661	2,601	3,011	1,151	7,580
Interest[(a)]	1,476	278	207	202	173	132	484
Net cash flows related to derivative instruments	**209**	**24**	**60**	**38**	**31**	**31**	**25**
Total	**20,617**	**4,230**	**928**	**2,841**	**3,215**	**1,314**	**8,089**

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2022.

Future contractual cash flows are shown on the basis of the carrying amount in the balance sheet at the reporting date, without reference to any subsequent management decision that might materially alter the structure of Sanofi's debt or its hedging policy.

The tables below show the amount of future undiscounted contractual cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt as of December 31, 2021 and 2020:

December 31, 2021		**Payments due by period**					
(€ million)	**Total**	**2022**	**2023**	**2024**	**2023**	**2026**	**2027 and later**
Debt	**21,728**	**3,330**	**3,826**	**791**	**1,937**	**3,176**	**8,668**
Principal	20,086	3,055	3,588	601	1,751	3,011	8,080
Interest[(a)]	1,642	275	238	190	186	165	588
Net cash flows related to derivative instruments	**(51)**	**(59)**	**(1)**	**2**	**2**	**2**	**3**
Total	**21,677**	**3,271**	**3,825**	**793**	**1,939**	**3,178**	**8,671**

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2021.

December 31, 2020		**Payments due by period**					
(€ million)	**Total**	**2021**	**2022**	**2023**	**2024**	**2023**	**2026 and later**
Debt	**24,339**	**2,943**	**3,019**	**3,808**	**791**	**1,937**	**11,841**
Principal	22,392	2,622	2,757	3,571	601	1,751	11,090
Interest[(a)]	1,947	321	262	237	190	186	751
Net cash flows related to derivative instruments	**163**	**135**	**28**	**–**	**–**	**–**	**–**
Total	**24,502**	**3,078**	**3,047**	**3,808**	**791**	**1,937**	**11,841**

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2020.

D.17.2. Lease liabilities

A maturity analysis of lease liabilities as of December 31, 2022, 2021 and 2020 is set forth below:

		Undiscounted future minimum lease payments				
(€ million)	Total	Less than 1 year	From 1 to 3 years	From 3 to 5 years	More than 5 years	Discounting effect
Total lease liabilities as of December 31, 2022	**2,181**	**320**	**515**	**436**	**1,129**	**(219)**
Total lease liabilities as of December 31, 2021	**2,108**	**314**	**476**	**362**	**1,184**	**(228)**
Total lease liabilities as of December 31, 2020	**1,163**	**247**	**357**	**225**	**482**	**(148)**

Lease liabilities as of December 31, 2022 and December 31, 2021 include leases relating to real estate assets located at Cambridge, MA (United States), as described in Note D.3., which have a lease term of 15 years.

D.18. Liabilities related to business combinations and to non-controlling interests

For a description of the nature of the liabilities reported in the line item ***Liabilities related to business combinations and to non-controlling interests***, refer to Note B.8.5. The principal acquisitions are described in Notes D.1. and D.2.

The liabilities related to business combinations and to non-controlling interests shown in the table below are level 3 instruments under the IFRS 7 fair value hierarchy (see Note D.12.).

Movements in liabilities related to business combinations and to non-controlling interests are shown below:

(€ million)	Bayer contingent consideration arising from the acquisition of Genzyme	MSD contingent consideration (European Vaccines business)	Shire contingent consideration arising from the acquisition of Translate Bio	Contingent consideration arising from acquisition of Amunix	Other	Total[a]
Balance at January 1, 2020	**156**	**385**	**—**	**—**	**259**	**800**
Payments made	(42)	(78)	—	—	(2)	(122)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount)[b]	9	9	—	—	(53)	(35)
Other movements	(8)	—	—	—	(2)	(10)
Currency translation differences	(11)	(4)	—	—	(13)	(28)
Balance at December 31, 2020	**104**	**312**	**—**	**—**	**189**	**605**
New transactions[c]	—	—	323	—	37	360
Payments made[d]	(31)	(75)	—	—	(152)	(258)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount)[b]	(18)	26	19	—	(31)	(4)
Other movements	—	—	—	—	(14)	(14)
Currency translation differences	4	6	12	—	3	25
Balance at December 31, 2021	**59**	**269**	**354**	**—**	**32**	**714**
New transactions	—	—	—	156	—	156
Payments made	(29)	(79)	—	—	(28)	(136)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount)[b]	(9)	14	2	(2)	—	5
Other movements	—	—	—	—	—	—
Currency translation differences	5	—	24	11	—	40
Balance at December 31, 2022	**26**	**204**	**380**	**165**	**4**	**779**

(a) Portion due after more than one year: €674 million as of December 31, 2022 (€577 million as of December 31, 2021 and €387 million as of December 31, 2020); portion due within less than one year: €105 million as of December 31, 2022 (€137 million as of December 31, 2021 and €218 million as of December 31, 2020).

*(b) Amounts reported within the income statement line item **Fair value remeasurement of contingent consideration**, and mainly comprising unrealized gains and losses.*

(c) Mainly corresponds to the recognition of the Shire Human Genetic Therapies Inc. (Shire) contingent consideration liability of $382 million resulting from the acquisition of Translate Bio in September 2021.

(d) The "Other" column mainly relates to the contingent consideration liability due to True North Therapeutics as a result of Sanofi's acquisition of Bioverativ which was settled in the first half of 2021.

As of December 31, 2022, ***Liabilities related to business combinations and to non-controlling interests*** mainly comprised:

- the Bayer contingent consideration liability arising from Sanofi's acquisition of Genzyme in 2011. As of December 31, 2022, Bayer was still entitled to receive the following potential payments:
  - a percentage of sales of alemtuzumab up to a maximum of $1,250 million or over a maximum period of 10 years, whichever is achieved first,
  - milestone payments subject to the attainment of specified levels of worldwide sales of alemtuzumab beginning in 2021.

The fair value of this liability was measured at €26 million as of December 31, 2022, compared with €59 million as of December 31, 2021 and €104 million as of December 31, 2020. The fair value of the Bayer liability is determined by applying the contractual terms to sales projections which have been weighted to reflect the probability of success, and discounted. If the discount rate were to fall by one percentage point, the fair value of the Bayer liability would increase by approximately 1%;

- the MSD contingent consideration liability arising from the 2016 acquisition of the Sanofi Pasteur activities carried on within the former Sanofi Pasteur MSD joint venture, which amounted to €204 million as of December 31, 2022, €269 million as of December 31, 2021 and €312 million as of December 31, 2020 (see Note D.12.). The fair value of this contingent consideration is determined by applying the royalty percentage stipulated in the contract to discounted sales projections. If the discount rate were to fall by one percentage point, the fair value of the MSD contingent consideration liability would increase by approximately 1%;
- a contingent consideration liability towards Shire Human Genetic Therapies Inc. (Shire) arising from Sanofi's acquisition of Translate Bio in September 2021. In a December 2016 business combination predating the acquisition of control by Sanofi, Translate Bio (then called Rana Therapeutics, Inc.) acquired from Shire the intellectual property rights relating to the latter's Messenger RNA Therapeutics (MRT) program. As of December 31, 2022, Shire was entitled to receive the following potential payments:
  - milestone payments contingent on the launch of products based on MRT technology, and on the attainment of a specified level of sales of those products, and
  - a percentage of sales of those products.

  The fair value of the Shire liability was measured at €380 million as of December 31, 2022, compared with €354 million as of December 31, 2021; it was determined by applying the contractual terms to development and sales projections which were weighted to reflect the probability of success, and discounted. If the discount rate were to fall by one percentage point, the fair value of the Shire liability would increase by approximately 13%;
- the contingent consideration liability arising from the 2022 acquisition of Amunix. The fair value of the liability is determined on the basis of the nominal value of payments due subject to the attainment of specified development milestones; these are weighted to reflect the probability of success, and discounted. The liability was measured at €165 million as of December 31, 2022. If the discount rate were to fall by one percentage point, the fair value of the liability would increase by approximately 1%.

The table below sets forth the maximum amount of contingent consideration payable in respect of already-marketed products:

December 31, 2022		**Payments due by period**			
(€ million)	**Total**	**Less than 1 year**	**From 1 to 3 years**	**From 3 to 5 years**	**More than 5 years**
Commitments relating to contingent consideration in connection with business combinations[(a)]	604	104	145	—	355

(a) Includes €0.4 billion for the Bayer contingent consideration, €0.2 billion for the MSD contingent consideration.

The nominal amount of contingent consideration was €689 million as of December 31, 2021 and €1,043 million as of December 31, 2020.

D.19. Provisions, income tax liabilities and other liabilities

The line item ***Non current provisions and other non-current liabilities*** comprises the following:

(€ million)	**2022**	**2021**	**2020** [(a)]
Provisions	5,822	6,430	6,998
Other non-current liabilities[(b)]	519	291	317
Total	**6,341**	**6,721**	**7,315**

(a) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods (IAS 19, Employee Benefits), as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

(b) Includes derivative financial instruments: €232 million as of December 31, 2022, €6 million as of December 31, 2021, €92 million as of December 31, 2020.

Non-current income tax liabilities are described in Note D.19.4., and other current liabilities in Note D.19.5.

The table below sets forth movements in non-current provisions for the reporting periods presented:

(€ million)	Provisions for pensions and other post-employment benefits (D.19.1.) [b]	Provisions for other long-term benefits	Restructuring provisions (D.19.2.)	Other provisions (D.19.3.)	Total
Balance at January 1, 2020	**3,599**	**855**	**600**	**2,071**	**7,125**
Changes in scope of consolidation	(3)	—	—	8	5
Increases in provisions	256 [a]	169	688	369	1,482
Provisions utilized	(566) [a]	(109)	(5)	(113)	(793)
Reversals of unutilized provisions	(226) [a]	(5)	(42)	(245)	(518)
Transfers	12	—	(369)	(64)	(421)
Net interest related to employee benefits, and unwinding of discount	55	2	1	8	66
Currency translation differences	(117)	(33)	(5)	(59)	(214)
Actuarial gains and losses on defined-benefit plans	266	—	—	—	266
Balance at December 31, 2020	**3,276**	**879**	**868**	**1,975**	**6,998**
Changes in scope of consolidation	(2)	—	—	37	35
Increases in provisions	247 [a]	156	67	261	731
Provisions utilized	(222) [a]	(122)	(8)	(107)	(459)
Reversals of unutilized provisions	(13) [a]	(7)	(35)	(145)	(200)
Transfers	(13)	(3)	(370)	(39)	(425)
Net interest related to employee benefits, and unwinding of discount	42	2	—	9	53
Currency translation differences	80	30	2	33	145
Actuarial gains and losses on defined-benefit plans	(448)	—	—	—	(448)
Balance at December 31, 2021	**2,947**	**935**	**524**	**2,024**	**6,430**
Changes in scope of consolidation	(96)	(28)	—	(76)	(200)
Increases in provisions	193 [a]	40	521	531	1,285
Provisions utilized	(275) [a]	(119)	(12)	(122)	(528)
Reversals of unutilized provisions	(66) [a]	(20)	(11)	(191)	(288)
Transfers	10	4	(265)	(23)	(274)
Net interest related to employee benefits, and unwinding of discount	43	4	5	12	64
Currency translation differences	63	28	(1)	23	113
Actuarial gains and losses on defined-benefit plans	(780)	—	—	—	(780)
Balance at December 31, 2022	**2,039**	**844**	**761**	**2,178**	**5,822**

(a) In the case of "Provisions for pensions and other post-employment benefits", the "Increases in provisions" line corresponds to rights vesting in employees during the period, and past service cost; the "Provisions utilized" line corresponds to contributions paid into pension funds and to beneficiaries; and the "Reversals of unutilized provisions" line corresponds to plan curtailments, settlements and amendments.

(b) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

D.19.1. Provisions for pensions and other post-employment benefits

Sanofi offers its employees pension plans and other post-employment benefit plans. The specific features of the plans (benefit formulas, fund investment policy and fund assets held) vary depending on the applicable laws and regulations in each country where the employees work. These employee benefits are accounted for in accordance with IAS 19 (see Note B.23.).

Sanofi's pension obligations in four major countries represented approximately 89% of the total value of the defined-benefit obligation and approximately 88% of the total value of plan assets as of December 31, 2022. The features of the principal defined-benefit plans in each of those four countries are described below.

France

Lump-sum retirement benefit plans

All employees working for Sanofi in France are entitled on retirement to a lump-sum payment, the amount of which depends both on their length of service and on the rights guaranteed by collective and internal agreements. The employee's final salary is used in calculating the amount of these lump-sum retirement benefits. These plans represent approximately 35% of Sanofi's total obligation in France.

Defined-benefit pension plans

These plans provide benefits from the date of retirement. Employees must fulfil a number of criteria to be eligible for these benefits. All of these plans are now closed. These plans represent approximately 65% of Sanofi's total obligation in France.

Germany

Top-up defined-benefit pension plan

The benefits offered under this pension plan are wholly funded by the employer (there are no employee contributions) via a Contractual Trust Agreement (CTA), under which benefits are estimated on the basis of a career average salary. Employees are entitled to receive an annuity under this plan if their salary exceeds the social security ceiling. The amount of the pension is calculated by reference to a range of vesting rates corresponding to salary bands. The plan also includes disability and death benefits. This plan represents approximately 62% of Sanofi's total obligation in Germany.

Sanofi-Aventis plus (SAV plus)

A top-up pension plan (SAV plus) replaced a previous top-up defined-benefit plan. New entrants joining the plan after April 1, 2015 contribute to a defined-contribution plan that is partially funded via the company's CTA.

All employees whose salary exceeds the social security ceiling are automatically covered by the plan. The employer's contribution is 15% of the amount by which the employee's salary exceeds the social security ceiling.

Multi-employer plan (Pensionskasse)

This is a defined-benefit plan treated as a defined-contribution plan, in accordance with the accounting policies described in Note B.23. Currently, contributions cover the level of annuities. Only the portion relating to the future revaluation of the annuities is included in the defined-benefit pension obligation. The obligation relating to this revaluation amounted to €652 million as of December 31, 2022, versus €877 million as of December 31, 2021 and €773 million as of December 31, 2020. This plan represents approximately 24% of Sanofi's total defined-benefit obligation in Germany.

United States

Defined-benefit pension plans

In the United States, there are two types of defined-benefit plan:

- "qualified" plans within the meaning of the Employee Retirement Income Security Act of 1974 (ERISA), which provide guaranteed benefits to eligible employees during retirement, and in the event of death or disability. Employees can elect to receive a reduced annuity, in exchange for an annuity to be paid in the event of their death to a person designated by them. An annuity is also granted under the plan if the employee dies before retirement age. Eligible employees do not pay any contributions. These plans are closed to new entrants, and the vesting of rights for future service periods is partially frozen. These plans represent approximately 60% of Sanofi's total obligation in the United States;
- "non-qualified" plans within the meaning of ERISA provide top-up retirement benefits to some eligible employees depending on the employee's level of responsibility and subject to a salary cap. These plans represent approximately 14% of Sanofi's total obligation in the United States.

Healthcare cover and life insurance

Sanofi companies provide some eligible employees with healthcare cover and life insurance during the retirement period (the company's contributions are capped at a specified level). These plans represent approximately 26% (or €409 million) of Sanofi's total obligation and 3% (or €28 million) of total plan assets in the United States.

United Kingdom

Defined-benefit pension plans

Sanofi operates a number of pension plans in the United Kingdom that reflect past acquisitions. The most significant arrangements are defined-benefit plans that have been closed since October 1, 2015. With effect from that date, employees can no longer pay into these plans.

Under these defined-benefit plans, an annuity is paid from the retirement date. This annuity is calculated on the basis of the employee's length of service as of September 30, 2015, and of the employee's final salary (or salary on the date he or she leaves Sanofi).

The rates used for the vesting of rights vary from member to member. For most members, rights vest at the rate of 1.25% or 1.50% of final salary for each qualifying year of service giving entitlement. The notional retirement age varies according to the category to which the member belongs, but in most cases retirement is at age 65. Members may choose to retire before or after the notional retirement age (60 years), in which case the amount of the annual pension is adjusted to reflect the revised estimate of the length of the retirement phase. Pensions are usually indexed to the Retail Price Index (RPI). Members paid a fixed-percentage contribution into their pension plan (the percentage varied according to the employee category), and the employer topped up the contribution to the required amount. These plans represent approximately 100% of Sanofi's total obligation in the United Kingdom.

For service periods subsequent to October 1, 2015, employees belong to a new defined-contribution plan.

Actuarial assumptions used to measure Sanofi's obligations

Actuarial valuations of Sanofi's benefit obligations were computed by management with assistance from external actuaries as of December 31, 2022, 2021 and 2020.

Those calculations were based on the following financial and demographic assumptions:

	2022				2021				2020			
	France	Germany	US	UK	France	Germany	US	UK	France	Germany	US	UK
Discount rate[a][b]	3.55% to 3.75%	3.55% to 3.75%	4.90%	4.75%	0.10% to 1.10%	0.10% to 1.10%	2.70%	1.90%	0.00% or 0.55%	0.00% or 0.55%	2.40%	1.35%
General inflation rate[c]	2.50%	2.50%	—	3.25%	1.95%	1.95%	—	3.30%	1.45%	1.45%	—	2.95%
Pension benefit indexation	2.50%	2.50%	—	3.00%	1.95%	1.95%	—	3.15%	1.45%	1.45%	—	2.85%
Healthcare cost inflation rate[d]	—	—	3.29% to 6.56%	—	—	—	3.50% to 4.50%	—	—	—	3.50% to 4.50%	—
Retirement age	62 to 67	63	55 to 70	60 to 65	62 to 67	62	55 to 70	60 to 65	62 to 67	62	55 to 70	60 to 65
Mortality table	TGH/TGF 05	Heubeck RT 2018 G	RP2012 Proj. MP2021 White Collar	SAPS S3	TGH/TGF 05	Heubeck RT 2018 G	RP2012 Proj. MP2020 White Collar	SAPS S3	TGH/TGF 05	Heubeck RT 2018 G	RP2012 Proj. G. Scale MP2019 White Collar	SAPS S2

(a) The discount rates used were based on market rates for high quality corporate bonds with a duration close to that of the expected benefit payments under the plans. The benchmarks used to determine discount rates were the same for all periods presented.

(b) The rate depends on the duration of the plan (0 to 7 years, 7 to 10 years, or more than 10 years).

(c) Inflation for the euro zone is determined using a multi-criterion method.

(d) No post-employment healthcare benefits are provided in France since 2020, Germany and UK.

Weighted average duration of obligation for pensions and other long-term benefits in principal countries

The table below shows the duration of Sanofi's obligations in the principal countries:

	2022				2021				2020			
(years)	France	Germany	US	UK	France	Germany	US	UK	France	Germany	US	UK
Weighted average duration	10	12	11	13	12	16	15	17	13	16	16	18

Sensitivity analysis

The table below shows the sensitivity of Sanofi's obligations for pensions and other post-employment benefits to changes in key actuarial assumptions:

(€ million)		Pensions and other post-employment benefits, by principal country			
Measurement of defined-benefit obligation	Change in assumption	France	Germany	US	UK
Discount rate	-0.50%	+72	+162	+75	+136
General inflation rate	+0.50%	+47	+306	—	+75
Pension benefit indexation	+0.50%	+51	+200	—	+53
Healthcare cost inflation rate	+0.50%	—	+2	+6	—
Mortality table	+1 year	+61	+51	+19	+74

The table below reconciles the net obligation in respect of Sanofi's pension and other post-employment benefit plans with the amounts recognized in the consolidated financial statements:

	Pensions and other post-employment benefits		
(€ million)	2022	2021	2020 [a]
Measurement of the obligation:			
Beginning of period	12,175	12,456	13,094
Current service cost	193	227	221
Interest cost	206	148	192
Actuarial losses/(gains) due to changes in demographic assumptions	(219)	(162)	52
Actuarial losses/(gains) due to changes in financial assumptions	(3,006)	(210)	936
Actuarial losses/(gains) due to experience adjustments	177	(120)	(26)
Plan amendments, curtailments or settlements not specified in the terms of the plan[b]	(229)	(4)	(938)
Plan settlements specified in the terms of the plan	(84)	(66)	(75)
Benefits paid	(463)	(503)	(545)
Changes in scope of consolidation and transfers	(114)	(8)	(12)
Currency translation differences	15	417	(443)
Obligation at end of period	**8,651**	**12,175**	**12,456**
Fair value of plan assets:			
Beginning of period	9,651	9,358	9,651
Interest income on plan assets	163	106	138
Difference between actual return and interest income on plan assets	(2,398)	207	696
Administration costs	(6)	(7)	(14)
Plan settlements specified in the terms of the plan	(84)	(66)	(75)
Plan settlements not specified in the terms of the plan	(161)	(9)	(739)
Contributions from plan members	6	6	6
Employer's contributions	238	176	490
Benefits paid	(426)	(458)	(469)
Changes in scope of consolidation and transfers	(32)	(6)	—
Currency translation differences	(52)	344	(326)
Fair value of plan assets at end of period	**6,899**	**9,651**	**9,358**
Net amount shown in the balance sheet:			
Net obligation	1,752	2,524	3,098
Effect of asset ceiling	18	15	1
Net amount shown in the balance sheet at end of period	**1,770**	**2,539**	**3,099**
Amounts recognized in the balance sheet:			
Pre-funded obligations (see Note D.7.)[c]	(269)	(408)	(177)
Obligations provided for	2,039	2,947	3,276
Net amount recognized at end of period	**1,770**	**2,539**	**3,099**
Benefit cost for the period:			
Current service cost	193	227	221
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan[b]	(68)	5	(199)
Net interest (income)/cost	43	42	55
Contributions from plan members	(6)	(6)	(7)
Administration costs and taxes paid during the period	6	7	14
Expense recognized directly in profit or loss	**168**	**276**	**84**
Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)[d]	(650)	(685)	266
Expense/(gain) for the period	**(482)**	**(409)**	**350**

(a) These amounts include the impact of applying the April 2021 IFRIC agenda decision on the attribution of benefits to periods of service.

(b) For 2020, this line mainly comprises a reduction in post-employment benefit liabilities following the announcement of voluntary redundancy programs, primarily in Europe.

(c) For 2022, this line includes €99 million of assets in the United Kingdom (versus €220 million for 2021); those amounts are not subject to any asset ceiling, in accordance with IFRIC 14.

(d) Amounts recognized in Other comprehensive income (see Note D.15.7.).

The tables below show Sanofi's net liability in respect of pension plans and other post-employment benefits by geographical region:

(€ million)	Pensions and other post-employment benefits by geographical region					
December 31, 2022	**France**	**Germany**	**US**	**UK**	**Other**	**Total**
Measurement of obligation	1,324	2,730	1,546	2,080	971	8,651
Fair value of plan assets	697	2,317	860	2,175	850	6,899
Effect of asset ceiling	—	—	—	—	(18)	(18)
Net amount shown in the balance sheet at end of period	**627**	**413**	**686**	**(95)**	**139**	**1,770**

(€ million)	Pensions and other post-employment benefits by geographical region					
December 31, 2021	**France**	**Germany**	**US**	**UK**	**Other**	**Total**
Measurement of obligation	1,657	3,576	2,099	3,414	1,429	12,175
Fair value of plan assets	838	2,808	1,127	3,629	1,249	9,651
Effect of asset ceiling	—	—	—	—	(15)	(15)
Net amount shown in the balance sheet at end of period	**819**	**768**	**972**	**(215)**	**195**	**2,539**

(€ million)	Pensions and other post-employment benefits by geographical region					
December 31, 2020	**France**	**Germany**	**US**	**UK**	**Other**	**Total**
Measurement of obligation	1,778	3,580	2,091	3,561	1,446	12,456
Fair value of plan assets	906	2,661	1,077	3,536	1,178	9,358
Effect of asset ceiling	—	—	—	—	(1)	(1)
Net amount shown in the balance sheet at end of period	**872**	**919**	**1,014**	**25**	**269**	**3,099**

The table below shows the fair value of plan assets relating to Sanofi's pension and other post-employment plans, split by asset category:

	2022	**2021**	**2020**
Securities quoted in an active market	**84.4%**	**86.9%**	**94.8%**
Cash and cash equivalents	0.7%	0.7%	3.5%
Equity instruments	21.7%	25.0%	24.8%
Bonds and similar instruments	52.4%	53.8%	59.9%
Real estate	4.0%	4.0%	3.4%
Derivatives	0.1%	—%	—%
Commodities	0.9%	1.0%	0.9%
Other	4.6%	2.4%	2.3%
Other securities	**15.6%**	**13.1%**	**5.2%**
Hedge funds	—%	—%	0.4%
Insurance policies	15.6%	13.1%	4.8%
Total	**100.0%**	**100.0%**	**100.0%**

Sanofi has a long-term objective of maintaining or increasing the extent to which its pension obligations are covered by assets. To this end, Sanofi uses an asset-liability management strategy, matching plan assets to its pension obligations. This policy aims to ensure the best fit between the assets held on the one hand, and the associated liabilities and expected future payments to plan members on the other. To meet this aim, Sanofi operates a risk monitoring and management strategy (mainly focused on interest rate risk and inflation risk), while investing a growing proportion of assets in high-quality bonds with comparable maturities to those of the underlying obligations and in contracts entered into with leading insurance companies to fund certain post-employment benefit obligations.

The tables below show the service cost for Sanofi's pension and other post-employment benefit plans, by geographical region:

(€ million)	Pensions and other post-employment benefits by geographical region					
Service cost for 2022	**France**	**Germany**	**US**	**UK**	**Other**	**Total**
Current service cost	61	44	50	—	38	193
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan	(60)	2	1	(6)	(5)	(68)
Net interest cost/(income) including administration costs and taxes paid during the period	10	7	30	(7)	9	49
Contributions from plan members	—	—	—	—	(6)	(6)
Expense/(gain) recognized directly in profit or loss	**11**	**53**	**81**	**(13)**	**36**	**168**
Remeasurement of net defined-benefit (asset)/ liability (actuarial gains and losses)	(156)	(204)	(382)	130	(38)	(650)
Expense/(gain) for the period	**(145)**	**(151)**	**(301)**	**117**	**(2)**	**(482)**

(€ million)	Pensions and other post-employment benefits by geographical region					
Service cost for 2021	**France**	**Germany**	**US**	**UK**	**Other**	**Total**
Current service cost	72	47	57	—	51	227
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan	2	—	—	3	—	5
Net interest cost/(income) including administration costs and taxes paid during the period	5	5	27	3	9	49
Contributions from plan members	—	—	—	—	(6)	(6)
Expense/(gain) recognized directly in profit or loss	**80**	**52**	**84**	**6**	**54**	**276**
Remeasurement of net defined-benefit (asset)/ liability (actuarial gains and losses)	(106)	(113)	(157)	(236)	(73)	(685)
Expense/(gain) for the period	**(26)**	**(61)**	**(73)**	**(230)**	**(19)**	**(409)**

(€ million)	Pensions and other post-employment benefits by geographical region					
Service cost for 2020	**France**	**Germany**	**US**	**UK**	**Other**	**Total**
Current service cost	65	49	51	—	56	221
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan	(87)	10	(123)	—	1	(199)
Net interest cost/(income) including administration costs and taxes paid during the period	7	13	34	5	10	69
Contributions from plan members	—	—	—	—	(7)	(7)
Expense/(gain) recognized directly in profit or loss	**(15)**	**72**	**(38)**	**5**	**60**	**84**
Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)	23	121	22	115	(15)	266
Expense/(gain) for the period	**8**	**193**	**(16)**	**120**	**45**	**350**

An analysis of the "Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)" line in the preceding tables is set forth below:

	2022				2021				2020			
(€ million)	**France**	**Germany**	**US**	**UK**	**France**	**Germany**	**US**	**UK**	**France**	**Germany**	**US**	**UK**
Actuarial gains/(losses) arising during the period	156	205	382	(131)	106	113	156	237	(23)	(121)	(22)	(115)
Comprising:												
Gains/(losses) on experience adjustments[(a)]	(120)	(620)	(287)	(1,328)	60	182	23	35	28	76	214	341
Gains/(losses) on demographic assumptions	—	—	129	54	—	—	51	125	9	—	(42)	(14)
Gains/(losses) on financial assumptions	276	825	540	1,143	46	(69)	82	77	(60)	(197)	(194)	(442)

(a) Experience adjustments are mainly due to the effect of trends in the financial markets on plan assets.

The net pre-tax actuarial loss (excluding investments accounted for using the equity method) recognized directly in equity is presented below:

(€ million)	2022	2021	2020
Net pre-tax actuarial loss	(2,090)	(2,738)	(3,423)

The present value of Sanofi's obligations in respect of pension and other post-employment benefit plans at the end of each reporting period is shown below:

(€ million)	2022	2021	2020
Present value of wholly or partially funded obligations in respect of pension and other post-employment benefit plans	7,463	10,416	10,734
Present value of unfunded obligations	1,188	1,759	1,722
Total	**8,651**	**12,175**	**12,456**

The total expense for pensions and other post-employment benefits (€168 million in 2022) is allocated between income statement line items as follows:

(€ million)	2022	2021	2020
Cost of sales	55	77	77
Research and development expenses	52	65	63
Selling and general expenses	81	87	88
Other operating (income)/expenses, net	(2)	(1)	(140)
Restructuring costs	(61)	6	(59)
Financial expenses	43	42	55
Total	**168**	**276**	**84**

The estimated amounts of employer's contributions to plan assets in 2023 are as follows:

(€ million)	France	Germany	US	UK	Other	Total
Employer's contributions in 2023 (estimate):						
2023	—	—	—	4	34	38

The table below shows the expected timing of benefit payments under pension and other post-employment benefit plans for future years:

(€ million)	France	Germany	US	UK	Other	Total
Estimated future benefit payments						
2023	99	195	118	125	59	596
2024	67	203	106	129	53	558
2025	72	209	107	134	53	575
2026	75	212	110	138	57	592
2027	94	219	100	142	59	614
2028 to 2032	505	1,135	499	784	323	3,246

The table below shows estimates as of December 31, 2022 for the timing of future payments in respect of unfunded pension and other post-employment benefit plans:

		Payments due by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Estimated payments	1,188	74	116	139	859

D.19.2. Restructuring provisions

The table below shows movements in restructuring provisions classified in non-current and current liabilities:

(€ million)	2022	2021	2020
Balance, beginning of period	**1,118**	**1,499**	**1,390**
Of which:			
• Classified in non-current liabilities	524	868	600
• Classified in current liabilities	594	631	790
Change in provisions recognized in profit or loss for the period	636	183	767
Provisions utilized[(a)]	(522)	(571)	(663)
Transfers	—	1	20
Unwinding of discount	5	—	1
Currency translation differences	(4)	6	(16)
Balance, end of period	**1,233**	**1,118**	**1,499**
Of which:			
• Classified in non-current liabilities	761	524	868
• Classified in current liabilities	472	594	631

(a) Provisions utilized mainly correspond to payments related to employees affected by separation programs.

Provisions for employee termination benefits as of December 31, 2022 amounted to €1,039 million (compared with €943 million as of December 31, 2021 and €1,260 million as of December 31, 2020).

The provisions apply mainly to France, and relate to various voluntary redundancy programs:

- agreement under the Job Management and Career Paths ("GEPP") scheme affecting several French legal entities, signed on February 28, 2022 and announced in April 2022 as part of the "Play to Win" strategy. The agreement provides internal transfer and outplacement opportunities for employees whose jobs are undergoing transformation, and also includes an end-of-career paid leave program and an external retraining program. The majority of the provisions charged in 2022 relate to this plan, which was implemented during 2022;
- collectively-agreed separation programs involving a number of legal entities were announced at the end of June 2020 as part of the rollout of the "Play to Win" strategy; these include an end-of-career paid leave plan and an external retraining program, and were still ongoing during 2022. In addition, Sanofi-Aventis Recherche & Développement (i) announced a voluntary redundancy program in 2020 in connection with the reorganization of R&D operations in France, which was implemented in 2021, and (ii) signed a collectively-agreed termination program in 2021 as part of the rollout of the "Play to Win" strategy; these programs, which cover support functions, include an end-of-career paid leave plan and an end-of-career transition plan;
- programs were announced in 2019 relating to (i) R&D (Sanofi-Aventis Recherche & Développement), and (ii) sales forces (the "SAF 2019" plan implemented by Sanofi-Aventis France); and
- collectively-agreed separation programs were announced in 2018 relating to the reorganization of support functions ("Horizon 2020" plan).

The remainder of the provision for France comprises termination benefits associated with previously-announced programs (early retirement plans and end-of-career transition plans).

The provision includes the present values of:

- gross annuities for self-funded plans;
- employer's social security charges on early retirement annuities for all plans (outsourced and self-funded); and
- the levy charged on those annuities under the "Fillon" law (only for plans with termination of employment contracts).

The average residual holding periods under these plans were 2.60 years, 1.94 year and 1.99 year as of December 31, 2022, 2021 and 2020, respectively.

The main other countries covered by restructuring provisions are Germany, Japan and the United States.

The timing of future termination benefit payments is as follows:

December 31, 2022		Benefit payments by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Employee termination benefits					
• France	804	185	412	207	—
• Other countries	235	189	36	8	2
Total	**1,039**	**374**	**448**	**215**	**2**

December 31, 2021		Benefit payments by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Employee termination benefits					
• France	614	269	288	53	4
• Other countries	329	207	106	14	2
Total	**943**	**476**	**394**	**67**	**6**

December 31, 2020		Benefit payments by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Employee termination benefits					
• France	889	295	457	124	13
• Other countries	371	195	149	18	9
Total	**1,260**	**490**	**606**	**142**	**22**

D.19.3. Other provisions

Other provisions include provisions for risks and litigation relating to environmental, tax, commercial and product liability matters.

(€ million)	2022	2021	2020
Environmental risks	526	650	713
Product liability risks, litigation and other	1,652	1,374	1,262
Total	**2,178**	**2,024**	**1,975**

Provisions for environmental risks relate primarily to contingencies arising from business divestitures, and include remediation costs relating to such environmental risks.

Identified environmental risks are covered by provisions estimated on the basis of the costs Sanofi believes it will be obliged to meet over a period not exceeding (other than in exceptional cases) 30 years. Sanofi expects that €96 million of those provisions will be utilized in 2023, and €201 million over the period from 2024 through 2027.

"Product liability risks, litigation and other" mainly comprises provisions for risks relating to product liability (including IBNR provisions as described in Note B.12.), government investigations, regulatory or antitrust law claims, contingencies arising from business divestitures (other than environmental risks), and remediation costs related to leases.

The main pending legal and arbitral proceedings and government investigations are described in Note D.22.

A full risk and litigation assessment is performed with the assistance of Sanofi's legal advisers, and provisions are recorded as required by circumstances in accordance with the principles described in Note B.12.

D.19.4. Non-current income tax liabilities

Non-current income tax liabilities amounted to €1,979 million as of December 31, 2022 (versus €2,039 million as of December 31, 2021 and €1,733 million as of December 31, 2020).

The estimated tax charge on deemed repatriation attributable to the accumulated earnings of non-US operations and payable over 8 years is recognized as a liability, and amounted to €1,020 million in 2022 versus €960 million in 2021 and €894 million in 2020. The resulting residual tax charge generated a non-current liability of €459 million as of December 31, 2022, versus €576 million in 2021 and €569 million in 2020. In accordance with Sanofi accounting policies, this non-current liability is not discounted.

Non-current income tax liabilities include uncertainties over income tax treatments amounting to €1,520 million as of December 31, 2022, versus €1,463 million as of December 31, 2021 and €1,164 million as of December 31, 2020.

A US legal restructuring resulted in a capital loss of €2.9 billion recognized in the 2020 final tax filing. One-third of the capital loss has been used against 2020 capital gains and the remaining balance will be eligible to carry back for three years. Due to management's judgement about potential alternative interpretations of the prevailing tax law, no tax benefit has been recognized on this transaction in accordance with IFRIC 23.

D.19.5. Current provisions and other current liabilities

Current provisions and other current liabilities comprise the following:

(€ million)	2022	2021	2020
Taxes payable, other than corporate income taxes	420	428	347
Employee-related liabilities	2,158	2,126	2,042
Restructuring provisions (see Note D.19.2.)	472	594	631
Interest rate derivatives (see Note D.20.)	—	1	—
Currency derivatives (see Note D.20.)	94	62	205
Equity derivatives (see Note D.20.)	—	16	—
Amounts payable for acquisitions of non-current assets	714	559	467
Customer contract liabilities[(a)]	264	319	252
Other current liabilities[(b)]	7,899	7,112	6,188
Total	**12,021**	**11,217**	**10,132**

(a) See Note A.5., "Agreements relating to the recombinant COVID-19 vaccine candidate developed by Sanofi in collaboration with GSK". The year-on-year change in this item includes revenue of €85 million recognized in profit or loss during 2022 that was included in the customer contract liabilities balance as of December 31, 2022.

(b) "Other current liabilities" mainly comprises provisions for customer rebates and returns; provisions for discounts and rebates granted to healthcare authorities and governmental programs (see Note D.23.); and the liability payable at each reporting date under the Monoclonal Antibody Alliance with Regeneron.

D.20. Derivative financial instruments and market risks

The table below shows the fair value of derivative instruments as of December 31, 2022, 2021 and 2020:

(€ million)	Non-current assets	Current assets	Total assets	Non-current liabilities	Current liabilities	Total liabilities	Market value at December 31, 2022 (net)	Market value at December 31, 2021 (net)	Market value at December 31, 2020 (net)
Currency derivatives	—	206	206	—	(94)	(94)	112	222	(209)
operating	—	88	88	—	(66)	(66)	22	10	7
financial	—	118	118	—	(28)	(28)	90	212	(216)
Interest rate derivatives	—	—	—	(232)	—	(232)	(232)	7	20
Equity derivatives	—	—	—	—	—	—	—	(16)	(26)
Total	**—**	**206**	**206**	**(232)**	**(94)**	**(326)**	**(120)**	**213**	**(215)**

Objectives of the use of derivative financial instruments

Sanofi uses derivative instruments to manage operating exposure to movements in exchange rates, and financial exposure to movements in interest rates and exchange rates (where the debt or receivable is not contracted in the functional currency of the borrower or lender entity). On occasion, Sanofi uses equity derivatives in connection with the management of its portfolio of equity investments.

Sanofi performs periodic reviews of its transactions and contractual agreements in order to identify any embedded derivatives, which are accounted for separately from the host contract in accordance with IFRS 9. Sanofi had no material embedded derivatives as of December 31, 2022, 2021 or 2020.

Counterparty risk

For a description of counterparty risk, refer to "Item 11. — Quantitative and Qualitative Disclosures about Market Risk".

a) Currency derivatives used to manage operating risk exposures

For a description of Sanofi's objectives, policies and procedures for the management of operating foreign exchange risk, refer to "Item 11. — Quantitative and Qualitative Disclosures about Market Risk".

The table below shows operating currency hedging instruments in place as of December 31, 2022, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2022			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
(€ million)	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
Forward currency sales	**5,403**	**49**	**—**	**—**	**—**	**5,403**	**49**
of which US dollar	*2,732*	*56*	*—*	*—*	*—*	*2,732*	*56*
of which Chinese yuan renminbi	*576*	*2*	*—*	*—*	*—*	*576*	*2*
of which Japanese yen	*240*	*(5)*	*—*	*—*	*—*	*240*	*(5)*
of which Singapore dollar	*180*	*1*	*—*	*—*	*—*	*180*	*1*
of which Korean won	*179*	*(14)*	*—*	*—*	*—*	*179*	*(14)*
Forward currency purchases	**3,459**	**(27)**	**—**	**—**	**—**	**3,459**	**(27)**
of which US dollar	*2,047*	*(21)*	*—*	*—*	*—*	*2,047*	*(21)*
of which Singapore dollar	*375*	*(7)*	*—*	*—*	*—*	*375*	*(7)*
of which Chinese yuan renminbi	*142*	*—*	*—*	*—*	*—*	*142*	*—*
of which Korean won	*130*	*4*	*—*	*—*	*—*	*130*	*4*
of which Taiwan dollar	*84*	*—*	*—*	*—*	*—*	*84*	*—*
Total	**8,862**	**22**	**—**	**—**	**—**	**8,862**	**22**

The table below shows operating currency hedging instruments in place as of December 31, 2021, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2021			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
(€ million)	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
Forward currency sales	**3,912**	**4**	**–**	**–**	**–**	**3,912**	**4**
of which US dollar	*1,392*	*5*	*–*	*–*	*–*	*1,392*	*5*
of which Chinese yuan renminbi	*665*	*(2)*	*–*	*–*	*–*	*665*	*(2)*
of which Singapore dollar	*355*	*(1)*	*–*	*–*	*–*	*355*	*(1)*
of which Japanese yen	*199*	*3*	*–*	*–*	*–*	*199*	*3*
of which Taiwan dollar	*122*	*(1)*	*–*	*–*	*–*	*122*	*(1)*
Forward currency purchases	**2,374**	**6**	**–**	**–**	**–**	**2,374**	**6**
of which US dollar	*833*	*(2)*	*–*	*–*	*–*	*833*	*(2)*
of which Singapore dollar	*696*	*7*	*–*	*–*	*–*	*696*	*7*
of which Chinese yuan renminbi	*255*	*—*	*–*	*–*	*–*	*255*	*—*
of which Hungarian forint	*77*	*—*	*–*	*–*	*–*	*77*	*—*
of which Russian rouble	*72*	*(1)*	*–*	*–*	*–*	*72*	*(1)*
Total	**6,286**	**10**	**–**	**–**	**–**	**6,286**	**10**

The table below shows operating currency hedging instruments in place as of December 31, 2020, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2020			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
(€ million)	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
Forward currency sales	**3,477**	**7**	**—**	**—**	**—**	**3,477**	**7**
of which US dollar	*1,367*	*10*	*—*	*—*	*—*	*1,367*	*10*
of which Chinese yuan renminbi	*521*	*2*	*—*	*—*	*—*	*521*	*2*
of which Singapore dollar	*287*	*(1)*	*—*	*—*	*—*	*287*	*(1)*
of which Japanese yen	*143*	*1*	*—*	*—*	*—*	*143*	*1*
of which Mexican peso	*121*	*—*	*—*	*—*	*—*	*121*	*—*
Forward currency purchases	**1,932**	**—**	**—**	**—**	**—**	**1,932**	**—**
of which US dollar	*580*	*(1)*	*—*	*—*	*—*	*580*	*(1)*
of which Singapore dollar	*571*	*(1)*	*—*	*—*	*—*	*571*	*(1)*
of which Chinese yuan renminbi	*286*	*1*	*—*	*—*	*—*	*286*	*1*
of which Russian rouble	*61*	*—*	*—*	*—*	*—*	*61*	*—*
of which Japanese yen	*55*	*—*	*—*	*—*	*—*	*55*	*—*
Total	**5,409**	**7**	**—**	**—**	**—**	**5,409**	**7**

b) Currency and interest rate derivatives used to manage financial exposure

For a description of Sanofi's objectives, policies and procedures for the management of financial foreign exchange risk and interest rate risk, refer to "Item 11. — Quantitative and Qualitative Disclosures about Market Risk".

The table below shows financial currency hedging instruments in place, with the notional amount translated into euros at the relevant closing exchange rate:

	2022			2021			2020		
(€ million)	Notional amount	Fair value	Expiry	Notional amount	Fair value	Expiry	Notional amount	Fair value	Expiry
Forward currency sales	**7,559**	**66**		**7,655**	**15**		**5,064**	**10**	
of which US dollar	*6,114* [(a)]	*59*	*2023*	*5,384*	*23*	*2022*	*3,721*	*20*	*2021*
of which Pound sterling	*384*	*7*	*2023*	*309*	*(2)*	*2022*	*257*	*(6)*	*2021*
of which Chinese yuan renminbi	*203*	*2*	*2023*	*70*	*(2)*	*2022*	*26*	*—*	*2021*
Forward currency purchases	**4,997**	**24**		**9,293**	**197**		**9,004**	**(226)**	
of which US dollar	*2,011* [(b) (c)]	*(4)*	*2023*	*4,816*	*128*	*2022*	*6,068*	*(200)*	*2021*
of which Singapore dollar	*2,154* [(d)]	*22*	*2023*	*2,910*	*75*	*2022*	*2,250*	*(27)*	*2021*
of which Japanese yen	*205*	*4*	*2023*	*235*	*(2)*	*2022*	*68*	*—*	*2021*
Total	**12,556**	**90**		**16,948**	**212**		**14,068**	**(216)**	

(a) Includes forward sales with a notional amount of $3,615 million expiring in 2023, designated as a hedge of Sanofi's net investment in Bioverativ. As of December 31, 2022, the fair value of these forward contracts represented an asset of €38 million; the opposite entry was recognized in "Other comprehensive income", with the impact on financial income and expense being immaterial.

(b) Includes forward purchases with a notional amount of $1,000 million expiring in 2023, designated as a fair value hedge of the exposure of $1,000 million of bond issues to fluctuations in the EUR/USD spot rate. As of December 31, 2022, the fair value of the contracts was an asset of €3 million, the opposite entry for €0.6 million of which was debited to "Other comprehensive income" under the cost of hedging accounting treatment.

(c) Includes receiver currency swaps with a notional amount of $1,000 million expiring in 2023, designated as a fair value hedge of the exposure of an equivalent amount of intragroup current accounts to fluctuations in the EUR/USD spot rate. As of December 31, 2022, the fair value of the swaps was a liability of €2 million, the opposite entry for €1.4 million of which was credited to "Other comprehensive income" under the cost of hedging accounting treatment.

(d) Includes forward purchases with a notional amount of SGD1,500 million expiring in 2023, designated as a fair value hedge of the exposure of an equivalent amount of intragroup current accounts to fluctuations in the EUR/SGD spot rate. As of December 31, 2022, the fair value of the contracts was an asset of €33 million, the opposite entry for €2.5 million of which was credited to "Other comprehensive income" under the cost of hedging accounting treatment.

The table below shows interest rate hedging instruments in place as of December 31, 2022:

	Notional amounts by expiry date as of December 31, 2022								Of which designated as fair value hedges		Of which designated as cash flow hedges		
(€ million)	2023	2024	2025	2026	2027	2028 and later	Total	Fair value	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
Interest rate swaps													
pay SOFR USD/receive 1.03%	—	—	—	—	—	467	467	(62)	467	(62)	—	—	—
pay SOFR USD/receive 1.32%	—	—	—	—	—	467	467	(56)	467	(56)	—	—	—
pay capitalized Ester/ receive 0.69%	—	—	850	—	—	—	850	(43)	850	(43)	—	—	—
pay capitalized Ester/ receive 0.92%	—	—	—	—	—	650	650	(71)	650	(71)	—	—	—
Total	**—**	**—**	**850**	**—**	**—**	**1,584**	**2,434**	**(232)**	**2,434**	**(232)**	**—**	**—**	**—**

The table below shows interest rate hedging instruments in place as of December 31, 2021:

	Notional amounts by expiry date as of December 31, 2021								Of which designated as fair value hedges		Of which designated as cash flow hedges		
(€ million)	2022	2023	2024	2025	2026	2027 and later	Total	Fair value	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
Interest rate swaps													
pay capitalized EONIA/ receive 0.06%	2,000	—	—	—	—	—	2,000	10	2,000	10	—	—	—
pay -0.57%/receive capitalized EONIA	600	—	—	—	—	—	600	1	—	—	600	1	—
pay SOFR USD/receive 1.03%	—	—	—	—	—	440	440	(5)	440	(5)	—	—	—
pay SOFR USD/receive 1.32%	—	—	—	—	—	440	440	3	440	3	—	—	—
receive capitalized EONIA/ pay 1.48%[(a)]	42	57	—	—	—	—	99	(3)	99	(3)	—	—	—
Total	**2,642**	**57**	**—**	**—**	**—**	**880**	**3,579**	**7**	**2,979**	**6**	**600**	**1**	**—**

(a) These interest rate swaps hedge fixed-rate bonds with a nominal of €99 million held in a Professional Specialized Investment Fund dedicated to Sanofi and recognized within "Loans, advances and other long-term receivables" (see Note D.7.).

The table below shows interest rate hedging instruments in place as of December 31, 2020:

	Notional amounts by expiry date as of December 31, 2020								Of which designated as fair value hedges		Of which designated as cash flow hedges		
(€ million)	2021	2022	2023	2024	2025	2026 and later	Total	Fair value	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
Interest rate swaps													
pay capitalized EONIA/ receive 0.06%	—	2,000	—	—	—	—	2,000	23	2,000	23	—	—	—
pay -0.57%/receive capitalized EONIA	—	600	—	—	—	—	600	1	—	—	600	1	1
receive capitalized Eonia/ pay 1.48%[(a)]	—	42	57	—	—	—	99	(4)	99	(4)	—	—	—
Total	**—**	**2,642**	**57**	**—**	**—**	**—**	**2,699**	**20**	**2,099**	**19**	**600**	**1**	**1**

(a) These interest rate swaps hedge fixed-rate bonds with a nominal of €99 million held in a Professional Specialized Investment Fund dedicated to Sanofi and recognized within "Loans, advances and other long-term receivables" (see Note D.7.).

c) Actual or potential effects of netting arrangements

The table below is prepared in accordance with the accounting policies described in Note B.8.3.:

	2022		2021		2020	
(€ million)	Derivative financial assets	Derivative financial liabilities	Derivative financial assets	Derivative financial liabilities	Derivative financial assets	Derivative financial liabilities
Gross carrying amounts before offset (a)	206	(326)	298	(85)	82	(297)
Gross amounts offset (in accordance with IAS 32) (b)	—	—	—	—	—	—
Net amounts as reported in the balance sheet (a) - (b) = (c)	**206**	**(326)**	**298**	**(85)**	**82**	**(297)**
Effects of other netting arrangements (not fulfilling the IAS 32 criteria for offsetting) (d)	—	—				
Financial instruments	(160)	160	(67)	67	(81)	81
Fair value of financial collateral	N/A	N/A	N/A	N/A	N/A	N/A
Net exposure (c) + (d)	**46**	**(166)**	**231**	**(18)**	**1**	**(216)**

D.21. Off balance sheet commitments

The off balance sheet commitments presented below are shown at their nominal value.

D.21.1. Off balance sheet commitments relating to operating activities

Off balance sheet commitments relating to Sanofi's operating activities comprise the following:

December 31, 2022		Payments due by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Leases with a term of less than 12 months, low value asset leases and lease contracts committed but not yet commenced[(a)(b)]	38	26	4	3	5
Irrevocable purchase commitments[(c)]					
• given[(d)]	10,921	5,957	2,922	1,062	980
• received	(1,025)	(482)	(335)	(86)	(122)
Research and development license agreements - commitments given					
• commitments related to R&D and other commitments[(e)]	259	197	39	10	13
• contingent milestone payments in connection with development programs in progress[(f)]	2,919	203	875	889	952
Total - net commitments given[(g)]	**13,112**	**5,901**	**3,505**	**1,878**	**1,828**

(a) Includes the variable portion of future lease payments not recognized as lease liabilities as of December 31, 2022; the equivalent amount of these commitments as of December 31, 2021 was €109 million.

(b) These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down-payments (see Note D.3.) and (ii) goods and services. As of December 31, 2021, irrevocable commitments amounted to €8,901 million given and €1,124 million received.

(c) Irrevocable purchase commitments given as of December 31, 2022 include €871 million of commitments to joint ventures, and the commitment to EUROAPI as described in Note D.1.

(d) Commitments related to R&D, and other commitments, amounted to €536 million as of December 31, 2021.

(e) This line includes only contingent milestone payments on development projects in progress. The equivalent amount as of December 31, 2021 was €2,892 million.

In pursuance of its strategy, Sanofi may acquire technologies and rights to products. Such acquisitions may be made in various contractual forms: acquisitions of shares, loans, license agreements, joint development, and co-marketing. These arrangements generally involve upfront payments on signature of the agreement, development milestone payments, and royalties. Some of these complex agreements include undertakings to fund research programs in future years and payments contingent upon achieving specified development milestones, the granting of approvals or licenses, or the attainment of sales targets once a product is commercialized.

The "Research and development license agreements" line comprises future service commitments to fund research and development or technology, and probable contingent milestone payments regarded as reasonably achievable (i.e. all potential milestone payments relating to projects in the development phase, for which the future financial consequences are known or probable and for which there is a sufficiently reliable estimate). This line excludes:

- commitments given relating to projects in the research phase for €18.0 billion as of December 31, 2022 (€6.7 billion as of December 31, 2021) and commitments given relating to contingent payments upon the attainment of sales targets once a product is commercialized for €18.5 billion as of December 31, 2022 (€8.1 billion as of December 31, 2021);

- commitments received amounting to €8.8 billion as of December 31, 2022 (€5.8 billion as of December 31, 2021), mainly comprising research, development and commercialization agreements with partners further to the acquisitions of Ablynx for €1.0 billion as of December 31, 2022 (€1.0 billion as of December 31, 2021) and of Kymab for €0.2 billion as of December 31, 2022 (€0.5 billion as of December 31, 2021), plus contingent consideration receivable based on attainment of regulatory and sales milestones for commercialized products under the terms of licenses or rights assignment agreements amounting to €7.6 billion as of December 31, 2022 (€4.2 billion as of December 31, 2021).

The major agreements entered into by Sanofi in 2022 are described below:

- on January 7, 2022, Sanofi entered into an innovative license agreement and research collaboration with Exscientia to develop up to 15 novel small molecule candidates across oncology and immunology, leveraging Exscientia's end-to-end AI-driven platform utilizing actual patient samples. Under the terms of the agreement, Sanofi made an upfront payment of $100 million and could pay up to $5.2 billion contingent on the attainment of certain objectives;
- on January 12, 2022, Sanofi entered into a licensing and collaboration agreement with ABL Bio for the development of ABL301, a bispecific antibody targeting alpha-synuclein and intended as a treatment for alpha-synucleinopathies. Under the terms of the agreement, Sanofi paid ABL Bio $75 million upfront, and could make potential milestone payments of up to approximately $985 million contingent on the attainment of certain objectives;
- on March 2, 2022, Sanofi entered into a collaboration and exclusive license agreement with Adagene Inc., a company transforming the discovery and development of antibody-based therapies. Under the terms of the agreement, Sanofi made an upfront payment of $17.5 million and could pay up to $2.5 billion contingent on the attainment of certain objectives;
- on March 15, 2022, Sanofi entered into a strategic risk-sharing collaboration with Blackstone under which funds managed by Blackstone Life Sciences (BXLS) will contribute up to €300 million to accelerate the global pivotal studies and clinical development program for the subcutaneous formulation and delivery of the anti-CD38 antibody Sarclisa®, to treat patients with multiple myeloma. That amount will be paid to Sanofi on the basis of development expenses incurred. In addition, Sanofi may pay royalties on future sales of this solution;
- on March 29, 2022, Sanofi entered into an exclusive collaboration agreement with IGM Biosciences, Inc. to create, develop, manufacture and commercialize IgM antibody agonists against three oncology targets and three immunology/inflammation targets. Under the terms of the agreement, IGM received an upfront payment of $150 million and could receive up to $6.0 billion for milestones in the development, regulatory approval and sales of each target;
- on July 5, 2022, Sanofi entered into a collaboration agreement with Skyhawk Therapeutics, Inc. to discover and develop novel small molecules that modulate RNA splicing to address challenging oncology and immunology targets. Under the terms of the agreement, Skyhawk received an upfront payment of $54 million and could receive more than $2.0 billion contingent on the attainment of certain objectives;
- on August 17, 2022, Sanofi entered into a strategic research collaboration with Atomwise, that will leverage its AtomNet® platform to identify and synthesize up to five drug targets. Under the terms of the agreement, Atomwise received an upfront payment of $20 million and could receive up to $1.0 billion contingent on the attainment of certain objectives;
- on September 27, 2022, Sanofi entered into a research collaboration with Scribe Therapeutics, to leverage its CRISPR by Design™ platform and to obtain a non-exclusive license to genome editing CasX-Editor(XE) technology for multiple oncology targets. Under the terms of the agreement, Scribe Therapeutics received an upfront payment of $25 million and could receive more than $1.0 billion contingent on the attainment of certain objectives;
- on October 4, 2022, Sanofi entered into a strategic collaboration with miRecule to accelerate the discovery and development of a Best-in-Class Antibody-RNA conjugate to treat Facioscapulohumeral Muscular Dystrophy (FSHD). Under the terms of the agreement, miRecule received an upfront payment of $20 million and could receive up to $0.4 billion contingent on the attainment of certain objectives;
- on November 8, 2022, Sanofi entered into a strategic research collaboration with Insilico Medicine to leverage Insilico Medicine's AI platform, Pharma.AI, to advance drug development candidates for up to six new targets. Under the terms of the agreement, Insilico Medicine received an upfront payment of $12.5 million and could receive up to $1.2 billion contingent on the attainment of certain objectives;
- on December 19 2022, Sanofi and Innate Pharma SA announced an expansion of their collaboration, with Sanofi licensing a natural killer (NK) cell engager program targeting B7H3 from Innate's ANKET™ (Antibody-based NK Cell Engager Therapeutics) platform. Innate received an upfront payment of €25 million and could receive up to €1.4 billion contingent on the attainment of certain objectives.

The amount of commitments as of December 31, 2022 also includes commitments under agreements entered into by Sanofi in prior years, the principal ones of which are described below:

- Biond Biologics (2021): license agreement for the development and commercialization of BND-22 (a humanized IgG4 antagonist antibody targeting the Ig-like transcript 2 (ILT2) receptor, in development for the treatment of solid tumors);
- Eureka Therapeutics and Memorial Sloan Kettering Cancer Center (MSK) (2021): license agreement with for the treatment of multiple myeloma;
- Kymera (2020): agreement to develop and commercialize protein degrader therapies targeting IRAK4 in patients with immune-inflammatory diseases;
- Nurix Therapeutics (2020): collaboration to develop novel targeted protein degradation therapies;
- Denali Therapeutics Inc. (2018): collaboration agreement on the development of multiple molecules with the potential to treat a range of neurological and systemic inflammatory diseases. The two lead molecules are DNL747 in multiple sclerosis and amyotrophic lateral sclerosis, and DNL758 in systemic inflammatory diseases such as rheumatoid arthritis and psoriasis;

- MedImmune (a division of AstraZeneca) (2017): agreement to develop and commercialize a monoclonal antibody (MEDI8897) for the prevention of Respiratory Syncytial Virus (RSV) associated illness in newborns and infants;
- Innate Pharma (2016): collaboration and licensing agreement to apply Innate Pharma's new proprietary technology to the development of innovative bispecific antibody formats engaging natural killer (NK) cells to kill tumor cells through the activating receptor NKp46;
- Eli Lilly and Company (2014): agreement to pursue regulatory approval for non-prescription Cialis® (tadalafil).

Sanofi and its alliance partners have decided to terminate the following agreements (the related commitments are no longer included in Sanofi's off balance sheet disclosures as of December 31, 2022):

- in October 2022, Sanofi and DiCE Molecules ended their global collaboration to discover potential new therapeutics for up to 12 targets that encompass all disease areas of strategic interest to Sanofi; and
- in December 2022, Sanofi and Revolution Medicines agreed, after a transitional phase, to end their partnership agreement in oncology signed in 2018.

In addition, under the collaboration agreement with Regeneron on monoclonal antibodies (see Note C.1.), Sanofi is entitled to receive an additional share of quarterly profits (capped at 10% of Regeneron's share of quarterly profits until March 31, 2022, and thereafter at 20%), until Regeneron has paid 50% of the cumulative development costs incurred by the parties to the alliance. As of December 31, 2022 this represented total commitments received of €2.7 billion (versus €2.9 billion as of December 31, 2021), against cumulative development costs of €8.4 billion.

Sanofi entered into an agreement with Royalty Pharma in December 2014 relating to development programs under which Royalty Pharma bears a portion of the remaining development costs of the project on a quarterly basis in return for royalties on future sales. This transaction is a co-investment, whereby the partner acquires an interest in the jointly-developed product by providing funding towards the development program. Consequently, the amounts received by Sanofi are recorded as a reduction in development costs, to the extent that the development costs incurred by Sanofi are recognized in profit or loss in accordance with the policies described in Note B.4.1. The products in development under the December 2014 agreement with Royalty Pharma have been launched in the United States and Europe, marking the end of the joint development programs.

On February 27, 2017, Sanofi and Lonza announced a strategic partnership in the form of a joint venture (BioAtrium AG) to build and operate a large-scale mammalian cell culture facility for monoclonal antibody production in Visp, Switzerland. An initial investment of approximately €0.3 billion to finance construction of the facility, split 50/50 between the two partners, has now been made in full. In addition, Sanofi could pay BioAtrium AG in the region of €0.6 billion over the next fifteen years as its share of operating expenses and the cost of producing future batches.

In February 2014, pursuant to the "Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits" (still effective as of December 31, 2022), Sanofi Pasteur and the World Health Organization (WHO) signed a bilateral "Standard Material Transfer Agreement" (SMTA 2). This agreement stipulates that Sanofi Pasteur will, during declared pandemic periods, (i) donate 7.5% of its real-time production of pandemic vaccines against any strain with potential to cause a pandemic, and (ii) reserve a further 7.5% of such production on affordable terms. The agreement cancels and replaces all preceding commitments to donate pandemic vaccines to the WHO.

D.21.2. Off balance sheet commitments relating to financing activities

Credit facilities

Undrawn credit facilities are as follows:

December 31, 2022		Expiry			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
General-purpose credit facilities	8,000	4,000	—	4,000	—

As of December 31, 2022, total credit facilities amounted to €8,000 million (versus €8,000 million as of December 31, 2021 and €8,000 million as of December 31, 2020).

Guarantees

The table below shows the amount of guarantees given and received:

(€ million)	2022	2021	2020
Guarantees given:	**3,815**	**3,794**	**3,291**
• Guarantees provided to banks in connection with credit facilities	1,007	1,042	695
• Other guarantees given	2,808	2,752	2,596
Guarantees received	**(1,229)**	**(1,149)**	**(964)**

D.21.3. Off balance sheet commitments relating to asset acquisitions and divestments, and to changes in the scope of consolidation

As of December 31, 2022, Sanofi had received commitments amounting in aggregate to €1.0 billion in respect of (i) divestments of assets relating to transactions not yet finalized as of that date and (ii) contingent consideration arising under past agreements.

Off balance sheet commitments of a financing nature with associates and joint ventures are disclosed in Note D.6.

The maximum amount of contingent consideration relating to business combinations is disclosed in Note D.18.

D.22. Legal and arbitral proceedings

Sanofi and its affiliates 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. Provisions related to legal and arbitral proceedings are recorded in accordance with the principles described in Note B.12.

Most of the issues raised by these claims are highly complex and subject to substantial uncertainties; therefore, the probability of loss and an estimation of damages are difficult to ascertain. Contingent liabilities are cases for which either we are unable to make a reasonable estimate of the expected financial effect that will result from ultimate resolution of the proceeding, or a cash outflow is not probable. In either case, a brief description of the nature of the contingent liability is disclosed and, where practicable, an estimate of its financial effect, an indication of the uncertainties relating to the amount and timing of any outflow, and the possibility of any reimbursement are provided in application of paragraph 86 of IAS 37.

In the cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed, we have indicated our losses or the amount of provision accrued that is the estimate of the probable loss.

In a limited number of ongoing cases, while we are able to make a reasonable estimate of the expected loss or range of the possible loss and have accrued a provision for such loss, we believe that publication of this information on a case-by-case basis or by class would seriously prejudice the Company's position in the ongoing legal proceedings or in any related settlement discussions. Accordingly, in those cases, we have disclosed information with respect to the nature of the contingency but have not disclosed our estimate of the range of potential loss, in accordance with paragraph 92 of IAS 37.

These assessments can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Our assessments are based on estimates and assumptions that have been deemed reasonable by management. We believe that the aggregate provisions recorded for the above matters are adequate based upon currently available information. However, given the inherent uncertainties related to these cases and involved in estimating contingent liabilities, we could in the future incur judgments that could have a material adverse effect on our net income in any particular period.

Long term provisions are disclosed in Note D.19. They include:

- provisions for product liability risks, litigation and other amount to €1,652 million in 2022. These provisions are mainly related to product liabilities, government investigations, competition law, regulatory claims, warranties in connection with certain contingent liabilities arising from business divestitures other than environmental matters and other claims;
- provisions for environmental risks and remediation amount to €526 million in 2022, the majority of which are related to contingencies that have arisen from business divestitures.

a) Products

Sanofi Pasteur Hepatitis B Vaccine Product Litigation

Since 1996, more than 180 lawsuits have been filed in various French civil courts against Sanofi Pasteur and/or Sanofi Pasteur MSD S.N.C., the former French subsidiary of Sanofi, and the latter a joint venture company with Merck & Co., Inc. now terminated, for which past ongoing litigation is now managed by the originating party. In such lawsuits, the plaintiffs allege that they suffer from a variety of neurological disorders and autoimmune diseases, including multiple sclerosis and Guillain-Barré syndrome as a result of receiving the hepatitis B vaccine.

In January 2018, the Appeal Court of Bordeaux found a causal link between hepatitis B vaccine and multiple sclerosis. In July 2019, the French Supreme Court *(Cour de cassation)* cancelled the judgment of the Appeal Court of Bordeaux and referred the case back to the Appeal Court of Toulouse. On March 30, 2022, the Appeal Court of Toulouse dismissed all the plaintiff's claims.

As of December 31, 2022, there were 49 ongoing lawsuits related to Sanofi Pasteur hepatitis B vaccine.

Taxotere® Product Litigation in the US

As of December 31, 2022, there were approximately 8,300 plaintiffs in courts across the country, with approximately 700 of those plaintiffs being spouses who have filed loss of consortium claims.

Lawsuits have been filed against affiliates of Sanofi under US state law for personal injuries allegedly sustained in connection with the use of Taxotere®. The actions are held in several jurisdictions, including the federal and/or state courts of Louisiana, New Jersey, California, and Delaware. To date, there have been two bellwether trials as part of a federal multi-district litigation in the Eastern District of Louisiana both resulting in jury verdicts in Sanofi's favor.

It is not possible, at this stage, to reliably assess the outcome of these lawsuits or the potential financial impact on the Company.

Taxotere® – Mississippi Attorney General Litigation in the US

In October 2018, the Attorney General for the State of Mississippi filed a civil action in Hinds County, Mississippi, Chancery Court against various Sanofi Defendants related to Taxotere®. The State asserts one cause of action based on the Mississippi Consumer Protection Act ("MCPA") and seeks a permanent injunction prohibiting Defendants' conduct and civil penalties of up to $10,000 for each violation. Sanofi filed a motion to dismiss the entire action in Hinds County, Mississippi, Chancery Court, which is currently pending.

It is not possible, at this stage, to assess reliably the outcome of this lawsuit or the potential financial impact on the Company.

Zantac® Litigation in the US

In September 2019, the US Food and Drug Administration ("FDA") announced it was investigating the claims of an online pharmacy's Citizen Petition that the medication Zantac® (the brand name for ranitidine) used for stomach heartburn contains or can generate the chemical N-Nitrosodimethylamine ("NDMA"), an alleged human carcinogen. As a precautionary measure, Sanofi initiated a voluntary recall of branded over-the-counter Zantac® in October 2019. Concurrent with FDA's investigation, multiple personal injury lawsuits and class actions alleging that Zantac® causes various cancers and seeking damages for either alleged personal injuries or alleged economic injuries were filed. Most of those cases have been coordinated into a Multi-District Litigation ("MDL") in the Southern District of Florida.

On June 30 and July 8, 2021, the Federal MDL Court entered orders granting in part and denying in part Defendants' motions to dismiss various aspects of Plaintiffs' amended complaints. The rulings narrowed the scope of plaintiffs' complaints and saw the dismissal of all retailers and generic manufacturers from the MDL, leaving branded manufacturers GSK, Pfizer, Boehringer Ingelheim, and Sanofi as the defendants.

On December 6, 2022, the MDL Court granted Sanofi and the other defendants' Daubert and Summary Judgment motions. As a result, the Court will dismiss approximately 50,000 cases involving plaintiffs' five designated cancers. We expect those plaintiffs to appeal the MDL's Court's decision.

Other cases are pending in various state courts. These state court cases still include numerous retail and generics manufacturing defendants in addition to branded manufacturers.

In addition, in November 2019, Sanofi received a Civil Investigative Demand ("CID") related to this issue from the Arizona Attorney General.

In June 2020, the New Mexico Attorney General filed a complaint against Sanofi, the previous marketing authorization holders for branded Zantac®, a dozen generic manufacturers, and several retailers. The complaint brings claims for alleged violations of the New Mexico Unfair Practices Act, violations of the New Mexico False Advertising Act, violations of the New Mexico Public Nuisance Statute, common law public nuisance, and negligence.

In June 2020, Sanofi received a notice from the US Department of Justice Civil Division and US Attorney's Office for the Eastern District of Pennsylvania of an investigation into allegations that pharmaceutical manufacturers violated the False Claims Act, 31 U.S.C. § 3729, in relation to the drug Zantac® and ranitidine hydrochloride through alleged failure to disclose to the federal government information about the potential presence of NDMA. The notice requests information and documents from Sanofi including applications and communications with FDA.

In November 2020, the Mayor and City Council of Baltimore filed a complaint against Sanofi, the previous marketing authorization holders for branded Zantac®, generic manufacturers, and several retailers. The complaint alleges violations of the Maryland Consumer Protection statute, public nuisance, and negligence.

In January 2021, Sanofi was served with the Center for Environmental Health's Second Amended Complaint alleging Proposition 65 violations. The case, which also names generic manufacturers and retailers, is pending in California Superior Court in Alameda County.

Overall between State and federal filings, there are currently 3,486 product liability "complaints" filed. These complaints encompass 68,355 individual product liability "plaintiffs" who have all filed against Sanofi. The vast majority of these plaintiffs participated in the MDL Court's census registry program, allege cancers that the plaintiffs' leadership decided not to designate and pursue in the MDL, and have since filed their complaints in state courts. Additional cases may be filed.

It is not possible, at this stage, to assess reliably the outcome of these lawsuits or the potential financial impact on Sanofi.

Zantac® Litigation in Canada

Between 2019 and 2022, 7 proposed class actions naming notably Sanofi Consumer Health Inc., Sanofi-Aventis Canada Inc., Chattem (Canada) Inc., Sanofi and Sanofi Pasteur Limited as Defendants, relating to ranitidine were filed in various Canadian States court on behalf of all Canadian provinces alleging they suffered personal injury, including cancer, from the ingestion of ranitidine and are seeking general special, statutory, punitive and aggravated damages in an unspecified amount as well as disgorgement of profits. Additionally, some plaintiffs seek restitution for unjust enrichment in an amount equivalent to the purchase price of Zantac® and subrogated damages on behalf of provincial health insurers for health care costs related to ranitidine use. These actions are pending before the courts of Alberta, British Columbia, Quebec and Ontario. A Certification hearing was held in the British Columbia action in October 2022 and the certification decision is under review of the Court.

It is not possible, at this stage, to assess reliably the outcome of these lawsuits or the potential financial impact on Sanofi.

Depakine® Product Litigation in France

Civil proceedings

As of December 31, 2022, 78 families brought a civil claim involving 131 people exposed in utero to sodium valproate against a French affiliate of Sanofi seeking indemnification under French law for personal injuries allegedly suffered by children in connection with the use of sodium valproate by their mothers during pregnancy to treat their epilepsy (Depakine®). These actions are held in several jurisdictions in France.

Twenty-nine lawsuits are proceedings on the merits, the most advanced was tried at the French Supreme Court level which issued in November 2019 a ruling sending the case before the Paris Appeal Court to rule on Sanofi's argument on the compliance of the product with mandatory regulations, as well as on the question of defectiveness of the product and the assessment of damages. In January 2023, the Paris Appeal Court ordered a stay in the proceedings until the second expert opinion report is handed down in the criminal investigation (see below).

Seven first instance rulings on the merits were handed down in 2022 by the Judicial Tribunal of Nanterre. In three cases, the Court declared the judicial expert report null and void and the Court dismissed one claim in another case.

Concerning three other cases relating to births that occurred between 2005 and 2009, the Court held, on the basis of a non-fault liability, that Sanofi was liable in light of the wording of the patient information leaflet. Provisional compensation amounts were set in the range of €0.1 million to €0.5 million.

All the judgments have been appealed.

In the class action lawsuit filed in May 2017 by the APESAC *(Association des Parents d'Enfants souffrant du Syndrome de l'Anti-Convulsivant)* against the French affiliate, the Judicial Tribunal of Paris ruled on January 5, 2022 that a class is admissible, retaining Sanofi's liability between 1984 and January 2006 for malformations and between 2001 and January 2006 for neuro-developmental disorders (NDD). This decision is based on the conclusions of a criminal expert report within the frame of ongoing criminal proceeding, for which the *Chambre de l'Instruction* of the Appeal Court of Paris had ordered a counter-expertise (see below). Sanofi and its insurers appealed the Judicial Tribunal of Paris' ruling related to the class action.

On July 21, 2021, a Judicial Tribunal in France dismissed a claim for damages brought against Sanofi regarding a child born in 1995. The Judicial Tribunal considered that the risk of occurrence of NDD in children born to mother exposed to sodium valproate during pregnancy was not demonstrated by the state of scientific knowledge at the time of her pregnancy. This decision was appealed and the proceeding is now pending before the Appeal Court of Paris, which had ordered a stay in the proceeding until the end of the criminal investigation.

In July 2020, a collective redress against the French affiliate was filed by 63 families, seeking indemnification for a prejudice of anxiety. There is no date set for the hearing on the merits in this case yet.

Criminal investigation

A criminal investigation was initiated in May 2015 before the Paris Civil Court. In January 2020, the French affiliate of Sanofi was indicted for aggravated deception and involuntary injuries and in July 2020 for involuntary manslaughter. In July 2020, a judicial supervision of the affiliate was ordered, together with the implementation of financial guarantees. In November 2020, the Health Authority (ANSM) was similarly indicted for involuntary injuries and involuntary manslaughters.

On March 9, 2022, the *Chambre de l'Instruction* of the Appeal Court of Paris ruled that certain complaints for involuntary manslaughter and several others for aggravated deception and involuntary injuries were time-barred. The Public Prosecutor, as well as the civil parties, have brought the matter before the *Chambre Criminelle* of the Supreme Court. In September 2022, the investigating judges appointed 2 experts for a counter-expertise following the *Chambre de l'Instruction's* ruling handed down end of 2021 and in October 2022 ordered 6 individual medical assessments.

Public compensation scheme

In 2017, the French government set up a public compensation scheme to indemnify patients for damages suffered in connection with the prescription of sodium valproate and its derivatives. The scheme was further amended through the 2020 Finance Law, with notably the introduction of presumptions of default for lack of information of the mother since 1982 for malformations and since 1984 for NDD. The scheme was amended again through the 2021 Finance Law in order to increase the maximum premium applicable in case of refusal to make an offer (or insufficient offer) which would be deemed unjustified by a court ruling.

The committee of the compensation scheme has issued several final opinions holding the French affiliate liable for damages either in full or in part along with the French State, and, in some cases, healthcare practitioners. The French affiliate disagreed with the committee's conclusions and has accordingly not offered indemnification to the claimants who have received compensation from the ONIAM *(Office National d'Indemnisation des Accidents Médicaux)*. The ONIAM is now seeking reimbursement from Sanofi who has filed legal actions to oppose ONIAM's payment orders.

Sanofi has also been notified of 63 exposed persons who have filed a request for indemnification before the public compensation scheme and who are also claimants against Sanofi in individual judicial proceedings (summary proceedings or actions on the merits).

Administrative Actions

In July 2020, March and June 2021, the Montreuil Administrative Court had held the French State liable in 5 administrative proceedings initiated by families against the State. In March 2021, the Administrative Court did not retain any lack of information of the mother regarding the risk of neurodevelopmental disorders for births in 1999 and in 2002, based on the state of scientific knowledge at the time. However, regarding the risk of malformations, liabilities were retained against the State, the healthcare professionals and Sanofi, notably for discrepancy between the SmPC (Summary of the Product Characteristics) and the patient leaflet. In other cases involving births in 2005-2008, the liability of the State was retained for both malformations and neurodevelopmental disorders, and partially exonerated, taking into account the roles of healthcare practitioners and Sanofi. Given that the French affiliate was not a party to these administrative proceedings, its arguments (i.e. notably several requests from the French affiliate to the Health Authorities to reinforce warnings to healthcare professionals and patients in relation to Depakine®) were not considered. All rulings were appealed by the claimants. Sanofi has filed requests for voluntary intervention in these proceedings to present its arguments before the Administrative Court of Appeal. In one proceeding, the claimants decided to withdraw their claims.

It is not possible, at this stage, to assess reliably the outcome of these cases or the potential financial impact on the Company.

Depakine® Product Litigation in other EU countries and in the UK

In Switzerland, 10 families have filed a civil claim for damages concerning 16 people exposed in utero. Some of them also involve the claimants' physicians. In November 2022, one action was declared time-barred by the judge. The claimant appealed this court decision on the merit. The appeal is on-going.

In Spain, there are 4 trials ongoing relating to 10 children. In March 2022, in one of the trials, the Court condemned Sanofi to indemnify 4 patients. Sanofi appealed this decision. In January 2023, in another trial filed by one patient, the Appeal Court confirmed the first instance's decision and dismissed the claim. The other actions are still at a preliminary stage.

In Belgium, there are 2 civil proceedings (currently on hold) and a criminal complaint against X and against Sanofi.

In Germany, there is one civil lawsuit before the Berlin Regional Court, relating to one child exposed *in utero* to valproate taken by the mother during pregnancy for bipolar disorder.

In Ireland, there are 2 Pre-Action Protocol cases and 2 civil claims on-going.

In the United Kingdom, there are 3 Pre-Action Protocol cases in Great Britain and 1 Pre-Action Protocol case in Northern Ireland on-going.

It is not possible, at this stage, to assess reliably the outcome of these cases or the potential financial impact on the Company.

Dengvaxia® (Philippines)

Since early 2018 up to present date, several claims were filed in the Philippines by parents of deceased children whose deaths were allegedly due to vaccination with Dengvaxia®. Early March 2019, 2020 and 2022, the Philippine Department of Justice (DOJ) prosecution panel announced it had found probable cause to indict several Sanofi employees/former employees and former Government officials for "reckless imprudence" resulting in homicides. Since then, several criminal actions have been filed in court as a result of this finding. Petitions for Review to the DOJ Secretary have been filed and the said petitions remain pending. Meanwhile, the majority of the respondents have challenged the jurisdiction of the lower court where the first 8 cases had been assigned and this issue is now filed with the Supreme Court. There are several claims that have not yet been filed in any court despite resolutions by the DOJ that there is probable cause.

b) Patents

Ramipril Canada Patent Litigation

Sanofi was involved in a number of legal proceedings involving companies which market generic Altace® (ramipril) in Canada. In 2004, Sanofi unsuccessfully brought Notice of Compliance proceedings (NOC proceedings) at the end of which eight manufacturers obtained marketing authorizations from the Canadian Minister of Health for generic versions of ramipril in Canada. Sanofi filed unsuccessful patent infringement actions against all those companies and ultimately Sanofi was liable for damages under Section 8. Sanofi made payment in complete satisfaction of those awards.

In June 2011, Apotex commenced an action in the Ontario Superior Court of Justice asserting damages under the Ontario Statute of Monopolies, the UK Statute of Monopolies, and the Trade-marks Act (the "Ontario Action").

At the request of the parties, in June 2021, the Court ordered that the action be stayed in view of the lower court's decision in March in the Apotex vs. Lilly case. In the Lilly case, the Court dismissed Apotex's Statute of Monopolies claim by way of summary judgment. If upheld on appeal, this decision may end Apotex's claim against Sanofi, also based on the Statute of Monopolies. In November 2022, Apotex filed an application for leave to appeal the Ontario Court of Appeal decision in the Lilly case with the Supreme Court of Canada. The Court will decide whether to grant the leave application in late Q1 2023.

Praluent® (alirocumab)-related Amgen Patent Litigation in the US

In 2014, Amgen filed four separate complaints against Sanofi and Regeneron in the US District Court for the District of Delaware ("District Court") asserting patent infringement relating to Sanofi and Regeneron's Praluent® product. Together these complaints alleged that Praluent® infringed seven patents for antibodies targeting PCSK9 and sought injunctive relief and unspecified damages.

In February 2021, the Federal Circuit affirmed the District Court's ruling invalidating the Amgen asserted patent claims. In November 2021, Amgen filed a petition with the US Supreme Court, asking it to overturn the Federal Circuit decision.

On November 4, 2022, the US Supreme Court granted Amgen's petition for review. Proceedings before the US Supreme Court are now underway.

Dupixent® (dupilumab)-related Amgen Patent Opposition and Revocation in Europe

Immunex Corporation, an Amgen affiliate, is the registered proprietor of European Patent EP2292665. The claims of this patent relate to, among other things, human monoclonal antibodies that are capable of inhibiting IL-4 induced biological activity and which compete with one of four reference antibodies for binding to a cell that expresses human IL-4R. In April 2016, Sanofi and Regeneron each filed an opposition in the European Patent Office (EPO) against EP2292665, seeking its revocation.

The EPO rendered its decision in November 2017 and revoked the patent in its entirety.

In September 2017, Sanofi and Regeneron filed oppositions in the EPO against Amgen's European Patent EP2990420, which is a divisional of the EP2292665 Patent discussed above.

In March 2022, the European Patent Office Technical Board of Appeals ("TBA") ruled in Sanofi and Regeneron's favor and affirmed the invalidation of Amgen/Immunex's EP2990420 patent. In December 2022, the TBA issued its written decision in favor of Sanofi and Regeneron. Amgen/Immunex may seek review of this decision by the Enlarged Board of Appeals.

In March 2022, Amgen/Immunex withdrew its appeal to the TBA for its EP2292665 patent.

Jevtana® (cabazitaxel)-related patent litigation in the US

Jevtana® is currently covered by four Orange Book listed patents US 7,241,907, US 8,927,592, US 10,583,110 and US 10,716,777. In May to July 2020, Sanofi filed patent infringement suits under Hatch-Waxman against 12 generic filers asserting the '110 patent and the '777 patent in the US District Court for the District of Delaware. The '592 patent was added to the suits after its amended claims issued in August 2021. In January 2021 and August 2022, the District Court issued two claim construction decisions in favor of the defendants. In September 2022, the district court issued a decision that granted the defendants' motion to dismiss in part related to the '592 patent but denied the motion to dismiss in part related to the '777 and '110 patents. Sanofi has reached settlement agreements with most of the defendants and the suit against the remaining defendant Sandoz is ongoing. Sanofi has voluntarily withdrawn the '110 patent from the suit and a 3-day trial on the '777 patent was held in January 2023. Sandoz has agreed not to launch any generic cabazitaxel product until the earlier of a district court decision in favor of the defendants or 120 days after the completion of the post-trial briefing.

Plavix® Litigation (Commonwealth) in Australia

In August 2007, GenRX (a subsidiary of Apotex) obtained registration of a generic clopidogrel bisulfate product on the Australian Register of Therapeutic Goods. At the same time, GenRX filed a patent invalidation action with the Federal Court of Australia, seeking revocation of Sanofi's Australian enantiomer patent claiming clopidogrel salts (a "nullity action"). In September 2007, Sanofi obtained a preliminary injunction from the Federal Court preventing commercial launch of this generic clopidogrel bisulfate product until judgment on the substantive issues of patent validity and infringement.

In August 2008, the Australian Federal Court confirmed that the claim in Sanofi's Australian enantiomer patent directed to clopidogrel bisulfate (the salt form in Plavix®) was valid and the patent infringed. On appeal, the Full Federal Court of Australia held in September 2009 that all claims in the patent are invalid. Sanofi's appeal to the Australia High Court was denied in March 2010.

In April 2013, the Australian Department of Health and Ageing ("Commonwealth") filed an application before the Federal Court of Australia seeking payment of damages from Sanofi related to the Apotex preliminary injunction of up to AUD449 million (€286 million as of December 31, 2022), plus interest.

Sanofi and BMS settled the patent litigation with Apotex in November 2014. In April 2020, the Commonwealth's claim was dismissed. In May 2020, the Commonwealth filed a Notice of Appeal to the Full Court of the Federal Court. On appeal, the Commonwealth reduced its claim to a range of AUD223.3 million (€142.1 million) to AUD280.2 million (€178.4 million) which, inclusive of interest to December 31, 2022, ranges from AUD343.4 million (€218.6 million) to AUD463.6 million (€295.1 million) depending on whether interest accrues from the date the Commonwealth claims the Apotex products would have been listed on the Government reimbursement scheme in the absence of the injunction (i.e. April 1, 2008) or the date the Commonwealth filed its claim (i.e. April 1, 2013). Appeal hearing took place in February 2021 before the Full Court of the Federal Court. The ruling is expected in 2023.

c) Other litigation

Aubagio® (teriflunomide)-related litigation in Europe

In October 2020, Mylan Ireland Ltd ("Mylan") brought an action before the General Court of the European Union requesting the annulment of the August 18, 2020 decision of the European Medicines Agency ("EMA") refusing to validate Mylan's marketing authorization application for a generic version of Aubagio® (teriflunomide). Sanofi has intervened in this court case between Mylan and the EMA in order to defend Aubagio®'s regulatory exclusivity. Mylan submitted a request for discontinuance of the proceedings in December 2022. The case is over.

Plavix® (clopidogrel) – Attorney General Action in Hawaii

In March 2014, the Hawaii Attorney General (AG) filed a complaint that sets forth allegations related to the sale and marketing of and variability of response to Plavix®. The Hawaii AG specifically alleged that Plavix® had a diminished effect in patients of certain genetic backgrounds and that Sanofi and BMS had failed to make an earlier disclosure of this information.

In February 2021, the Court issued its decision, imposing penalties in the total amount of $834,012,000 against both Sanofi and Bristol Myers Squibb (BMS), with $417,006,000 being apportioned to each company. In June 2021, Sanofi and BMS appealed this judgment. To the extent this judgment or possibly a reduced judgment remains after the appeal, the judgment would be split evenly with BMS. On May 3, 2022, the Hawaii Supreme Court granted a request to transfer the appeal directly to the Hawaii Supreme Court, thereby eliminating review by the Hawaii intermediate Court of Appeals. The Hawaii Supreme Court had oral argument in December 2022 and a decision is expected in or around March 2023.

Plavix® (clopidogrel) - Attorney General Action in New Mexico

In September 2016, the New Mexico Attorney General (AG) filed a complaint, claiming that Sanofi and Bristol Meyers Squibb (BMS) engaged in unfair and deceptive practices related to the marketing and labelling of Plavix®. The New Mexico AG specifically alleged that Plavix® had a diminished effect in patients of certain genetic backgrounds and that the Companies failed to make an earlier disclosure of this information. This matter has been concluded and dismissed by way of a settlement by all parties that was finalized in Q4 2022.

Plavix® (clopidogrel)-related litigation in France

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. 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 its French affiliate received a summons before the Paris Commercial Court from the French *Caisse Nationale d'Assurance Maladie* – CNAM (French Social Security) claiming €115.8 million for their alleged damages. On October 1, 2019, the Paris Commercial Court dismissed the CNAM's action as time barred. On February 9, 2022, the Paris Court of Appeals overturned the Paris Commercial Court's ruling, finding the French *Caisse Nationale d'Assurance Maladie* - CNAM (French Social Security)'s action as not time-barred and designated an expert to determine the amount of damages. The expertise is on-going.

340B Drug Pricing Program in the United States

Sanofi is currently involved in several matters relating to the 340B program in the US (a federal program that requires drug manufacturers to supply certain products to certain "covered entities" at reduced prices). In 2021, Sanofi filed a lawsuit against the Department of Health and Human Services ("HHS"), the Health Resources and Services Administration ("HRSA"), and certain of their administrators in the US District Court for the District of New Jersey challenging (i) HHS's December 2020 Advisory Opinion (the "AO") stating that drug manufacturers are legally obligated to deliver discounts under the 340B program to an unlimited number of contract pharmacies; (ii) HHS's December 2020 Administrative Dispute Resolution ("ADR") Rule; and (iii) HRSA's May 2021 letter to Sanofi concluding that Sanofi's 340B integrity initiative (under which Sanofi collects limited, de-identified, claims data on 340B-priced drugs dispensed by contract pharmacies) violates section 340B and that Sanofi has therefore "overcharged" certain covered entities. The court issued its opinion in November 2021, upholding HRSA's conclusion in the May 2021 letter, but did not impose any fines, penalties or refund obligations against Sanofi for any "overcharges". The court also rejected Sanofi's challenge to the ADR Rule and dismissed its challenge to the AO as moot. Sanofi appealed the court's decision to the Third Circuit Court of Appeals and the government filed a cross-appeal. The Third Circuit issued its opinion on January 30, 2023. It held that Sanofi's restrictions on delivery to contract pharmacies do not violate Section 340B. It also enjoined HHS from enforcing against Sanofi its reading of Section 340B in the AO and the May 2021 violation letter. As to Sanofi's challenge to the ADR Rule, the Third Circuit held that HHS did not violate the Administrative Procedure Act's notice-and-comment requirement in promulgating the ADR Rule.

In January 2021, the National Association of Community Health Centers ("NACHC") filed an ADR proceeding before HRSA on behalf of a number of covered entities, seeking to require Sanofi and AstraZeneca to supply contract pharmacies with 340B discounts without conditions. On August 10, 2022, the ADR panel granted the motions to dismiss filed both by Sanofi and AstraZeneca, holding that the Delaware district court's decision granting AstraZeneca's motion for summary judgment precluded NACHC's ADR claims against both AstraZeneca and Sanofi.

In September 2021, HRSA referred Sanofi (as well as other manufacturers) to the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule.

In February 2021, the Vermont Attorney General issued a Civil Investigative Subpoena seeking certain information about Sanofi's participation in the 340B Drug Pricing Program. Sanofi continues to cooperate with this investigation.

In addition, in July 2021, Mosaic Health Inc. and Central Virginia Health Services (covered entities) filed a nationwide antitrust class action complaint against Sanofi and three other manufacturers in the United States District Court for the Western District of New York. Plaintiffs allege that Sanofi and the other defendants conspired to eliminate favorable 340B pricing, particularly with respect to diabetes therapies. On September 2, 2022, the court granted Defendants' motion to dismiss the complaint. On October 3, 2022, plaintiff filed a motion for leave to file a second amended complaint. A motion to dismiss the second amended complaint is fully briefed and pending before the court.

d) Contingencies arising from certain mergers & acquisitions transactions

As a result of divestitures, the Company is subject to a number of ongoing contractual and legal obligations regarding the state of the sold businesses, their assets, and their liabilities, some of which may be subject to dispute.

Aventis CropScience Retained Liabilities

The sale by Aventis Agriculture S.A. and Hoechst GmbH (both legacy companies of Sanofi) of their aggregate 76% participation in Aventis CropScience Holding (ACS) to Bayer and Bayer CropScience AG (BCS), the wholly owned subsidiary of Bayer which holds the ACS shares, was effective on June 3, 2002. The Stock Purchase Agreement (SPA) dated October 2, 2001, contained customary representations and warranties with respect to the sold business, as well as a number of indemnifications subject to limitation periods and caps, in particular with respect to environmental liabilities for which some outstanding claims from Bayer remain unresolved.

Infraserv Hoechst Retained Liabilities

By the Asset Contribution Agreement dated December 19/20, 1996, as amended in 1997, Hoechst contributed all lands, buildings, and related assets of the Hoechst site at Frankfurt Hoechst to Infraserv GmbH & Co. Hoechst KG. Infraserv Hoechst undertook to indemnify Hoechst against environmental liabilities at the Hoechst site and with respect to certain landfills. As consideration for the indemnification undertaking, Hoechst transferred to Infraserv Hoechst approximately €57 million to fund reserves. In 1997, Hoechst also agreed it would reimburse current and future Infraserv Hoechst environmental expenses up to €143 million. As a former operator of the land and as a former user of the landfills, Hoechst may ultimately be liable for costs of remedial action in excess of this amount.

Boehringer Ingelheim (BI) Consumer Healthcare Liabilities

Sanofi and Boehringer Ingelheim (BI) are involved in an ICC (International Chamber of Commerce) arbitration regarding their respective indemnification obligations for liabilities connected to ongoing US court proceedings regarding Zantac® manufactured by BI (see above - Zantac® Litigation in the US). The dispute arises from indemnification obligations agreed between Sanofi and BI as part of the swap of Sanofi's Animal Health (AH) business for BI's Consumer Health Care (CHC) business in January 2017 and under a Global Settlement Agreement concluded in September 2019 regarding notably the offset of respective AH and CHC claims notified under the SPAs.

In February 2020, BI initiated an arbitration against Sanofi seeking indemnification for losses it could incur as a result of the Zantac® litigation in the US. Sanofi is disputing BI's claim for indemnification and has asserted several counterclaims under relevant agreements, including a counterclaim for indemnification of losses Sanofi and its affiliates have incurred and may incur in connection with the same US court proceedings involving Zantac®. The arbitration is expected to conclude at the earliest in March 2023.

D.23. Provisions for discounts, rebates and sales returns

Adjustments between gross sales and net sales, as described in Note B.13., are recognized either as provisions or as reductions in accounts receivable, depending on their nature.

The table below shows movements in these items:

(€ million)		Government and State programs[a]	Managed care and GPO programs[b]	Chargeback incentives	Rebates and discounts	Sales returns	Other deductions	Total
Balance at January 1, 2020		**2,178**	**726**	**312**	**1,330**	**621**	**51**	**5,218**
Provision related to current period sales		5,970	2,752	4,633	6,221	628	110	20,314
Net change in provision related to prior period sales		(54)	—	—	(113)	(34)	—	(201)
Payments made		(5,552)	(2,556)	(4,604)	(5,838)	(512)	(112)	(19,174)
Currency translation differences		(35)	(14)	(8)	(43)	(15)	(3)	(118)
Balance at December 31, 2020	[c]	**2,507**	**908**	**333**	**1,557**	**688**	**46**	**6,039**
Changes in scope of consolidation		3	—	—	(2)	1	—	2
Provision related to current period sales		5,855	3,037	3,813	6,330	582	97	19,714
Net change in provision related to prior period sales		(136)	(3)	(4)	(152)	56	(3)	(242)
Payments made		(5,561)	(2,979)	(3,828)	(6,291)	(697)	(105)	(19,461)
Currency translation differences		(72)	(32)	(11)	(17)	(20)	(1)	(153)
Balance at December 31, 2021	[c]	**2,596**	**931**	**303**	**1,425**	**610**	**34**	**5,899**
Provision related to current period sales		6,744	3,246	4,147	7,244	578	182	22,141
Net change in provision related to prior period sales		(120)	(47)	(21)	(138)	(8)	19	(315)
Payments made		(6,824)	(3,208)	(4,093)	(6,809)	(599)	(166)	(21,699)
Currency translation differences		207	99	26	83	48	1	464
Balance at December 31, 2022	[c]	**2,603**	**1,021**	**362**	**1,805**	**629**	**70**	**6,490**

(a) Primarily US government programs: Medicaid (€1,307 million in 2022, €1,244 million in 2021, €1,015 million in 2020) and Medicare (€775 million in 2022, €941 million in 2021 and €726 million in 2020).

(b) Mainly rebates and other price reductions granted to healthcare authorities in the United States (including Managed Care: €934 million in 2022, €896 million in 2021 and €692 million in 2020).

(c) Provisions related to US net sales amounted to €4,270 million as of December 31, 2022, €4,057 million as of December 31, 2021 and €3,982 million as of December 31, 2020.

D.24. Personnel costs

Total personnel costs (other than termination benefits, presented in Note D.27.) include the following items:

(€ million)	2022	2021	2020
Salaries	7,145	6,625	6,508
Social security charges (including defined-contribution pension plans)	2,098	1,929	1,874
Stock options and other share-based payment expense	245	244	274
Defined-benefit plans[a]	236	273	162
Other employee benefits	267	269	261
Total	**9,991**	**9,340**	**9,079**

(a) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

The total number of registered employees was 91,573 as of December 31, 2022, compared with 95,442 as of December 31, 2021 and 99,412 as of December 31, 2020.

D.25. Other operating income

Other operating income totaled €1,969 million in 2022, versus €859 million in 2021 and €697 million in 2020.

Other operating income includes (i) gains from asset divestments, amounting to €655 million in 2022 (versus €418 million in 2021 and €307 million in 2020); and (ii) income from Sanofi's pharmaceutical partners, amounting to €1,178 million in 2022 (including €1,147 million from Regeneron, see Note D.26. below and Note C.1.), compared with €245 million in 2021 and €199 million in 2020. For 2021, it includes a payment of €119 million from Daiichi Sankyo relating to the termination of a vaccines collaboration agreement in Japan.

D.26. Other operating expenses

Other operating expenses totaled €2,531 million in 2022, compared with €1,805 million in 2021 and €1,415 million in 2020.

For 2022, this line item includes €2,378 million of expenses relating to the alliance with Regeneron (see Note C.1.), compared with €1,568 million for 2021 and €1,090 million for 2020 (as shown in the table below):

(€ million)	2022	2021	2020
Income & expense related to sharing of (profits)/losses under the Monoclonal Antibody Alliance	(2,325)	(1,253)	(727)
Additional share of profit paid by Regeneron towards development costs [b]	434	127	75
Reimbursement to Regeneron of selling expenses incurred	(476)	(303)	(349)
Total - Monoclonal Antibody Alliance	**(2,367)**	**(1,429)**	**(1,001)**
Immuno-Oncology Alliance	**16**	**68**	**89**
Other (mainly Zaltrap® and Libtayo®)[a]	**1,120**	**(12)**	**(14)**
Other operating income/(expenses), net related to the Regeneron Alliance	**(1,231)**	**(1,373)**	**(926)**
of which amount presented in Other operating income (Note D.25.)	*1,147*	*195*	*164*

(a) Following the restructuring of the Immuno-Oncology agreement between Sanofi and Regeneron, applicable from July 1, 2022 (see Note C.1.).

(b) As of December 31, 2022, the commitment received by Sanofi in respect of the additional profit share payable by Regeneron towards development costs amounted to €2.7 billion, compared with €2.9 billion as of December 31, 2021 (see note D.21).

Charges to provisions for litigation and environmental risks are also recorded within this line item.

D.27. Restructuring costs and similar items

Restructuring costs and similar items amounted to €1,336 million in 2022, €820 million in 2021 and €1,089 million in 2020, and were comprised of the following items:

(€ million)	2022	2021	2020 [a]
Employee-related expenses	507	193	697
Charges, gains or losses on assets[b]	261	110	149
Compensation for early termination of contracts (other than contracts of employment)	1	34	40
Transformation programs costs	547	463	191
Others	20	20	12
Total	**1,336**	**820**	**1,089**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

(b) This line consists of impairment losses and accelerated depreciation charges related to site closures (including leased sites), and gains or losses on divestments of assets arising from reorganization decisions made by Sanofi.

In 2022, the employee-related expenses of €507 million related to termination benefits further to announcements made during the year, and the line "Charges, gains or losses on assets" related mainly to a strategic decision to close an industrial facility outside France. The costs of Sanofi's transformation program (as defined in Note B.19.) relate mainly to the ongoing creation of the new standalone Consumer Healthcare entity, and to the implementation of Sanofi's new digital strategy.

In 2021, the costs of Sanofi's transformation program were mainly related to the creation of the new standalone Consumer Healthcare entity and of EUROAPI (the new European market leader in active pharmaceutical ingredients), and to the implementation of Sanofi's new digital strategy.

In 2020, employee-related expenses amounted to €697 million, and consisted of termination benefits further to the announcement of plans to adapt Sanofi's organization (primarily in Europe) in line with the new "Play to Win" strategy announced in December 2019.

D.28. Other gains and losses, and litigation

Other gains and losses, and litigation for 2022 represent a charge of €370 million, including the pre-tax loss arising on the deconsolidation of EUROAPI (see Note D.1.) and costs related to major litigation, including the estimated future defense costs which Sanofi may be exposed in connection with the Zantac® litigation.

For 2021, this line item represented a charge of €5 million.

For 2020, this line item represented a net gain of €136 million, mainly relating to the sale of Sepraﬁlm®.

D.29. Financial expenses and income

An analysis of ***Financial expenses*** and ***Financial income*** is set forth below:

(€ million)	2022	2021	2020 [a]
Cost of debt[b]	(365)	(313)	(328)
Interest income[c]	241	54	103
Cost of net debt	**(124)**	**(259)**	**(225)**
Non-operating foreign exchange gains/(losses)	(4)	2	(6)
Unwinding of discounting of provisions[d]	(20)	(11)	(11)
Net interest cost related to employee benefits	(47)	(44)	(57)
Gains/(losses) on disposals of financial assets	1	3	6
Net interest expense on lease liabilities	(40)	(35)	(38)
Other	—	16	(4)
Net financial income/(expenses)	**(234)**	**(328)**	**(335)**
comprising: Financial expenses	**(440)**	**(368)**	**(388)**
Financial income	**206**	**40**	**53**

(a) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

(b) Includes net gains/(losses) on interest rate and currency derivatives used to manage debt: €(11) million in 2022, €14 million in 2021, €93 million in 2020.

(c) Includes net gains on interest rate and currency derivatives used to manage cash and cash equivalents: €68 million in 2022, €51 million in 2021, €66 million in 2020.

(d) Primarily on provisions for environmental risks, restructuring provisions, and provisions for product-related risks (see Note D.19.).

In 2022, 2021 and 2020, the impact of the ineffective portion of hedging relationships was not material.

D.30. Income tax expense

Sanofi has elected for tax consolidations in a number of countries, principally France, Germany, the United Kingdom and the United States.

The table below shows the allocation of income tax expense between current and deferred taxes:

(€ million)	2022	2021	2020 [a]
Current taxes	(2,774)	(1,908)	(1,913)
Deferred taxes	768	350	106
Total	**(2,006)**	**(1,558)**	**(1,807)**
Income before tax and investments accounted for using the equity method	**10,422**	**7,798**	**13,778**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

The difference between the effective tax rate and the standard corporate income tax rate applicable in France is explained as follows:

(as a percentage)	2022	2021	2020
Standard tax rate applicable in France	25.8	28.4	32.0
Difference between the standard French tax rate and the rates applicable to Sanofi[a]	(6.5)	(9.5)	(18.2)
Revisions to tax exposures and settlements of tax disputes	(0.8)	1.0	0.5
Fair value remeasurement of contingent consideration	(0.2)	—	—
Other items[b]	0.9	0.1	(1.2)
Effective tax rate	**19.2**	**20.0**	**13.1**

(a) The difference between the French tax rate and tax rates applicable to foreign subsidiaries reflects the fact that Sanofi has operations in many countries, most of which have lower tax rates than France. For 2020, this line includes the difference between the standard French tax rate and the tax rate applicable to the gain on divestment of Regeneron shares.

(b) In determining the amount of the deferred tax liability for 2022, 2021 and 2020, Sanofi took into account changes in the ownership structure of certain subsidiaries.

For the periods presented, the amount of deferred tax assets recognized in profit or loss that were initially subject to impairment losses at the time of a business combination is immaterial.

D.31. Share of profit/loss from investments accounted for using the equity method

The line item ***Share of profit/(loss) from investments accounted for using the equity method*** amounted to €68 million for 2022, compared with €39 million for 2021 and €359 million for 2020 (including €343 million for the share of Regeneron profits up to and including May 29, 2020, the date on which Sanofi ceased to exercise significant influence over Regeneron: see Note D.2.).

D.32. Net income attributable to non-controlling interests

The table below shows ***Net income attributable to non-controlling interests*** for the reporting periods presented:

(€ million)	2022	2021	2020
Share of net income attributable to other non-controlling interests	113	56	36
Total	**113**	**56**	**36**

D.33. Related party transactions

The principal related parties are companies over which Sanofi has control or significant influence, joint ventures, key management personnel, and principal shareholders.

Sanofi has not entered into any material transactions with any key management personnel. Financial relations with Sanofi's principal shareholders fall within the ordinary course of business and were immaterial in the years ended December 31, 2022, 2021 and 2020.

Note F.1. lists the principal companies controlled by Sanofi; those companies are fully consolidated, as described in Note B.1. Transactions between those companies, and between the parent company and its subsidiaries, are eliminated when preparing the consolidated financial statements.

Transactions with companies over which Sanofi has significant influence, and with joint ventures, are presented in Note D.6.

Key management personnel include corporate officers and the members of the Executive Committee (an average of 11 members in 2022, in 2021 and in 2020).

The table below shows, by type, the compensation paid to key management personnel:

(€ million)	2022	2021	2020 [(a)]
Short-term benefits[(b)]	31	33	36
Post-employment benefits	2	2	3
Share-based payment	19	20	18
Total recognized in profit or loss	**52**	**55**	**57**

(a) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods (see Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021).

(b) Compensation, employer's social security contributions, directors' attendance fees, and any termination benefits (net of reversals of termination benefit obligations).

The table below shows the aggregate obligation as of December 31 for each period presented for individuals who hold or have held executive positions within Sanofi during that period.

(€ million)	2022	2021	2020 [(a)]
Aggregate top-up pension obligation in favor of certain corporate officers and of Executive Committee members	10	28	32
Aggregate termination benefits and lump-sum retirement benefits in favor of key management personnel	5	7	5

(a) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods (see Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021).

D.34. Disclosures about major customers and credit risk

Credit risk is the risk that customers (wholesalers, distributors, pharmacies, hospitals, clinics or government agencies) may fail to pay their debts; for Sanofi, that risk is mainly concentrated on amounts receivable from wholesalers in the United States. Sanofi manages credit risk by vetting customers in order to set credit limits and risk levels, and asking for guarantees or insurance where necessary; performing controls; and monitoring qualitative and quantitative indicators of accounts receivable balances, such as the period of credit taken and overdue payments.

Sales generated by Sanofi with its biggest customers, in particular certain wholesalers in the United States, represented 27% of net sales in 2022. The three largest customers respectively accounted for approximately 12%, 8% and 7% of Sanofi's net sales in 2022 (10%, 7% and 6% in 2021; 10%, 6% and 5% in 2020).

D.35. Segment information

As indicated in Note B.26., Sanofi has three operating segments: Pharmaceuticals, Vaccines, and Consumer Healthcare.

The Pharmaceuticals segment comprises, for all geographical territories, the commercial operations of the following global franchises: Specialty Care (Dupixent®, Neurology & Immunology, Rare Diseases, Oncology, and Rare Blood Disorders) and General Medicines (Core and Non-Core Assets), together with research, development and production activities dedicated to the Pharmaceuticals segment. This segment also includes associates whose activities are related to pharmaceuticals. Following the transaction of May 29, 2020, Regeneron is no longer an associate of Sanofi (see Note D.2.). Consequently, the Pharmaceuticals segment no longer includes Sanofi's equity-accounted share of Regeneron's profits for the periods presented.

The Vaccines segment comprises, for all geographical territories, the commercial operations of Vaccines, together with research, development and production activities dedicated to vaccines.

The Consumer Healthcare segment comprises, for all geographical territories, the commercial operations for Sanofi's Consumer Healthcare products, together with research, development and production activities dedicated to those products.

Inter-segment transactions are not material.

The costs of Sanofi's global support functions (Corporate Affairs, Finance, People & Culture, Legal, Ethics & Business Integrity, Information Solutions & Technologies, Sanofi Business Services, etc.) are primarily managed centrally at the group-wide level. 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.

Following the Capital Markets Day in February 2021, Sanofi changed the presentation of the net sales of the General Medicines and Consumer Healthcare GBUs, and also reallocated certain expenses. In particular, IT costs relating to Sanofi's new digital organization – previously allocated to the Pharmaceuticals, Vaccines, and Consumer Healthcare segments – are now included within the "Other" segment. The 2020 segment results presented below have been amended for comparative purposes in order to reflect those adjustments.

In accordance with IAS 8, Sanofi treated the first-time application of the IFRIC agenda decisions on (i) the calculation of provisions for pensions and other post-employment benefits under IAS 19 and (ii) accounting for costs of configuring or customizing a supplier's application software in a Software as a Service (SaaS) arrangement as retrospective changes in accounting policy. The impacts are described in Note A.2.1 to the consolidated financial statements for the year ended December 31, 2021.

D.35.1. Segment results

D.35.1.1. Analysis of net sales

The table below sets forth Sanofi's net sales for the years ended December 31, 2022, 2021 and 2020:

(€ million)		Europe	United States	Other countries	2022	Europe	United States	Other countries	2021	Europe	United States	Other countries	2020
Pharmaceuticals		**7,157**	**13,694**	**9,837**	**30,688**	**7,201**	**10,484**	**9,285**	**26,970**	**6,819**	**9,635**	**9,220**	**25,674**
Dupixent®		**940**	**6,346**	**1,007**	**8,293**	**649**	**3,971**	**629**	**5,249**	**386**	**2,808**	**340**	**3,534**
Neurology & Immunology		**639**	**1,637**	**174**	**2,450**	**638**	**1,482**	**204**	**2,324**	**578**	**1,631**	**185**	**2,394**
of which	Aubagio®	511	1,420	100	2,031	512	1,312	131	1,955	473	1,448	124	2,045
Rare Diseases		**1,104**	**1,367**	**974**	**3,445**	**1,069**	**1,142**	**915**	**3,126**	**1,010**	**1,122**	**879**	**3,011**
of which	Cerezyme®	239	194	274	707	244	173	266	683	249	177	264	690
	Fabrazyme®	228	471	239	938	223	395	226	844	200	406	211	817
	Myozyme®/ Lumizyme®	408	318	232	958	410	373	220	1,003	389	359	200	948
Oncology		**239**	**515**	**198**	**952**	**327**	**410**	**175**	**912**	**299**	**368**	**131**	**798**
of which	Jevtana®	33	275	83	391	112	253	90	455	187	246	103	536
Rare Blood Disorders		**94**	**983**	**240**	**1,317**	**81**	**842**	**218**	**1,141**	**41**	**837**	**339**	**1,217**
of which	Alprolix®	—	406	98	504	—	332	82	414	—	320	146	466
	Eloctate®	—	450	130	580	—	429	134	563	—	445	193	638
Core Assets		**1,917**	**1,653**	**2,819**	**6,389**	**1,868**	**1,315**	**2,585**	**5,768**	**1,759**	**1,413**	**2,409**	**5,581**
of which	Lovenox®	658	17	635	1,310	703	29	754	1,486	656	30	665	1,351
	Toujeo®	421	283	413	1,117	394	259	316	969	374	267	292	933
	Plavix®	101	9	873	983	115	9	805	929	126	10	777	913
Non-Core Assets		**1,637**	**1,176**	**4,409**	**7,222**	**1,846**	**1,281**	**4,515**	**7,642**	**2,088**	**1,389**	**4,849**	**8,326**
of which	Lantus®	426	757	1,076	2,259	474	861	1,159	2,494	537	929	1,195	2,661
	Other non-core assets	1,129	412	2,944	4,485	1,285	410	3,034	4,729	1,451	438	3,222	5,111
Industrial sales		**587**	**17**	**16**	**620**	**723**	**41**	**44**	**808**	**658**	**67**	**88**	**813**
Vaccines		**1,341**	**3,291**	**2,597**	**7,229**	**1,225**	**2,762**	**2,336**	**6,323**	**973**	**2,759**	**2,241**	**5,973**
of which	Polio/Pertussis/ Hib Vaccines	325	456	1,504	2,285	306	470	1,383	2,159	331	412	1,363	2,106
	Influenza Vaccines	681	1,737	559	2,977	729	1,366	533	2,628	441	1,575	456	2,472
Consumer Healthcare[(a)]		**1,501**	**1,290**	**2,289**	**5,080**	**1,333**	**1,139**	**1,996**	**4,468**	**1,359**	**1,071**	**1,964**	**4,394**
of which	Allergy	55	439	240	734	49	371	192	612	51	361	205	617
	Pain Care	555	212	446	1,213	515	196	382	1,093	481	181	389	1,051
	Digestive Wellness	432	144	742	1,318	389	124	618	1,131	371	85	532	988
Total net sales		**9,999**	**18,275**	**14,723**	**42,997**	**9,759**	**14,385**	**13,617**	**37,761**	**9,151**	**13,465**	**13,425**	**36,041**

(a) For the Consumer Healthcare GBU, Sanofi has since 2021 adopted a more granular presentation by introducing new sub-categories that reflect consumer trends and the strengths and opportunities of the portfolio.

D.35.1.2. Business operating income

Sanofi reports segment results on the basis of "Business operating income". This indicator is used internally by Sanofi's chief operating decision maker to measure the performance of each operating segment and to allocate resources.

"Business operating income" is derived from ***Operating income***, adjusted as follows:

- the amounts reported in the line items ***Restructuring costs and similar items***, ***Fair value remeasurement of contingent consideration*** relating to business combinations (IFRS 3) and ***Other gains and losses, and litigation*** (gains and losses on major disposals of assets, asset groups ore operations, and costs related to major litigation) are eliminated;
- expenses arising from the remeasurement of inventories following a business combination (IFRS 3) are eliminated;
- amortization and impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature) are eliminated;
- upfront payments and regulatory milestone payments recognized within the line item ***Other operating income*** and related to transactions outside the ordinary activities of Sanofi are eliminated;
- the share of profits/losses from investments accounted for using the equity method is added, to the extent that this relates to joint ventures and associates with which Sanofi has a strategic alliance (for 2020, excludes Regeneron up to and including May 29, 2020; see Note D.2.);

- acquisition-related effects and restructuring costs relating to investments accounted for using the equity method (joint ventures and associates with which Sanofi has a strategic alliance) are eliminated;
- net income attributable to non-controlling interests is deducted; and
- for 2020, the gain on the divestment of Regeneron shares on May 29, 2020 is eliminated. This elimination does not include the gain on the remeasurement of the 400,000 retained shares at market value as of that date.

The table below shows Sanofi's segment results for the years ended December 31, 2022, December 31, 2021 and December 31, 2020:

	2022				
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Other[a]	Total Sanofi
Net sales	**30,688**	**7,229**	**5,080**	**—**	**42,997**
Other revenues	657	1,666	62	7	2,392
Cost of sales	(7,511)	(4,101)	(1,827)	(253)	(13,692)
Research and development expenses	(5,067)	(936)	(187)	(516)	(6,706)
Selling and general expenses	(5,923)	(870)	(1,478)	(2,221)	(10,492)
Other operating income and expenses	(1,800)	132	152	2	(1,514)
Share of profit/(loss) from investments accounted for using the equity method	28	48	12	—	88
Net income attributable to non-controlling interests	(29)	—	(4)	—	(33)
Business operating income	**11,043**	**3,168**	**1,810**	**(2,981)**	**13,040**

(a) This caption reconciles segment financial information to total consolidated financial information.

	2021				
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Other[a]	Total Sanofi
Net sales	**26,970**	**6,323**	**4,468**	**—**	**37,761**
Other revenues	264	1,095	55	—	1,414
Cost of sales	(6,965)	(3,430)	(1,606)	(250)	(12,251)
Research and development expenses	(4,330)	(712)	(153)	(497)	(5,692)
Selling and general expenses	(5,326)	(805)	(1,388)	(2,036)	(9,555)
Other operating income and expenses	(1,172)	128	111	(13)	(946)
Share of profit/(loss) from investments accounted for using the equity method	17	11	11	—	39
Net income attributable to non-controlling interests	(49)	(1)	(5)	(1)	(56)
Business operating income	**9,409**	**2,609**	**1,493**	**(2,797)**	**10,714**

(a) This caption reconciles segment financial information to total consolidated financial information.

	2020[a][b]				
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Other[c]	Total Sanofi
Net sales	**25,674**	**5,973**	**4,394**	**—**	**36,041**
Other revenues	128	1,141	59	—	1,328
Cost of sales	(6,982)	(3,312)	(1,528)	(284)	(12,106)
Research and development expenses	(4,171)	(682)	(153)	(524)	(5,530)
Selling and general expenses	(4,927)	(789)	(1,419)	(2,256)	(9,391)
Other operating income and expenses	(487)	3	53	(130)	(561)
Share of profit/(loss) from investments accounted for using the equity method	5	2	9	—	16
Net income attributable to non-controlling interests	(33)	—	(5)	—	(38)
Business operating income	**9,207**	**2,336**	**1,410**	**(3,194)**	**9,759**

(a) 2020 figures have been adjusted to take account of the reallocation of certain expenses (in particular IT costs related to Sanofi's new digital organization) from the Pharmaceuticals, Vaccines and Consumer Healthcare operating segments to the "Other" segment.

(b) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

(c) This caption reconciles segment financial information to total consolidated financial information.

The table below, presented in compliance with IFRS 8, shows a reconciliation between aggregated "Business operating income" for the segments and ***Income before tax and investments accounted for using the equity method***:

(€ million)	2022	2021	2020 [(h)]
Business operating income	**13,040**	**10,714**	**9,759**
Share of profit/(loss) from investments accounted for using the equity method[(a)]	(88)	(39)	(16)
Net income attributable to non-controlling interests[(b)]	33	56	38
Amortization and impairment of intangible assets [(c)]	(1,599)	(1,772)	(2,011)
Fair value remeasurement of contingent consideration	27	(4)	124
Expenses arising from the impact of acquisitions on inventories[(d)]	(3)	(4)	(53)
Restructuring costs and similar items	(1,336)	(820)	(1,089)
Other gains and losses, and litigation[(e)]	(370)	(5)	136
Gain on divestment of Regeneron shares on May 29, 2020[(f)]	—	—	7,225
Income from out-licensing[(g)]	952	—	—
Operating income	**10,656**	**8,126**	**14,113**
Financial expenses	(440)	(368)	(388)
Financial income	206	40	53
Income before tax and investments accounted for using the equity method	**10,422**	**7,798**	**13,778**

(a) Excludes restructuring costs relating to investments accounted for using the equity method and expenses arising from the impact of acquisitions on investments accounted for using the equity method. For the first two quarters of 2020, this line has been restated to exclude any effect of equity method accounting for the investment in Regeneron following the divestment of Sanofi's entire equity interest (with the exception of the 400,000 shares retained by Sanofi) on May 29, 2020.

(b) Excludes (i) restructuring costs and (ii) other adjustments attributable to non-controlling interests.

(c) For 2022, this line includes a reversal of €2,154 million on Eloctate franchise products following FDA approval of ALTUVIIIO™ dated February 22, 2023, partially offset by an impairment of €1,586 million relating to the development project for SAR444245 (non-alpha interleukin-2).

(d) This line records the impact of the workdown of acquired inventories remeasured at fair value at the acquisition date.

(e) For 2020, this line mainly comprises the gain on the sale of operations related to the Seprafilm® activity to Baxter.

(f) This line includes the gain on the sale of (i) 13 million shares of Regeneron common stock in the registered public offering and (ii) the 9.8 million shares repurchased by Regeneron, but does not include the gain arising from the remeasurement of the 400,000 retained shares at market value as of May 29, 2020.

(g) For 2022, this line includes an upfront payment of $900 million and a regulatory milestone payment of $100 million related to the out-licensing of Libtayo® following the restructuring of the Immuno-Oncology Collaboration and License Agreement with Regeneron (see Note C.1.).

(h) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

D.35.2. Other segment information

The tables below show the split by operating segment of (i) the carrying amount of investments accounted for using the equity method, (ii) acquisitions of property, plant and equipment, and (iii) acquisitions of intangible assets.

The principal investments accounted for using the equity method in the Pharmaceuticals segment are entities majority owned by EUROAPI, MSP Vaccine Company, and Infraserv GmbH & Co. Höchst KG (see Note D.6.).

Acquisitions of intangible assets and property, plant and equipment correspond to acquisitions paid for during the period.

	2022			
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Total
Investments accounted for using the equity method	536	104	37	677
Acquisitions of property, plant and equipment	1,025	504	77	1,606
Acquisitions of other intangible assets	463	111	21	595

	2021			
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Total
Investments accounted for using the equity method	159	91	—	250
Acquisitions of property, plant and equipment	1,024	382	73	1,479
Acquisitions of other intangible assets[(a)]	450	108	6	564

	2020			
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Total
Investments accounted for using the equity method	154	47	—	201
Acquisitions of property, plant and equipment	755	404	95	1,254
Acquisitions of other intangible assets[a]	501	322	6	829

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

D.35.3. Information by geographical region

The geographical information on net sales provided below is based on the geographical location of the customer. In accordance with IFRS 8, the non-current assets reported below exclude right-of-use assets relating to leases as determined under IFRS 16, investments accounted for using the equity method, other non-current assets, non-current income tax assets, and deferred tax assets.

	2022					
(€ million)	Total	Europe	of which France	North America	of which United States	Other countries
Net sales	**42,997**	**9,999**	**2,296**	**18,984**	**18,275**	**14,014**
Non-current assets:						
• property, plant and equipment owned	9,869	5,365	2,875	3,284	2,457	1,220
• goodwill	49,892	—	—	—	—	—
• other intangible assets	21,640	6,257	—	14,178	—	1,205

	2021					
	Total	Europe	of which France	North America	of which United States	Other countries
Net sales	**37,761**	**9,759**	**2,256**	**15,075**	**14,385**	**12,927**
Non-current assets:						
• property, plant and equipment owned	10,028	5,959	3,253	2,998	2,234	1,071
• goodwill	48,056	—	—	—	—	—
• other intangible assets[a]	21,407	7,059	—	13,187	—	1,161

	2020					
(€ million)	Total	Europe	of which France	North America	of which United States	Other countries
Net sales	**36,041**	**9,151**	**2,223**	**14,060**	**13,465**	**12,830**
Non-current assets:						
• property, plant and equipment owned	9,365	5,895	3,189	2,542	1,899	928
• goodwill	44,364	—	—	—	—	—
• other intangible assets[a]	18,341	6,208	—	10,665	—	1,468

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement, as described in Note A.2.1. to the consolidated financial statements for the year ended December 31, 2021.

As stated in Note D.5., goodwill is not allocated by geographical region.

E/ Principal accountants' fees and services

PricewaterhouseCoopers Audit and Ernst & Young et Autres served as independent auditors of Sanofi for the year ended December 31, 2022 and for all other reporting periods presented. The table below shows fees charged by those firms and member firms of their networks to Sanofi and consolidated subsidiaries in the years ended December 31, 2022 and 2021.

	Ernst & Young				PricewaterhouseCoopers			
	2022		2021		2022		2021	
(€ million)	Amount	%	Amount	%	Amount	%	Amount	%
Audit: Statutory audit of separate and consolidated financial statements[(a)]	14.2	89%	13.9	82%	14.1	97%	13.8	97%
Services other than statutory audit[(b)]	1.8	11%	3.0	18%	0.5	3%	0.4	3%
Audit-related services[(c)]	1.5		2.8		0.5		0.4	
Tax	0.0		—		0.0		—	
Other	0.3		0.2		—		—	
Total	**16.0**	**100%**	**16.9**	**100%**	**14.6**	**100%**	**14.2**	**100%**

(a) Includes services provided by the independent auditors of the parent company and French subsidiaries: Ernst & Young €7.3 million in 2022, €7.2 million in 2021; PricewaterhouseCoopers €7.7 million in 2022, €7.7 million in 2021.

(b) Services other than statutory audit provided by Ernst & Young et Autres during 2022 comprised:

- work on share capital transactions and securities issues submitted to the Annual General Meeting (in extraordinary business) for approval;
- additional procedures to enable reports previously signed by the firm to be incorporated by reference;
- agreed-upon and audit procedures in connection with a proposed divestment; and
- issuance of the Independent third party's report on the consolidated statement of extra-financial performance.

Services other than statutory audit provided by PricewaterhouseCoopers Audit during 2022 comprised:

- work on share capital transactions and securities issues submitted to the Annual General Meeting (in extraordinary business) for approval;
- additional procedures to enable reports previously signed by the firm to be incorporated by reference;
- contractual audits, assurance engagements, agreed-upon procedures, tax compliance work, and technical consultancy.

(c) Includes services provided by the independent auditors of the parent company and French subsidiaries: Ernst & Young: €1.4 million in 2022, €2.7 million in 2021; PricewaterhouseCoopers €0.3 million in 2022, €0.3 million in 2021.

Audit Committee pre-approval and procedures

The Audit Committee of Sanofi has adopted a policy and established certain procedures for the approval of audit services and for the pre-approval of other services to be provided by the independent auditors. In 2022, the Audit Committee established a limit for permitted audit-related and other services (i.e. services other than statutory audit) that can be provided by the independent auditors, and the related fees.

F/ List of principal companies included in the scope of consolidation during 2022

F.1. Principal fully consolidated companies

The table below shows Sanofi's principal subsidiaries and their country of incorporation:

Europe		Financial interest (%) as of December 31, 2022
Hoechst GmbH	Germany	100.0
Sanofi-Aventis Deutschland GmbH	Germany	100.0
A. Nattermann & Cie. GmbH	Germany	100.0
Sanofi-Aventis GmbH	Austria	100.0
Sanofi Belgium	Belgium	100.0
Ablynx N.V.	Belgium	100.0
Genzyme Flanders BVBA	Belgium	100.0
Sanofi A/S	Denmark	100.0
Sanofi-Aventis S.A.	Spain	100.0
Opella Healthcare Spain, S.L.	Spain	100.0
Sanofi Oy	Finland	100.0
Sanofi	France	100.0
Sanofi-Aventis France	France	100.0
Sanofi Winthrop Industrie	France	100.0
Sanofi-Aventis Recherche & Développement	France	100.0
Sanofi-Aventis Groupe	France	100.0
Sanofi Chimie	France	100.0
Sanofi-Aventis Participations	France	100.0
Sanofi Pasteur	France	100.0
Aventis Pharma S.A.	France	100.0
Sanofi Biotechnology	France	100.0
Sanofi Mature IP	France	100.0
Sanofi Pasteur NVL	France	100.0
Sanofi Pasteur Europe	France	100.0
SECIPE SAS	France	100.0
Sanofi Pasteur Merieux S.A.S.	France	100.0
Sanofi 2015 D SAS	France	100.0
Opella Healthcare International SAS	France	100.0
Opella Healthcare France SAS	France	100.0
Opella Healthcare Group SAS	France	100.0
Sanofi-Aventis A.E.B.E.	Greece	100.0
Sanofi-Aventis Private Co, Ltd	Hungary	99.6
Chinoin Private Co. Ltd	Hungary	99.6
Opella Healthcare Hungary Commercial K.F.T	Hungary	100.0
Carraig Insurance DAC	Ireland	100.0
Genzyme Ireland Limited	Ireland	100.0
Sanofi-Aventis Holdings (Ireland) Ltd	Ireland	100.0
Sanofi S.R.L.	Italy	100.0
Opella Healthcare Italy S.R.L.	Italy	100.0
Genzyme Global Sarl	Luxembourg	100.0
Genzyme Luxembourg Sarl	Luxembourg	100.0
Sanofi-Aventis Norge AS	Norway	100.0
Genzyme Europe B.V.	Netherlands	100.0
Sanofi Foreign Participations B.V.	Netherlands	100.0
Sanofi-Aventis Sp. z.o.o.	Poland	100.0
Opella Healthcare Poland sp.Z.O.O	Poland	100.0
Sanofi Pasteur Sp. z.o.o.	Poland	100.0
Sanofi Produtos Farmaceuticos Lda	Portugal	100.0
Sanofi-Aventis, s.r.o.	Czech Republic	100.0
Opella Healthcare Czech s.r.o	Czech Republic	100.0
Sanofi Romania SRL	Romania	100.0

Europe		Financial interest (%) as of December 31, 2022
Opella Healthcare Romania S.R.L.	Romania	100.0
Sanofi-Aventis UK Holdings Limited	United Kingdom	100.0
Aventis Pharma Limited	United Kingdom	100.0
Sanofi-Synthelabo UK Ltd	United Kingdom	100.0
Aventis Pharma Holdings Ltd	United Kingdom	100.0
Opella Healthcare UK Limited	United Kingdom	100.0
AO Sanofi Russia	Russia	100.0
Opella Healthcare LLC	Russia	100.0
Sanofi AB	Sweden	100.0
Sanofi-Aventis (Suisse) SA	Switzerland	100.0
Genzyme Global Sarl Baar Intellectual Property Branch	Switzerland	100.0
Sanofi Ilac Sanayi ve Ticaret A.S.	Turkey	100.0
Sanofi Pasteur Asi Ticaret A.S.	Turkey	100.0
Sanofi Saglik Urunleri Limited Sirketi	Turkey	100.0

United States		Financial interest (%) as of December 31, 2022
Genzyme Therapeutic Products Limited Partnership	United States	100.0
Aventis Inc.	United States	100.0
Sanofi US Services Inc.	United States	100.0
Sanofi-Aventis U.S. LLC	United States	100.0
Chattem, Inc.	United States	100.0
Aventisub LLC	United States	100.0
Genzyme Corporation	United States	100.0
Sanofi Pasteur Inc.	United States	100.0
VaxServe, Inc.	United States	100.0
Bioverativ Inc.	United States	100.0
Bioverativ U.S. LLC	United States	100.0
Bioverativ Therapeutics Inc.	United States	100.0
Principia Biopharma Inc.	United States	100.0
Sanofi Research Invest LLC	United States	100.0
Sanofi Bioverativ Holdings LLC	United States	100.0
RPR US Ltd.	United States	100.0
Kadmon Holdings, Inc.	United States	100.0
Kadmon Corporation, LLC	United States	100.0
Amunix	United States	100.0
Synthorx, Inc	United States	100.0
Translate Bio, Inc	United States	100.0

Other Countries		Financial interest (%) as of December 31, 2022
Sanofi-Aventis South Africa (Pty) Ltd	South Africa	100.0
Sanofi-Aventis Algérie	Algeria	100.0
Sanofi Arabia Trading Company Limited	Saudi Arabia	75.0
Sanofi-Aventis Argentina S.A.	Argentina	100.0
Genzyme de Argentina S.A.	Argentina	100.0
Opella Healthcare Argentina S.A.U.	Argentina	100.0
Sanofi-Aventis Healthcare Pty Ltd	Australia	100.0
Sanofi-Aventis Australia Pty Ltd	Australia	100.0
Sanofi Medley Farmaceutica Ltda	Brazil	100.0
Sanofi-Aventis Canada Inc.	Canada	100.0
Sanofi Pasteur Limited	Canada	100.0
Merieux Canada Holdings ULC (Canada)	Canada	100.0
Sanofi-Aventis de Chile S.A.	Chile	100.0
Sanofi (Hangzhou) Pharmaceuticals Co., Ltd	China	100.0
Sanofi (China) Investment Co., Ltd	China	100.0
Sanofi (Beijing) Pharmaceuticals Co.Ltd	China	100.0
Sanofi Pasteur Biologies Co., Ltd	China	100.0
Shenzhen Sanofi pasteur Biological Products Co, Ltd	China	100.0
Shanghai Rongheng Pharmaceutical Co, Ltd	China	100.0
Genfar S.A.	Colombia	100.0
Sanofi-Aventis de Colombia S.A.	Colombia	100.0
Sanofi-Aventis Korea Co. Ltd	South Korea	100.0
Sanofi Pasteur Ltd	South Korea	100.0
Opella healthcare Korea Inc.	South Korea	100.0
Sanofi-Aventis Gulf FZE	United Arab Emirates	100.0
Sanofi Egypt	Egypt	99.8
Opella Healthcare Egypt LLC	Egypt	100.0
Sanofi Hong-Kong Limited	Hong Kong	100.0
Sanofi India Limited	India	60.4
Sanofi Healthcare India Private Limited	India	99.9
Sanofi-Aventis Israël Ltd	Israel	100.0
Sanofi K.K.	Japan	100.0
SSP Co.,Ltd	Japan	100.0
Sanofi-Aventis (Malaysia) SDN. BHD.	Malaysia	100.0
Sanofi-Aventis Maroc	Morocco	100.0
Sanofi-Aventis de Mexico S.A. de C.V.	Mexico	100.0
Sanofi Pasteur S.A. de C.V.	Mexico	100.0
Azteca Vacunas, S.A. de C.V.	Mexico	100.0
Sanofi-Aventis Pakistan Limited	Pakistan	52.9
Sanofi-Aventis de Panama S.A.	Panama	100.0
Sanofi-Aventis del Peru S.A.	Peru	100.0
Sanofi-Aventis Puerto Rico Inc	Puerto Rico	100.0
Sanofi-Aventis Philippines Inc.	Philippines	100.0
Opella Healthcare Philippines Inc.	Philippines	100.0
Sanofi-Aventis Singapore Pte. Ltd	Singapore	100.0
Aventis Pharma (Manufacturing) Pte. Ltd	Singapore	100.0
Sanofi Manufacturing Pte Ltd	Singapore	100.0
Sanofi Taiwan Co., Ltd	Taiwan	100.0
Sanofi-Aventis (Thailand) Ltd	Thailand	100.0
Sanofi-Aventis de Venezuela S.A.	Venezuela	100.0
Sanofi-Aventis Vietnam Company Limited	Vietnam	100.0
Sanofi Vietnam Shareholding Company Limited	Vietnam	85.0

F.2. Principal investments accounted for using the equity method

		Financial interest (%) as of December 31, 2022
GlaxoSmithKline Consumer Healthcare, L.P.	United States	11.7
Infraserv GmbH & Co. Höchst KG	Germany	31.2
Maphar	Morocco	48.3
MCM Vaccine B.V.	Netherlands	50.0
MSP Vaccine Company (formerly MCM company)	United States	50.0
EUROAPI	France	30.1

G/ Events subsequent to December 31, 2022

On February 22, 2023, the US Food and Drug Administration (FDA) approved ALTUVIIIO™. That decision resulted in the reversal, in 2022 books, of €2,154 million of impairment losses against the intangible assets associated with the Eloctate franchise, in accordance with IAS 36 (Impairment of Assets); the asset had been partially written down in 2019. For more information please refer to Note D.5. to the financial statements of the present annual report. The adjustment is presented within the line item ***Impairment of intangible assets*** in the consolidated income statement; the net impact after tax is €1,651 million.

Notes

Notes

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