FIRST SUPPLEMENT DATED 3 MARCH 2025 TO THE BASE PROSPECTUS DATED 23 MAY 2024

Sanofi

(Incorporated as a société anonyme *in France)*

€25,000,000,000
Euro Medium Term Note Programme

This first supplement (the "**Supplement**") is supplemental to, and must be read in conjunction with, the base prospectus dated 23 May 2024 (the "**Base Prospectus**") prepared in connection with the €25,000,000,000 Euro Medium Term Note Programme (the "**Programme**") established by Sanofi (the "**Issuer**"). This Supplement constitutes a supplement to the Base Prospectus for the purposes of article 23 of Regulation (EU) 2017/1129 of the European Parliament and of the European Council of 14 June 2017, as amended (the "**Prospectus Regulation**"). The Base Prospectus received the approval number 24-165 on 23 May 2024 from the *Autorité des marchés financiers* (the "**AMF**"). The Base Prospectus, together with the Supplement, constitutes a base prospectus in accordance with Article 8 of the Prospectus Regulation.

Unless the context otherwise requires, terms defined in the Base Prospectus have the same meaning when used in this Supplement.

Application has been made to the AMF, as competent authority pursuant to the Prospectus Regulation to approve this Supplement.

This Supplement has been prepared pursuant to Article 23 of the Prospectus Regulation for the purposes of:

A. incorporating by reference the Issuer's annual report on the United States Securities and Exchange Commission's Form 20-F for the financial year ended 31 December 2024 (the "**2024 Annual Report on Form 20-F**");
B. amending the "Risk Factors" section of the Base Prospectus;
C. amending the "Business of Sanofi" section of the Base Prospectus;
D. amending the "Recent Developments" section of the Base Prospectus; and
E. amending the "General Information" section of the Base Prospectus.

A copy of the document herein incorporated by reference and a copy of this Supplement can be obtained from the registered office of the Issuer as set out at the end of the Base Prospectus and at the office of the Fiscal Agent, as described on page 125 of the Base Prospectus. A copy of such document incorporated by reference as well as a copy of this Supplement are also available on the website of the Issuer (www.sanofi.com), and a copy of this Supplement is available on the website of the AMF (www.amf-france.org).

To the extent that there is any inconsistency between (a) any statement included or incorporated by reference in this Supplement and (b) any statement included or incorporated by reference in the Base Prospectus, the statements in (a) above will prevail.

Save as disclosed in this Supplement, there has been no significant new factor, material mistake or inaccuracy relating to information included in the Base Prospectus since the publication thereof which is capable of affecting the assessment of Notes to be issued under the Programme.

TABLE OF CONTENTS

RISK FACTORS

The sub-section entitled "*Risk factors relating to Sanofi*" of the section entitled "*Risk Factors*" on pages 15 to 33 of the Base Prospectus is hereby deleted and replaced by the following:

"Sanofi presents below and under the section "*Cautionary statement regarding forward-looking statements*" of the 2024 Annual Report on Form 20-F, the significant risk factors to which Sanofi believes it is exposed as at the date of this Base Prospectus. The risk factors considered to be the most important, based on the probability of their occurrence and the expected magnitude of their negative impact and after consideration of the effects of the measures implemented by Sanofi in order to manage these risk factors, are mentioned first in their respective category and followed by an asterisk. Investors are invited to read carefully the information provided in the risk factors before investing in Sanofi's securities. Investors' attention is drawn to the fact that other risks, not identified as at the date of this Base Prospectus or whose realization is not considered likely to have, as at this same date, a significant negative impact on Sanofi's business, financial situation and results, its perspectives, its development and/or on Sanofi's securities, may exist or occur.

A. Risks relating to legal and regulatory matters

Product liability claims could adversely affect Sanofi's business, results of operations and financial condition*

Product liability is a significant risk for any pharmaceutical company, given that liability claims relating to Sanofi's 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 Sanofi's potential liability, and Sanofi may incur different liability claims to what Sanofi has handled in the past, regarding their nature, scope, and level. For a detailed analysis of the regulatory environment in which Sanofi operates, refer to "*Item 4. Information on the Company - B. Business Overview - B.5.3. Regulatory framework*" of the 2024 Annual Report on Form 20-F. 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 using 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.

Sanofi is currently defending several product liability claims (see Note D.22.a. to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F) notably with respect to Taxotere, Zantac, Depakine and Gold Bond, and there can be no assurance that Sanofi will be successful in defending these claims, or that Sanofi 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 studies 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 the 2024 Annual Report on Form 20-F).

Furthermore, Sanofi commercializes 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, competitive, operational, business, or reputational harm*" below).

Although Sanofi continues to insure a portion of Sanofi's 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 Sanofi's pharmaceuticals and vaccines businesses (see "*Item 4. Information on the Company — B. Business Overview — B.8. Insurance and risk coverage*" of the 2024 Annual Report on Form 20-F). In cases where Sanofi self-insures, the legal costs that Sanofi would bear for handling such claims, and potential damage awards to be paid to claimants, could have a negative impact on Sanofi's financial condition. Due to insurance conditions, even when Sanofi has 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 Sanofi's ability to recover claims on policies for which Sanofi has already paid a premium.

Product liability claims, regardless of their merits or the ultimate success of Sanofi's defense, are costly, divert management's attention, may harm Sanofi's reputation, and can impact the demand for Sanofi's products and generate speculative news flows and/or rumors relating to such claims. Substantial product liability claims could materially adversely affect Sanofi's business, results of operations and financial condition, and/or may have an impact on market perception of Sanofi's company and negatively affect

Sanofi's stock price.

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

Sanofi's industry is heavily regulated and legal requirements vary from country to country, and new requirements are imposed on Sanofi's 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, and respect for the human rights of workers.

Sanofi has 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. Sanofi also has policies and procedures designed to help ensure that Sanofi, Sanofi's officers, employees, agents, intermediaries and other third parties comply with applicable laws and regulations (including but not limited to the US 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 Sanofi and/or Sanofi's management.

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/or competition law and tax audits. Sanofi is currently the target of a number of lawsuits relating to pricing and marketing practices (including, for example, "whistleblower" litigation in the United States), which Sanofi is vigorously defending. 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 provisions Sanofi has booked. See "*Item 8. Financial Information — A. Consolidated Financial Statements and Other Financial Information — Information on Legal or Arbitration Proceedings*" and Note D.22. to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F. In addition, responding to such investigations is costly and may divert management's attention from Sanofi's business.

Unfavorable outcomes in any of these matters, or in similar matters that may arise in the future, could preclude the commercialization of Sanofi's products, harm Sanofi's reputation, negatively affect the profitability of existing products and subject Sanofi 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 Sanofi's 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, 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 28 February 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 Sanofi to meet and maintain certain compliance requirements in the United States.

Sanofi's activities (including Sanofi's products and manufacturing activities) are subject to significant government regulations and regulatory approvals, which are often costly and could result in adverse consequences to Sanofi's business if Sanofi fails 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 Sanofi 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 these requirements, including post-marketing requirements, have increased the costs associated with maintaining marketing authorizations (see "*Item 4. Information on the Company — B. Business Overview — B.5. Markets — B.5.3. Regulatory framework*" of the 2024 Annual Report on Form 20-F).

Moreover, to monitor Sanofi's compliance with applicable regulations, the FDA, EMA, WHO and comparable national agencies in other jurisdictions routinely conduct regulatory inspections of Sanofi's facilities, distribution centers, commercial activities and development centers (including hospitals), and may identify potential deficiencies which Sanofi must adequately address. More generally, if Sanofi fails 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, Sanofi 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. For example, in January 2025, the FDA issued a warning letter related to certain GMP practices at Sanofi's Framingham facility. In addition, Sanofi has an obligation to monitor and report adverse events and safety signals. To comply with these duties, Sanofi must regularly train its employees and certain third parties (such as external sales forces and distributor employees) on regulatory matters, including on pharmacovigilance. If Sanofi fails to train these people, or fail to train them appropriately, or if they do not comply with contractual requirements, Sanofi may be exposed to the risk that safety events are not reported or not reported in a timely manner in breach of Sanofi's reporting obligations.

Due to regulatory or geopolitical constraints, Sanofi may face delays in Sanofi's clinical studies due, for example, to the new EU Clinical Trials Regulation review process for approvals of new studies or for the transition of ongoing studies under such new regulation, and/or restrictions imposed on clinical study sites, and/or delays in the supply chain for investigational products and/or the initiation and enrollment of patients in Sanofi's clinical studies, and/or disruptions related to regulatory approvals, for instance due to the inability of health authorities to perform inspections in other countries and/or delays in label expansions for existing products, and/or delays due to the complexities of the review processes for clinical studies which involve an investigational device or diagnostic combined with the investigational product. Sanofi may not be able to fully mitigate these delays, which could negatively impact the timing of Sanofi's pipeline development programs and may have a negative impact on Sanofi's product development and launches and hence on future product sales, business, and results of operations.

In addition, all aspects of Sanofi's 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 Sanofi's business.

For example, the pharmaceutical industry has experienced challenges due to the implementation of the new European Union regulations for Medical Devices (EU MDR) and for In-Vitro Diagnostic Devices (IVDR), which entered into force in May 2021 and May 2022, respectively. In October 2024, the European Parliament adopted a resolution for a revision of these regulations with a view to addressing challenges, in particular obstacles associated with the implementation of the EU MDR and IVDR; however, the outcome of that resolution is uncertain at this stage. The FDA's recent rulemaking on laboratory-developed tests (LDTs), implemented in May 2024, introduces significant regulatory uncertainty and potential delays in product availability as clinical testing laboratories in the US adapt to new requirements; this poses a risk to Sanofi clinical study timelines and the availability of testing to support commercial products given that LDTs are used for patient selection, product dose decisions, treatment monitoring and clinical study endpoints.

For information about risks related to changes (i) in proprietary rights rules and regulations, see "– *Sanofi relies on Sanofi's patents and other proprietary rights to provide exclusive rights to market certain of Sanofi's products. If such patents and other rights were limited, invalidated, or circumvented, Sanofi's financial results could be adversely affected*" below; and (ii) in environmental rules and regulations, see "– *Management of the historical contamination related to Sanofi's past industrial activities could adversely impact Sanofi's 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 Sanofi's 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. As a result of the 2024 presidential and legislative elections in the United States, changes to applicable laws and regulations that have been announced, proposed, and/or adopted, or could be made or expanded in the future, may result in new or expanded trade restrictions by the United States and/or other countries, including, but not limited to, tariffs or import taxes being applied to imported goods and services which could affect Sanofi's operations and Sanofi's exports into the United States. Other countries may implement trade restrictions and/or retaliatory measures as well. Any such trade restrictions or measures could affect Sanofi's operations, Sanofi's exports into the United States and other countries and/or Sanofi's supply chains. Significant modifications to tax legislation are also expected in some of the markets where Sanofi operates, such as France and the United States. All these elements could negatively impact Sanofi's business and operating results.

Furthermore, most of the jurisdictions in which Sanofi operates have double tax treaties with other foreign jurisdictions, which provide a framework for mitigating the impact of double taxation on Sanofi's revenues and capital gains. However, the outcome of those mechanisms developed to resolve such conflicting claims can in some circumstances be uncertain and can be expected to be very lengthy. Provisions 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.

Sanofi relies on Sanofi's patents and other proprietary rights to provide exclusive rights to market certain of Sanofi's products. If such patents and other rights were limited, invalidated, or circumvented, Sanofi's financial results could be adversely affected

Through patent and other proprietary rights, such as data exclusivity or supplementary protection certificates in Europe, Sanofi holds exclusivity rights for several of Sanofi's research-based products. However, the protection that Sanofi is able to obtain varies

in its duration and scope. Furthermore, patents and other proprietary rights do not always provide effective protection for Sanofi's products. Sanofi cannot be certain that Sanofi 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 using accelerated regulatory pathways for generic and biosimilar drug approvals. At the EU level, the proposed wide-ranging revision of the general pharmaceutical legislation may pose downside risks to innovation and competitiveness in Europe, primarily due to the reduction of intellectual property (IP) protections and a stricter incentives framework for orphan medicinal products (OMPs). Such regulatory proposals could make patent prosecution for new products more difficult and time consuming or could adversely affect the exclusivity period for Sanofi's 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, Sanofi may not prevail, and the decision rendered may not conclude that Sanofi's patent or other proprietary rights are valid, enforceable, or infringed. Sanofi's competitors may also successfully avoid Sanofi's patents. Even in cases where Sanofi ultimately prevails in an infringement claim, legal remedies available for harm caused to Sanofi by infringing products may be inadequate to make Sanofi whole. Moreover, a successful result against a competing product for a given patent or in a specific country is not necessarily predictive of Sanofi's future success against another competing product or in another country because of local variations in the patents and patent laws.

In addition, if Sanofi loses patent protection because of an adverse court decision or a settlement, Sanofi faces 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.

Sanofi also relies on unpatented proprietary technology, know-how, trade secrets and other confidential information, which Sanofi seeks 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 Sanofi's other protective measures should fail, then Sanofi's contractual or other remedies may not be adequate to cover Sanofi's losses.

In certain cases, to terminate or avoid patent litigation Sanofi or Sanofi's collaboration partners may be required to obtain licenses from the holders of third-party intellectual property rights. Any payments under these licenses may reduce Sanofi's profits from such products and Sanofi 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 Sanofi from marketing a product if they consider that Sanofi infringes their patent rights in that country. If third parties obtain a preliminary or permanent injunction or if Sanofi fails 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 Sanofi is unable to alter the design of Sanofi's technology to fall outside the scope of third-party intellectual property rights, Sanofi may be unable to market some of Sanofi's products in certain countries, which may limit Sanofi's profitability.

In addition, the pursuit of valid business opportunities may require Sanofi to challenge intellectual property rights held by others that Sanofi believes were improperly granted, including through negotiation and litigation, and such challenges may not always be successful. Third parties may claim that Sanofi's 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.

Sanofi has increased the proportion of biological therapeutics in Sanofi's 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, Sanofi's ability to successfully challenge third-party patent rights is dependent on the legal interpretation and case law of national courts. In addition, Sanofi expects 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 Sanofi sells 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 Sanofi's products were to be approved, it could reduce Sanofi's sales and/or profitability of that product.

Sanofi currently holds 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 Sanofi's products mature, Sanofi's reliance on Sanofi's trademarks and trade dress to differentiate Sanofi from its competitors

increases and, as a result, Sanofi's business could be adversely affected if Sanofi is unable to prevent third parties from adopting, registering, or using trademarks and trade dress that infringe, dilute, or otherwise violate Sanofi's rights.

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

Failure to comply with data ethics and privacy regulations could adversely affect Sanofi's business and reputation

Sanofi operates in an environment that relies on the collection, processing, analysis, and interpretation of large sets of patients' and other individuals' personal data, and the operation of Sanofi's business requires data to flow freely across borders of numerous countries.

The legal and regulatory environment of data privacy is diversified, with regional legislation such as the General Data Protection Regulation (GDPR) in Europe, the Personal Information Protection Law (PIPL) in China, and other significant privacy legislation, including the California Consumer Privacy Act (CCPA) in the United States. As the framework continues to evolve, some uncertainty remains with respect to absence of clear guidance or case law.

Such uncertainty could result in an operational risk limiting or preventing the transfer of data across borders, which may have an impact on Sanofi's activities (e.g., on clinical studies). Breach of the regulations described above could also carry financial sanctions and may harm Sanofi's reputation and those of Sanofi's activities that rely on personal data processing.

Furthermore, the increasing volume of data processed and advances in new technologies, such as artificial intelligence, have resulted in a greater focus on data governance and the ethical use of personal data. Failure in Sanofi's data governance and ethical use of personal data could affect Sanofi's business and reputation.

B. Risks relating to Sanofi's business

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

The commercial success of Sanofi's existing products and Sanofi's product candidates depends in part on their pricing and reimbursement conditions. Sanofi's 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,
    - Medicare drug price negotiations under the US Inflation Reduction Act (IRA),
    - 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, such as the Vaccine Alliance (GAVI), the BeNeLuxA alliance in Europe, and the Pan American Health Organization (PAHO),
    - shifting of the payment burden to US patients and access disruptions through copay accumulator and maximizer programs as well as alternative funding programs,
    - more aggressive formulary utilization management controls (including stepped therapy, strict prior authorization criteria, formulary exclusions) 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, and
- 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:
  - increasingly restrictive HTA decisions with significant variation across markets; increased generic and biosimilar competition, accelerating price erosion, and
  - next generation biosimilars coming to the market across major therapeutic areas; and
- potential savings from increased biosimilar use, which are expected to be a cumulative $290 billion globally from 2023 to 2027 and could reach $383 billion according to the IQVIA Institute's recent Global Use of Medicines report:
  - 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 48.7% of Sanofi's net sales in 2024, the Inflation Reduction Act (IRA) was enacted in August 2022. The law includes three core drug pricing provisions (Medicare negotiation, Part D redesign, and Medicare inflation penalties). Significant uncertainties remain on the process and methods of Medicare negotiation. While no Sanofi product was among the first ten drugs to face Medicare price negotiations in 2024, the new legislation may likely have a negative impact on Sanofi's revenue growth and will influence Sanofi's portfolio strategy in the mid- to longer term. However, recent election results in the US may spark uncertainty for the IRA. Although a full repeal of the IRA may be unlikely due to budgetary impact, the new US administration could change some of the IRA provisions, including Medicare drug price negotiations.

Furthermore, Sanofi faces increasing pricing pressure and gross-to-net (GTN) erosion from continuing vertical integration and consolidation of the US health insurance market, as well as political scrutiny over insulin prices, which resulted in the list price of Lantus being lowered by 78% effective January 1, 2024. With the three largest pharmacy benefit manager group purchasing organizations (PBM GPOs) (Ascent, Zinc and Emisar) now covering over 85% of prescription drug claims, consolidation has led to increased utilization management and restrictive formularies, increasing the negotiating power of PBMs over drug manufacturers and thereby adversely impacting Sanofi's sales.

Under the new US administration Sanofi could face unpredictable drug pricing policies, an increasing focus on price transparency, persistent supply chain challenges due to high dependency on active pharmaceutical ingredient imports, an 'America First' protectionist policy, and explosive growth of the federal 340B drug pricing program.

In China, high pricing pressure and intensifying local competition are expected to continue as a growing number of Sanofi's products are subject to national reimbursement drug list (NRDL) negotiations and national volume-based procurement (VBP) tenders, giving priority to the lowest prices with limited acceptability of value based-pricing. At market entry, new drugs listed on the NRDL had an average price cut of 60.1% over the past five years. Further expansion of the (VBP) policy to biologics and biosimilars also poses a growing threat to Sanofi's key established products and Sanofi's biologics portfolio, with over 500 drugs targeted for inclusion by 2025.

Several factors may hinder or delay Sanofi's research and development efforts to renew Sanofi's portfolio of medicines and vaccines*

Discovering and developing a new medicine or vaccine is a costly, lengthy, and uncertain process. To be successful in the highly competitive biopharmaceutical industry, Sanofi must commit substantial resources each year to research and development in order to develop new medicines and vaccines to compensate for decreasing sales of medicines and vaccines facing patent expiration and termination of regulatory data exclusivity, introduction of lower-priced generics and biosimilars, or competition from new product launches by competitors that are perceived as being equivalent or superior to Sanofi's therapies. Sanofi must pursue both research and early- and late-stage development to achieve a sustainable and well-balanced portfolio. In 2024, Sanofi spent €7,394 million on research and development, amounting to 18.0% of Sanofi's net sales. As part of an update on Sanofi's Play to Win strategy, Sanofi announced in October 2023 its intent to increase Sanofi's research and development spend. Failure to invest in the right technology platforms, disease areas, medicine or vaccine classes, geographic markets, and licensing or acquisition opportunities could adversely impact the productivity of Sanofi's internal pipeline.

Sanofi is pursuing a pipeline-driven transformation, including potential multi-indication opportunities such as amlitelimab, frexalimab, and the oral TNFR1si, intended to address unmet medical needs in markets with a low penetration of novel therapies, or where there is no current effective therapy approved. Sanofi focuses its R&D strategy on therapeutics in immunology, rare diseases, neurology, and selectively in oncology. 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 with an acceptable safety profile remains to be fully asserted. Sanofi may fail to improve its development productivity sufficiently to sustain Sanofi's pipeline (see also "*— Sanofi may fail to successfully identify external business opportunities or realize the anticipated benefits from Sanofi's strategic investments or divestments*" below).

The competitive landscape includes a high level of uncertainty as numerous companies are working on or may be evaluating similar targets to us. A medicine or vaccine 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 Sanofi's pipeline candidates will be proven safe or effective (see "*Item 4. Information on the Company — B. Business Overview — B.4. Global research & development*" of the 2024 Annual Report on Form 20-F). 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 studies – that Sanofi will not achieve Sanofi's goals of safety and/or efficacy and that Sanofi will have to abandon a medicine or vaccine in which Sanofi has invested substantial amounts of money and human resources. For instance, the global clinical development program of amcenestrant for breast cancer was discontinued in August 2022 following the outcome of the prespecified interim analysis of a Phase 3 study. As another example, in late 2023, based on the outcome of a prespecified interim analysis of a Phase 3 study, the global clinical development program for tusamitamab ravtansine was discontinued after the Independent Data Monitoring Committee found that the compound, as a monotherapy, did not meet its dual primary endpoints. Studies are increasingly designed with clinical endpoints of superiority, which means that failure to achieve those endpoints could damage the medicine or vaccine's outlook and Sanofi's overall development program.

Decisions concerning the studies to be carried out can have a significant impact on the marketing strategy for a given medicine or vaccine. Multiple in-depth studies can demonstrate that a medicine or vaccine has additional benefits, facilitating the marketing, but such studies are expensive and time consuming and may delay the medicine or vaccine's submission to regulatory authorities for approval.

In addition, following (or in some cases in parallel with) the marketing authorization, a dossier is also submitted to governmental agencies and/or national or regional third-party payers for review. These Health Technology Assessment (HTA) bodies evaluate evidence on the value of the new medicine or vaccine, 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 medicine or vaccine treats, and add costs to the development. Sanofi's continuous investments in Sanofi's research and development pipeline, and in launches of newly registered molecules, could therefore result in increased costs without a proportionate increase in revenues, which would negatively affect Sanofi's operating results and profitability.

Furthermore, there can be no assurance that all medicines or vaccines approved or launched will generally achieve commercial success.

Finally, even after a medicine or vaccine reaches the market, certain developments following regulatory approval may reduce demand for them. Clinical studies and post-marketing surveillance of certain marketed medicines and vaccines have the potential to raise concerns among some prescribers and patients relating to the safety, efficacy, or tolerability of pharmaceuticals in general, which could negatively affect sales 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*

Sanofi's 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 largely dependent on Sanofi's 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 Sanofi's patients, clinical studies, vendors, customers, employees, collaborators and others). Sanofi is 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.

Sanofi and its third-party service providers, suppliers, contract manufacturers, distributors or other contracting third parties use, to the best of Sanofi's ability, secure information technology systems for the protection of data and threat detection. Like many companies, Sanofi 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 Sanofi's 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, US and European legislation related to the financing of terrorism imposes increasing restrictions on payments of ransom. As a result, Sanofi's ability to recover the data might be limited. Therefore, Sanofi's business continuity could be at risk if Sanofi is unable to recover data through back-ups and restorations. In addition, in the EU, a number of existing and forthcoming rules and laws – including NIS2, the European Health Data Space (EHDS), the Data Act, the Cyber Resilience Act and the AI Act – are changing privacy and cybersecurity compliance requirements, and creating new potential enforcement risks.

Sanofi is increasingly using generative artificial intelligence (AI) to enhance Sanofi's business processes. Although Sanofi has set up a governance body to control the AI initiatives taken on a company-wide scale and have made a generative AI charter available to all Sanofi's employees, this new technology, like other AI technology, entails risks linked to transparency, fairness, data privacy and confidentiality, eco-responsibility, and cybersecurity. These risks could result in unintended consequences such as unethical practices, business and reputational harm, cyber-attacks, and security breaches (see "— *Sanofi may fail to develop or take advantage of digitalization and prioritizing data as an organizational asset*" below). There is a global trend towards more comprehensive regulation of AI that may require Sanofi to modify existing or adopt new compliance procedures or developments.

Each of these events could negatively impact important processes, such as scientific research and clinical studies, 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 Sanofi's business, results of operations and financial condition*" above). This could result in material financial, legal, competitive, operational, business, or reputational harm.

Although Sanofi maintains relevant insurance coverage, this insurance may not be sufficiently available in the future to cover the financial, business, or reputational losses that may result from an interruption or breach of Sanofi's systems. For example, certain types of cyber-attacks could be considered as an act of war subject to insurance exclusion.

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

Many of Sanofi's 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. Sanofi 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) Sanofi's own quality standards. Third parties supply Sanofi with a portion of Sanofi's raw materials, active ingredients, and medical devices, which exposes Sanofi to the risk of a supply shortage or interruption especially if these suppliers are unable to manufacture Sanofi's products in line with quality standards or if they experience financial difficulties.

Epidemics and other public health crises, such as the COVID-19 pandemic, expose Sanofi to risks of a slowdown or temporary suspension in the production of Sanofi's active pharmaceutical ingredients, raw materials, and some of Sanofi's products. Any prolonged restrictive measures put in place to control an outbreak of contagious disease or other adverse public health development, in a country, state or region in which any of Sanofi's principal production sites are located, may have a material and adverse effect on Sanofi's manufacturing operations. Any of these factors could adversely affect Sanofi's business, operating results, or financial condition (see "*Item 4. Information on the Company — B. Business Overview — B.7. Production and raw materials*" of the 2024 Annual Report on Form 20-F for a description of these outsourcing arrangements and "*A failure in Sanofi's crisis and business continuity management processes in case of unpredictable events could have negative consequences for Sanofi's business, operations, and reputation*" below).

Sanofi's business may require the transformation and adaptation of Sanofi's plants to ensure the continuity of production of Sanofi's products in sufficient quantities to satisfy demand. This may be necessary to meet the need to produce 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. Furthermore, Sanofi's biological products 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.

The complexity of Sanofi's production processes, as well as standards required for the manufacture of Sanofi's products, subject Sanofi 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 Sanofi's operating results and financial condition, and cause reputational damage and the risk of product liability (see "— *Product liability claims could adversely affect Sanofi's business, results of operations and financial condition*" above). In addition, some of Sanofi's production sites, and some of Sanofi's suppliers' and/or contractors' sites, are in areas exposed to natural disasters such as floods, earthquakes, and hurricanes (see "— *Climate change or legal, regulatory or market measures to address climate change may negatively affect Sanofi's business and results of operations*" below). Such disasters could be exacerbated by climate change. In the event of a major disaster, Sanofi could experience severe destruction or interruption of Sanofi's operations and production capacity at these sites.

When manufacturing disruptions occur, Sanofi may not have alternate manufacturing capacity, particularly for certain biologics. In

the event of manufacturing disruptions, Sanofi's 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 Sanofi aims to have backup sources of supply whenever possible, including by manufacturing backup supplies of Sanofi's principal active ingredients at additional facilities when practicable, Sanofi cannot be certain they will be sufficient if Sanofi's 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*

Sanofi's strategy, as presented in December 2019 and completed as part of its R&D Day presentation in December 2023, focuses on key growth drivers including (but not limited to) Dupixent, Vaccines, and key therapeutic areas in immunology. Nevertheless, market expansion and new launches of medicines and vaccines may not deliver the anticipated benefits. Sanofi may also encounter delays or failures in Sanofi's launch strategy (in terms of timing, pricing, market access, marketing efforts, and dedicated sales forces), such that Sanofi's products may not deliver the expected benefits. The competitive environment for a given medicine or vaccine may also have changed by the time of the actual launch, modifying Sanofi's initial forecasts. The need to prioritize the allocation of resources may also cause delays in or hamper the launch or expansion of certain medicines or vaccines.

Also, Sanofi currently generates a substantial share of Sanofi's net sales from certain key products (see "*Item 5. Operating and Financial Review and Prospects — A.2.1. Net sales — 3/Net Sales – Biopharma segment*" of the 2024 Annual Report on Form 20-F). For example, Dupixent generated net sales of €13,072 million in 2024 representing 31.8% of Sanofi's net sales for the year and is Sanofi's biggest product in terms of sales.

Among Sanofi's flagship products, Lantus, Lovenox, Plavix, Jevtana and Aubagio already face generic competition on the market. In 2024, Lantus was one of Sanofi's leading products with net sales of €1,628 million. With respect to influenza, which represented 30.8% of vaccines net sales in 2024, Sanofi may face potential challenges. The influenza market is expected to have several new competitive entrants, both from standalone flu mRNA and COVID-flu combinations, who could be on the market ahead of us. Additionally, the influenza market globally is subject to intense pricing pressure, as well as a decrease in vaccination coverage. The combination of such factors could result in a lowering of revenue from sales of influenza vaccines. Beyfortus, which represented 20.3% of Sanofi's vaccines net sales in 2024, may also face competition from another monoclonal antibody in the coming years, which could negatively impact Sanofi's revenue in this area.

More generally, expiration of effective intellectual property protections for Sanofi's 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 from those products (for information regarding ongoing patent litigation see Note D.22.b. to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F).

The introduction of a generic product results in adverse price and volume effects for Sanofi's branded or genericized products. For example, although Sanofi 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 Sanofi's consolidated net sales for 2024 and 2023 for the main products affected by generic and biosimilar competition shows a loss of €794 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*" of the 2024 Annual Report on Form 20-F). 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 Sanofi's 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 Sanofi's business, results of operations and financial condition could be significant.

Sanofi relies on third parties for the discovery, manufacture, marketing, and distribution of some of Sanofi's products

Sanofi's 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. Sanofi expects that it will continue to rely on third parties for key aspects of Sanofi's business and Sanofi needs to ensure Sanofi's attractiveness as a potential partner.

Sanofi conducts several significant research and development programs and market some of its products in collaboration with other biotechnology and pharmaceutical companies. For example, Sanofi currently has 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. Operating and Financial Review and Prospects — A.1.7. Financial Presentation of Alliances — 1/ Alliance Arrangements with Regeneron Pharmaceuticals Inc.*" of the 2024 Annual Report on Form 20-F). Sanofi relies upon Regeneron to successfully carry out their responsibilities regarding the manufacture and supply of these collaboration

antibodies (see "*Item 4. Information on the Company — B. Business Overview*" of the 2024 Annual Report on Form 20-F). In May 2024, Sanofi announced a co-exclusive licensing agreement to develop novel flu-COVID-19 combination vaccines with Novavax (see above —"*Several factors may hinder or delay Sanofi's research and development efforts to renew Sanofi's portfolio of medicines and vaccines*"). Sanofi may also rely on partners to design and manufacture medical devices, in particular for the administration of Sanofi's products. Finally, Sanofi may rely on partners for the development and commercialization of in-vitro diagnostic tests used in clinical studies, and in-vitro diagnostic tests specified in the labeling of Sanofi's products as necessary or useful for the management of patients taking Sanofi's products. As regards some products launched or under development for which Sanofi has a collaboration agreement with partners, the terms of the applicable alliance agreement may require Sanofi to share profits and losses arising from commercialization of such products with Sanofi's partners. This differs from the treatment of revenue and costs generated by other products for which Sanofi has no alliance agreement, and such profit sharing may deliver a lower contribution to Sanofi's financial results.

Sanofi could also be subject to the risk that Sanofi may not properly manage the decision-making process with Sanofi's partners. Decisions may be controlled by, or subject to the approval of Sanofi's collaboration partners, who may have views that differ from Sanofi's. Sanofi is also subject to the risk that Sanofi's partners may not perform effectively, which could have a detrimental effect when Sanofi's collaboration partners are responsible for the performance of certain key tasks or functions, for example related to manufacturing or distribution. This risk is further increased by the growing number of distribution centers divested by Sanofi as part of its global strategy and by the resulting growing externalization of distribution tasks and functions.

Any failures in the development process or differing priorities may adversely affect Sanofi's business, including the activities conducted through Sanofi's collaboration arrangements. Sanofi also cannot guarantee that third-party manufacturers will be able to meet Sanofi's near-term or long-term manufacturing requirements, for internal reasons (e.g. in case of financial difficulties), reasons directly related to their contractual relationship with Sanofi, or external reasons (e.g. in the event of a health crisis). Thereby, following the completion of the spin-off of EUROAPI in May 2022, EUROAPI became a third-party manufacturer and continues to manufacture a certain number of active pharmaceutical ingredients for Sanofi. Sanofi is also subject to the risk that contract research organizations or other vendors (for instance regarding digital activities) retained by us, or Sanofi's collaboration partners may not perform effectively.

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

Sanofi is subject to the risk of non-payment by Sanofi's customers[1]

Sanofi's customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics, and government agencies, present risks related to delayed payments or even non-payment. This risk is accentuated by recent concentrations among distributors and retailers, as well as by ongoing uncertainties in global credit markets and economic conditions, in particular in emerging markets. As a result, Sanofi may be affected by fluctuations in the buying patterns of such customers. The United States presents specific customer credit risk issues because of the concentrated pharmaceutical distribution system: in 2024 Sanofi's three main customers represented respectively 15%, 11% and 8% of Sanofi's consolidated net sales, respectively. Sanofi is also exposed to large wholesalers in other regions, particularly in Europe. An inability of one or more of these wholesalers to honor their debts to Sanofi could adversely affect Sanofi's financial condition (see Note D.34. to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F).

In certain countries, some of Sanofi's customers are public or subsidized health systems. The economic and credit conditions in these countries could further extend the average collection period for accounts receivable, putting additional strain on Sanofi's working capital.

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

Over the past several years, growth of the global pharmaceutical market has increasingly been tied to global economic trends. In this context, a substantial and lasting slowdown or instability of the global economy, major national economies or emerging markets could negatively affect the global pharmaceutical market's growth and, as a result, adversely affect Sanofi's business. For example, unpredictable geopolitical conditions that currently exist in various parts of the world could have a material negative impact on Sanofi's business, in particular the armed conflict between Russia and Ukraine, and the escalation of violence and potential further conflicts in the Middle East. The consequences of these conflicts remain uncertain, and will depend on developments outside Sanofi's control, including, but not limited to the duration and severity of the conflicts, and the consequences of the ongoing and additional financial and economic sanctions imposed by governments in response. Sanofi faces rising tensions between the US and

[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 the consolidated financial statements, provided at Item 18. of the 2024 Annual Report on Form 20-F.

[2] The information in this section supplements the disclosures required under IFRS 7 as presented in Note B.8.7. to the consolidated financial statements, provided at Item 18. of the 2024 Annual Report on Form 20-F.

China, two of Sanofi's key markets. Trade, economic, technological and military conflicts could disrupt supply chains, raise raw material costs, and affect clinical and manufacturing operations and business strategy. 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 Sanofi's products is negatively affected by increasing cost containment pressures and decisions of governmental authorities and other third parties*" above).

The challenging economic environment could also negatively impact Sanofi's net sales. In regions with high unemployment, rising inflation, or limited third-party payer systems, patients may turn to more affordable generic alternatives, delay treatments, or reduce observance to cut 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. Additionally, rising healthcare costs have prompted some employers to transfer a greater share of these costs to their employees, which further decreases demand for brand-name pharmaceuticals and intensifies downward pressure on prices.

Sanofi's Opella business (which is classified in "discontinued operations" in Sanofi's income statement following the announcement of exclusive negotiations for the sale of a 50% controlling stake to CD&R, with the transaction expected to close at the earliest in second quarter 2025, see generally "*Item 5. Operating and Financial Review and Prospects*" of the 2024 Annual Report on Form 20-F) could also be adversely impacted by deteriorating economic conditions, as consumers may have reduced purchasing power, prompting them to opt for lower-cost alternatives.

Should global economic conditions worsen, or in the event of default or failure of major players including wholesalers or public sector buyers financed by insolvent states, Sanofi's financial situation, profitability, operational results, and distribution channels of products could be adversely affected. See also "— *Sanofi is subject to the risk of non-payment by Sanofi's customers*" above.

A failure in Sanofi's crisis and business continuity management processes in case of unpredictable events could have negative consequences for Sanofi's business, operations, and reputation

Sanofi has increased crisis preparedness and response in recent years due in particular to crises such as the COVID-19 pandemic and ongoing war in Ukraine and conflicts in the Middle East. Nevertheless, unpredictable and extraordinary internal or external events, or a combination of escalating events that may occur as a result of a large scale cyber-attack (see also "— *Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, competitive, operational, business, or reputational harm*" above), a pandemic or natural disasters, could result in the failure of critical processes within Sanofi or a third party on whom Sanofi relies. Moreover, lack of resources and/or low maturity level in crisis management of Sanofi's service providers faced with an increasing number of major international crises may hamper Sanofi's ability to implement Sanofi's business continuity plans. Such failure or limited implementation of Sanofi's business continuity plans may adversely impact Sanofi's business, operations, and reputation.

The occurrence of these unforeseen events may also heighten other risks such as a disruption or temporary suspension in production of active pharmaceutical ingredients, raw materials and some of other products and/or lead to manufacturing delays or disruptions and supply chain interruptions (including to the extent those measures apply to Sanofi's third-party suppliers) and may have an adverse effect on Sanofi's business (see "— *The manufacture of Sanofi's products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect Sanofi's operating results and financial condition, delay the launch of new products and negatively impact Sanofi's image*" above). Also, a sudden increase in demand for selected medicinal products in the event of a crisis can result in short-term unavailability or shortages of raw materials.

Climate change or legal, regulatory or market measures to address climate change may negatively affect Sanofi's business and results of operations

Climate change resulting from increased concentrations of carbon dioxide and other greenhouse gases in the atmosphere could present both physical and transition risks to Sanofi's operations.

Physical risks include adverse impacts on global temperatures, weather patterns and the frequency and severity of extreme weather and natural disasters. Natural disasters and extreme weather conditions, such as a hurricane, tornado, earthquake, wildfire, or flooding, may pose physical risks to Sanofi's facilities and disrupt the operation of Sanofi's supply chain. The impacts of the changing climate on water resources may result in water scarcity, limiting Sanofi's ability to access sufficient high-quality water in certain locations, which may increase operational costs. For example, in 2023 and 2024, Sanofi's sites located in North Africa were exposed to intermittent shortages of drinking water distribution following severe episodes of water scarcity and maintenance issues of municipal utilities systems.

Concern over climate change may also result in new or additional legal or regulatory requirements, designed to reduce greenhouse gas emissions and/or mitigate the effects of climate change on the environment. If such laws or regulations were to be more stringent than current legal or regulatory obligations (e.g., increased carbon taxation risk), Sanofi may experience disruption in, or an increase in the costs associated with sourcing, manufacturing, and distribution of Sanofi's products, which may adversely affect Sanofi's business, results of operations or financial condition.

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

Sanofi increasingly relies on social media, new technologies and digital tools to communicate about Sanofi's 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 Sanofi's image and reputation and on Sanofi's stock price. Negative or inaccurate posts or comments about Sanofi, Sanofi's business, directors, or officers on any social networking website could seriously damage Sanofi's reputation. In addition, Sanofi's 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 Sanofi's reputation, business, financial condition, and results of operations.

C. Risks relating to Sanofi's structure and strategy

Sanofi may fail to successfully identify external business opportunities or realize the anticipated benefits from Sanofi's strategic investments or divestments*

Sanofi pursues a strategy of selective acquisitions, in-licensing, and collaborations to reinforce Sanofi's pipeline and portfolio. Sanofi is also proceeding to selective divestments to focus on key business areas. The implementation of this strategy depends on Sanofi's ability to identify transaction opportunities, mobilize the appropriate resources 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 C. to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F and "— *Sanofi relies on third parties for the discovery, manufacture, marketing, and distribution of some of Sanofi's products*" above). Once a strategic transaction is agreed upon with a third party, Sanofi may not be able to complete the transaction in a timely manner or at all. For example, Sanofi's planned separation of Opella may not be completed on the terms or timeline currently contemplated, if at all, and may not achieve the expected results (see "— *Completion of the separation of Opella is subject to conditions that may not be satisfied and Sanofi may fail to realize any or all of the anticipated benefits of the separation and/or face unintended adverse impacts on Sanofi's business*" below).

For newly acquired activities or businesses, Sanofi's growth objectives could be delayed or ultimately not realized, and expected synergies could be adversely impacted if, for example: Sanofi is unable to integrate those activities or businesses quickly or efficiently; key employees leave; or Sanofi has higher than anticipated integration costs.

The Translate Bio acquisition (see in "— *Several factors may hinder or delay Sanofi's research and development efforts to renew Sanofi's portfolio of medicines and vaccines*" 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 because of the difficulty of integrating the activity quickly and efficiently into the Group.

Sanofi 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 regarding 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 Sanofi faces significant financial claims or significant post-closing price adjustments. Furthermore, the value of the assets to be divested may deteriorate while Sanofi is in the process of executing Sanofi's divestment strategy, with the risk that Sanofi does not realize the anticipated benefits.

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

Completion of the separation of Opella is subject to conditions that may not be satisfied and Sanofi may fail to realize any or all of the anticipated benefits of the separation and/or face unintended adverse impacts on Sanofi's business

In October 2024, Sanofi announced that Sanofi had entered into exclusive negotiations with CD&R for the potential sale and purchase of a 50% controlling stake in Opella and that Sanofi would remain a significant shareholder in Opella. This intended separation aims at paving the way for Opella to become a new, standalone leader in Consumer Healthcare, while supporting Sanofi's strategy and increased focus on innovative medicines and vaccines.

This intended separation may not be completed on the expected terms or may be delayed or may not be completed at all. In particular, completion of the separation will be subject to obtaining regulatory approvals from the competent authorities. There can be no assurance that any or all of these conditions will be satisfied. There can also be no assurance regarding the ultimate timing of the planned separation. Unanticipated developments could delay, prevent or otherwise adversely affect the planned separation, including disruptions in general or financial market conditions, the political and geopolitical situations, and potential problems or delays in obtaining various regulatory approvals or clearances.

Failure to complete the separation would result in the potential benefits of the separation not being realized and could have a material adverse effect on the success of Sanofi as a whole, including Sanofi's results of operations and financial condition. In addition, if completion of the separation does not occur, the Opella business will remain part of Sanofi, which could (i) have an adverse effect on Sanofi's strategy, including but not limited to the allocation of resources to the Biopharma segment, where value-creating opportunities and longer-term operational changes have been identified to support Sanofi's intended accelerated R&D expenditure; (ii) cause potential delay in the execution of the strategic objectives of Sanofi and the Opella business; and (iii) have a disruptive effect on management and employees of Sanofi and/or the Opella business. Moreover, failure to complete the separation could have an adverse effect on Sanofi's reputation and on external perception of Sanofi's ability to implement large scale projects successfully, even where due to factors outside Sanofi's control. There are also costs associated with the separation that Sanofi would still be required to pay even if the separation is not completed.

Completion of the planned separation, for which Sanofi has incurred and are expected to incur significant costs, may not achieve the expected benefits in full or in part and there is no guarantee as to the timing of when or if any such benefits may be realized. The success of the operation and its expected benefits will depend on several factors, including many factors outside of Sanofi's control, and a number of assumptions that may prove incorrect.

Post-separation, Sanofi may face a number of challenges relating to the implementation of the separation and to operating without the Opella business. There may be adverse financial, operational, regulatory, consumer, patient and reputational implications if Sanofi fails (either wholly or in part) to meet such challenges. Such adverse implications could impact Sanofi's financial condition, results of operations and/or prospects. For example, Sanofi's business will be smaller and less diversified than currently, and will be more susceptible to adverse developments in the remaining business and markets in which Sanofi operates. Accordingly, should any part of Sanofi's remaining business underperform, this could have a greater adverse impact on Sanofi's results or financial conditions following separation than would have been the case prior to the separation. In addition, post-separation Sanofi will have greater relative exposure to the global pharmaceuticals and vaccines markets and the associated risks and will no longer benefit from exposure to the Consumer Healthcare market Sanofi had prior to separation from the Opella business, which would make Sanofi more reliant on the R&D process (see "*—Several factors may hinder or delay Sanofi's research and development efforts to renew Sanofi's portfolio of medicines and vaccines*).

Finally, as Sanofi will retain a holding in Opella of up to 48% with veto rights only on certain matters, Sanofi will not control operational decisions and Opella's success will depend on its ability to retain talent and skilled professionals and take advantage of the opportunities that lie ahead in its segment. Therefore, Sanofi's remaining holding in Opella may fall in value if Opella's strategy does not deliver the expected benefits.

The globalization of Sanofi's business exposes Sanofi to increased risks in specific areas*

As part of the presentation of Sanofi's strategy in December 2019, Sanofi identified its strong presence in China among Sanofi's core drivers, with revenue amounting to 6.5% of Sanofi's net sales in 2024.

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 Sanofi's ability to take advantage of growth opportunities and could adversely affect Sanofi's business, results of operations or financial condition. For instance, 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 Sanofi's targeted markets, it would reduce Sanofi's sales due to lower healthcare spending on other diseases and fewer promotional activities, and could significantly impact Sanofi's business operations. Furthermore, it is not possible to predict if or how such health crisis would impact any affected jurisdiction, or to what extent (see also "*— Global economic conditions and an unfavorable financial environment could have negative consequences for Sanofi's business*" above).

Emerging markets also expose Sanofi to more volatile economic conditions; legal, regulatory and political instability, both globally and locally (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; difficulties that may adversely affect Sanofi's ability to supply Sanofi's products, 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 and other legal matters could adversely affect Sanofi's business, results of operations and financial condition*" above).

Given the increasing globalization of Sanofi's business, if relations between the United States, European Union countries and other governments deteriorate, Sanofi's business and investments in such markets may also be adversely affected. For example, the BIOSECURE Act in the United States, which would prohibit federal agencies from entering into certain contracts with or expenditures related to companies that have specified commercial connections with "biotechnology companies of concern" (the identification criteria for which have not been determined, and the list of which has not been defined and could be very extensive, including companies in China), has been proposed in the US Congress, and, if enacted, could restrict Sanofi's ability to contract or collaborate with such biotechnology companies. This, in turn, could materially and adversely affect its or Sanofi's collaboration partners' ability to manufacture or supply marketed products and product candidates, or to advance its or Sanofi's collaboration partners' preclinical research, which could materially and adversely affect Sanofi's business and future prospects.

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

Sanofi has undertaken several digital initiatives, such as the implementation of artificial intelligence (AI) across Sanofi's business. For example, in research and development, Sanofi has built multiple AI programs to reduce research times through improved predictive modelling. Sanofi is also seeking to automate time-consuming activities, enabling research and development teams to scale and accelerate research processes and improve potential target identification in therapeutic areas such as immunology, oncology and neurology. In manufacturing and supply, Sanofi has developed an in-house AI-enabled yield optimization solution that delivers higher yield levels and optimizes usage of raw materials.

Sanofi's success in these efforts will depend on many factors including data availability; entering into successful partnerships and alliances with technology companies (such as the AI collaboration with Formation Bio and OpenAI announced in May 2024, aimed at building AI-powered software to accelerate drug development); a profound transformation of Sanofi's organization; a cultural change among Sanofi's employees, and the development of relevant skills; Sanofi's ability to adopt AI agents; attracting and retaining employees with appropriate skills and mindsets in a tight labor market; and successfully innovating across a variety of technology fields, while seeking to comply with evolving external regulations. In recent years, Sanofi has accelerated Sanofi's digital transformation, including in the ways Sanofi engage and interact with Sanofi's stakeholders. However, there is no guarantee that Sanofi's efforts towards digital transformation will succeed. More generally, Sanofi may fail to capture the benefits of AI, 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 Sanofi in this fast-moving area. If Sanofi fails to adequately integrate digital capabilities into Sanofi's organization and business model, Sanofi could lose patients and market share. This could have an adverse impact on Sanofi's business, prospects, and results of operations. Because AI is an emerging technology, it is possible that Sanofi's use of AI technologies may not have the intended effects or benefits, such as increasing efficiency. In addition, the use of AI technologies presents certain risks, including the use of personal data as described above (see "— *Failure to comply with data ethics and privacy regulations could adversely affect Sanofi's business and reputation*" above).

The success of digital initiatives will also depend on Sanofi's ability to shift Sanofi's culture to a data-driven culture and to transform the architecture of Sanofi's business process designs to integrate AI. This calls for management of data as an asset and the definition of a robust life-cycle management process for data that is applied consistently across Sanofi. Misuse of such technologies could negatively affect Sanofi's reputation, disrupt Sanofi's operations, or otherwise have a material adverse impact on Sanofi's financial results and could also subject Sanofi to legal and reputational risks.

Sanofi may fail to accelerate Sanofi's operational efficiency and perform Sanofi's transformation program*

As part of the presentation of the next chapter of Sanofi's Play to Win strategy in October 2023, Sanofi announced its intent to improve Sanofi's operating efficiencies to fund growth. Sanofi also announced savings of a total of up to €2 billion from 2024 to the end of 2025, most of which will be reallocated to fund innovation and growth drivers. Sanofi also announced its intent to separate Opella, with an anticipated closing date of the transaction at the earliest in the second quarter 2025, subject to obtaining regulatory approvals from the competent authorities. (See also "— *Completion of the separation of Opella is subject to conditions that may not be satisfied and Sanofi may fail to realize any or all of the anticipated benefits of the separation and/or face unintended adverse impacts on Sanofi's business*"). To deploy Sanofi's strategy, Sanofi must also disrupt Sanofi's normal course of business and transform Sanofi's operations. Nevertheless, Sanofi may not succeed in federating employees behind the transformation program, which may hamper Sanofi's ability to execute such organizational changes. Besides, there is no guarantee that Sanofi will be able to fully deliver these operating efficiencies or separate the Opella business within the targeted timeline, or at all, or generate the expected benefits.

Unsuccessful management of sustainability (environmental, social and governance) matters could adversely affect Sanofi's reputation and Sanofi may experience difficulties meeting the expectations of Sanofi's stakeholders

Companies are increasingly expected to behave in a responsible manner on a variety of sustainability 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, including the EU's Corporate Sustainability Reporting Directive (CSRD), 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 sustainability matters. These evolving regulatory requirements are also likely to result in increased costs and complexities of compliance in order to collect, measure and report on the relevant ESG-related information, and may expose Sanofi to additional regulatory, litigation and reputational risk. Given recent political and geopolitical pressures, there is also the possibility that some or part of these rules or regulations are rolled back or amended, in which case Sanofi would face additional compliance costs and, depending on such changes, Sanofi may face other adverse effects described below.

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

Furthermore, statements about Sanofi's ESG-related initiatives and goals, and progress against those goals, may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve and assumptions that are subject to change in the future.

Sanofi may also be unable to meet the ever more demanding criteria used by rating agencies in their sustainability assessments process, leading to a downgrading in Sanofi's rating. Financial investments in companies which perform well in sustainability assessments are increasingly popular, and major institutional investors have made known their interest in investing in such companies.

Depending on sustainability assessments, Sanofi's ability to fulfill its sustainability strategy, and on the rapidly changing views on acceptable levels of action across a range of sustainability topics from investors, Sanofi may be unable to meet society's or investors' expectations or the targets or goals contained in Sanofi's sustainability strategy, in which case, Sanofi's reputation may be harmed; Sanofi may face increased compliance or other costs; and interest in subscribing to securities issued by us, and Sanofi's ability to participate in the debt and equity markets, may decrease. In addition, Sanofi could be criticized for the scope or nature of such initiatives or goals, or for any revisions to these goals.

In addition, in recent years "anti-ESG" sentiment has gained momentum across the US, with several states and Congress having proposed or enacted "anti-ESG" policies, legislation, or initiatives or issued related legal opinions, and the US President having recently issued an executive order opposing diversity equity and inclusion ("DEI") initiatives in the private sector. Such anti-ESG and anti-DEI-related policies, legislation, initiatives, litigation, scrutiny and other actions could result in additional compliance obligations, Sanofi becoming the subject of investigations and enforcement actions, or otherwise suffering reputational harm.

Sanofi's success depends in part on Sanofi's senior management team and other key employees and Sanofi's ability to attract, integrate and retain key personnel and qualified individuals in the face of intense competition

Sanofi's success depends on the expertise of its senior management team and other key employees. In 2024, there were 2,282 "Senior Leaders" within Sanofi. In addition, Sanofi relies heavily on recruiting and retaining talented people to help Sanofi meet its strategic objectives. Sanofi faces 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. Sanofi's ability to hire qualified personnel also depends in part on its ability to reward performance, incentivize its employees and pay competitive compensation. The inability to attract, integrate and/or retain highly skilled personnel, in particular those in leadership positions, may weaken its succession plans, may materially adversely affect the implementation of Sanofi's strategy and Sanofi's ability to meet its strategic objectives, and could ultimately adversely impact Sanofi's business or results of operations.

D. Environmental and safety risks of Sanofi's industrial activities

Risks from manufacturing activities and the handling of hazardous materials could adversely affect Sanofi's results of operations and reputation*

Manufacturing activities, such as the chemical manufacturing of the active ingredients in Sanofi's products and the related storage and transportation of raw materials, products and waste, expose Sanofi 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 Sanofi's operating results and reputation. Although Sanofi maintains property damage, business interruption and casualty insurance that its believes is in accordance with customary industry practices, this insurance may not be adequate to fully cover all potential hazards incidental to Sanofi's business.

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

The environmental laws of various jurisdictions impose actual and potential obligations on Sanofi to manage and/or remediate contaminated sites. These obligations may relate to sites (i) that Sanofi currently owns or operates; (ii) that Sanofi formerly owned or operated; or (iii) where waste from Sanofi's operations was disposed.

These environmental remediation obligations could reduce Sanofi's operating results. Sanofi accrues provisions for remediation when Sanofi's management believes the need is probable and that it is reasonably possible to estimate the cost (see Note D.22 to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F). Sanofi's provisions for these obligations may be insufficient if the assumptions underlying these provisions prove incorrect or if Sanofi is held responsible for additional, currently undiscovered contamination. These judgments and estimates may later prove inaccurate, and any shortfalls could have an adverse effect on Sanofi's results of operations and financial condition. For more detailed information on environmental policies and issues, see "*Item 4. Information on the Company — B. Business Overview — B.9. Health, Safety and Environment*" and Notes "*B.12. Provisions for risks*" and "D.*19.3. Other provisions*" to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F.

Sanofi is 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 (CERCLA, also known as "Superfund"), and similar statutes or obligations in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligations, Sanofi and/or its subsidiaries may retain responsibility for environmental liabilities at some of the sites of Sanofi's predecessor companies, or of subsidiaries that Sanofi demerged, divested, or may divest. Sanofi has 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 Sanofi's operating results. See Note D.22.d to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F and "*Item 8. Financial Information — A. Consolidated Financial Statements and Other Financial Information — Information on Legal or Arbitration Proceedings*" of the 2024 Annual Report on Form 20-F.

Environmental regulations are evolving. For example, in Europe, new or evolving regulatory regimes include the Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (which may include, in the future, a restriction on per- and polyfluoroalkyl substances (PFAS) based on a recent draft released by the European Chemicals Agency (ECHA)); 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; and the recently adopted Urban Wastewater Treatment Directive, as well as other regulations aimed at protecting public health or preventing climate change. Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to Sanofi and could subject its 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 Sanofi's business, results of operations or financial condition.

E. Risks related to financial markets[3]

Counterparty risk *

Sanofi's financing and investing transactions, and its currency and interest rate hedges, are contracted with leading counterparties. Sanofi sets 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 Sanofi's total exposure as of 31 December 2024 by rating and in terms of Sanofi's percentage exposure to the dominant counterparty.

[3] The information in this section supplements the disclosures required under IFRS 7 as presented in Note B.8.7. to the consolidated financial statements, provided at Item 18. of the 2024 Annual Report on Form 20-F.

(€ 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	390	967	23	—	—	500
AA-	652	10,157	188	1,083	(49)	1,000
A+	649	10,512	217	690	(37)	4,000
A	427	6,393	110	347	(21)	2,000
A-	3	504	11	347	(20)	500
BBB+	—	—	—	—	—	—
Unallocated	128	—	—	—	—	—
Total	**2,249**	**28,534**	**550**	**2,466**	**(128)**	**8,000**
%/rating of dominant counterparty	24,8% / AA-	12,1% /A+		20,1% /A+		6% /A+

(a) Cash equivalents include mutual fund investments of €4,157 million.
(b) The notional amounts are translated into euros at the relevant closing exchange rate as of 31 December 2024.

As of 31 December 2024, Sanofi 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 Sanofi's liquidity in certain circumstances.

Foreign exchange risk

Operating foreign exchange risk

A substantial portion of Sanofi's net sales is generated in countries where the euro, which is Sanofi's reporting currency, is not the functional currency. In 2024, for example, 48.7% of its net sales were generated in the United States; 22.0% in Europe; and 29.4% in the Rest of the World region (see the definition in "*Item 5. Operating and Financial Review and Prospects. A/Operating results*" in the 2024 Annual Report on Form 20-F), including countries that are, or may in the future become, subject to exchange controls, of which 6.5% was generated in China and 3.4% in Japan. Although Sanofi also incurs expenses in those countries, the impact of those expenses is not enough wholly to offset the impact of exchange rates on its net sales. Consequently, Sanofi's 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 31 December 2024, with the notional amount translated into euros at the relevant closing exchange rate (see Note D.20. to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F for the accounting classification of those instruments as of 31 December 2024).

Operating foreign exchange derivatives as of 31 December 2024

(€ million)	Notional amount	Fair value
Forward currency sales	**7,521**	**(67)**
of which US dollar	3,974	(59)
of which Chinese yuan renminbi	703	(5)
of which Pound sterling	368	(1)
of which Japanese yen	241	2
of which Turkish lira	216	(23)
Forward currency purchases	**4,796**	**37**
of which US dollar	2,660	24
of which Singapore dollar	484	3
of which Chinese yuan renminbi	451	2
of which Turkish lira	203	19
of which Canadian dollar	126	—

Total	**12,317**	**(30)**

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 31 December 2024 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) was immaterial in 2024.

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 31 December 2024, with the notional amounts translated into euros at the relevant closing exchange rate (see also Note D.20. to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F for the accounting classification of these instruments as of 31 December 2024).

Financial foreign exchange derivatives as of 31 December 2024

(€ million)	**Notional amount**		**Fair value**	**Expiry**
Forward currency sales	**10,377**		**(195)**	
of which US dollar	*8,923*	(a)	*(176)*	*2025*
of which Japanese yen	*371*		*4*	*2025*
of which Chinese yuan renminbi	*235*		*(1)*	*2025*
Forward currency purchases	**6,884**		**112**	
of which US dollar	*4,397*	(b)	*123*	*2025*
of which Singapore dollar	*819*		*2*	*2025*
of which Hungarian forint	*641*		*(9)*	*2025*
Total	**17,261**		**(83)**	

(a) Includes forward sales with a notional amount of $3,615 million expiring in 2025, designated as a hedge of Sanofi's net investment in Bioverativ. As of 31 December 2024, the fair value of these forward contracts represented a liability of €88 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 2025, 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 31 December 2024, the fair value of the contracts represented an asset of €75 million, the opposite entry for €0.2 million of which was debited from "Other comprehensive income" under the cost of hedging accounting treatment.

(c) Includes forward purchases with a notional amount of $1,250 million expiring in 2025, designated as a fair value hedge of the exposure of $1,250 million of commercial paper. As of 31 December 2024, the fair value of these forward contracts swaps represented an asset of €23 million, the opposite entry for €0.1 million of which was credited to "Other comprehensive income" under the cost of hedging accounting treatment.

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 the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F). Sanofi may also hedge some future foreign-currency investment or divestment cash flows.

Other foreign exchange risks

A significant proportion of Sanofi's net assets is denominated in US dollars (see Note D.35. to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F). As a result, any fluctuation in the exchange rate of the US dollar against the euro automatically impacts the amount of Sanofi's equity as expressed in euros.

In addition, Sanofi uses the euro as its 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 Sanofi can obtain financing and on its financial results, the extent and consequences of which are not currently foreseeable.

Liquidity risk

Sanofi operates a centralized treasury platform whereby all surplus cash and financing needs of its subsidiaries are invested with or funded by the parent company (where permitted by local legislation). The central treasury department manages its 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 its operations and the maturity of its debt (see Notes D.17.1.c. and D.17.1.g. to the consolidated financial statements included at Item 18. of the 2024 Annual Report on Form 20-F).

Sanofi diversify its short-term investments with leading counterparties using money-market products with instant access or with a maturity of less than three months.

As of 31 December 2024, cash and cash equivalents amounted to €7,441 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; and

amounts invested directly with banks and non-financial institutions in the form of instant access deposits, term deposits, and Negotiable European Commercial Paper with a maturity of no more than three months.

As of 31 December 2024, Sanofi also had €8 billion of undrawn general corporate purpose confirmed credit facilities, half of which expires in December 2027 and half in March 2030. Those credit facilities are not subject to financial covenant ratios.

Sanofi's policy is to diversify its 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, its A-1+/P-1 short-term rating gives Sanofi access to commercial paper programs in the United States, and to Negotiable European Commercial Paper programs in France. The average maturity of Sanofi's total debt was 3.56 years as of 31 December 2024, compared with 4.45 years as of 31 December 2023. Average drawdowns under the Negotiable European Commercial Paper program during 2024 were €0.1 billion (with a maximum of €0.4 billion); the average maturity of those drawdowns was two months. As of 31 December 2024, this program was not being utilized.

Average drawdowns under the US Commercial Paper program during 2024 were €5.8 billion (with a maximum of €8.9 billion); the average maturity of those drawdowns was three months. As of 31 December 2024, drawdowns under the program amounted to €1.3 billion.

In the event of a liquidity crisis, Sanofi could be exposed to difficulties in calling up its available cash, a scarcity of sources of funding including the above-mentioned programs, and/or a deterioration in their terms. This situation could damage Sanofi's capacity to refinance its 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 Sanofi's debt, net of cash and cash equivalents for 2024 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	34	—
+25 bp	8	—
-25 bp	(8)	—
-100 bp	(34)	—

Stock market risk

It is Sanofi's policy not to trade on the stock market for speculative purposes.

F. Risks relating to an investment in Sanofi's shares or ADSs

Foreign exchange fluctuations may adversely affect the US dollar value of Sanofi's ADSs and dividends (if any) regardless of its operating performance

Holders of American depositary shares (ADSs) face exchange rate risks. Sanofi's ADSs trade in US dollars and Sanofi's shares trade in euros. The value of the ADSs and Sanofi's shares could fluctuate substantially as the exchange rates between these currencies fluctuate. If and when Sanofi pays 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 Sanofi pays dividends, in addition to any amounts that a holder would receive upon Sanofi's 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 Sanofi issues 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 Sanofi or Sanofi's directors or executive officers.

Sales of Sanofi's shares may cause the market price of Sanofi's shares or ADSs to decline

Sales of large numbers of Sanofi's shares, or a perception that such sales may occur, could adversely affect the market price for Sanofi's shares and ADSs. L'Oréal, Sanofi's largest shareholder, is not subject to any contractual restrictions on the sale of the shares it holds in Sanofi's Company. L'Oréal does not consider its stake in Sanofi's Company as strategic and completed an off-market block trade of which 2.3% was bought back by Sanofi in February 2025.

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

Following the buy-back Sanofi made of a block of shares from L'Oréal in February 2025, and after cancellation of said shares, L'Oréal will own (excluding treasury shares) 7.2% of Sanofi's share capital and 13.1% of Sanofi's voting rights. Affiliates of L'Oréal currently serve on Sanofi's Board of Directors. To the extent L'Oréal continues to hold a large percentage of Sanofi's 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.

DOCUMENTS INCORPORATED BY REFERENCE

The section entitled "*Documents Incorporated by Reference*" on pages 45 to 49 of the Base Prospectus is hereby deleted and replaced by the following:

"This Base Prospectus should be read and construed in conjunction with the pages and sections of the following documents, listed in the cross-reference list, which shall be incorporated in, and form part of, this Base Prospectus:

(1) the Issuer's annual report on the United States Securities and Exchange Commission's Form 20-F for the financial year ended 31 December 2024 (the "**2024 Annual Report on Form 20-F**");

(2) the Issuer's annual report on the United States Securities and Exchange Commission's Form 20-F for the financial year ended 31 December 2023 (the "**2023 Annual Report on Form 20-F**"); and

(3) the section "Terms and Conditions of the Notes" of the base prospectus dated 10 March 2020 (the "**2020 Conditions**") which received the approval number. 20-084 from the AMF (the "**2020 Base Prospectus**") relating to the Programme.

The 2024 Annual Report on Form 20-F and 2023 Annual Report on Form 20-F have been previously published and have been filed with the AMF for the purpose of the EU Prospectus Regulation. The pages and sections of the 2024 Annual Report on Form 20-F and the 2023 Annual Report on Form 20-F listed in the cross-reference list shall be incorporated in and form part of this Base Prospectus, save that:

(a) the non-incorporated parts of the 2024 Annual Report on Form 20-F and the 2023 Annual Report on Form 20-F are either not relevant for investors or are covered elsewhere in this Base Prospectus; and

(b) any statement contained in the 2024 Annual Report on Form 20-F and the 2023 Annual Report on Form 20-F which is incorporated by reference herein shall be modified or superseded for the purpose of this Base Prospectus to the extent that (i) a statement contained herein modifies or supersedes such earlier statement (whether expressly, by implication or otherwise) or (ii) it is modified or incorporated by way of a supplement prepared in accordance with Article 23 of the EU Prospectus Regulation. Any statement so modified or superseded shall not, except as so modified or superseded, constitute a part of this Base Prospectus.

The information on the website of the Issuer does not form part of this Base Prospectus (unless that information is incorporated by reference into this Base Prospectus) and has not been scrutinised or approved by the competent authority.

For as long as any Notes are outstanding, this Base Prospectus, any supplement to this Base Prospectus and all documents incorporated by reference into this Base Prospectus may be obtained, free of charge, (i) at the office of the Fiscal Agent and the Paying Agents set out at the end of this Base Prospectus during normal business hours, (ii) at the registered office of the Issuer during normal business hours, and (iii) on the website of the Issuer (www.sanofi.com). Provision of such documents does not constitute a representation that such documents have not been modified or superseded in whole or in part as specified above. Written or oral requests for such documents should be directed to the principal office of BNP Paribas in its capacity as Fiscal Agent (as defined in the "*Terms and Conditions*" of the Notes below) or to the Issuer at its registered office set out at the end of this Base Prospectus. This Base Prospectus and any supplement to this Base Prospectus will also be available on the website of the AMF (www.amf-france.org).

The Final Terms related to Notes admitted to trading on Euronext Paris will be published on the websites of (x) the AMF (www.amf-france.org) and (y) the Issuer (www.sanofi.com). If the Notes are admitted to trading on a Regulated Market other than Euronext Paris, the relevant Final Terms will provide whether additional methods of publication are required and what they consist of.

The relevant documents and page references for the information incorporated by reference herein in response to the specific requirements of Annex 7 of Commission Delegated Regulation 2019/980 are as follows:

Information incorporated by reference

Rule	Information	Page in 2024 Annual Report on Form 20-F	Page in 2023 Annual Report on Form 20-F
4	**INFORMATION ABOUT THE ISSUER**		
4.1	History and development of the Issuer	17-18	-
4.1.1	The legal and commercial name of the Issuer	17	-
4.1.2	The place of registration of the Issuer, its registration number and legal entity identifier ('LEI').	17; 165	-
4.1.3	The date of incorporation and the length of life of the Issuer, except where the period is indefinite.	17	-
4.1.4	The domicile and legal form of the Issuer, the legislation under which the Issuer operates, its country of incorporation, the address, telephone number of its registered office (or principal place of business if different from its registered office) and website of the Issuer, if any, with a disclaimer that the information on the website does not form part of the Base Prospectus unless that information is incorporated by reference into the Base Prospectus.	17	-
4.1.5	Any recent events particular to the Issuer and which are to a material extent relevant to an evaluation of the Issuer's solvency.	163; F103	-
5	**BUSINESS OVERVIEW**		
5.1	Principal activities		
5.1.1	A brief description of the Issuer's principal activities stating the main categories of products sold and/or services performed.	17-39	-
5.1.2	The basis for any statements made by the Issuer regarding its competitive position.	40-41; 59-60	-
6	**ORGANISATIONAL STRUCTURE**		
6.1	If the Issuer is part of a group, a brief description of the group and the Issuer's position within the group. This may be in the form of, or accompanied by, a diagram of the organizational structure if this helps to clarify the structure.	52	-
9	**ADMINISTRATIVE, MANAGEMENT, AND SUPERVISORY BODIES**		
9.1	Names, business addresses and functions within the Issuer of the following persons and an indication of the principal activities performed by them outside of that Issuer where these are significant with respect to that Issuer: (a) members of the administrative, management or supervisory bodies; (b) partners with unlimited liability, in the case of a limited partnership with a share capital.	93-124	-
9.2	Administrative, management, and supervisory bodies conflicts of interests. Potential conflicts of interests between any duties to the Issuer, of the persons referred to in item 9.1, and their private interests and or other duties must be clearly stated. In the event that there are no such conflicts, a statement to that effect must be made.	120	-
10	**MAJOR SHAREHOLDERS**		
10.1	To the extent known to the Issuer, state whether the Issuer is directly or indirectly owned or controlled and by whom and describe the nature of such control and describe the measures in place to ensure that such control is not abused.	159-160	-
11	**FINANCIAL INFORMATION CONCERNING THE ISSUER'S ASSETS AND LIABILITIES, FINANCIAL POSITION AND PROFITS AND LOSSES**		
11.1	Historical financial information		
11.1.1	Historical financial information covering the latest two financial years (at least 24 months) and the audit report in respect of each year.	187-190; F1-103	175-178; F1-F101
11.1.3	Accounting standards	F10-F13	F10-F13
11.1.5	Consolidated financial statements	F1-103	F1-F101
11.1.6	Age of financial information	F1-103	F1-F101

Rule	Information	Page in 2024 Annual Report on Form 20-F	Page in 2023 Annual Report on Form 20-F
	The balance sheet date of the last year of audited financial information may not be older than 18 months from the date of the registration document		
11.2	Auditing of historical financial information	187-190	175-178
11.2.1	Qualifications, modifications of opinion, disclaimers or an emphasis of matter in audit reports	187-189	175-177
11.3	Legal and arbitration proceedings	162-163; F82-89	149; F81-F87
12	**MATERIAL CONTRACTS**	169	156

EMTN Previous Conditions incorporated by reference	References in the Previous Base Prospectuses
The 2020 Conditions	Pages 39 to 68 of the 2020 Base Prospectus

"

BUSINESS OF SANOFI

The section entitled "*Business of Sanofi*" on pages 100 to 102 of the Base Prospectus is hereby deleted and replaced by the following:

"**Information on the Company**

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

Its net sales were €43,070 million in 2023 and €41,081 million in 2024.

Sanofi is a holding company and as a result its financial and trading position depends on the financial and trading position of its principal subsidiaries. Sanofi operates under the laws of France.

Sanofi is the parent company of a consolidated group of almost 260 companies. A list of its principal subsidiaries can be found in Note F to its consolidated financial statements included at Item 18 of the 2024 Annual Report on Form 20-F incorporated by reference herein.

Sanofi reports segment information for the Biopharma operating segment, further to the opening of exclusive negotiations between Sanofi and Clayton, Dubilier & Rice (CD&R) on 21 October 2024 and the signing the share purchase agreement on 18 February 2025 with a view to selling an equity interest in Opella, which would lead to loss of control over Opella on the effective closing date, scheduled for the second quarter of 2025 at the earliest.

Prior to the opening of those exclusive negotiations, Opella (formerly Consumer Healthcare) was an operating segment of Sanofi. As a result of the announcement of the Proposed Opella Transaction (as defined in Note D.1.1.2. Project to divest a controlling interest in Opella of the 2024 Annual Report on Form 20-F), as of the fourth quarter of 2024 Opella meets the criteria for a discontinued operation under IFRS 5 (see Note B.7. of the 2024 Annual Report on Form 20-F), and the net income from this business is now presented separately within the line item "*Net income from discontinued operations*" in the consolidated income statement of Sanofi. This presentation in a separate line item in the income statement applies to results of operations for the current period, and for the comparative periods presented. With effect from that date, Sanofi became a dedicated Biopharma company of which the performance, based on internal management reporting, is subject to regular review by the Chief Executive Officer, Sanofi's chief operating decision-maker.

The Biopharma operating segment comprises commercial operations and research, development and production activities relating to the Specialty Care, General Medicines and Vaccines franchises plus support and corporate functions, for all geographical territories. It also includes revenues generated by legal entities within the Biopharma segment (and included in the scope of continuing operations) from the manufacture of Consumer Healthcare products on behalf of legal entities within Opella; those revenues are presented within Other Revenues in the income statement. The Biopharma operating segment also includes the purchase price of Biopharma products manufactured by legal entities within the Opella scope.

Sanofi's activities are organized around the following categories: Immunology & Inflammation, Rare Diseases, Neurology, Oncology, Other Medicines, Vaccines, and Opella. Except for Opella, which is a held-for-sale operation and therefore presented as a discontinued operation in the 2024 Annual Report on Form 20-F in accordance with IFRS 5, all of Sanofi's activities fall within the Biopharma operating segment.

Biopharma segment[4]

Within its Biopharma segment, which generated net sales of €37,890 million in 2023 and €41,081 million in 2024, Sanofi specialises in the following therapeutic areas:

- Immunology & Inflammation
    - 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

[4] As of the date of the 2024 Annual Report on Form 20-F, all commercial trademarks mentioned here are protected, and are trademarks of Sanofi and/or its subsidiaries, with the exception of:

- trademarks used or that may be or have been used under license by Sanofi and/or its affiliates, such as 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; Eloctate, a trademark of Swedish Orphan Biovitrum AB in Europe; Stamaril, a trademark of the 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; Libtayo, a trademark of Regeneron; Praluent, a trademark of Regeneron in the United States; and

and Regeneron under a global collaboration agreement. To date, dupilumab has been studied across more than 59 completed studies and 23 ongoing studies, involving more than 12,000 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 3 studies, 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.

  - 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 (RA).

- Rare diseases
  - Cerezyme (imiglucerase) is an ERT used to treat Gaucher disease, a chronic, inherited, progressive and potentially life-threatening lysossomal storage disorders (LSD).
  - Cerdelga (eliglustat) is the first and only first-line oral therapy for Gaucher disease type 1 adult patients.
  - Myozyme (alglucosidase alfa) is an ERT used to treat both Infantile Onset and Late Onset Pompe disease (IOPD and LOPD).
  - Nexviazyme / Nexviadyme (avalglucosidase alfa-ngpt) is a novel mannose-6-phosphate (M6P) enriched enzyme replacement therapy (ERT) treatment designed as a monotherapy for the entire spectrum of infantile-onset and late-onset Pompe disease (IOPD, LOPD), including patients who have changed treatments and naive patients, who have not received treatment previously.
  - Fabrazyme (agalsidase beta) is an ERT used to treat Fabry disease (FD).
  - Aldurazyme (laronidase) is the only approved ERT 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).
  - Xenpozyme (olipudase alfa) is an 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.
  - ALTUVIIIO (Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein) is a first-in-class high-sustained factor VIII therapy that is designed to extend protection from bleeds with once-weekly prophylactic dosing for adults and children with hemophilia A.
  - Eloctate (antihemophilic factor (recombinant), Fc fusion protein) is an extended half-life factor VIII therapy clotting-factor therapy to control and prevent bleeding episodes in adults and children with hemophilia A.
  - Alprolix (coagulation Factor IX (recombinant), Fc fusion protein) is an extended half-life factor IX clotting-factor therapy to control and prevent bleeding episodes in adults and children with hemophilia B.
  - Cablivi (caplacizumab) is a bivalent anti-von Willebrand Factor (vWF) NANOBODY VHH for the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP).
  - 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.

- Neurology
  - Aubagio (teriflunomide) is used to help manage multiple sclerosis (MS). This small molecule agent, taken once daily, works by reducing inflammation and modulating the immune system to prevent the immune attacks that cause MS symptoms.

- other third party trademarks such as Stoxx, a trademark of Stoxx Ltd; and Zantac, a trademark of Glaxo Group Limited (except in the US and Canada).

- Oncology
    - 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.
    - 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.
    - Fasturtec/Elitek is used for the management of plasma uric levels in patients with leukemia, lymphoma, and solid tumor malignancies receiving anticancer therapies.
- Other medicines
    - 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 two years and above.
    - Toujeo (insulin glargine 300 units/mL) is a long-acting analog of human insulin, indicated for the treatment of diabetes mellitus in adults.
    - Lovenox or Clexane (enoxaparin sodium) is a low molecular weight heparin (LMWH) indicated for the prophylaxis and treatment of venous thromboembolism and in the treatment of acute coronary syndrome.
    - Plavix or Iscover (clopidogrel bisulfate) is a platelet adenosine diphosphate (ADP) receptor antagonist.
    - Rezurock (belumosudil) is a first-in-class selective ROCK2 (rho-associated coiled-coil–containing protein kinase-2) inhibitor.
    - Praluent (alirocumab) is a human monoclonal antibody (mAb) for self-administered injection every two weeks or once-monthly.
    - Thymoglobulin (anti-thymocyte globulin) is a polyclonal anti-human thymocyte antibody preparation that acts as a broad immunosuppressive and immunomodulating agent.
    - Aprovel, also known as Avapro or Karvea (irbesartan), is an angiotensin II receptor antagonist indicated in the treatment of hypertension and for the treatment of renal disease in patients with hypertension and type 2 diabetes.
    - 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.
    - 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.
    - Mozobil (plerixafor injection) is a hematopoietic stem cell mobilizer.
    - Tzield (Teplizumab) is a CD3-directed antibody (CD3 is a cell surface antigen present on T lymphocytes).
- Vaccines activity of which the portfolio includes: influenza vaccines, COVID vaccine, poliomyelitis, pertussis and Haemophilus influenzae type b (Hib) pediatric vaccines, vaxelis, booster vaccines, respiratory syncytial virus (RSV) protection, and meningitis and travel & endemic vaccines.

Opella

The implementation and simplification of Sanofi's autonomous Opella business unit continued in 2024. Mainly as a result of divestments, the portfolio was further reduced to approximately 100 brands by the end of the year. Opella operates in 100 countries and manages 13 strategic state-of-the-art production sites as well as four research and innovation centers, with a portfolio of leading brands.

In October 2024, in line with its strategy of focusing on innovative medicines and vaccines, Sanofi announced that it had entered into exclusive negotiations for the sale of a controlling stake of around 50% in Opella. The agreements in connection with the potential sale and purchase of a 50% controlling stake in Opella are described as follows:

- Share Purchase Agreement

In connection with the sale of a 50% controlling stake in Opella Healthcare SAS ("**Opella**") to Clayton, Dubilier & Rice (CD&R) (the "**Proposed Opella Transaction**"), Sanofi has exercised on 3 February 2025 its put option pursuant to the put option agreement entered into with Opal Bidco SAS ("**Bidco**") on 21 October 2024. Pursuant to the exercise of its put option, Sanofi has entered into

a share purchase agreement (the "**SPA**") on 18 February 2025 with Bidco. The purchase price for the acquisition of Opella will be determined and paid at closing of the Proposed Opella Transaction ("**Closing**"), based on an enterprise value of approximately €16 billion.

The transaction is expected to close in the second quarter of 2025 at the earliest, subject to obtaining customary regulatory approvals from the competent authorities. The SPA may be terminated by either party if the conditions are not satisfied and Closing has not occurred by an agreed long stop date or such other date as the parties otherwise agree.

Pursuant to the SPA, Sanofi and Bidco have made certain customary representations and warranties and have agreed to certain customary covenants. Specifically, before the Closing, Sanofi is subject to certain business conduct restrictions with respect to the Opella business.

Sanofi has also agreed to enter into a shareholders' agreement (the "**Shareholders' Agreement**") with CD&R (and certain co-investors) to govern from Closing their respective shareholding and management of a joint venture company ("**JV Co**") to be formed at or prior to Closing with CD&R that is contemplated to, following the Closing, indirectly wholly own Opella. It is anticipated that Bpifrance will ultimately take an approximately 2% stake in JV Co but the terms of Bpifrance's investment are subject to ongoing negotiation.

The Shareholders' Agreement will provide for a lock-up period during which Sanofi is only permitted to carry out certain types of direct or indirect transfers of its securities in JV Co.

- Separation Agreement

In connection with the separation of the Opella business, Sanofi entered into a Separation Agreement and certain other agreements with Opella on 22 July 2024 (to be amended on or around the date of the SPA) to effect the separation of the Opella business and provide a framework for their ongoing relationship. The Separation Agreement sets out the rights and obligations of the parties with respect to the separation, including the terms and conditions governing the transfer of assets to, and assumption of liabilities by, each of the Opella group and the Sanofi group.

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

The contact address of the directors and senior management, as described under "*Item 6. Directors, Senior Management and Employees*" of the 2024 Annual Report on Form 20-F incorporated by reference herein, is the same as the registered office of the Issuer as found on page 125 of this Base Prospectus."

RECENT DEVELOPMENTS

The "*Recent developments*" section of the Base Prospectus on pages 103 and 104 is hereby deleted and replaced by the following paragraph before "*Issue of U.S. commercial paper*":

"**Paris and Tarrytown, NY – 18 February 2025.** The US Food and Drug Administration (FDA) has accepted for priority review the supplemental biologics license application (sBLA) for Dupixent (dupilumab) to treat adults with bullous pemphigoid (BP). The sBLA is supported by data from a pivotal study evaluating the efficacy and safety of Dupixent in 106 adults with moderate-to-severe BP. The primary endpoint was met, with five times more Dupixent patients achieving sustained disease remission compared to those on placebo. Sustained disease remission was defined as complete clinical remission with completion of oral corticosteroids (OCS) taper by week 16 (off OCS treatment and only treated with Dupixent for at least 20 weeks) without relapse and no rescue therapy use during the 36-week treatment period. The study also showed that Dupixent significantly reduced disease severity, itch, and use of OCS compared to placebo.

Paris – 19 February 2025. Following completion of the required social and corporate procedures, Sanofi and CD&R announce today they have signed the share purchase agreement in relation to the sale of a 50% controlling stake in Opella to CD&R. Bpifrance is expected to participate as a minority shareholder with a c.2% stake in Opella, with Sanofi remaining a significant shareholder. The terms of the transaction remain unchanged from those previously disclosed, and closing is expected to take place in Q2 2025 at the earliest. This transaction remains subject to obtaining customary regulatory approvals from the competent authorities.

Paris and Parsippany, NJ – 22 February 2025. Sanofi and Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd., today presented new, detailed results from the RELIEVE UCCD phase 2b study of duvakitug, a human IgG1-λ2 monoclonal antibody targeting TL1A, in patients with moderate-to-severe ulcerative colitis (UC) and Crohn's disease (CD), the two most common forms of inflammatory bowel disease (IBD). These results were shared in two oral presentations at the 20th Congress of the European Crohn's and Colitis Organisation (ECCO) in Berlin, Germany.

Paris – 25 February 2025. The Ministry of Health, Labour and Welfare (MHLW) in Japan has approved Sarclisa, in combination with bortezomib, lenalidomide, and dexamethasone (VRd), for the treatment of adult patients with newly diagnosed multiple myeloma (NDMM) based on data from the IMROZ phase 3 study."

The paragraphs "*Issue of U.S. commercial papers*" and "*Issue of NeuCP*" of the "*Recent developments*" section of the Base Prospectus on page 104 are hereby amended as follows:

"*Issue of U.S. commercial paper*
The total aggregate amount of U.S. commercial paper outstanding as at 28 February 2025 was U.S.$ 3,000,000,000.

Issue of NeuCP
There was no Negotiable EUropean Commercial Paper outstanding as at 28 February 2025."

GENERAL INFORMATION

The section entitled "*General Information*" on pages 120 to 123 of the Base Prospectus is amended as follows.

- Paragraph (1) of the section "*General Information*" on page 120 of the Base Prospectus entitled "***Authorisation***" is deleted and replaced by the following:

"The issue of Notes under the Programme constituting *obligations* under French law requires a resolution of the *Conseil d'Administration* (Board of Directors) of the Issuer and a decision of the *Directeur Général* (Chief Executive Officer) or *Directeur Financier* (Chief Financial Officer), the dates of which will be specified in the Final Terms.

A resolution was passed by the *Conseil d'administration* (Board of Directors) of the Issuer on 29 January 2025 whereby the Board of Directors authorised for a duration of one year from 29 January 2025, the issue of Notes up to an aggregate amount of €3,000,000,000."

- Paragraph (5) of the section "*General Information*" on pages 120-121 of the Base Prospectus entitled "***Documents***" is deleted and replaced by the following:

"So long as any Notes are capable of being issued under the Programme and/or remain outstanding, copies of the following documents will, when published, be available from the registered office of the Issuer and the office of the Fiscal Agent:

(i) the constitutional documents (together with an English translation) of the Issuer (as the same may be updated from time to time);

(ii) the 2024 Annual Report on Form 20-F and the 2023 Annual Report on Form 20-F;

(iii) the Agency Agreement;

(iv) a copy of this Base Prospectus; and

(v) any future prospectuses (including Final Terms (save those Final Terms relating to an unlisted Note will only be available for inspection by a Holder of such Note and such Holder must produce evidence satisfactory to the Fiscal Agent as to the identity of such Holder)) and supplements to this Base Prospectus and any other documents incorporated herein or therein by reference.

This Base Prospectus and any supplement to this Base Prospectus will be made available on the website of the AMF (www.amf-france.org).

The documents listed in (i), (ii), (iv) and (v) above will be available on the website of the Issuer (www.sanofi.com)."

- Paragraph (7) of the section "*General Information*" on page 121 of the Base Prospectus entitled "***Trend Information and No Significant Change***" is deleted and replaced by the following:

"There has been no material adverse change in the prospects of the Issuer since 31 December 2024, nor has there been any significant change in the financial position or financial performance of the Issuer or of the Group since 31 December 2024".

- Paragraph (8) of the section "*General Information*" on page 121 of the Base Prospectus entitled "***Litigation and Arbitration Proceedings***" is deleted and replaced by the following:

"Save as disclosed under the heading "*Information on Legal or Arbitration Proceedings*" on page 162 and pages and F-82 to F-89 of the 2024 Annual Report on Form 20-F incorporated by reference herein, the Issuer has not been involved in any governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Issuer is aware) during the twelve (12) months before the date of this Base Prospectus which may have, or have had in the recent past, significant effects on the financial position or profitability of the Issuer and /or the Group."

- Paragraph (9) of the section "*General Information*" on page 121 of the Base Prospectus entitled "***Administrative, Management and Supervisory Bodies' Conflicts of Interest***" is deleted and replaced by the following:

"Sanofi's corporate governance structure is disclosed at "*Item 6. Directors, Senior Management and Employees*" on pages 93 to 119 of the 2024 Annual Report on Form 20-F incorporated by reference in the Base Prospectus; there has been no change to such corporate governance structure as of the date of this Supplement.

The Issuer believes that there are currently no potential conflicts of interest between the duties of the directors and chief corporate officers to the Issuer, their private interests or other duties.

The contact address of the directors and senior management is the same as the registered office of the Issuer as found on page 124 of the Base Prospectus."

- Paragraph (10) of the section "*General Information*" on page 121 of the Base Prospectus entitled "***Statutory Auditors***" is deleted and replaced by the following:

"Ernst & Young et Autres and PricewaterhouseCoopers Audit were the statutory auditors of the Issuer until 30 April 2024. Ernst & Young et Autres and PricewaterhouseCoopers Audit have audited or reviewed, and rendered unqualified reports on, the consolidated financial statements of the Issuer as at, and for period ended, 31 December 2023. Mazars was appointed as statutory auditors of the Issuer by shareholders' meeting of the Issuer (*assemblée générale des actionnaires*) on 30 April 2024, therefore Mazars and PricewaterhouseCoopers Audit are the statutory auditors of the Issuer and they have audited, and rendered unqualified reports on, the consolidated financial statements of the Issuer as at, and for period ended, 31 December 2024. Ernst & Young et Autres, PricewaterhouseCoopers Audit and Mazars are registered as *Commissaires aux Comptes* (members of the *Compagnie Nationale des Commissaires aux Comptes*) and regulated by the *Haute autorité de l'audit*."

PERSONS RESPONSIBLE FOR THE PROSPECTUS SUPPLEMENT

In the name of the Issuer

To the best of the knowledge of the Issuer, the information contained or incorporated by reference in this Supplement is in accordance with the facts and does not omit anything likely to affect the import of such information.

Sanofi
46, avenue de la Grande Armée,
75017 Paris

Duly represented by Olivier Klaric, Senior Vice President, Financing, Treasury & Insurance

Signed in Paris
Dated 3 March 2025

APPROVAL FROM THE AUTORITE DES MARCHES FINANCIERS

AMF | AUTORITÉ DES MARCHÉS FINANCIERS

This Supplement has been approved on 3 March 2025 under the approval number n°25-056 by the AMF, in its capacity as competent authority under Regulation (EU) 2017/1129.

The AMF has approved this Supplement after having verified that the information it contains is complete, coherent and comprehensible within the meaning of Regulation (EU) 2017/1129. The approval does not imply the verification of the accuracy of this information by the AMF.

This approval is not a favourable opinion on the Issuer and on the quality of the Notes described in this Supplement. Investors should make their own assessment of the opportunity to invest in such Notes.