

Sanofi Q3: 15.7% sales growth boosted by earlier-than-anticipated vaccine sales; 2024 business EPS guidance raised due to strong business performance

Paris, October 25, 2024

Q3 sales growth of 15.7% at CER and business EPS⁽¹⁾ of €2.86

- Dupixent sales up 23.8% to €3,476 million; full-year 2024 target of ~€13 billion confirmed
- Pharma launches up 67.1% to €727 million, led by ALTUVIIIQ, Nexviazyme and Rezurock
- Vaccines sales up 25.5%, boosted by phasing of flu sales, and by Beyfortus due to approved extra capacity
- Opella up 7.9%, driven by the Qunol acquisition
- Research and Development expenses grew 12.7%
- Selling, general and administrative expenses grew 6.4%, substantially below sales growth, having a positive impact on profitability
- Business EPS⁽¹⁾ of €2.86, +12.2% reported and +17.6% at CER and IFRS EPS of €2.25, +11.9% reported

Q3 pipeline progress

- Four regulatory approvals: Dupixent COPD (US, CN), Dupixent CRSwNP adolescents (US), and Sarclisa NDMM, TI (US)
- Four positive phase 3 data readouts: Dupixent BP, Dupixent CSU, tolebrutinib nrSPMS, and Sarclisa NDMM, TE

Opella (consumer healthcare)

- On October 21, Sanofi and CD&R entered exclusive negotiations to transfer a controlling stake of Opella.*

2024 business EPS⁽¹⁾ guidance

- On October 21, 2024, the 2024 business EPS⁽¹⁾ guidance was upgraded to growth of at least a low single-digit percentage at CER⁽²⁾ supported by the underlying strong business performance. This reflects the new scope of guidance excluding Opella detailed in the October 21, 2024 press release. Applying the average October 2024 exchange rates, the currency impact on 2024 business EPS⁽¹⁾ is estimated to be -5.5% to -6.5%.

Paul Hudson, Chief Executive Officer: “We reached almost 16% sales growth in the third quarter, illustrating the underlying strength of our portfolio. Our performance was boosted by the phasing of flu and Beyfortus, while we saw steady growth of 67% for our launch medicines as well as volume-driven growth by Dupixent. Dupixent is now approved as the first-ever biologic medicine to treat COPD across the EU, China, and the US allowing us to bring this innovative new treatment to hundreds of thousands of patients. Our pipeline-driven transformation continued to progress with the delivery of four new approvals and four positive phase 3 data readouts, including for tolebrutinib in secondary progressive multiple sclerosis, a disease with significant unmet medical need. We entered exclusive negotiations with CD&R on a controlling stake in Opella, allowing Sanofi to focus on innovative medicines and vaccines. Based on the strong business performance in the quarter, we recently upgraded our business EPS guidance. This momentum is already paving the way for the strong rebound we said we expected in 2025 business EPS.”

		Q3 2024	Change	Change at CER		YTD 2024	Change	Change at CER
IFRS net sales reported	€	13,438 m	+12.3%	+15.7%	€	34,647 m	+7.8%	+11.1%
IFRS net income reported	€	2,815 m	+11.5%	—	€	5,061 m	-15.0%	—
IFRS EPS reported	€	2.25	+11.9%	—	€	4.05	-14.9%	—
Free cash flow ⁽³⁾	€	3,327 m	+79.5%	—	€	3,872 m	-22.3%	—
Business operating income	€	4,607 m	+14.4%	+19.9%	€	10,263 m	+1.7%	+8.8%
Business net income ⁽¹⁾	€	3,585 m	+12.2%	+17.5%	€	7,965 m	-1.3%	+5.5%
Business EPS ⁽¹⁾	€	2.86	+12.2%	+17.6%	€	6.37	-1.2%	+5.6%

*Changes in net sales are expressed at constant exchange rates (CER) unless stated otherwise (definition in Appendix 7). (1) In order to facilitate an understanding of operational performance, Sanofi comments on the business net income statement. Business net income is a non-IFRS financial measure (definition in Appendix 7). The consolidated income statement for Q3 and YTD 2024 is provided in Appendix 3 and a reconciliation of reported IFRS net income to business net income is set forth in Appendix 4. (2) Based on 2023 preliminary business EPS of €7.25 excluding Opella. (3) Free cash flow is a non-IFRS financial measure (definition in Appendix 7). *The proposed transaction is subject to finalization of definitive agreements, completion of the appropriate social processes and subject to customary closing conditions.*

Q3 and YTD 2024 summary

A conference call and webcast for investors and analysts will begin at 14:00 CEST. Details can be accessed via sanofi.com, including presentation slides.

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The performance shown in this press release covers the three-month period to September 30, 2024 (the quarter or Q3 2024) and the nine-month period to September 30, 2024 (the year to date or YTD 2024) compared to the three-month period to September 30, 2023 (Q3 2023) and the nine-month period to September 30, 2023 (the year to date or YTD 2023) respectively. All percentage changes in sales in this press release are at CER¹, unless stated otherwise.

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In Q3 2024, sales were €13,438 million and increased by 15.7%. Exchange rate movements had a negative effect of 3.4 percentage points (pp); therefore, as reported, sales increased by 12.3%. In YTD 2024, sales were €34,647 million and increased by 11.1%. Exchange rate movements had a negative effect of 3.3pp; reported, sales increased by 7.8%. The commentary below emphasizes the recent quarterly performance unless stated otherwise.

Sales by segment and business

Net sales (€ million)	Q3 2024	Change at CER	% of total sales	YTD 2024	Change at CER	% of Total sales
Biopharma	12,167	+16.6%	90.5%	30,545	+11.5%	88.2%
Pharma	8,365	+13.0%	62.2%	24,424	+10.7%	70.5%
Vaccines	3,802	+25.5%	28.3%	6,121	+14.5%	17.7%
Opella	1,271	+7.9%	9.5%	4,102	+8.8%	11.8%
Total	13,438	+15.7%	100%	34,647	+11.1%	100%

Sales by geography

Net sales (€ million)	Q3 2024	Change at CER	YTD 2024	Change at CER
United States	6,886	+23.6%	15,953	+17.6%
Europe	2,886	+6.6%	7,768	+0.2%
Rest of World	3,666	+10.3%	10,926	+10.8%
of which China	757	+3.6%	2,279	+3.0%

US sales were €6,886 million and increased by 23.6%. The strong performance was driven by new launches, including Beyfortus, and by Dupixent, insulins and all Vaccines businesses with sales of legacy medicines slightly offsetting growth.

Europe sales were €2,886 million and increased by 6.6%. Growth was driven by new launches, Dupixent, and Vaccines. Some legacy medicines declined, including Aubagio from generic competition.

Rest of World sales were €3,666 million and increased by 10.3%. Performance was led by Dupixent and Vaccines, and partly by new launches and Toujeo. **China** sales were €757 million and increased by 3.6%, driven by strong performance by Dupixent mostly offset by Lovenox and Other medicines. With higher inflation, the contribution of Argentina to the total Sanofi sales growth rate was 1.2pp.

Business operating income

In Q3 2024, business operating income (BOI) was €4,607 million and increased by 14.4% (19.9% at CER). The ratio of BOI to net sales was 34.3% and increased by 0.6pp (34.9% at CER, up by 1.2pp). This improvement was mainly driven by a higher gross margin and operating leverage. In YTD 2024, BOI was €10,263 million and increased by 1.7% (8.8% at CER). The ratio of BOI to net sales was 29.6% and decreased by 1.8pp (30.7% at CER, down by 0.7pp).

Business development

Business development, including strategic investments in external innovation is an integrated part of Sanofi's efforts to continuously access optionality on new and promising scientific developments and platforms and replenish the pipeline.

In September, Sanofi made an equity investment of \$40 million in Ventyx Biosciences, Inc. (NASDAQ: VTYX), a clinical-stage biopharmaceutical company in autoimmune and inflammatory disorders. Ventyx granted Sanofi an exclusive right of first negotiation to an NLRP3 inhibitor. Sanofi also participated in the rights issue for \$10 million in Vicore Pharma Holding AB (STO: VICO), a clinical-stage pharmaceutical company in respiratory and fibrotic diseases, including idiopathic pulmonary fibrosis.

¹ See Appendix 7 for definitions of financial indicators.

Further in September, Sanofi entered an exclusive licensing agreement with RadioMedix, Inc. and Orano Med for the late-stage project, AlphaMedix™ (²¹²Pb-DOTAMTATE), for the treatment of adult patients with unresectable or metastatic, progressive somatostatin-receptor expressing neuroendocrine tumors, a rare cancer.

In August, Sanofi made two equity investments, including \$30 million in MeiraGTx Holdings plc (NASDAQ: MGTX), a clinical-stage genetic medicine company, and \$40 million in AnaptysBio (NASDAQ: ANAB), a clinical-stage biotechnology company focused on immunology therapeutics, including in rheumatoid arthritis and ulcerative colitis.

Biopharma

The **Biopharma** segment includes Pharma and Vaccines. In Q3 2024, sales were €12,167 million and increased by 16.6%, driven by continued strong performance of new launches and Dupixent growth. The divestments of medicines/portfolio streamlining had a negative impact of 0.7pp. In YTD 2024, sales were €30,545 million and increased by 11.5% driven by the same aforementioned factors.

Pharma

Pharma launches

Net sales (€ million)	Q3 2024	Change at CÉR	YTD 2024	Change at CÉR
ALTUVIIIIO	172	+278.3%	452	+600.0%
Nexviazyme/Nexviadyme	163	+53.6%	483	+69.7%
Rezurock	131	+57.8%	338	+50.9%
Sarclisa	114	+23.7%	341	+29.5%
Cablivi	63	+12.5%	176	+4.7%
Xenpozyme	41	+51.9%	113	+75.4%
Enjaymo	28	+81.3%	83	+75.5%
Tzield	15	+66.7%	36	+140.0%
Total	727	+67.1%	2,022	+78.2%

ALTUVIIIIO (hemophilia A) sales were €172 million of which more than 90% were in the US. Growth continued to be driven by patient switches from existing factor medicines, including some from Eloctate, and from non-factor medicines. The hemophilia A franchise (ALTUVIIIIO + Eloctate) sales were €268 million and increased by 63.3%, increasing market share.

Nexviazyme/Nexviadyme (Pompe disease) sales were €163 million and increased by 53.6%. Growth was higher in Europe (104.3%) and the Rest of World (121.4%). Growth in the US was 24.7% where most patients have already converted from Myozyme/Lumizyme. The Pompe franchise (Nexviazyme/Nexviadyme + Myozyme/Lumizyme) sales were €331 million and increased by 15.2%. Nexviazyme/Nexviadyme sales now accounts for 49% of the total Pompe franchise.

Rezurock (chronic graft-versus-host disease) sales were €131 million and increased by 57.8%, driven by fast uptake in launch countries, including the US, China, and the UK, and persistence in use by patients.

Sarclisa (multiple myeloma) sales were €114 million and increased by 23.7%. Growth was driven by market share gains in Europe, and by the Rest of World, specifically Japan.

Cablivi (acquired thrombotic thrombocytopenic purpura) sales were €63 million and increased by 12.5%, driven by patient growth in the US.

Xenpozyme (acid sphingomyelinase deficiency) sales were €41 million and increased by 51.9%, driven by more patients across all regions.

Enjaymo (cold agglutinin disease) sales were €28 million and increased by 81.3%, driven by all regions. On October 4, 2024, Recordati announced the acquisition of global rights to Enjaymo. The transaction is expected to close this quarter.

Tzield (delay onset of type 1 diabetes) sales were €15 million, a sequential increase from Q2 2024 of €4 million, mostly reflecting continued growth in infusions supported by ongoing efforts to increase awareness and screening.

Immunology

Net sales (€ million)	Q3 2024	Change at CÉR	YTD 2024	Change at CÉR
Dupixent	3,476	+23.8%	9,614	+25.9%

Dupixent sales were €3,476 million and increased by 23.8%. In the US, sales were €2,556 million and increased by 19.1%. Growth was driven by strong demand in the approved indications of atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis and prurigo nodularis. In Europe, Dupixent sales were €417 million and increased by 35.1% reflecting continued growth in all approved indications and emerging sales in COPD. In the Rest of World, sales were €503 million and increased by 41.9%, driven mainly by sales in Japan and China. In YTD 2024, Dupixent sales were €9,614 million and increased by 25.9%, on track to achieve ~€13 billion in sales in 2024 at constant exchange rates. More than one million patients are currently being treated with Dupixent globally.

Other main medicines

Net sales (€ million)	Q3 2024	Change at CÉR	YTD 2024	Change at CÉR
Lantus	431	+33.8%	1,189	+10.6%
Toujeo	303	+18.1%	937	+15.6%
Fabrazyme	253	+4.0%	779	+8.0%
Lovenox	233	-1.2%	751	-7.1%
Plavix	230	+8.3%	703	+5.6%
Myozyme/Lumizyme	168	-7.5%	539	-11.1%
Cerezyme	164	+8.0%	571	+17.0%
Alprolix	148	+8.7%	419	+6.3%
Praluent	126	+10.4%	373	+23.7%
Thymoglobulin	121	+4.1%	367	+4.9%
Eloctate	96	-19.2%	287	-20.7%
Aubagio	92	-52.3%	301	-62.8%
Cerdelga	81	+12.3%	246	+11.7%

Lantus sales were €431 million and increased by 33.8%. US sales were €175 million and increased by 162.7%, benefiting from another quarter of windfall sales due to the continued unavailability of a competing medicine as well as a lower base of comparison from net-price adjustments.

Toujeo sales were €303 million and increased by 18.1%, mainly driven by the Rest of World, including China where Toujeo continued to increase its basal insulin market share. US sales benefited from the continued unavailability of a competing medicine.

Fabrazyme sales were €253 million and increased by 4.0%, mainly driven by growth in the number of patients.

Lovenox sales were €233 million and decreased by 1.2%, reflecting the impact from volume-based procurement in China and biosimilar competition in the EU.

Plavix sales were €230 million and increased by 8.3%, underpinned by increased use and market share in the Rest of World, including China from the inclusion in volume-based procurement.

Myozyme/Lumizyme sales were €168 million and decreased by 7.5% due to the conversion to Nexviazyme/Nexviadyne.

Cerezyme sales were €164 million and increased by 8.0%, driven by growth in the number of patients in the Rest of World. The Gaucher disease franchise (Cerezyme + Cerdelga) sales were €245 million and increased by 9.2%.

Alprolix sales were €148 million and increased by 8.7%, driven by supply sales to the partner.

Praluent sales were €126 million and increased by 10.4%, underpinned by Europe.

Thymoglobulin sales were €121 million and increased by 4.1%, mostly reflecting increased sales in the Rest of World.

Eloctate sales were €96 million and decreased by 19.2%, mainly due to patients converting to ALTUVIII O in the US.

Aubagio sales were €92 million and decreased by 52.3%, reflecting the loss of exclusivity starting in the US in March 2023 followed by Europe in September 2023. Aubagio sales are expected to continue to decrease albeit at a slower rate.

Cerdelga sales were €81 million and increased by 12.3%, primarily driven by the US and an increased number of patients.

Vaccines

Net sales (€ million)	Q3 2024	Change at CÉR	YTD 2024	Change at CÉR
Influenza vaccines	1,913	+10.9%	2,101	+12.3%
Polio/Pertussis/Hib vaccines incl. Boosters	760	+2.0%	2,108	-1.2%
RSV (Beyfortus)	645	+381.8%	845	+537.2%
Meningitis, Travel and endemic vaccines	485	+13.1%	1,067	+7.9%
Total	3,802	+25.5%	6,121	+14.5%

Vaccines sales were €3,802 million and increased by 25.5%, driven by Beyfortus rollout and boosted by the earlier phasing of both flu and Beyfortus deliveries. In YTD 2024, sales were €6,121 million and increased by 14.5%, driven mainly by Beyfortus, partly offset by the absence of COVID-19 sales compared to €226 million in YTD 2023.

Influenza vaccines sales reached €1,913 million and increased by 10.9%, boosted by earlier-than-anticipated deliveries.

Polio/Pertussis/Hib (PPH) vaccines sales were €760 million and increased by 2.0%, with a favorable benefit from slightly increased Boosters demand in several countries.

Beyfortus sales were €645 million, driven by early deliveries in the US and rollout in a number of countries, including Canada, France, Germany, Spain, Portugal, Belgium, and Ireland. In collaboration with AstraZeneca, responsible for manufacturing, increased supply was enabled by additional capacity after a second, external filling line was licensed.

Meningitis, Travel and endemic vaccines sales were €485 million and increased by 13.1% reflecting growth in all regions. In the US, Meningitis benefited from favorable Centers for Disease Control and Prevention buying patterns.

Biopharma business operating income

In Q3 2024, Biopharma BOI was €4,340 million and increased by 15.8% (21.2% at CER). The ratio of BOI to net sales was 35.7% and increased by 0.7pp (36.3% at CER, up by 1.3pp). This improvement was mainly driven by a higher gross margin and operating leverage. In YTD 2024, BOI was €9,271 million and increased by 3.4% (9.8% at CER). The ratio of BOI to net sales was 30.4% and decreased by 1.4pp (31.3% at CER, down by 0.5pp).

Pipeline update

Sanofi has 78 projects in a pipeline across four main disease areas (Immunology, Rare diseases, Neurology, and Oncology) and Vaccines, including 36 potential new medicines (NMEs) and vaccines. The following section highlights significant developments in the late- and mid-stage pipeline in the quarter:

Highlights

Regulatory approvals	Dupixent – COPD (US, CN) Dupixent – CRSwNP adolescents (US) Sarclisa – NDMM, TI (IMROZ study) (US)
Regulatory recommendations	Dupixent – EoE children (EU) Cerdelga – GD1 children (EU)
Regulatory submission acceptances	MenQuadfi – Meningitis six weeks+ (US) Rezurock – cGvHD, 3L (EU)
Phase 3 data readouts	Dupixent – CSU (Study C) (primary endpoint met) Dupixent – CPUO (Study A) (primary endpoint not met) Dupixent – BP (primary endpoint met) tolebrutinib – RMS (primary endpoint not met) tolebrutinib – nrSPMS (primary endpoint met) losmapimod – FSHD (primary endpoint not met) Sarclisa – NDMM, TE (HD7 study) (primary endpoint met)

Immunology

Dupixent (dupilumab)

- The US Food and Drug Administration (FDA) approved Dupixent as an add-on maintenance treatment of adults with inadequately controlled **chronic obstructive pulmonary disease** (COPD) and an eosinophilic phenotype. Dupixent is the first biologic medicine approved in the US to treat these patients. The National Medical Products Administration in China approved Dupixent as an add-on maintenance treatment for adults with uncontrolled **COPD** characterized by raised blood eosinophils. Specifically, the approval covers patients already on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate. Dupixent for the treatment of COPD has now been approved in more than 30 countries worldwide, including the 27 countries in the EU.
- The FDA approved Dupixent as an add-on maintenance treatment for adolescent patients aged 12 to 17 years with inadequately controlled **chronic rhinosinusitis with nasal polyps** (CRSwNP). This approval expands the initial FDA approval in CRSwNP from June 2019 for patients aged 18 years and older. The FDA evaluated Dupixent for this expanded indication under a priority review.
- The European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the expanded approval of Dupixent in the EU for **eosinophilic esophagitis** (EoE) in children down to one year of age. The recommendation is for children aged one to 11 years who weigh at least 15 kg and who are inadequately controlled by, intolerant to, or who are not candidates for conventional medicinal therapy, supported by the two-part (Part A and B) EoE KIDS phase 3 study (clinical study identifier: NCT04394351). The European Commission is expected to announce a final decision in the coming months. Dupixent is already approved in the EU for certain adults and adolescents aged 12 years and older with EoE.
- Dupixent's confirmatory LIBERTY-CUPID Study C phase 3 study (clinical study identifier: NCT04180488) met the primary and key secondary endpoints for the treatment of patients with uncontrolled, biologic-naïve **chronic spontaneous urticaria** (CSU) receiving background therapy with antihistamines. CSU is a chronic skin condition that causes sudden and debilitating hives and persistent itch, which can impact quality of life. This positive study confirms results from Study A, the first phase 3 study of Dupixent in this setting. Earlier this year, Japan was the first country in the world to approve and launch Dupixent for adult and adolescent CSU patients based on the results from Study A. The indication is under review in the EU based on results from Study A and Study B (patients uncontrolled on standard-of-care H1 antihistamines and refractory to omalizumab), and the new Study C data will support regulatory resubmission in the US by the end of the year.
- The LIBERTY-CPUO-CHIC Study A phase 3 study (clinical study identifier: NCT05263206) evaluating the use of Dupixent in adults with uncontrolled and severe **chronic pruritus of unknown origin** (CPUO) did not achieve statistical significance in its primary itch responder endpoint (despite favorable numerical improvements), but showed nominally significant improvements in all other itch endpoints. The Dupixent phase 3 study program in CPUO consists of Study A and Study B. Study B is planned to initiate as a subsequent pivotal study.

- Dupixent’s pivotal LIBERTY-BP phase 3 study (clinical study identifier: NCT04206553) in **bullous pemphigoid** (BP) met the primary and all key secondary endpoints evaluating its use in adults with moderate-to-severe disease. Dupixent was previously granted orphan drug designation by the FDA for BP, which applies to medicines intended for the treatment of rare diseases that affect fewer than 200,000 people in the US. This study will support regulatory submissions around the world in the first half of 2025. BP is a chronic and relapsing disease, characterized by intense itch and blisters, reddening of the skin, and painful chronic lesions. The blisters and rash can form over much of the body and cause the skin to bleed and crust, resulting in patients being more prone to infection and affecting their daily functioning.

Rezurock (belumosudil)

The EMA accepted for review the regulatory submission of Rezurock for the treatment of **chronic graft-versus-host disease** (cGVHD), third line (3L). The EMA granted an orphan designation in 2019 for the treatment of cGVHD, and Rezurock, first approved by the FDA in 2021, is now approved in 14 other countries, including China, the UK and Canada.

amlitelimab (OX40L mAb)

- The amlitelimab proof-of concept TIDE-Asthma phase 2 study (clinical study identifier: NCT05421598) in **moderate-to-severe asthma** has a 60-week double-blind placebo-controlled period, in which patients are dosed once every four weeks during the initial 24 weeks and once every 12 weeks for the subsequent 36 weeks. Sanofi anticipates the internal data availability of top-line results for the full and completed 60-week treatment and follow-up period to move over the year-end and into H1 2025.
- The ASPIRION phase 2 study (clinical study identifier: NCT06557772) assessing efficacy and safety of subcutaneous injections of amlitelimab in adults with non-responsive **celiac disease** has commenced dosing its first patient.

lunsekimig (IL13xTSLP Nanobody® VHH)

A proof-of-concept phase 2 study (clinical study identifier: NCT06454240) assessing efficacy and safety of lunsekimig compared with placebo in adults with **CRSwNP** has commenced dosing its first patient.

Rare diseases

ALTUVIIIIO (efanesoctocog alfa)

The New England Journal of Medicine published full results from the second pivotal phase 3 study, XTEND-Kids (clinical study identifier: NCT04759131), highlighting efficacy, safety, and the pharmacokinetic profile of ALTUVIIIIO, as a first-in-class, high-sustained factor VIII replacement therapy, for adults and children with **hemophilia A** for routine prophylaxis and on-demand treatment to control bleeding episodes as well as for perioperative management (surgery). In May, FDA updated the label for ALTUVIIIIO to include the results from the XTEND-Kids phase 3 study in children with hemophilia A.

fitusiran (RNAi targeting antithrombin)

Sanofi’s collaborator Siemens Healthineers has submitted for FDA review the INNOVANCE® Antithrombin Assay as a **companion diagnostic** that will measure antithrombin levels in people living with hemophilia who are prescribed fitusiran, a potential antithrombin-lowering medicine for the prophylactic treatment of people with **hemophilia A or B**, with or without inhibitors. The prescription drug user fee act (PDUFA) action date for fitusiran is March 28, 2025.

rilzabrutinib (BTK inhibitor)

During the quarter, a single-arm phase 2 study (clinical study identifier: NCT05002777) of rilzabrutinib in **warm autoimmune hemolytic anemia** read out positively with clinically meaningful outcomes on response rate and additional disease markers. Data are planned to be shared at a medical meeting later this year. The results of this study build on the successful phase 3 study in immune thrombocytopenic purpura (ITP) and reinforce its efficacy in autoimmune cytopenias.

losmapimod (p38α/β MAPK inhibitor)

Fulcrum announced that the losmapimod REACH phase 3 study (clinical study identifier: NCT05397470) assessing efficacy and safety in adults with **facioscapulohumeral muscular dystrophy** (FSHD) did not meet the primary endpoint.

Cerdelga (eliglustat)

The CHMP adopted a positive opinion recommending the expanded approval of Cerdelga to include treatment of pediatric patients with **Gaucher disease type 1** (GD1), who are six years and older with a minimum body weight of 15 kg, who have been previously treated with enzyme replacement therapy, and who are CYP2D6 poor metabolizers, intermediate metabolizers or extensive metabolizers. The EMA granted an orphan designation in 2007 for the treatment of GD1, and Cerdelga is approved in the US and EU for adults patients with GD1.

Neurology

tolebrutinib (BTK inhibitor)

Positive results from the HERCULES phase 3 study (clinical study identifier: NCT04411641) showed that tolebrutinib met the primary endpoint of improvement over placebo in delaying time to onset of confirmed disability progression (CDP) in people with non-relapsing **secondary progressive multiple sclerosis** (nrSPMS). Specifically, tolebrutinib delayed the time to onset of 6-month CDP by 31% (HR 0.69; 95% CI 0.55-0.88; p=0.0026). Further analysis of secondary endpoints showed that the number of participants who experienced confirmed disability improvement increased by nearly two-fold, 10% with tolebrutinib compared to 5% with placebo (HR 1.88; 95% CI 1.10 to 3.21; nominal p=0.021).

In the HERCULES study, nrSPMS was defined at baseline as having a SPMS diagnosis with an expanded disability status scale score between 3.0 and 6.5, no clinical relapses for the previous 24 months and documented evidence of disability accumulation in the previous 12 months. Preliminary analysis of liver safety was consistent with previous tolebrutinib studies.

Results from the GEMINI 1 and 2 phase 3 studies (clinical study identifiers: NCT04410978/NCT04410991, respectively) evaluating tolebrutinib did not meet the primary endpoint of reducing annualized relapse rate, compared to Aubagio, a standard of care treatment, in people with **relapsing MS** (RMS). However, analysis of the key secondary endpoint of pooled 6-month CDW data showed a considerable delay in time to onset, which supports the CDP data observed in HERCULES.

These results were presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) conference 2024 in Copenhagen, Denmark. Sanofi expects making regulatory submissions in SPMS starting this quarter.

frexalimab (CD40L mAb)

New efficacy and safety data at 18 months from the phase 2 open-label extension study of frexalimab (clinical study identifier: NCT04879628), for the treatment of **RMS**, demonstrated sustained reduction of disease activity as measured by MRI, with stable clinical surrogate endpoints. Frexalimab remained well tolerated with no new safety signals. These results were also presented at ECTRIMS 2024 and support the ongoing clinical development with two phase 3 studies in RMS and one phase 3 study in nrSPMS.

oditrasertib (RIPK1 inhibitor)

The K2 phase 2 study (clinical study identifier: NCT05630547) evaluating safety and the efficacy of oditrasertib on serum neurofilament light chain levels in patients with **MS** was discontinued based on not meeting the primary and key secondary endpoints.

Oncology

Sarclisa (isatuximab)

- The FDA approved Sarclisa in combination with bortezomib, lenalidomide, and dexamethasone (VRd) as a first-line treatment option for adult patients with **newly diagnosed multiple myeloma** who are not eligible for autologous stem cell transplant (NDMM, TI). Sarclisa is the first anti-CD38 therapy in combination with standard-of-care VRd to significantly reduce disease progression or death (by 40%, HR 0.60; 95% CI: 0.44 to 0.81, p=0.0009) compared to VRd alone for patients with NDMM not eligible for transplant. Other regulatory submissions based on the IMROZ phase 3 study (clinical study identifier: NCT03319667) in this third indication for Sarclisa are currently under review in the EU, Japan, and China.
- New results from the two-part, double-randomized, German-speaking Myeloma Multicenter Group (GMMG)-HD7 phase 3 study (clinical study identifier: NCT03617731) showed that Sarclisa in combination with lenalidomide, bortezomib, and dexamethasone (RVd) during induction therapy in **NDMM**, transplant-eligible (TE), significantly prolonged progression-free survival from first randomization, resulting in a statistically significant and clinically meaningful reduction in disease progression or death, compared to RVd induction regardless of the maintenance regimen. Full results will be submitted for presentation at a forthcoming medical meeting with regulatory submission later this year in the EU.

Vaccines

Beyfortus (nirsevimab)

New data from the HARMONIE phase 3b study (clinical study identifier: NCT05437510) demonstrated that Beyfortus consistently reduced **respiratory syncytial virus (RSV) hospitalizations** by 82.7% (95% CI: 67.8% to 91.5%) through six months (180 days) with no evidence of waning protection after dosing compared to no intervention. Beyfortus also reduced RSV lower respiratory tract disease in infants by 87.2% (95% CI: 81.7% to 91.1%), regardless of the healthcare setting (outpatient, emergency department or inpatient) compared to no RSV intervention, according to new real-world

evidence from the Beyfortus Effectiveness Against medically attended RSV events in infants (BEAR) study following 31,900 US healthy infants in their first RSV season. These findings confirm the significant positive efficacy and safety profile that Beyfortus demonstrated in multi-country, real-world conditions over a long period of time.

MenQuadfi (quadrivalent meningococcal vaccine)

The FDA accepted for review the supplemental biologics license application for MenQuadfi (clinical study identifier: NCT03547271) for the potential extension of the indication to include children aged six weeks to 23 months through active immunization for the prevention of invasive **meningococcal disease** caused by *Neisseria meningitidis* serogroups A, C, W, and Y. The PDUFA date is May 23, 2025.

NVX-CoV2705 (COVID-19 vaccine)

The EMA approved and the FDA authorized for emergency use the updated Novavax protein-based **COVID-19** vaccine. The vaccine has been refined to also target the JN.1 parent strain of the COVID-19 virus. A regulatory submission for full approval in the US is being prepared. In 2025, Sanofi will take on the commercialization from Novavax.

Anticipated major upcoming pipeline milestones

	Medicine/vaccine	Indication	Description
H2 2024	Dupixent	EoE children	Regulatory decision (EU)
		CSU (Study C)	Regulatory submission (US)
	rilzabrutinib	ITP	Regulatory submission (US, EU)
		IgG4-related disease	Phase 2 data
	duvakitug	Inflammatory bowel disease	Phase 2 data
	tolebrutinib	Secondary progressive MS	Regulatory submission (US)
	Cerezyme	Gaucher disease type 3	Regulatory submission (US)
Cerdelga	Gaucher disease type 1 children	Regulatory decision (EU)	
H1 2025	Dupixent	COPD	Regulatory decision (JP)
		BP	Regulatory submission
		CSU	Regulatory decision (EU)
	amlitelimab	Asthma	Phase 2 data
		Hidradenitis suppurativa (HS)	Phase 2 data
	Oral TNFR1si	Psoriasis	Phase 2 data
	TNFa/OX40L	HS	Phase 2 data
	IRAK4 degrader	HS	Phase 2 data
		AD	Phase 2 data
	fitusiran	Hemophilia A/B	Regulatory decision (US)
	rilzabrutinib	ITP	Regulatory submission (JP, CN)
	tolebrutinib	Secondary progressive MS	Regulatory submission (EU)
	Sarclisa	NDMM, TI (IMROZ)	Regulatory decision (EU, JP, CN)
MM, R/R (IRAKLIA), subcutaneous		Regulatory submission (US, EU)	
MenQuadfi	Meningitis six weeks+	Regulatory decision (US)	
SPO087	Rabies	Phase 3 data	
H2 2025	itepekimab	COPD	Phase 3 data
			Regulatory submission (US, EU)
	lunsekimig	Asthma	Phase 2 data
	Oral TNFR1si	Rheumatoid arthritis	Phase 2 data
	AAT recombinant Fc	Alpha-1 antitrypsin deficiency	Phase 2 data
	fitusiran	Hemophilia A/B	Regulatory decision (CN)
		Fabry disease	Phase 3 data
	venglustat	Gaucher disease type 3	Phase 3 data
			Phase 3 data
	tolebrutinib	Primary progressive MS	Regulatory submission (US)
	Rezurock	Chronic graft-versus-host disease, third line	Regulatory decision (EU)
	Tzield	Delay onset of type 1 diabetes	Regulatory decision (CN)
SPO087	Rabies	Regulatory submission (US)	
SPO230	Meningitis	Phase 2 data	
SPO256	RSV older adults	Phase 2 data	

An update of the Sanofi pipeline as of September 30, 2024, is available at: <https://www.sanofi.com/en/our-science/our-pipeline>.

Opella (consumer healthcare)

Net sales (€ million)	Q3 2024	Change at CER	YTD 2024	Change at CER
Wellness brands	574	+24.9%	1,832	+22.5%
Seasonal symptoms & pain relief	538	-3.1%	1,754	-1.1%
Others	159	-4.1%	516	+1.5%
Total	1,271	+7.9%	4,102	+8.8%

Opella sales were €1,271 million and increased by 7.9%. Growth was enhanced by the acquisition of Qunol (c.5%), organic sales growth (c.3%), and industrial sales transferred from Biopharma in January 2024 (c.2%) but tempered by divestments (c.2%). In North America, growth benefited mainly from the Qunol acquisition with some impacts from lower demand in the Seasonal symptoms & pain relief category, more specifically in allergy. Europe delivered steady sales with improving in-market performance supported by price, offset by negative volume impact. In the Rest of World, sales were driven by the Wellness category. In YTD 2024, sales increased by 8.8%, driven by Qunol (c.6%), organic growth (c.3%) and industrial sales (c.2%). This momentum was partially offset by the negative effect of divestments linked to strategic portfolio rationalization (c.2%).

Opella business operating income

In Q3 2024, Opella BOI was €287 million and increased by 1.1% (12.0% at CER). The ratio of BOI to net sales was 22.6% and decreased by 0.2pp (23.7% at CER, up by 0.9pp). This development was mainly driven by a higher gross margin, lower R&D expenses, and higher other operating income partly offset by higher SG&A expenses. In YTD 2024, BOI was €1,026 million and decreased by 9.5% (increased by 1.7% at CER). The ratio of BOI to net sales was 25.0% and decreased by 3.6pp (26.7% at CER, down by 1.9pp).

For future Opella reporting and accounting, please refer to the separate press release from October 21, 2024.

Corporate Social Responsibility update at the end of Q3 2024

Access

Living wage pledge

In many countries, minimum wages are insufficient to guarantee that workers and their families can meet basic needs. Sanofi is proud to go beyond the minimum by committing to a living wage for all employees.

Since 2023, Sanofi has adopted the Fair Wage Network's methodology to ensure every employee earns above their respective local living wage benchmarks. Providing a living wage not only improves employees' health and well-being but also strengthens local economies.

As a Living Wage employer and a proud signatory of the UN Global Compact's Forward Faster initiative, Sanofi is setting a new standard.

Sanofi's commitment to fair wages extends beyond the workforce, and the company will continue to advocate for living wages across key supply chain partners.

Raise your voice: the annual DE&I report

In the annual diversity, equity and inclusion (DE&I) Report, Sanofi takes stock of progress on the three pillars of the DE&I strategy.

On the 'building representative leadership' pillar:

- 45%¹ of senior leaders are women (2025 ambition: 50%)
- 42%¹ of executives are women (2025 ambition: 40%+)

On the 'creating an inclusive work environment' pillar:

- Grade of 8.1 out of 10 on the internal DE&I index in the latest "Your voice" survey, with a 2025 target score above 8 (grade of 8 in 2022)
- 95% of audited workplaces ranked bronze or higher for accessibility, with a 2025 ambition of 100%

On the 'beyond the workplace' pillar:

- €1.45 billion spend is made with small and diverse businesses with a 2025 ambition of €1.5 billion
- all clinical studies in the US have set diversity targets

(1) As of Q3 2024

"Cancer & Work: Acting Together": a holistic approach to care for Sanofi employees

"Cancer & Work: Acting Together" has been rolled out internationally since early 2024. It is a holistic approach that is based on three pillars: a human resources policy that offers a high degree of social protection, an international network of employees trained in counseling who run confidential listening and exchange spaces for personalized support, and active communication that sheds light on the issues of cancer and other critical illnesses.

- Since January 1, 2024, the program's flagship measure - 12 months' salary, social protection and employment guarantee - has been in place for all employees affected by cancer, regardless of their geographical location. In the interests of fairness and inclusion, Sanofi has also extended this coverage to other serious illnesses.
- To date, the international network has 113 Sanofi employees in 36 countries, all of whom have completed a 10-hour training program in "Cancer & Work" counseling. The network is structured geographically to offer locally-adapted actions and support, and is also connected globally on a monthly basis to develop its knowledge and practices.
- Finally, a worldwide awareness campaign has been launched in October to raise awareness amongst employees on the challenges of prevention, screening and "Cancer & Work" support, to promote the program and to develop an inclusive culture.

ESG ratings

See Sanofi's latest ESG rankings below:

Sanofi ESG ratings

Rating agencies

        								
Q3 2024								
= A	= 18.8 Low risk	▼ 57/100	= 87/100	= Climate Change: A- = Water: A-	= B	= 4.5/5	= 3.47/5	= 65/100
Q2 2024								
A	18.8	77/100	87/100	A-/A-	B	4.5/5	3.47/5	65/100
Score stable since 2021	17th among 451 pharmaceutical companies	Score change related to the impact of legacy alleged controversies (-24/100)	Disclosure score of 87/100 vs. a 67/100 average for the healthcare sector 2023 WDI Awards Special mention for Workforce Action	Score decreased due to non climate related legacy controversies	1 st decile of the 546 companies in the industry	With very high rating across the 3 pillars ESG	Top 10 company	Compared to an average sector score of 38/100

▲ vs. previous rating
▼

Scores assigned by the rating agencies are not equivalent.

Q3 and YTD 2024 financial results

Business net income²

Net sales were €13,438 million and increased by 12.3% (15.7% at CER). In YTD 2024, net sales were €34,647 million and increased by 7.8% (11.1% at CER).

Other revenues were €719 million and decreased by 2.0% (0.7% at CER), including VaxServe sales of non-Sanofi products of €545 million (decreased by 11.4% at CER). In YTD 2024, other revenues were €2,008 million and decreased by 4.0% (0.8% at CER), including VaxServe sales of non-Sanofi products of €1,399 million (decreased by 3.6% at CER).

Gross profit was €10,074 million and increased by 13.7% (17.4% at CER). The gross margin was 75.0% and increased by 1.0pp (75.1% at CER, up by 1.1pp). The higher gross margin benefited from overall improved product and country mix in Biopharma and the reducing impact from the loss of exclusivity for Aubagio. In YTD 2024, the gross profit was €25,742 million and increased by 7.0% (11.0% at CER). The gross margin was 74.3% and decreased by 0.5pp (74.7% at CER, down by 0.1pp).

Research and Development expenses were €1,852 million and increased by 11.4% (12.7% at CER). This reflected increased activity in mid- and late-stage development. The ratio of R&D to net sales was 13.8% and decreased by 0.1pp. In YTD 2024, R&D expenses were €5,275 million and increased by 8.6% (10.0% at CER). The ratio of R&D to net sales was 15.2% and increased by 0.1pp.

Selling, general and administrative expenses were €2,681 million and increased by 4.0% (6.4% at CER), substantially less than sales growth. The ratio of SG&A to net sales was 20.0% and decreased by 1.6pp. In YTD 2024, SG&A expenses were €7,941 million and increased by 2.3% (4.7% at CER). The ratio of SG&A to net sales was 22.9% and decreased by 1.2pp.

Total operating expenses were €4,533 million and increased by 6.9% (8.9% at CER). In YTD 2024, total operating expenses were €13,216 million and increased by 4.7% (6.8% at CER).

Other current operating income net of expenses were -€971 million compared to -€598 million in Q3 2023. Other current operating income net of expenses included an expense of €1,066 million from the share of profit to Regeneron from the monoclonal antibody alliance, the share of profit paid by Regeneron towards development costs and the reimbursement of commercialization-related expenses incurred by Regeneron compared to an expense of €889 million in Q3 2023. This line also included €31 million of capital gains from divestments of medicines/portfolio streamlining, compared to €103 million in Q3 2023. Sanofi expects the amount of capital gains from divestments of medicines/portfolio streamlining in Biopharma to be c.€400 million in 2024. In YTD 2024, expenses from the monoclonal antibody alliance with Regeneron were €2,903 million compared to €2,307 million in YTD 2023.

Share of profit from associates was €43 million compared to €20 million in Q3 2023 and included the share of US profit related to Vaxelis. In YTD 2024, share of profit from associates was €118 million compared to €75 million in YTD 2023.

Business operating income⁵ was €4,607 million and increased by 14.4% (19.9% at CER). The ratio of BOI to net sales was 34.3% and increased by 0.6pp (34.9% at CER, up by 1.2pp). In YTD 2024, BOI was €10,263 million and increased by 1.7% (8.8% at CER). The ratio of BOI to net sales was 29.6% and decreased by 1.8pp (30.7% at CER, down by 0.7pp).

Net financial expenses were €79 million compared to €83 million in Q3 2023. In YTD 2024, net financial expenses were €208 million compared to €132 million in YTD 2023, reflecting increased net debt and higher interest rates.

The effective tax rate increased to 21.0% from 19.0% in Q3 2023 and YTD 2023. Sanofi expects its effective tax rate to be around 20% in 2024 excluding Opella.

Business net income² was €3,585 million and increased by 12.2% (17.5% at CER). The ratio of business net income to net sales remained stable at 26.7% and increased by 0.4pp at CER. In YTD 2024, business net income was €7,965 million and decreased by 1.3% (increased by 5.5% at CER). The ratio of business net income to net sales was 23.0% and decreased by 2.1pp (1.3pp at CER).

Business earnings per share² (EPS) was €2.86 and increased by 12.2% on a reported basis (17.6% at CER). The average number of shares outstanding was 1,253.0 million compared to 1,253.2 million in Q3 2023. In YTD 2024, business earnings per share was 6.37 and decreased by 1.2% on a reported basis (increased by 5.6% at CER). The average number of shares outstanding was 1,250.6 million compared to 1,251.0 million in YTD 2023.

Reconciliation of IFRS net income reported to business net income (see Appendix 4)

In YTD 2024, the IFRS net income was €5,061 million. The main items excluded from the business net income were:

- An amortization charge of €1,540 million related to intangible assets measured at their acquisition-date fair values of €1,485 million (mainly Bioverativ €475 million, Provention Bio €160 million, Boehringer Ingelheim consumer healthcare business €134 million, Genzyme €133 million, Ablynx €126 million, Kadmon €122 million, Beyfortus €85 million and Qunol €60 million) and to intangible assets from separate acquisitions, measured initially at acquisition cost (licenses/products) of €55 million. These items had no cash impact.

² See Appendix 3 for Q3 and YTD 2024 consolidated income statement; see Appendix 7 for definitions of financial indicators, and Appendix 4 for reconciliation of IFRS net income reported to business net income.

- A net reversal of impairment losses of €191 million mainly due to an increase in the expected recoverable amounts of certain marketed products and other rights in the Biopharma segment. The YTD 2024 net reversal is partially offset by €180 million impairment expenses recorded in Q3 2024 mainly related to discontinued research and development projects.
- Restructuring costs and similar items of €1,587 million mainly related to redundancy plans announced during YTD 2024 as well as some separation costs for Opella.
- Other gains and losses, and litigation charge of €452 million mainly comprising a provision recognized in respect of the litigation related to Plavix (clopidogrel) in the US State of Hawaii.
- A financial charge of €229 million related to the remeasurement of expected future royalty on Beyfortus US sales.
- A €911 million tax effect arising from the items listed above, mainly comprising €275 million of deferred taxes generated by amortization of intangible assets and €471 million associated with restructuring costs and similar items (see Appendix 4).
- A loss of €53 million corresponding to the equity investment in EUROAPI.

Capital allocation

In YTD 2024, free cash flow before restructuring, acquisitions and disposals amounted to €5,099 million, after negative change of net working capital (-€2,309 million), notably including the decrease of US rebates provisions (€1,260 million) following the decision to reduce the Lantus list price effective January 1, 2024, and capital expenditures (-€1,378 million). After acquisitions³ (-€710 million), proceeds from disposals⁴ (€665 million) and payments related to restructuring and similar items (-€1,182 million), free cash flow⁴ was €3,872 million. After the acquisition of Inhibrx Inc. (-€1,900 million) and the dividend paid by Sanofi (-€4,704 million), net debt increased from €7,793 million on December 31, 2023, to €11,483 million on September 30, 2024 (amount net of €8,243 million cash and cash equivalents).

³ Not exceeding €500 million per transaction (inclusive of all payments related to the transaction).

⁴ Non-IFRS financial measure (definition in Appendix 7).

Forward-looking statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, business transformations, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans”, “potential”, “outlook”, “guidance” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi’s ability to benefit from external growth opportunities, to complete capital markets or other transactions and/or obtain regulatory clearances, risks associated with developing standalone businesses, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and capital market conditions, cost containment initiatives and subsequent changes thereto, and the impact that pandemics, political disruption or armed conflicts or other global crises may have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2023. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements. All Sanofi trademarks mentioned in this document are protected.

Appendices

- Appendix 1: Q3 and YTD 2024 sales by medicine/vaccine/business and geographic region
- Appendix 2: Q3 and YTD 2024 business net income statement
- Appendix 3: Q3 and YTD 2024 consolidated income statement
- Appendix 4: Reconciliation of IFRS net income reported to business net income
- Appendix 5: Change in net debt
- Appendix 6: Currency sensitivity
- Appendix 7: Definitions of non-IFRS financial indicators
- Appendix 8: CSR dashboards

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Appendix 1: Q3 2024 net sales by medicine/vaccine/business and geographic region

Q3 2024 (€ million)	Total Sales	% CER	% reported	United States	% CER	Europe	% CER	Rest of World	% CER
Immunology									
Dupixent	3,476	+23.8%	+22.1%	2,556	+19.1%	417	+35.1%	503	+41.9%
Kevzara	109	+28.7%	+25.3%	65	+40.4%	30	—%	14	+60.0%
Rare diseases									
Fabrazyme	253	+4.0%	—%	131	+7.3%	62	+5.1%	60	-2.8%
ALTUVIIIIO (*)	172	+278.3%	+273.9%	160	+250.0%	—	—%	12	—%
Myozyme	168	-7.5%	-10.2%	63	+4.9%	60	-26.5%	45	+11.6%
Cerezyme	164	+8.0%	-6.8%	47	—%	55	—%	62	+18.9%
Nexviазyme/Nexviadyme (*)	163	+53.6%	+48.2%	90	+24.7%	47	+104.3%	26	+121.4%
Alprolix	148	+8.7%	+7.2%	110	-2.6%	—	—%	38	+62.5%
Eloctate	96	-19.2%	-20.0%	56	-37.1%	—	—%	40	+32.3%
Cerdelga	81	+12.3%	+11.0%	46	+17.9%	31	+6.9%	4	—%
Aldurazyme	67	+4.5%	—%	18	+12.5%	18	-10.5%	31	+9.4%
Cablivi (*)	63	+12.5%	+12.5%	34	+34.6%	24	—%	5	-33.3%
Xenpozyme (*)	41	+51.9%	+51.9%	20	+42.9%	14	+40.0%	7	+133.3%
Enjaymo (*)	28	+81.3%	+75.0%	17	+70.0%	4	+300.0%	7	+60.0%
Neurology									
Aubagio	92	-52.3%	-53.8%	49	-27.5%	30	-74.6%	13	+25.0%
Oncology									
Sarclisa (*)	114	+23.7%	+17.5%	46	+4.5%	34	+22.2%	34	+57.7%
Jevtana	72	+10.4%	+7.5%	56	+21.3%	1	-50.0%	15	-11.1%
Fasturtec	46	+15.0%	+15.0%	29	+11.5%	13	+20.0%	4	+25.0%
Other Pharma									
Lantus	431	+33.8%	+25.7%	175	+162.7%	85	+2.4%	171	+2.6%
Toujeo	303	+18.1%	+14.3%	54	+14.6%	118	+6.3%	131	+32.1%
Lovenox	233	-1.2%	-8.6%	1	—%	131	-8.4%	101	+8.1%
Plavix	230	+8.3%	+5.5%	2	—%	23	-4.2%	205	+9.9%
Rezurock (*)	131	+57.8%	+57.8%	118	+48.8%	8	+700.0%	5	+100.0%
Praluent	126	+10.4%	+9.6%	—	—%	85	+14.9%	41	+2.4%
Thymoglobulin	121	+4.1%	-1.6%	73	+1.4%	10	+11.1%	38	+7.3%
Aprovel	98	+1.0%	+1.0%	1	-100.0%	18	—%	79	+6.7%
Multaq	72	-21.5%	-22.6%	65	-23.5%	2	—%	5	—%
Soliqua/iGlarLixi	55	+12.0%	+10.0%	17	-18.2%	12	+44.4%	26	+31.6%
Mozobil	16	-70.6%	-68.6%	4	-85.2%	7	-58.8%	5	-42.9%
Tzield (*)	15	+66.7%	+66.7%	15	+66.7%	—	—%	—	—%
Others	1,055	-6.5%	-11.1%	94	-16.5%	296	-5.7%	665	-5.3%
Industrial Sales	126	+0.8%	—%	1	—%	125	+6.8%	—	-100.0%
Total Pharma	8,365	+13.0%	+9.8%	4,213	+18.4%	1,760	+2.2%	2,392	+12.7%
Vaccines									
Influenza vaccines	1,913	+10.9%	+8.3%	1,239	+9.0%	480	+20.1%	194	+3.9%
Polio/Pertussis/Hib vaccines & Boosters	760	+2.0%	-0.3%	225	+8.5%	133	-2.9%	402	+0.2%
RSV (Beyfortus) (**)	645	+381.8%	+370.8%	532	+494.6%	98	+117.8%	15	—%
Meningitis, Travel and endemic vaccines	485	+13.1%	+11.8%	334	+10.4%	51	+25.0%	100	+17.4%
Vaccines	3,802	+25.5%	+22.7%	2,331	+34.4%	762	+22.4%	709	+5.8%
Biopharma	12,167	+16.6%	+13.5%	6,544	+23.7%	2,522	+7.6%	3,101	+11.1%
Opella	1,271	+7.9%	+2.1%	342	+21.8%	364	+0.3%	565	+5.9%
Company	13,438	+15.7%	+12.3%	6,886	+23.6%	2,886	+6.6%	3,666	+10.3%
New Pharma launches (*)	727	+67.1%	+63.7%	500	+66.9%	131	+51.2%	96	+92.9%
New launches (*), (**)	1,372	+141.3%	+136.1%	1,032	+166.8%	229	+74.0%	111	+119.6%

Appendix 1: YTD 2024 net sales by medicine/vaccine and geographic region

YTD 2024 (€ million)	Total Sales	% CER	% reported	United States	% CER	Europe	% CER	Rest of World	% CER
Immunology									
Dupixent	9,614	+25.9%	+24.5%	6,993	+19.9%	1,187	+32.5%	1,434	+55.5%
Kevzara	298	+21.0%	+18.3%	170	+26.9%	89	+6.0%	39	+35.3%
Rare diseases									
Fabrazyme	779	+8.0%	+4.0%	392	+5.1%	191	+5.5%	196	+16.0%
ALTUVIIIIO (*)	452	+600.0%	+595.4%	419	+566.7%	—	—%	33	+1650.0%
Myozyme	539	-11.1%	-13.5%	185	-5.1%	205	-22.3%	149	—%
Cerezyme	571	+17.0%	+3.3%	143	+1.4%	181	+3.4%	247	+36.3%
Nexviazyme/Nexviadyme (*)	483	+69.7%	+64.3%	264	+35.2%	142	+118.5%	77	+178.8%
Alprolix	419	+6.3%	+5.3%	335	+2.1%	—	—%	84	+26.1%
Eloctate	287	-20.7%	-22.0%	183	-32.7%	—	—%	104	+13.5%
Cerdelga	246	+11.7%	+10.3%	136	+11.5%	96	+9.1%	14	+30.8%
Aldurazyme	228	+11.1%	+5.1%	54	+8.0%	63	+1.6%	111	+17.9%
Cablivi (*)	176	+4.7%	+4.1%	94	+13.1%	67	-8.2%	15	+25.0%
Xenpozyme (*)	113	+75.4%	+73.8%	57	+62.9%	38	+52.0%	18	+280.0%
Enjaymo (*)	83	+75.5%	+69.4%	47	+62.1%	14	+180.0%	22	+66.7%
Neurology									
Aubagio	301	-62.8%	-63.9%	145	-65.0%	125	-65.9%	31	-22.0%
Oncology									
Sarclisa (*)	341	+29.5%	+22.7%	146	+21.7%	98	+16.9%	97	+56.0%
Jevtana	213	-10.3%	-12.3%	156	-10.3%	5	-50.0%	52	-3.4%
Fasturtec	132	+2.3%	+1.5%	85	+1.2%	36	+6.1%	11	—%
Other Pharma									
Lantus	1,189	+10.6%	+4.0%	445	+80.6%	260	-5.1%	484	-10.3%
Toujeo	937	+15.6%	+10.9%	171	+3.6%	359	+8.1%	407	+28.5%
Lovenox	751	-7.1%	-12.9%	7	+16.7%	436	-7.8%	308	-6.5%
Plavix	703	+5.6%	+1.3%	5	-16.7%	69	-4.2%	629	+7.0%
Rezurock (*)	338	+50.9%	+50.9%	306	+39.5%	20	+566.7%	12	+1000.0%
Praluent	373	+23.7%	+22.7%	—	-100.0%	255	+18.1%	118	+36.0%
Thymoglobulin	367	+4.9%	+0.3%	230	+4.1%	29	+3.6%	108	+6.9%
Aprovel	311	+1.6%	—%	3	-71.4%	55	-5.2%	253	+5.3%
Multaq	234	-8.6%	-8.9%	210	-9.5%	8	-11.1%	16	+6.3%
Soliqua/iGlarLixi	169	+11.5%	+8.3%	55	-16.4%	35	+38.5%	79	+30.2%
Mozobil	62	-66.8%	-66.8%	9	-91.9%	35	-34.0%	18	-21.7%
Tzield (*)	36	+140.0%	+140.0%	35	+133.3%	1	—%	—	—%
Others	3,275	-6.9%	-11.3%	279	-14.6%	954	-5.9%	2,042	-6.3%
Industrial Sales	404	-0.2%	-0.5%	4	-20.0%	399	+4.7%	1	-90.0%
Total Pharma	24,424	+10.7%	+7.6%	11,763	+14.5%	5,452	+1.9%	7,209	+11.9%
Vaccines									
Influenza vaccines	2,101	+12.3%	+9.0%	1,255	+8.6%	510	+16.7%	336	+20.0%
Polio/Pertussis/Hib vaccines & Boosters	2,108	-1.2%	-3.7%	536	-3.4%	381	+3.5%	1,191	-1.7%
RSV (Beyfortus) (**)	845	+537.2%	+516.8%	648	+621.7%	105	+133.3%	92	—%
Meningitis, Travel and endemic vaccines	1,067	+7.9%	+6.4%	635	+6.8%	148	+31.3%	284	+1.0%
Vaccines	6,121	+14.5%	+11.5%	3,075	+28.6%	1,144	-4.1%	1,902	+8.0%
Biopharma	30,545	+11.5%	+8.4%	14,838	+17.2%	6,596	+0.8%	9,111	+11.1%
Opella	4,102	+8.8%	+3.5%	1,115	+23.6%	1,172	-2.7%	1,815	+9.1%
Company	34,647	+11.1%	+7.8%	15,953	+17.6%	7,768	+0.2%	10,926	+10.8%
New Pharma launches (*)	2,022	78.2%	74.5%	1,368	80.1%	380	49.2%	274	+119.6%
New launches (*), (**)	2,867	+126.7%	+121.2%	2,016	+138.4%	485	+61.9%	366	+192.3%

Appendix 3: Consolidated income statements

€ million	Q3 2024	Q3 2023	YTD 2024	YTD 2023
Net sales	13,438	11,964	34,647	32,151
Other revenues	719	734	2,008	2,092
Cost of sales	(4,085)	(3,841)	(10,934)	(10,188)
Gross profit	10,072	8,857	25,721	24,055
Research and development expenses	(1,852)	(1,663)	(5,275)	(4,856)
Selling and general expenses	(2,681)	(2,579)	(7,941)	(7,761)
Other operating income	187	388	804	1,005
Other operating expenses	(1,158)	(986)	(3,168)	(2,408)
Amortization of intangible assets	(479)	(562)	(1,540)	(1,597)
Impairment of intangible assets	(180)	(4)	191	(19)
Fair value remeasurement of contingent consideration	(8)	(3)	(74)	(29)
Restructuring costs and similar items	(256)	(259)	(1,587)	(806)
Other gains and losses, and litigation	(10)	22	(452)	(51)
Operating income	3,635	3,211	6,679	7,533
Financial expenses	(265)	(318)	(851)	(688)
Financial income	133	143	414	429
Income before tax and associates and joint ventures	3,503	3,036	6,242	7,274
Income tax expense	(737)	(563)	(1,200)	(1,293)
Share of profit/(loss) of associates and joint ventures	78	65	65	13
Net income	2,844	2,538	5,107	5,994
Net income attributable to non-controlling interests	29	13	46	39
Net income attributable to equity holders of Sanofi	2,815	2,525	5,061	5,955
Average number of shares outstanding (million)	1,253.0	1,253.2	1,250.6	1,251.0
IFRS Earnings per share (in euros)	2.25	2.01	4.05	4.76

Appendix 4: Reconciliation of net income attributable to equity holders of Sanofi to business net income

€ million	Q3 2024	Q3 2023	YTD 2024	YTD 2023
Net income attributable to equity holders of Sanofi	2,815	2,525	5,061	5,955
Amortization of intangible assets ⁽¹⁾	479	562	1,540	1,597
Impairment of intangible assets	180	4	(191)	19
Fair value remeasurement of contingent consideration	31	6	103	39
Expenses arising from the impact of acquisitions on inventories	2	1	21	6
Restructuring costs and similar items	256	259	1,587	806
Other gains and losses, and litigation	10	(22)	452	51
Financial (income) / expense related to liabilities carried at amortized cost other than net indebtedness	53	92	229	127
Tax effect of the items listed above:	(220)	(192)	(911)	(607)
<i>Amortization and impairment of intangible assets</i>	<i>(125)</i>	<i>(101)</i>	<i>(221)</i>	<i>(327)</i>
<i>Fair value remeasurement of contingent consideration</i>	<i>(2)</i>	<i>(2)</i>	<i>(19)</i>	<i>(8)</i>
<i>Expenses arising from the impact of acquisitions on inventories</i>	<i>—</i>	<i>—</i>	<i>(3)</i>	<i>—</i>
<i>Restructuring costs and similar items</i>	<i>(63)</i>	<i>(73)</i>	<i>(471)</i>	<i>(230)</i>
<i>Other items</i>	<i>(30)</i>	<i>(16)</i>	<i>(197)</i>	<i>(42)</i>
Other tax effects	14	6	21	17
Other items	(35)	(45)	53	62
Business net income	3,585	3,196	7,965	8,072
IFRS earnings per share ⁽²⁾ (in euros)	2.25	2.01	4.05	4.76

¹ Of which related to amortization expense generated by the intangible assets measured at their acquisition-date fair values: €462 million in the third quarter of 2024 and €540 million in the third quarter of 2023.

² Q3: based on an average number of shares outstanding of 1,253.0 million in the third quarter of 2024 and 1,253.2 million in the third quarter of 2023.

YTD: based on an average number of shares outstanding of 1,250.6 million in YTD 2024 and 1,251.0 million in YTD 2023.

Appendix 5: Change in net debt

€ million	YTD 2024	YTD 2023
Business net income	7,965	8,072
Depreciation, amortization and impairment of property, plant and equipment and software	1,196	1,163
Other items	(375)	(591)
Operating cash flow	8,786	8,644
Changes in Working Capital	(2,309)	(1,674)
Acquisitions of property, plant and equipment and software	(1,378)	(1,257)
Free cash flow before restructuring, acquisitions and disposals	5,099	5,713
Acquisitions of intangibles assets, investments and other long-term financial assets ⁽¹⁾	(710)	(667)
Restructuring costs and similar items paid	(1,182)	(884)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets net of taxes ⁽¹⁾	665	820
Free cash flow	3,872	4,982
Acquisitions ⁽²⁾	(2,507)	(3,915)
Issuance of Sanofi shares	180	187
Acquisition of treasury shares	(302)	(363)
Dividends paid to shareholders of Sanofi	(4,704)	(4,454)
Other items	(229)	(577)
Change in net debt	(3,690)	(4,140)
Beginning of period	7,793	6,437
Closing of net debt	11,483	10,577

¹ Free cash flow includes investments and divestments not exceeding a cap of €500 million per transaction (inclusive of all payments related to the transaction).

² Includes transactions that are above a cap of €500 million per transaction (inclusive of all payments related to the transaction).

Appendix 6: Currency sensitivity

2024 business EPS currency sensitivity

Currency	Variation	Business EPS Sensitivity
US Dollar	+0.05 USD/EUR	-EUR 0.17
Japanese Yen	+5 JPY/EUR	-EUR 0.02
Chinese Yuan	+0.2 CNY/EUR	-EUR 0.02
Brazilian Real	+0.4 BRL/EUR	-EUR 0.01
Russian Ruble	+10 RUB/EUR	-EUR 0.01

Currency exposure on Q3 2024 sales

Currency	Q3 2024
US Dollar	52.5 %
Euro	18.6 %
Chinese Yuan	5.3 %
Japanese Yen	3.0 %
Mexican pesos	1.9 %
Brazilian Real	1.7 %
Canadian Dollar	1.4 %
British Pound	1.1 %
South Korean won	1.0 %
Australian Dollar	0.9 %
Others	12.6 %

Currency average rates

	Q3 2023	Q3 2024	Change
€/€	1.088	1.099	+1.0%
€/Yen	157.211	163.727	+4.1%
€/Yuan	7.896	7.876	-0.2%
€/Real	5.311	6.095	+14.7%
€/Ruble	102.548	98.161	-4.3%

Appendix 7: Definitions of non-IFRS financial indicators

Company sales at constant exchange rates (CER)

References to changes in net sales “at constant exchange rates” (CER) means that it excludes the effect of changes in exchange rates.

The effect of exchange rates are eliminated by recalculating net sales for the relevant period at the exchange rates used for the previous period.

Reconciliation of net sales to company sales at constant exchange rates for Q3 and YTD 2024

€ million	Q3 2024	YTD 2024
Net sales	13,438	34,647
Effect of exchange rates	(406)	(1,088)
Company sales at constant exchange rates	13,844	35,735

Business net income

Sanofi publishes a key non-IFRS indicator. Business net income is defined as net income attributable to equity holders of Sanofi excluding:

- amortization of intangible assets,
- impairment of intangible assets,
- fair value remeasurement of contingent consideration related to business combinations or to disposals,
- expenses arising from the impact of acquisitions on inventories
- restructuring costs and similar items⁽¹⁾,
- other gains and losses (including gains and losses on disposals of non-current assets⁽¹⁾),
- costs or provisions associated with litigation⁽¹⁾,
- financial (income)/expense related to liabilities carried at amortized cost other than net indebtedness,
- tax effects related to the items listed above as well as effects of major tax disputes,
- the share of profits/losses from investments accounted for using the equity method, except for joint ventures and associates with which Sanofi has a strategic alliance,
- net income attributable to non-controlling interests related to the items listed above.

¹ Reported in the line items Restructuring costs and similar items and Gains and losses on disposals, and litigation, which are defined in Notes B.16. and B.17. to the consolidated financial statements.

Free cash flow

Free cash flow is a non-IFRS financial indicator which is reviewed by management, and which management believes provides useful information to measure the net cash generated from Sanofi’s operations that is available for strategic investments¹ (net of divestments¹), for debt repayment, and for capital return to shareholders. Free cash flow is determined from the Business net income adjusted for depreciation, amortization and impairment, share of profit/loss in associates and joint ventures net of dividends received, gains and losses on disposals, net change in provisions including pensions and other post-employment benefits, deferred taxes, share-based expense and other non-cash items. It comprises net changes in working capital, capital expenditures and other asset acquisitions² net of disposal proceeds², and payments related to restructuring and similar items. Free cash flow is not defined by IFRS and it is not a substitute measure for the IFRS aggregate net cash flows in operating activities.

¹ Amount of the transaction above a cap of €500 million per transaction (inclusive of all payments related to the transaction).

² Not exceeding a cap of €500 million per transaction (inclusive of all payments related to the transaction).

Appendix 8: CSR dashboards

Data are presented in YTD unless stated otherwise.

Topic	Ambition	Progress	
		Q3 2024	Q2 2024
Affordable access			
Sanofi global health	Reach 1.5 million non-communicable disease patients by 2026 (cumulative since 2022) and 2 million by 2030	285,563 patients treated in 28 countries	127,746 patients treated in 24 countries
		67 active healthcare partnerships in 39 countries	46 active healthcare partnerships in 21 countries
		7 investments signed through the Impact Fund	4 investments signed through the Impact Fund
Vials donations	Donate 100,000 vials a year to treat people with rare diseases, via the Humanitarian Program launched by Sanofi Specialty Care	1,198 patients treated 83,341 vials donated	1,164 patients treated 46,124 vials donated
Global access plans	Develop a global access plan for all new medicines/vaccines to make them available within two years after first launch	11 global access plans initiated or developed covering more than 15 indications	10 global access plans initiated or developed covering more than 14 indications
R&D for unmet needs			
		FY 2023	FY 2022
Sleeping sickness	Develop and supply innovative treatments to support the elimination of sleeping sickness by 2030 (annual update)	2.4 million patients tested 699 patients treated	1.5 million patients tested 837 patients treated
		Q3 2024	Q2 2024
Polio	Provide inactivated polio vaccines (IPV) to UNICEF for GAVI countries to support polio eradication efforts	27.8 million IPV doses supplied to UNICEF for GAVI countries	16.2 million IPV doses supplied to UNICEF for GAVI countries
Pediatric cancer treatment development	Develop innovative treatments to eliminate cancer death in children	3 projects undergoing preclinical assessment	3 projects undergoing preclinical assessment
		1 project in clinical study	1 project in clinical study
		8 partnerships on scientific projects and engagement	8 partnerships on scientific projects and engagement
		2 external publications	
Planet care			
		Q3 2024	Q2 2024
Climate change – carbon footprint (CO ₂ emissions)	55% reduction in scope 1&2 greenhouse gas emissions (CO ₂ equivalent) by 2030 (cumulative vs 2019 baseline) to contribute to carbon neutrality by 2030 and net zero emissions by 2045 (all scopes)	44% GHG reduction vs 2019	43% GHG reduction vs 2019
Renewable electricity	100% of renewable electricity in all sites by 2030	85%	85%
Eco-car fleet	100% eco-car fleet in 2030	50% eco-car fleet	48% eco-car fleet
Blister-free syringe vaccines	100% blister-free syringe vaccines by 2027	Data updated annually, next update in Q4 2024	
Eco-design	All new medicines/vaccines to be eco-designed by 2025	27 life-cycle assessments completed (new and marketed medicines/vaccines)	17 life-cycle assessments completed (new and marketed medicines/vaccines)
In and beyond the workplace			
		Q3 2024	Q2 2024
Global gender balance	Ambition of 50% of women in senior leadership roles by 2025	45%	45%
	Ambition of 40% of women in executive roles by 2025	42%	42%
Engagement with communities	Engage socially and economically with all communities with operations	Next update in Q4 2024	2,732 volunteers 25,945 hours
From leaders to citizens	100% of leaders have CSR in their development path	77% of leaders have completed the e-learning phase	77% of leaders have completed the e-learning phase
		34% of leaders have completed the full program	33% of leaders have completed the full program

End.