Annexes

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Annexe 1 :

Rapport annuel 2021 Sanofi :

Formulaire 20-F (Sanofi, 2021a)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

Or

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

For the fiscal year ended December 31, 2021

Or

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

Or

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

Date of event requiring this shell company report

For the transition period from to

Commission File Number: 001-31368

Sanofi

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

France

(Jurisdiction of incorporation or organization)

54, rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Roy Papatheodorou , Executive Vice President, General Counsel & Head of Legal, Ethics and Business Integrity
54, rue La Boétie, 75008 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

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

Securities registered pursuant to Section 12(g) of the Act: None
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None
The number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2021 was:
Ordinary shares: 1,263,560,695

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

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

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

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

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

Consolidated balance sheets - assets

(€ million)	Note	December 31, 2021	December 31, 2020 [(a)]	December 31, 2019 [(a)]
Property, plant and equipment	D.3.1.	10,028	9,365	9,717
Right-of-use assets	D.3.2.	1,948	1,198	1,300
Goodwill	D.4.	48,056	44,364	44,519
Other intangible assets	D.4.	21,407	18,341	16,509
Investments accounted for using the equity method	D.6.	250	201	3,591
Other non-current assets	D.7.	3,127	2,734	2,503
Non-current income tax assets		175	248	164
Deferred tax assets	D.14.	4,598	4,176	5,391
Non-current assets		**89,589**	**80,627**	**83,694**
Inventories	D.9.	8,715	8,352	7,994
Accounts receivable	D.10.	7,568	7,491	7,937
Other current assets	D.11.	3,571	2,737	2,445
Current income tax assets		612	1,208	808
Cash and cash equivalents	D.13. - D.17.1.	10,098	13,915	9,427
Current assets		**30,564**	**33,703**	**28,611**
Assets held for sale or exchange	D.8.	89	83	325
Total assets		**120,242**	**114,413**	**112,630**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

Consolidated balance sheets – equity and liabilities

(€ million)	Note	December 31, 2021	December 31, 2020 [a]	December 31, 2019 [a]
Equity attributable to equity holders of Sanofi	D.15.	68,681	63,106	59,056
Equity attributable to non-controlling interests	D.16.	350	146	174
Total equity		**69,031**	**63,252**	**59,230**
Long-term debt	D.17.1.	17,123	19,745	20,131
Non-current lease liabilities	D.17.2.	1,839	931	987
Non-current liabilities related to business combinations and to non-controlling interests	D.18.	577	387	508
Non-current provisions and other non-current liabilities	D.19.	6,721	7,315	7,413
Non-current income tax liabilities	D.19.4.	2,039	1,733	1,680
Deferred tax liabilities	D.14.	1,617	1,770	2,294
Non-current liabilities		**29,916**	**31,881**	**33,013**
Accounts payable		6,180	5,295	5,313
Current liabilities related to business combinations and to non-controlling interests	D.18.	137	218	292
Current provisions and other current liabilities	D.19.5.	11,217	10,132	9,703
Current income tax liabilities		309	604	258
Current lease liabilities	D.17.2.	269	232	261
Short-term debt and current portion of long-term debt	D.17.1.	3,183	2,767	4,554
Current liabilities		**21,295**	**19,248**	**20,381**
Liabilities related to assets held for sale or exchange	D.8.	—	32	6
Total equity and liabilities		**120,242**	**114,413**	**112,630**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

Consolidated income statements

(€ million)	Note	2021	2020 [a]	2019 [a]
Net sales	**D.35.1.**	**37,761**	**36,041**	**36,126**
Other revenues		1,414	1,328	1,505
Cost of sales		(12,255)	(12,159)	(11,979)
Gross profit		**26,920**	**25,210**	**25,652**
Research and development expenses		(5,692)	(5,530)	(6,020)
Selling and general expenses		(9,555)	(9,391)	(9,884)
Other operating income	D.25.	859	697	783
Other operating expenses	D.26.	(1,805)	(1,415)	(1,207)
Amortization of intangible assets	D.4.	(1,580)	(1,681)	(2,146)
Impairment of intangible assets	D.5.	(192)	(330)	(3,604)
Fair value remeasurement of contingent consideration	D.12. - D.18.	(4)	124	238
Restructuring costs and similar items	D.27.	(820)	(1,089)	(1,088)
Other gains and losses, and litigation	D.28.	(5)	136	327
Gain on Regeneron investment arising from transaction of May 29, 2020	D.2.	—	7,382	—
Operating income		**8,126**	**14,113**	**3,051**
Financial expenses	D.29.	(368)	(388)	(440)
Financial income	D.29.	40	53	141
Income before tax and investments accounted for using the equity method	**D.35.1.**	**7,798**	**13,778**	**2,752**
Income tax expense	D.30.	(1,558)	(1,807)	(121)
Share of profit/(loss) from investments accounted for using the equity method	D.31.	39	359	255
Net income excluding the exchanged/held-for-exchange Animal Health business		**6,279**	**12,330**	**2,886**
Net income/(loss) of the exchanged/held-for-exchange Animal Health business[b]		—	—	(101)
Net income		**6,279**	**12,330**	**2,785**
Net income attributable to non-controlling interests	D.32.	56	36	31
Net income attributable to equity holders of Sanofi		**6,223**	**12,294**	**2,754**
Average number of shares outstanding (million)	D.15.9.	1,252.5	1,253.6	1,249.9
Average number of shares after dilution (million)	D.15.9.	1,257.9	1,260.1	1,257.1
• Basic earnings per share (in euros)		4.97	9.81	2.20
• Basic earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)		4.97	9.81	2.28
• Diluted earnings per share (in euros)		4.95	9.76	2.19
• Diluted earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)		4.95	9.76	2.27

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

(b) Net income/losses arising from the divestment of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations).

Consolidated statements of comprehensive income

(€ million)		2021	2020 [(a)]	2019 [(a)]
Net income		**6,279**	**12,330**	**2,785**
Attributable to equity holders of Sanofi		*6,223*	*12,294*	*2,754*
Attributable to non-controlling interests		*56*	*36*	*31*
Other comprehensive income:				
• Actuarial gains/(losses)	D.15.7.	686	(267)	(336)
• Change in fair value of equity instruments included in financial assets and financial liabilities	D.15.7.	165	320	106
• Tax effects	D.15.7.	(54)	(39)	101
Sub-total: items not subsequently reclassifiable to profit or loss (A)		**797**	**14**	**(129)**
• Change in fair value of debt instruments included in financial assets	D.15.7.	(21)	15	28
• Change in fair value of cash flow hedges	D.15.7.	(6)	4	(13)
• Change in currency translation differences	D.15.7.	2,459	(3,976)	751
• Tax effects	D.15.7.	78	(64)	47
Sub-total: items subsequently reclassifiable to profit or loss (B)		**2,510**	**(4,021)**	**813**
Other comprehensive income for the period, net of taxes (A+B)		**3,307**	**(4,007)**	**684**
Comprehensive income		**9,586**	**8,323**	**3,469**
Attributable to equity holders of Sanofi		*9,519*	*8,307*	*3,439*
Attributable to non-controlling interests		*67*	*16*	*30*

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

Consolidated statements of changes in equity

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi [a]	Attributable to non-controlling interests	Total equity
Balance at January 1, 2019	**2,495**	**13**	**(153)**	**53,093**	**3,596**	**(168)**	**58,876**	**159**	**59,035**
Impact of applying IFRIC agenda decision on IAS 19[a]	—	—	—	171	—	—	171	—	171
Impact of applying IFRIC agenda decision on SaaS arrangements[a]				(31)			(31)		(31)
Balance at January 1, 2019 after impact of IFRIC agenda decisions on IAS 19 and SaaS arrangements(a)	**2,495**	**13**	**(153)**	**53,233**	**3,596**	**(168)**	**59,016**	**159**	**59,175**
Other comprehensive income for the period[a]	—	—	—	(128)	—	813	685	(1)	684
Net income for the period[a]	—	—	—	2,754	—	—	2,754	31	2,785
Comprehensive income for the period[a]	**—**	**—**	**—**	**2,626**	**—**	**813**	**3,439**	**30**	**3,469**
Dividend paid out of 2018 earnings (€3.07 per share)	—	—	—	(3,834)	—	—	(3,834)	—	(3,834)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(14)	(14)
Share repurchase program[b]	—	—	(12)	—	—	—	(12)	—	(12)
Share-based payment plans:									
• Exercise of stock options[b]	6	141	—	—	—	—	147	—	147
• Issuance of restricted shares and vesting of existing restricted shares[b][d]	7	(7)	153	(153)	—	—	—	—	—
• Proceeds from sale of treasury shares on exercise of stock options	—	—	3	—	—	—	3	—	3
• Value of services obtained from employees	—	—	—	—	252	—	252	—	252
• Tax effects of the exercise of stock options	—	—	—	—	15	—	15	—	15
Other changes arising from issuance of restricted shares[c]	—	—	—	30	—	—	30	—	30
Change in non-controlling interests without loss of control	—	—	—	(7)	—	—	(7)	(1)	(8)
Other[e]	—	—	—	7	—	—	7	—	7
Balance at December 31, 2019	**2,508**	**147**	**(9)**	**51,902**	**3,863**	**645**	**59,056**	**174**	**59,230**

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi	Attributable to non-controlling interests	Total equity
Balance at January 1, 2020[a]	**2,508**	**147**	**(9)**	**51,902**	**3,863**	**645**	**59,056**	**174**	**59,230**
Other comprehensive income for the period[a]	—	—	—	14	—	(4,001)	(3,987)	(20)	(4,007)
Net income for the period[a]	—	—	—	12,294	—	—	12,294	36	12,330
Comprehensive income for the period[a]	**—**	**—**	**—**	**12,308**	**—**	**(4,001)**	**8,307**	**16**	**8,323**
Dividend paid out of 2019 earnings (€3.15 per share)	—	—	—	(3,937)	—	—	(3,937)	—	(3,937)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(44)	(44)
Share repurchase program[b]	—	—	(822)	—	—	—	(822)	—	(822)
Share-based payment plans:									
• Exercise of stock options[b]	2	49	—	—	—	—	51	—	51
• Issuance of restricted shares and vesting of existing restricted shares[b][d]	3	(3)	126	(126)	—	—	—	—	—
• Employee share ownership plan	5	169	—	—	—	—	174	—	174
• Value of services obtained from employees	—	—	—	—	274	—	274	—	274
• Tax effects of the exercise of stock options	—	—	—	—	1	—	1	—	1
Other changes arising from issuance of restricted shares[c]	—	—	—	2	—	—	2	—	2
Balance at December 31, 2020	**2,518**	**362**	**(705)**	**60,149**	**4,138**	**(3,356)**	**63,106**	**146**	**63,252**

Consolidated statements of changes in equity

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi	Attributable to non-controlling interests	Total equity
Balance at January 1, 2021[a]	**2,518**	**362**	**(705)**	**60,149**	**4,138**	**(3,356)**	**63,106**	**146**	**63,252**
Other comprehensive income for the period	—	—	—	797	—	2,499	3,296	11	3,307
Net income for the period	—	—	—	6,223	—	—	6,223	56	6,279
Comprehensive income for the period	**—**	**—**	**—**	**7,020**	**—**	**2,499**	**9,519**	**67**	**9,586**
Dividend paid out of 2020 earnings (€3.20 per share)	—	—	—	(4,008)	—	—	(4,008)	—	(4,008)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(49)	(49)
Share repurchase program[b]	—	—	(382)	—	—	—	(382)	—	(382)
Share-based payment plans:									
• Exercise of stock options[b]	—	11	—	—	—	—	11	—	11
• Issuance of restricted shares and vesting of existing restricted shares[b][d]	4	(4)	148	(148)	—	—	—	—	—
• Employee share ownership plan	5	163	—	—	—	—	168	—	168
• Value of services obtained from employees	—	—	—	—	244	—	244	—	244
• Tax effects of the exercise of stock options	—	—	—	—	23	—	23	—	23
Other changes in non-controlling interests[f]	—	—	—	—	—	—	—	186	186
Balance at December 31, 2021	**2,527**	**532**	**(939)**	**63,013**	**4,405**	**(857)**	**68,681**	**350**	**69,031**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

(b) See Notes D.15.1., D.15.3., D.15.4. and D.15.5.

(c) Issuance of restricted shares to former employees of the Animal Health business and the European Generics business subsequent to the date of divestment.

(d) This line includes the use of existing shares to fulfill vested rights under restricted share plans.

(e) This line includes the impact of the settlement of a put option granted to non-controlling interests in connection with a divestment.

(f) This line includes changes in non-controlling interests arising from divestments and acquisitions.

Consolidated statements of cash flows

(€ million)	Note	2021	2020 [h]	2019 [h]
Net income attributable to equity holders of Sanofi		**6,223**	**12,294**	**2,754**
Net (income)/loss of the exchanged/held-for-exchange Animal Health business		—	—	101
Non-controlling interests	D.32.	56	36	31
Share of undistributed earnings from investments accounted for using the equity method		(15)	(339)	(192)
Depreciation, amortization and impairment of property, plant and equipment, right-of-use assets and intangible assets		3,351	3,671	7,445
Gains and losses on disposals of non-current assets, net of tax[a]		(300)	(301)	(286)
Gain on Regeneron investment arising from transaction of May 29, 2020, net of tax[f]	D.2.	—	(6,880)	—
Net change in deferred taxes		(356)	(221)	(1,772)
Net change in non-current provisions and other non-current liabilities[b]		(37)	(133)	107
Cost of employee benefits (stock options and other share-based payments)	D.15.2. - D.15.3. - D.15.8.	244	274	252
Impact of the workdown of acquired inventories remeasured at fair value	D.35.1.	4	53	3
Other profit or loss items with no cash effect on cash flows generated by operating activities[g]		(57)	(711)	(309)
Operating cash flow before changes in working capital and excluding the exchanged/held-for-exchange Animal Health business		**9,113**	**7,743**	**8,134**
(Increase)/decrease in inventories		(357)	(593)	(547)
(Increase)/decrease in accounts receivable		185	(134)	(462)
Increase/(decrease) in accounts payable		451	86	169
Net change in other current assets and other current liabilities		1,130	316	421
Net cash provided by/(used in) operating activities excluding the exchanged/held-for-exchange Animal Health business[c]		**10,522**	**7,418**	**7,715**
Acquisitions of property, plant and equipment and intangible assets	D.3. - D.4.	(2,043)	(2,083)	(1,787)
Acquisitions of consolidated undertakings and investments accounted for using the equity method[d]	D.1. - D.18.	(5,594)	(5,336)	(488)
Acquisitions of other equity investments	D.7.	(311)	(137)	(38)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax[e]		718	918	1,224
Net proceeds from sale of Regeneron shares on May 29, 2020	D.2.	—	10,370	—
Net change in other non-current assets		(68)	(113)	(94)
Net cash provided by/(used in) investing activities excluding the exchanged/held-for-exchange Animal Health business		**(7,298)**	**3,619**	**(1,183)**
Net cash inflow from the exchange of the Animal Health business for BI's Consumer Healthcare business		**—**	**—**	**154**
Issuance of Sanofi shares	D.15.1.	186	203	162
Dividends paid:				
• to shareholders of Sanofi		(4,008)	(3,937)	(3,834)
• to non-controlling interests		(48)	(44)	(14)
Payments received/(made) on changes of ownership interest in a subsidiary without loss of control		—	—	(7)
Additional long-term debt contracted	D.17.1.	—	2,019	1,997
Repayments of long-term debt	D.17.1.	(2,241)	(3,952)	(2,067)
Repayments of lease liabilities		(149)	(234)	(267)
Net change in short-term debt and other financial instruments[i]		(414)	282	(154)
Acquisitions of treasury shares	D.15.4.	(382)	(822)	(9)
Net cash provided by/(used in) financing activities excluding the exchanged/held-for-exchange Animal Health business		**(7,056)**	**(6,485)**	**(4,193)**
Impact of exchange rates on cash and cash equivalents		**15**	**(64)**	**9**
Net change in cash and cash equivalents		**(3,817)**	**4,488**	**2,502**
Cash and cash equivalents, beginning of period		**13,915**	**9,427**	**6,925**
Cash and cash equivalents, end of period	**D.13.**	**10,098**	**13,915**	**9,427**

(a) Includes non-current financial assets.
(b) This line item includes contributions paid to pension funds (see Note D.19.1.).

(c) Including:

	2021	2020	2019
• Income tax paid	(1,280)	(2,051)	(1,695)
• Interest paid	(334)	(315)	(379)
• Interest received	3	37	92
• Dividends received from non-consolidated entities	2	—	—

(d) This line item includes payments made in respect of contingent consideration identified and recognized as a liability in business combinations. For 2021, it includes the net cash outflows on the acquisitions of Kymab, Kiadis, Tidal, Translate Bio, Kadmon and Origimm (see Note D.1.). For 2020, it includes the net cash outflows on the acquisitions of Synthorx and Principia (see Note D.2.1.).

(e) This line item includes proceeds from disposals of investments in consolidated entities and of other non-current financial assets. For 2021, it includes in particular the divestment of two activities relating to certain established prescription products for a total selling price (before taxes) of €187 million, and the divestment of certain Consumer Healthcare products for a selling price (before taxes) of €109 million. For 2020, it includes the sale to Baxter of operations relating to Sepraflm® for a selling price (before taxes) of €311 million and the divestment of certain established prescription products for €97 million (before taxes), plus contingent consideration of €167 million (before taxes) relating to a past divestment. For 2019, it includes the proceeds from the divestments of Sanofi's entire equity interests in Alnylam for €706 million and in MyoKardia for €118 million (see Note D.7.1.).

(f) The gain on the sale of Regeneron shares is presented net of taxes, including deferred taxes of €115 million.

(g) This line item mainly comprises unrealized foreign exchange gains and losses arising on the remeasurement of monetary items in non-functional currencies and on instruments used to hedge such items.

(h) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

(i) This line item includes realized foreign exchange differences on (i) cash and cash equivalents in non-functional currencies (primarily the US dollar) and (ii) derivative instruments used to manage such cash and cash equivalents.

B.3. Business combinations and transactions with non-controlling interests

B.3.1. Accounting for business combinations, transactions with non-controlling interests and loss of control

Business combinations are accounted for in accordance with IFRS 3 (Business Combinations) and IFRS 10 (Consolidated Financial Statements).

Business combinations are accounted for using the acquisition method. Under this method, the acquiree's identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 (Business Combinations) are measured initially at their fair values at the date of acquisition, except for (i) non-current assets classified as held for sale (which are measured at fair value less costs to sell) and (ii) assets and liabilities that fall within the scope of IAS 12 (Income Taxes) and IAS 19 (Employee Benefits). Restructuring liabilities are recognized as a liability of the acquiree only if the acquiree has an obligation as of the acquisition date to carry out the restructuring.

The principal accounting rules applicable to business combinations and transactions with non-controlling interests include:

- acquisition-related costs are recognized as an expense on the acquisition date, as a component of ***Operating income***;
- contingent consideration is recognized in equity if the contingent payment is settled by delivery of a fixed number of the acquirer's equity instruments; otherwise, it is recognized in ***Liabilities related to business combinations***. Contingent consideration is recognized at fair value at the acquisition date irrespective of the probability of payment. If the contingent consideration was originally recognized as a financial liability, subsequent adjustments to the liability are recognized in profit or loss in the line item ***Fair value remeasurement of contingent consideration***, unless the adjustment is made within the twelve months following the acquisition date and relates to facts and circumstances existing as of that date;
- goodwill may be calculated on the basis of either (i) the entire fair value of the acquiree, or (ii) a share of the fair value of the acquiree proportionate to the interest acquired. This option is elected for each acquisition individually.

Purchase price allocations are performed under the responsibility of management, with assistance from an independent valuer in the case of major acquisitions. IFRS 3 does not specify an accounting treatment for contingent consideration arising from a business combination made by an entity prior to the acquisition of control in that entity and carried as a liability in the acquired entity's balance sheet. The accounting treatment applied by Sanofi to such a liability is to measure it at fair value as of the acquisition date and to report it in the line item ***Liabilities related to business combinations and to non-controlling interests***, with subsequent remeasurements recognized in profit or loss. This treatment is consistent with the accounting applied to contingent consideration in the books of the acquirer.

Finally, management may where it deems fit elect to apply the optional test to identify concentration of fair value permitted under IFRS 3 in order to determine whether a transaction is a business combination within the meaning of IFRS 3, or merely the acquisition of an asset or of a group of similar assets.

B.3.2. Goodwill

The excess of the cost of an acquisition over Sanofi's interest in the fair value of the identifiable assets and liabilities of the acquiree is recognized as goodwill at the date of the business combination.

Goodwill arising on the acquisition of subsidiaries is shown in a separate balance sheet line item, whereas goodwill arising on the acquisition of investments accounted for using the equity method is recorded in ***Investments accounted for using the equity method***.

Goodwill arising on foreign operations is expressed in the functional currency of the country concerned and translated into euros using the exchange rate prevailing at the end of the reporting period.

In accordance with IAS 36 (Impairment of Assets), goodwill is carried at cost less accumulated impairment (see Note B.6.).

Goodwill is tested for impairment annually and whenever events or circumstances indicate that impairment might exist. Such events or circumstances include significant changes more likely than not to have an other-than-temporary impact on the substance of the original investment.

B.4. Other intangible assets

Other intangible assets are initially measured at acquisition cost or production cost, including any directly attributable costs of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. Intangible assets are amortized on a straight line basis over their useful lives.

The useful lives of other intangible assets are reviewed at the end of each reporting period. The effect of any adjustment to useful lives is recognized prospectively as a change in accounting estimate.

Amortization of other intangible assets is recognized in the income statement within ***Amortization of intangible assets*** except for amortization charged against (i) acquired or internally-developed software and (ii) other rights of an industrial or operational nature, which is recognized in the relevant classification of expense by function.

Sanofi does not own any intangible assets with an indefinite useful life, other than goodwill.

Intangible assets (other than goodwill) are carried at cost less accumulated amortization and accumulated impairment, if any, in accordance with IAS 36 (see Note B.6.).

B.4.1. Research and development not acquired in a business combination

Internally generated research and development

Under IAS 38, research expenses are recognized in profit or loss when incurred.

Internally generated development expenses are recognized as an intangible asset if, and only if, all the following six criteria can be demonstrated: (a) the technical feasibility of completing the development project; (b) Sanofi's intention to complete the project; (c) Sanofi's ability to use the project; (d) the probability that the project will generate future economic benefits; (e) the availability of adequate technical, financial and other resources to complete the project; and (f) the ability to measure the development expenditure reliably.

Due to the risks and uncertainties relating to regulatory approval and to the research and development process, the six criteria for capitalization are usually considered not to have been met until the product has obtained marketing approval from the regulatory authorities. Consequently, internally generated development expenses arising before marketing approval has been obtained, mainly the cost of clinical trials, are generally expensed as incurred within ***Research and development expenses***.

Some industrial development expenses (such as those incurred in developing a second-generation synthesis process) are incurred after marketing approval has been obtained, in order to improve the industrial process for an active ingredient. To the extent that the six IAS 38 criteria are considered as having been met, such expenses are recognized as an asset in the balance sheet within ***Other intangible assets*** as incurred. Similarly, some clinical trials, for example those undertaken to obtain a geographical extension for a molecule that has already obtained marketing approval in a major market, may in certain circumstances meet the six capitalization criteria under IAS 38, in which case the related expenses are recognized as an asset in the balance sheet within ***Other intangible assets***.

Separately acquired research and development

Payments for separately acquired research and development are capitalized within ***Other intangible assets*** provided that they meet the definition of an intangible asset: a resource that is (i) controlled by Sanofi, (ii) expected to provide future economic benefits for Sanofi, and (iii) identifiable (i.e. it is either separable or arises from contractual or legal rights). Under paragraph 25 of IAS 38, the first condition for capitalization (the probability that the expected future economic benefits from the asset will flow to the entity) is considered to be satisfied for separately acquired research and development. Consequently, upfront and milestone payments to third parties related to pharmaceutical products for which marketing approval has not yet been obtained are recognized as intangible assets, and amortized on a straight line basis over their useful lives beginning when marketing approval is obtained.

Payments under research and development arrangements relating to access to technology or to databases, and payments made to purchase generics dossiers, are also capitalized, and amortized over the useful life of the intangible asset.

Subcontracting arrangements, payments for research and development services, and continuous payments under research and development collaborations which are unrelated to the outcome of that collaboration, are expensed over the service term.

B.4.2. Other intangible assets not acquired in a business combination

Licenses other than those related to pharmaceutical products and research projects, in particular software licenses, are capitalized at acquisition cost, including any directly attributable cost of preparing the software for its intended use. Software licenses are amortized on a straight line basis over their useful lives for Sanofi (three to five years).

Internally generated costs incurred to develop or upgrade software are capitalized if the IAS 38 recognition criteria are satisfied, and amortized on a straight line basis over the useful life of the software from the date on which the software is ready for use.

B.4.3. Other intangible assets acquired in a business combination

Other intangible assets acquired in a business combination which relate to in-process research and development and currently marketed products and are reliably measurable are identified separately from goodwill, measured at fair value, and capitalized within ***Other intangible assets*** in accordance with IFRS 3 (Business Combinations) and IAS 38 (Intangible Assets). The related deferred tax liability is also recognized if a deductible or taxable temporary difference exists.

In-process research and development acquired in a business combination is amortized on a straight line basis over its useful life from the date of receipt of marketing approval.

Rights to products currently marketed by Sanofi are amortized on a straight line basis over their useful lives, determined on the basis of cash flow forecasts which take into account the patent protection period of the marketed product.

B.5. Property, plant and equipment owned and leased

B.5.1. Property, plant and equipment owned

Property, plant and equipment is initially measured and recognized at acquisition cost, including any directly attributable cost of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. The component-based approach to accounting for property, plant and equipment is applied. Under this approach, each component of an item of property, plant and equipment with a cost which is significant in relation to the total cost of the item and which has a different useful life from the other components must be depreciated separately.

After initial measurement, property, plant and equipment is carried at cost less accumulated depreciation and impairment, except for land which is carried at cost less impairment.

Subsequent costs are not recognized as assets unless (i) it is probable that future economic benefits associated with those costs will flow to Sanofi and (ii) the costs can be measured reliably.

Borrowing costs attributable to the financing of items of property, plant and equipment, and incurred during the construction period, are capitalized as part of the acquisition cost of the item.

Government grants relating to property, plant and equipment are deducted from the acquisition cost of the asset to which they relate.

The depreciable amount of items of property, plant and equipment, net of any residual value, is depreciated on a straight line basis over the useful life of the asset. The useful life of an asset is usually equivalent to its economic life.

The customary useful lives of property, plant and equipment are as follows:

Buildings	15 to 40 years
Fixtures	10 to 20 years
Machinery and equipment	5 to 15 years
Other	3 to 15 years

Useful lives and residual values of property, plant and equipment are reviewed annually. The effect of any adjustment to useful lives or residual values is recognized prospectively as a change in accounting estimate.

Depreciation of property, plant and equipment is recognized as an expense in the income statement, in the relevant classification of expense by function.

B.5.2. Property, plant and equipment leased

Effective from January 1, 2019 leases contracted by Sanofi have been accounted for in accordance with IFRS 16 (Leases). Sanofi recognizes a right-of-use asset and a lease liability for all of its lease contracts, except for (i) leases relating to low-value assets and (ii) short-term leases (12 months or less). Payments made in respect of leases not recognized on the balance sheet are recognized as an operating expense on a straight line basis over the lease term.

On commencement of a lease, the liability for future lease payments is discounted at the incremental borrowing rate, which is a risk-free rate adjusted to reflect the specific risk profile of each Sanofi entity. Because lease payments are spread over the lease term, Sanofi applies a discount rate based on the duration of those payments.

The payments used to determine the liability for future lease payments exclude non-lease components, but include fixed payments that Sanofi expects to make to the lessor over the estimated lease term.

After commencement of the lease, the liability for future lease payments is reduced by the amount of the lease payments made, and increased to reflect interest on the liability. In the event of a reassessment or modification of future lease payments, the lease liability is remeasured. The right-of-use asset – which is initially measured at cost including direct costs of the lessee, prepayments made at or prior to the commencement date, less lease incentives received and restoration costs – is depreciated on a straight line basis over the lease term, and tested for impairment as required.

Sanofi recognizes deferred taxes in respect of right-of-use assets and lease liabilities.

Leasehold improvements are depreciated over their economic life, which is capped at the lease term as determined under IFRS 16.

B.6. Impairment of property, plant and equipment, intangible assets, and investments accounted for using the equity method

B.6.1. Impairment of property, plant and equipment and intangible assets

In accordance with IAS 36 (Impairment of Assets), assets that generate separate cash flows and assets included in cash-generating units (CGUs) are assessed for impairment when events or changes in circumstances indicate that the asset or CGU may be impaired. A CGU is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets.

Under IAS 36, each CGU or group of CGUs to which goodwill is allocated must (i) represent the lowest level within the entity at which the goodwill is monitored for internal management purposes, and (ii) not be larger than an operating segment determined in accordance with IFRS 8 (Operating Segments), before application of the IFRS 8 aggregation criteria (see Note B.26.).

Quantitative and qualitative indications of impairment (primarily relating to the status of the research and development portfolio, pharmacovigilance, patent litigation, and the launch of competing products) are reviewed at the end of each reporting period. If there is any internal or external indication of impairment, Sanofi estimates the recoverable amount of the asset or CGU.

Other intangible assets not yet available for use (such as capitalized in-process research and development), and CGUs or groups of CGUs that include goodwill, are tested for impairment annually whether or not there is any indication of impairment, and more frequently if any event or circumstance indicates that they might be impaired. Such assets are not amortized.

When there is an internal or external indication of impairment, Sanofi estimates the recoverable amount of the asset and recognizes an impairment loss if the carrying amount of the asset exceeds its recoverable amount. The recoverable amount of the asset is the higher of its fair value less costs to sell or its value in use. To determine value in use, Sanofi uses estimates of future cash flows generated by the asset or CGU, prepared using the same methods as those used in the initial measurement of the asset or CGU on the basis of medium-term strategic plans.

In the case of goodwill, estimates of future cash flows are based on a five-year strategic plan, an extrapolation of the cash flows over a further five-year period, and a terminal value. In the case of other intangible assets, the period used is based on the economic life of the asset.

Estimated cash flows are discounted at long-term market interest rates that reflect the best estimate by Sanofi of the time value of money, the risks specific to the asset or CGU, and economic conditions in the geographical regions in which the business activity associated with the asset or CGU is located.

Certain assets and liabilities that are not directly attributable to a specific CGU are allocated between CGUs on a basis that is reasonable, and consistent with the allocation of the corresponding goodwill.

Impairment losses arising on property, plant and equipment, on software and on certain rights are recognized in the relevant classification of expense by function.

Impairment losses arising on other intangible assets are recognized within ***Impairment of intangible assets*** in the income statement.

B.6.2. Impairment of investments accounted for using the equity method

In accordance with IAS 28 (Investments in Associates and Joint Ventures), Sanofi determines whether investments accounted for using the equity method may be impaired based on indicators such as default in contractual payments, significant financial difficulties, probability of bankruptcy, or a prolonged or significant decline in quoted market price. If an investment is impaired, the amount of the impairment loss is determined by applying IAS 36 (see Note B.6.1.) and recognized in ***Share of profit/(loss) from investments accounted for using the equity method***.

B.6.3. Reversals of impairment losses charged against property, plant and equipment, intangible assets, and investments accounted for using the equity method

At the end of each reporting period, Sanofi assesses whether events or changes in circumstances indicate that an impairment loss recognized in a prior period in respect of an asset (other than goodwill) or an investment accounted for using the equity method can be reversed. If this is the case, and the recoverable amount as determined based on the revised estimates exceeds the carrying amount of the asset, Sanofi reverses the impairment loss only to the extent of the carrying amount that would have been determined had no impairment loss been recognized for the asset.

Reversals of impairment losses in respect of other intangible assets are recognized within the income statement line item ***Impairment of intangible assets***, while reversals of impairment losses in respect of investments accounted for using the equity method are recognized within the income statement line item ***Share of profit/(loss) from investments accounted for using the equity method***. Impairment losses taken against goodwill are never reversed, unless the goodwill is part of the carrying amount of an investment accounted for using the equity method.

B.7. Assets held for sale or exchange and liabilities related to assets held for sale or exchange

In accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations), non-current assets and groups of assets are classified as held for sale in the balance sheet if their carrying amount will be recovered principally through a sale transaction rather than through continuing use. Within the meaning of IFRS 5, the term “sale” also includes exchanges for other assets.

Non-current assets or asset groups held for sale must be available for immediate sale in their present condition, subject only to terms that are usual and customary for sales of such assets, and a sale must be highly probable. Criteria used to determine whether a sale is highly probable include:

- the appropriate level of management must be committed to a plan to sell;
- an active program to locate a buyer and complete the plan must have been initiated;
- the asset must be actively marketed for sale at a price that is reasonable in relation to its current fair value;
- completion of the sale should be foreseeable within the twelve months following the date of reclassification to ***Assets held for sale or exchange***; and
- actions required to complete the plan should indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn.

Before initial reclassification of the non-current asset (or asset group) to ***Assets held for sale or exchange***, the carrying amounts of the asset (or of all the assets and liabilities in the asset group) must be measured in accordance with the applicable standards.

Subsequent to reclassification to ***Assets held for sale or exchange***, the non-current asset (or asset group) is measured at the lower of carrying amount or fair value less costs to sell, with any write-down recognized by means of an impairment loss. Once a non-current asset has been reclassified as held for sale or exchange, it is no longer depreciated or amortized.

In a disposal of an equity interest leading to loss of control, all the assets and liabilities of the entity involved are classified as held-for-sale assets or liabilities within the balance sheet line items ***Assets held for sale or exchange*** or ***Liabilities related to assets held for sale or exchange***, provided that the disposal satisfies the IFRS 5 classification criteria.

The profit or loss generated by a held-for-sale asset group is reported in a separate line item in the income statement for the current period and for the comparative periods presented, provided that the asset group:

- represents a separate major line of business or geographical area of operations; or
- is part of a single coordinated plan to dispose of a separate major line of business or geographical area of operations; or
- is a subsidiary acquired exclusively with a view to resale.

The table below shows the disclosures required under IFRS 7 relating to the measurement principles applied to financial instruments.

					Method used to determine fair value		
						Market data	
Note	Type of financial instrument	Measurement principle	Level in fair value hierarchy	Valuation technique	Valuation model	Exchange rate	Interest rate
D.7.	Financial assets measured at fair value (quoted equity instruments)	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets measured at fair value (quoted debt instruments)	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets measured at fair value (unquoted equity instruments)	Fair value	3	Cost / Approach based on comparables	If cost ceases to be a representative measure of fair value, an internal valuation is carried out, based mainly on comparables.		
D.7.	Financial assets measured at fair value (contingent consideration receivable)	Fair value	3	Revenue-based approach	The fair value of contingent consideration receivable is determined by adjusting the contingent consideration at the end of the reporting period using the method described in Note D.7.3.		
D.7.	Financial assets measured at fair value held to meet obligations under post-employment benefit plans	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets designated at fair value held to meet obligations under deferred compensation plans	Fair value	1	Market value	Quoted market price		N/A
D.7.	Long-term loans and advances and other non-current receivables	Amortized cost	N/A	N/A	The amortized cost of long-term loans and advances and other non-current receivables at the end of the reporting period is not materially different from their fair value.		
D.13.	Investments in mutual funds	Fair value	1	Market value	Net asset value		N/A
D.13.	Negotiable debt instruments, commercial paper, instant access deposits and term deposits	Amortized cost	N/A	N/A	Because these instruments have a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as disclosed in the notes to the consolidated financial statements.		
D.17.1.	Debt	Amortized cost[(a)]	N/A	N/A	In the case of debt with a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as reported in the notes to the consolidated financial statements. For debt with a maturity of more than 3 months, fair value as reported in the notes to the consolidated financial statements is determined either by reference to quoted market prices at the end of the reporting period (quoted instruments) or by discounting the future cash flows based on observable market data at the end of the reporting period (unquoted instruments).		
D.17.2.	Lease liabilities	Amortized cost	N/A	N/A	The liability for future lease payments is discounted using the incremental borrowing rate.		
D.20.	Forward currency contracts	Fair value	2		Present value of future cash flows	Mid Market	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon
D.20.	Interest rate swaps	Fair value	2	Revenue-based approach	Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon
D.20.	Cross-currency swaps	Fair value	2		Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon
D.18.	Liabilities related to business combinations and to non-controlling interests (CVRs)	Fair value	1	Market value	Quoted market price		
D.18.	Liabilities related to business combinations and to non-controlling interests (other than CVRs)	Fair value	3	Revenue-based approach	Under IAS 32, contingent consideration payable in a business combination is a financial liability. The fair value of such liabilities is determined by adjusting the contingent consideration at the end of the reporting period using the method described in Note B.8.4.		

(a) In the case of debt designated as a hedged item in a fair value hedging relationship, the carrying amount in the consolidated balance sheet includes changes in fair value attributable to the hedged risk(s).

The fair value of the Dexcom equity derivatives (see Note D.20.c.) is classified as Level 2 because the valuation is based on a generally accepted technique (the Black & Scholes model) that uses inputs from directly observable market parameters (share price, risk free rate and implied volatility).

B.8.6. Derecognition of financial instruments

Financial assets are derecognized when the contractual rights to cash flows from the asset have ended or have been transferred and when Sanofi has transferred substantially all the risks and rewards of ownership of the asset. If Sanofi has neither transferred nor retained substantially all the risks and rewards of ownership of a financial asset, it is derecognized if Sanofi does not retain control of the asset.

A financial liability is derecognized when Sanofi's contractual obligations in respect of the liability are discharged, cancelled or extinguished.

VaxServe is a Vaccines segment entity whose operations include the distribution within the United States of vaccines and other products manufactured by third parties. VaxServe sales of products sourced from third-party manufacturers are presented within ***Other revenues***.

B.14. Cost of sales

Cost of sales consists primarily of the industrial cost of goods sold, payments made under licensing agreements, and distribution costs. The industrial cost of goods sold includes the cost of materials, depreciation of property, plant and equipment, amortization of software, personnel costs, and other expenses attributable to production.

B.15. Research and development

Note B.4.1. "Research and development not acquired in a business combination" and Note B.4.3. "Other intangible assets acquired in a business combination" describe the principles applied to the recognition of research and development costs.

Contributions or reimbursements received from alliance partners are recorded as a reduction of ***Research and development expenses***.

B.16. Other operating income and expenses

B.16.1. Other operating income

Other operating income includes the share of profits that Sanofi is entitled to receive from alliance partners in respect of product marketing agreements. It also includes revenues generated under certain complex agreements, which may include partnership and co-promotion arrangements.

This line item also includes realized and unrealized foreign exchange gains and losses on operating activities (see Note B.8.3.), and operating gains on disposals not regarded as major disposals (see Note B.20.).

B.16.2. Other operating expenses

Other operating expenses mainly comprise the share of profits that alliance partners are entitled to receive from Sanofi under product marketing agreements.

B.17. Amortization and impairment of intangible assets

B.17.1. Amortization of intangible assets

The expenses recorded in this line item comprise amortization of product rights and other intangible assets (see Note D.4.), given that the benefit of those rights to Sanofi's commercial, industrial and development functions cannot be separately identified.

Amortization of software, and of other rights of an industrial or operational nature, is recognized as an expense in the income statement, in the relevant line items of expense by function.

B.17.2. Impairment of intangible assets

This line item records impairment losses (other than those associated with restructuring) recognized against intangible assets (including goodwill, but excluding software and other rights of an industrial or operational nature), and any reversals of such impairment losses.

B.18. Fair value remeasurement of contingent consideration

Changes in the fair value of contingent consideration that was (i) already carried in the books of an acquired entity, or (ii) granted in connection with a business combination and initially recognized as a liability in accordance with IFRS 3, are reported in profit or loss. Such adjustments are reported separately in the income statement, in the line item ***Fair value remeasurement of contingent consideration.***

This line item also includes changes in the fair value of contingent consideration receivable in connection with a divestment and classified as a financial asset at fair value through profit or loss.

Finally, it includes the effect of the unwinding of discount, and of exchange rate movements where the asset or liability is expressed in a currency other than the functional currency of the reporting entity.

B.19. Restructuring costs and similar items

Restructuring costs are expenses incurred in connection with the transformation or reorganization of Sanofi's operations or support functions. Such costs include collective redundancy plans, compensation to third parties for early termination of contracts, and commitments made in connection with transformation or reorganization decisions. They also include accelerated depreciation charges arising from site closures (including closures of leased sites), and losses on asset disposals resulting from such decisions.

In addition, this line item includes expenses incurred in connection with programs implemented as part of the transformation strategy announced in December 2019 (and previously in November 2015), and intended primarily to (i) deliver a global information systems solution, further supported by the implementation in 2021 of Sanofi's new digital strategy; (ii) create a standalone Consumer Healthcare

At the same date an amendment to the Investor Agreement became effective, which stipulates inter alia that (i) the "standstill" provisions in the Investor Agreement, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron, will continue to apply; (ii) the voting commitments contained in the Investor Agreement will continue to apply to shares held by Sanofi; (iii) Sanofi will no longer have the right to designate an independent board member on the Regeneron Board of Directors.

Pursuant to subsequent sales, as of December 31, 2021 Sanofi held 279,766 shares of Regeneron stock.

C.2. Alliance arrangements with Bristol-Myers Squibb (BMS)

Two of Sanofi's leading products were jointly developed with BMS: the anti-hypertensive agent irbesartan (Aprovel®/Avapro®/Karvea®) and the anti-atherothrombosis treatment clopidogrel bisulfate (Plavix®/Iscover®).

On September 27, 2012, Sanofi and BMS signed an agreement relating to their alliance following the loss of exclusivity of Plavix® and Avapro®/Avalide® in many major markets.

Under the terms of this agreement, effective January 1, 2013, BMS returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the United States and Puerto Rico ("Territory B"), giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS received royalty payments on Sanofi's sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in Territory B) until 2018, and also received a payment of $200 million from Sanofi in December 2018, part of which is for buying out the non-controlling interests. Rights to Plavix® in Territory B remained unchanged and continued to be governed by the terms of the original agreement until February 28, 2020.

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/Avalide®) as defined in the new agreement, Sanofi recognized in its consolidated financial statements the revenue and expenses generated by its own operations. Since January 2019 onwards, there has no longer been any share of profits reverting to BMS (previously presented within ***Net income attributable to non-controlling interests*** in the income statement).

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

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

D/ Presentation of the financial statements

D.1. Principal changes in the scope of consolidation in 2021

Acquisition of Kymab

On April 8, 2021, Sanofi acquired the entire share capital of Kymab for an upfront payment of $1.1 billion (€973 million) and up to $350 million contingent upon reaching certain development milestones.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was accounted for as an asset acquisition given that the principal asset (the KY1005 project, currently in Phase II clinical development, and relating to the human monoclonal antibody OX40L, an essential regulator of the immune system) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €965 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €932 million.

Acquisition of Kiadis

On November 2, 2020, Sanofi and Kiadis, a biopharmaceutical company developing novel "off-the-shelf" natural killer (NK) cell therapies for patients with life-threatening diseases, entered into a definitive agreement whereby Sanofi was to make a public offer to acquire the entire share capital of Kiadis, i.e. 61 million shares, at a cash price of €5.45 per share.

The acquisition was approved unanimously by the Boards of Directors of Sanofi and Kiadis, and 95.03% of the share capital of Kiadis had been tendered into the offer as of April 16, 2021. As of the end of the post-closing acceptance period on April 29, 2021, Sanofi held 97.39% of the share capital of Kiadis, and launched a statutory public buy-out procedure in order to obtain 100% of the share capital.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was accounted for as an asset acquisition given that the principal asset (the K-NK technology platform) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €341 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €326 million.

Acquisition of Tidal

On April 9, 2021, Sanofi acquired Tidal Therapeutics, a privately owned, pre-clinical stage biotech company with a unique mRNA-based approach for in vivo reprogramming of immune cells. The new technology platform will expand Sanofi's research capabilities in immuno-oncology and inflammatory diseases, and may have applicability to other disease areas as well.

Tidal Therapeutics was acquired for an upfront payment of $160 million (€136 million), and up to $310 million contingent upon reaching certain development milestones.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was accounted for as an asset acquisition given that the principal asset (the unique mRNA-based in vivo reprogramming technology) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €130 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €135 million.

Acquisition of Translate Bio

On August 3, 2021, Sanofi entered into a definitive agreement with Translate Bio, a clinical-stage mRNA therapeutics company, under which Sanofi was to acquire all outstanding shares of Translate Bio for $38 per share. The Sanofi and Translate Bio Boards of Directors unanimously approved the transaction.

The acquisition of Translate Bio by Sanofi was completed on September 14, 2021, with Sanofi holding the entire share capital of Translate Bio upon expiration of the squeeze-out procedure.

The provisional purchase price allocation, as presented in the table below, led to the recognition of goodwill of €2,179 million:

(€ million)	Fair value at acquisition date
Other intangible assets	396
Deferred tax liabilities	(93)
Other current and non-current assets and liabilities	174
Cash and cash equivalents	247
Shire contingent consideration liability (see Note D.18.)	(323)
Net assets of Translate Bio	**401**
Goodwill	2,179
Purchase price	**2,580**

The other intangible assets mainly comprise a messenger RNA technological platform applied to the development of vaccines and therapeutic agents.

Goodwill mainly represents the effects of expected future synergies and other benefits to be derived from the integration of Translate Bio into the Sanofi group, in particular by accelerating the delivery of development programs.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

Translate Bio has no commercial operations, and has made a negative contribution of €72 million to Sanofi's consolidated net income since the acquisition date.

Acquisition-related costs recognized in profit or loss in 2021 were mainly recorded within the line item ***Other operating expenses***, and amounted to €13 million.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €2,333 million.

Under the terms of the collaboration agreement between Sanofi and Translate Bio as announced on June 23, 2020, Sanofi held an equity interest of approximately 5% in Translate Bio. As of the date when Sanofi obtained control of Translate Bio, that interest was remeasured at the purchase price of $38 per share. The change in fair value was recognized within ***Other comprehensive income***, in accordance with paragraph 42 of IFRS 3 (see Note D.7.).

Acquisition of Kadmon

On September 8, 2021, Sanofi entered into a definitive merger agreement with Kadmon, a biopharmaceutical company that discovers, develops and markets transformative therapies for disease areas with significant unmet medical needs. Shareholders of Kadmon common

stock received $9.50 per share in cash, representing a transaction valued at $1.9 billion on a fully-diluted basis. The Sanofi and Kadmon Boards of Directors unanimously approved the transaction.

The acquisition of Kadmon by Sanofi was completed on November 9, 2021, with Sanofi holding the entire share capital of Kadmon upon expiration of the squeeze-out procedure.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was therefore accounted for as an asset acquisition given that the principal asset (belumosudil, commercialized in the United States under the brand name Rezurock™) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €1,739 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €1,575 million.

Acquisition of Origimm

On December 3, 2021, Sanofi acquired the entire share capital of Origimm Biotechnology GmbH, a privately owned Austrian biotechnology company specializing in the discovery of virulent skin microbiome components and antigens from bacteria that cause skin diseases such as acne, for an upfront payment of €55 million and up to €95 million contingent upon reaching certain development and regulatory milestones.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was therefore accounted for as an asset acquisition given that the principal asset (the group of Propionibacterium acnes antigens) concentrates substantially all of the fair value of the acquired set of activities and assets.

Nearly €55 million of the acquisition price paid was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows for the year ended December 31, 2021 is a net cash outflow of €50 million.

D.2. Principal changes in the scope of consolidation in 2020 and 2019

D.2.1. Principal changes in the scope of consolidation in 2020

Acquisition of Principia

On August 17, 2020, Sanofi and Principia Biopharma Inc. (“Principia”), a late-stage biopharmaceutical company focused on developing treatments for autoimmune diseases, entered into a definitive agreement under which Sanofi was to acquire all the outstanding shares of Principia for $100 per share. The transaction was approved unanimously by the Boards of Directors of Sanofi and Principia. Sanofi's acquisition of Principia was completed on September 28, 2020, with Sanofi holding the entire share capital of Principia upon expiration of the squeeze-out procedure. The final purchase price allocation, as presented in the table below, led to the recognition of goodwill of €912 million:

(€ million)	Fair value at acquisition date
Other intangible assets	2,534
Other current and non-current assets and liabilities	(38)
Cash and cash equivalents	186
Net deferred tax position	(436)
Net assets of Principia	**2,246**
Goodwill	912
Purchase price	**3,158**

The other intangible assets mainly comprise:

- rilzabrutinib (PRN 1008), a molecule undergoing clinical trials for various indications in immuno-inflammatory diseases and rare blood disorders; and
- tolebrutinib (PRN 2246/SAR442168), a molecule currently undergoing clinical trials for the treatment of multiple sclerosis and other diseases of the central nervous system.

Goodwill represents (i) the pipeline of future products in pre-clinical research and development; (ii) the capacity to draw on a specialized structure to refresh the existing product portfolio; and (iii) the competencies of Principia staff.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

No material adjustment was required on completion of the final purchase price allocation.

Acquisition of Synthorx

On December 9, 2019, Sanofi and Synthorx Inc. ("Synthorx"), a clinical-stage biotechnology company focused on prolonging and improving the lives of people suffering from cancer and autoimmune disorders, entered into a definitive agreement under which Sanofi was to acquire all of the outstanding shares of Synthorx for $68 per share. The transaction was unanimously approved by both the Sanofi and Synthorx Boards of Directors. On December 23, 2019, Sanofi launched a public tender offer to acquire all of the outstanding ordinary shares of Synthorx for $68 per share in cash, without interest and net of any applicable withholding taxes. The acquisition of Synthorx was completed on January 23, 2020, with Sanofi holding the entire share capital of Synthorx upon expiration of the squeeze-out procedure. The final purchase price allocation, as presented in the table below, led to the recognition of goodwill of €930 million:

(€ million)	Fair value at acquisition date
Other intangible assets	1,549
Other current and non-current assets and liabilities	36
Net deferred tax position	(269)
Net assets of Synthorx	**1,316**
Goodwill	930
Purchase price	**2,246**

The other intangible assets mainly comprise THOR-707, a molecule currently in Phase I clinical trials that stimulates T lymphocytes, and as such has potential as a cancer immunotherapy.

Goodwill represents (i) the pipeline of future products in pre-clinical research and development; (ii) the capacity to draw on a specialized structure to refresh the existing product portfolio; (iii) the competencies of Synthorx staff; (iv) benefits derived from the creation of new growth platforms; and (v) expected future synergies and other benefits from the combination of Synthorx and Sanofi.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

No material adjustment was required on completion of the final purchase price allocation.

Transaction related to the equity-accounted investment in Regeneron

From the beginning of April 2014, Sanofi accounted for its investment in Regeneron using the equity method. As from that date, in accordance with the Investor Agreement as amended in early 2014, Sanofi had the right to designate a member of the Regeneron Board of Directors.

On May 29, 2020, Sanofi closed the transaction announced on May 25, 2020 involving the sale of its equity investment in Regeneron (with the exception of 400,000 shares), through (i) a registered public offering in the United States and internationally and (ii) a share repurchase by Regeneron. Sanofi divested 13 million shares of Regeneron common stock (of which 10.6 million were sold by Sanofi) through the public offering at a price of $515 per share, raising a total amount of $6,703 million; and Regeneron repurchased 9.8 million of its own shares of common stock directly from Sanofi for $5,000 million, at the offer price less a subscription discount ($509.85 per share). The total sale proceeds (before transaction-related costs) amounted to €10,575 million. At the same time, Sanofi as a result of this transaction lost the right to designate a member of the Regeneron Board of Directors under the amended Investor Agreement. Finally, as of May 29, 2020 Sanofi retained ownership of 400,000 Regeneron shares in order to continue to partially fund its commitments to invest in the development programs for cemiplimab (REGN2810) and dupilumab, in line with the 2018 Letter Agreement under which Sanofi is permitted to sell up to 1.4 million shares through the end of 2020. As of December 31, 2021, Sanofi had sold 779,320 Regeneron shares under that agreement. The number of Regeneron shares retained by Sanofi is 279,766 as of December 31, 2021 (see Note C.1.).

Sanofi's equity investment in Regeneron was accounted for by the equity method until May 29, 2020. As of that date, the carrying amount of the investment was €3,668 million; that amount was reversed out on closing of the transaction. Before tax effects, the gain on the divestment amounted to €7,382 million, including (i) a gain of €318 million arising on the currency translation reserve associated with Regeneron, which was taken to profit or loss in accordance with IAS 21; (ii) the deduction of transaction-related costs of €64 million; and (iii) a gain of €157 million on the remeasurement of the 400,000 retained shares at their quoted market price as of May 29, 2020 ($612.81). In accordance with IFRS 9 (Financial Instruments), the retained shares were classified in the ***"Equity instruments at fair value through other comprehensive income"*** category on the transaction date, at a value of €221 million (see Note D.7.).

The tax charge arising on the transaction was €502 million.

Given the material impact of this transaction, and to facilitate users' understanding of the financial statements, the pre-tax gain on this transaction is presented as a separate line item in the consolidated income statement, ***Gain on Regeneron investment arising from the transaction of May 29, 2020***.

The net cash inflow from the transaction was €10,370 million, which (for the reason cited above) is presented as a separate line item in the consolidated statement of cash flows, ***Net proceeds from sale of Regeneron shares on May 29, 2020.***

Sale of Seprafilm®

On November 27, 2019, Sanofi entered into a definitive agreement to sell Seprafilm® to Baxter. The sale was completed on February 14, 2020. Sanofi recognized a pre-tax gain of €129 million.

The impact of this sale, reflected in the line item ***Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax*** within the consolidated statement of cash flows, was a net cash inflow before tax of €311 million.

D.4. Goodwill and other intangible assets

Movements in goodwill comprise:

(€ million)	Goodwill
Balance at January 1, 2019	**44,235**
Acquisitions during the period	—
Other movements during the period[(a)]	(244)
Currency translation differences	528
Balance at December 31, 2019	**44,519**
Acquisitions during the period	1,843
Other movements during the period[(a)]	(75)
Currency translation differences	(1,923)
Balance at December 31, 2020	**44,364**
Acquisitions during the period	2,179
Other movements during the period[(a)]	(89)
Currency translation differences	1,602
Balance at December 31, 2021	**48,056**

(a) This line includes the amount of goodwill allocated to divested operations in accordance with paragraph 86 of IAS 36.

Acquisition of Translate Bio (2021)

The provisional purchase price allocation for Translate Bio resulted in the recognition of intangible assets (other than goodwill) of €396 million as of the acquisition date (September 14, 2021), and of goodwill provisionally measured at €2,179 million as of the acquisition date (see Note D.1.).

Acquisition of Principia (2020)

The final purchase price allocation for Principia resulted in the recognition of intangible assets (other than goodwill) of €2,534 million as of the acquisition date (September 28, 2020), and of goodwill measured at €912 million as of the acquisition date (see Note D.2.1.).

Acquisition of Synthorx (2020)

The final purchase price allocation for Synthorx resulted in the recognition of intangible assets (other than goodwill) totaling €1,549 million as of the acquisition date (January 23, 2020), and of goodwill measured at €930 million as of the acquisition date (see Note D.2.1.).

Movements in other intangible assets comprise:

(€ million)	Acquired R&D	Products, trademarks and other rights	Software	Total other intangible assets
Gross Value at January 1, 2019[a]	**7,422**	**61,800**	**1,504**	**70,726**
Acquisitions and other increases[a]	272	19	155	446
Disposals and other decreases	(236)	(569)	(50)	(855)
Currency translation differences[a]	86	889	9	984
Transfers[b]	(1,814)	1,814	(5)	(5)
Gross value at December 31, 2019[a]	**5,730**	**63,953**	**1,613**	**71,296**
Changes in scope of consolidation[c]	3,951	132	—	4,083
Acquisitions and other increases[a]	654	58	106	818
Disposals and other decreases	(44)	(243)	(46)	(333)
Currency translation differences[a]	(593)	(2,926)	(38)	(3,557)
Transfers[b]	(98)	100	(2)	—
Gross value at December 31, 2020[a]	**9,600**	**61,074**	**1,633**	**72,307**
Changes in scope of consolidation[c]	1,805	1,821	—	3,626
Acquisitions and other increases	339	159	118	616
Disposals and other decreases	(313)	(173)	(16)	(502)
Currency translation differences	560	2,234	24	2,818
Transfers[b]	(784)	791	(7)	—
Gross value at December 31, 2021	**11,207**	**65,906**	**1,752**	**78,865**
Accumulated amortization & impairment at January 1, 2019[a]	**(2,678)**	**(45,228)**	**(971)**	**(48,877)**
Amortization expense[a]	—	(2,167)	(127)	(2,294)
Impairment losses, net of reversals[d]	(847)	(2,757)	(23)	(3,627)
Disposals and other decreases	158	488	51	697
Currency translation differences	(31)	(648)	(8)	(687)
Transfers[b]	2	(2)	1	1
Accumulated amortization & impairment at December 31, 2019[a]	**(3,396)**	**(50,314)**	**(1,077)**	**(54,787)**
Amortization expense[a]	—	(1,707)	(112)	(1,819)
Impairment losses, net of reversals[d]	(328)	(2)	—	(330)
Disposals and other decreases	44	232	45	321
Currency translation differences	158	2,460	31	2,649
Transfers[b]	14	(14)	—	—
Accumulated amortization & impairment at December 31, 2020[a]	**(3,508)**	**(49,345)**	**(1,113)**	**(53,966)**
Amortization expense	—	(1,621)	(119)	(1,740)
Impairment losses, net of reversals[d]	(150)	(42)	—	(192)
Disposals and other decreases	313	133	16	462
Currency translation differences	(132)	(1,869)	(21)	(2,022)
Accumulated amortization & impairment at December 31, 2021	**(3,477)**	**(52,744)**	**(1,237)**	**(57,458)**
Carrying amount at December 31, 2019	2,334	13,639	536	16,509
Carrying amount at December 31, 2020	6,092	11,729	520	18,341
Carrying amount at December 31, 2021	**7,730**	**13,162**	**515**	**21,407**

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement (see Note A.2.1.).

(b) The "Transfers" line mainly relates to acquired R&D that came into commercial use during the period and is being amortized from that date.

(c) The "Changes in scope of consolidation" line corresponds to the fair value of intangible assets recognized in connection with acquisitions made during the period (see Notes D.1. and D.2.1.).

(d) See Note D.5.

"Products, trademarks and other rights" mainly comprise:

- "marketed products", with a carrying amount of €11.7 billion as of December 31, 2021 (versus €11.4 billion as of December 31, 2020 and €13.3 billion as of December 31, 2019) and a weighted average amortization period of approximately 10 years;
- "technological platforms", with a carrying amount of €1.2 billion as of December 31, 2021 (versus €0.2 billion as of December 31, 2020 and €0.2 billion as of December 31, 2019) and a weighted average amortization period of approximately 18 years; and
- "trademarks", with a carrying amount of €0.1 billion as of December 31, 2021 (versus €0.1 billion as of December 31, 2020 and €0.1 billion as of December 31, 2019) and a weighted average amortization period of approximately 13 years.

The table below provides information about the principal "marketed products", which were recognized in connection with major acquisitions made by Sanofi and represented 92% of the carrying amount of that item as of December 31, 2021:

(€ million)	Gross value	Accumulated amortization & impairment	Carrying amount at December 31, 2021	Amortization period (years)[a]	Residual amortization period (years)[b]	Carrying amount at December 31, 2020	Carrying amount at December 31, 2019
Genzyme	10,177	(9,145)	1,032	10	3	1,485	2,095
Boehringer Ingelheim Consumer Healthcare	3,647	(1,434)	2,213	17	13	2,489	2,699
Aventis	33,687	(33,614)	73	9	8	110	219
Chattem	1,280	(687)	593	23	12	602	711
Protein Sciences	806	(274)	532	13	9	554	667
Ablynx	1,966	(472)	1,494	14	11	1,861	2,029
Bioverativ	6,841	(3,776)	3,065	13	10	3,240	3,788
Kadmon	1,771	(21)	1,750	12	12	—	—
Total: principal marketed products	**60,175**	**(49,423)**	**10,752**			**10,341**	**12,208**

(a) Weighted averages. The amortization periods for these products vary between 1 and 25 years.
(b) Weighted averages.

Acquisitions of other intangible assets (excluding software) during 2021 amounted to €498 million.

Transfers during 2021 include the Translate Bio mRNA technological platform, which was brought into service during the period.

During 2020, some of the acquired research and development came into commercial use, and started being amortized from the date of marketing approval; the main items involved were Sarclisa®, indicated for the treatment of relapsed refractory multiple myeloma, and the meningococcal vaccine MenQuadfi®.

During 2019, some of the acquired research and development came into commercial use, and started being amortized from the date of marketing approval; the item involved was the acquired thrombotic thrombocytopenic purpura (aTTP) treatment Cablivi®.

Amortization of other intangible assets is recognized in the income statement within the line item ***Amortization of intangible assets***, except for amortization of software and other rights of an industrial or operational nature which is recognized in the relevant classification of expense by function. An analysis of amortization of software is shown in the table below:

(€ million)	2021	2020 [a]	2019 [a]
Cost of sales	18	19	11
Research and development expenses	3	2	3
Selling and general expenses	98	87	107
Other operating expenses	—	4	6
Total	**119**	**112**	**127**

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement (see Note A.2.1.).

D.5. Impairment of intangible assets and property, plant and equipment

Goodwill

In accordance with IAS 36, goodwill is allocated to groups of cash generating units (CGUs) at a level corresponding to the Pharmaceuticals, Consumer Healthcare and Vaccines segments. When testing goodwill annually for impairment, the recoverable amount is determined for each segment on the basis of value in use, determined using discounted estimates of the future cash flows in accordance with the policies described in Note B.6.1.

The allocation of goodwill as of December 31, 2021 is shown below:

(€ million)	Pharmaceuticals	Consumer Healthcare	Vaccines	Total
Goodwill	**37,902**	**6,567**	**3,587**	**48,056**

The value in use of each segment was determined by applying an after-tax discount rate to estimated future after-tax cash flows.

A separate discount rate is used for each segment to reflect the specific economic conditions of that segment.

The rates used for impairment testing in 2021 were 7.25% for the Pharmaceuticals segment, 7.00% for the Consumer Healthcare segment and 7.25% for the Vaccines segment; an identical value in use for Sanofi as a whole would be obtained by applying a uniform 7.2% rate to all three segments.

The pre-tax discount rates applied to estimated pre-tax cash flows are calculated by iteration from the previously-determined value in use. Those pre-tax discount rates were 9.5% for the Pharmaceuticals segment, 9.1% for the Consumer Healthcare segment and 9.9% for the Vaccines segment, and equate to a uniform rate of 9.6% for Sanofi as a whole.

The assumptions used in testing goodwill for impairment are reviewed annually. Apart from the discount rate, the principal assumptions used in 2021 were as follows:

- the perpetual growth rates applied to future cash flows were zero for the Pharmaceuticals and Vaccines segments, and 1% for the Consumer Healthcare segment;
- Sanofi also applies assumptions on the probability of success of current research and development projects, and more generally on its ability to renew the product portfolio in the longer term.

Value in use (determined as described above) is compared with the carrying amount, and this comparison is then subjected to sensitivity analyses by reference to the principal parameters, including:

- changes in the discount rate;
- changes in the perpetual growth rate; and
- fluctuations in operating margin.

No impairment of goodwill would need to be recognized in the event of a reasonably possible change in the assumptions used in 2021.

A value in use calculation for each of the segments would not result in an impairment loss using:

- a discount rate up to 4.1 percentage points above the rates actually used; or
- a perpetual growth rate up to 15.3 percentage points below the rates actually used; or
- an operating margin up to 8.8 percentage points below the rates actually used.

No impairment losses were recognized against goodwill in the years ended December 31, 2021, 2020 or 2019.

Other intangible assets

When there is evidence that an asset may have become impaired, the asset's value in use is calculated by applying an after-tax discount rate to the estimated future after-tax cash flows from that asset. For the purposes of impairment testing, the tax cash flows relating to the asset are determined using a notional tax rate incorporating the notional tax benefit that would result from amortizing the asset if its value in use were regarded as its depreciable amount for tax purposes. Applying after-tax discount rates to after-tax cash flows gives the same values in use as would be obtained by applying pre-tax discount rates to pre-tax cash flows.

The after-tax discount rates used in 2021 for impairment testing of other intangible assets in the Pharmaceuticals, Consumer Healthcare and Vaccines segments were obtained by adjusting Sanofi's weighted average cost of capital to reflect specific country and business risks, giving after-tax discount rates in a range from 7.25% to 8.25%.

In most instances, there are no market data that would enable fair value less costs to sell to be determined other than by means of developing a similar estimate based on future cash flows. Consequently, recoverable amount is in substance equal to value in use. The estimates used to determine value in use are sensitive to assumptions specific to the nature of the asset and to Sanofi's activities. Apart from the discount rate, the principal assumptions used in 2021 were as follows:

- mid-term and long-term sales forecasts;
- perpetual growth or attrition rates, when applicable; and
- probability of success of current research and development projects.

The assumptions used in testing intangible assets for impairment are reviewed at least annually.

In 2021, 2020 and 2019, impairment testing of other intangible assets (excluding software) resulted in the recognition of net impairment losses as shown below:

(€ million)	2021	2020	2019
Impairment of other intangible assets (excluding software)	**192**	**330**	**3,604**
Marketed products	42	2	2,757
Pharmaceuticals[(a)]	*1*	*2*	*2,405*
Consumer Healthcare[(b)]	*41*	—	*352*
Research and development projects[(c)]	150	328	847

(a) Impairment losses recognized in the year ended December 31, 2019 include €2,236 million on products in the Eloctate® franchise and €163 million on the marketed product Lemtrada®.

(b) The impairment loss of €352 million recognized in the year ended December 31, 2019 related to Zantac®.

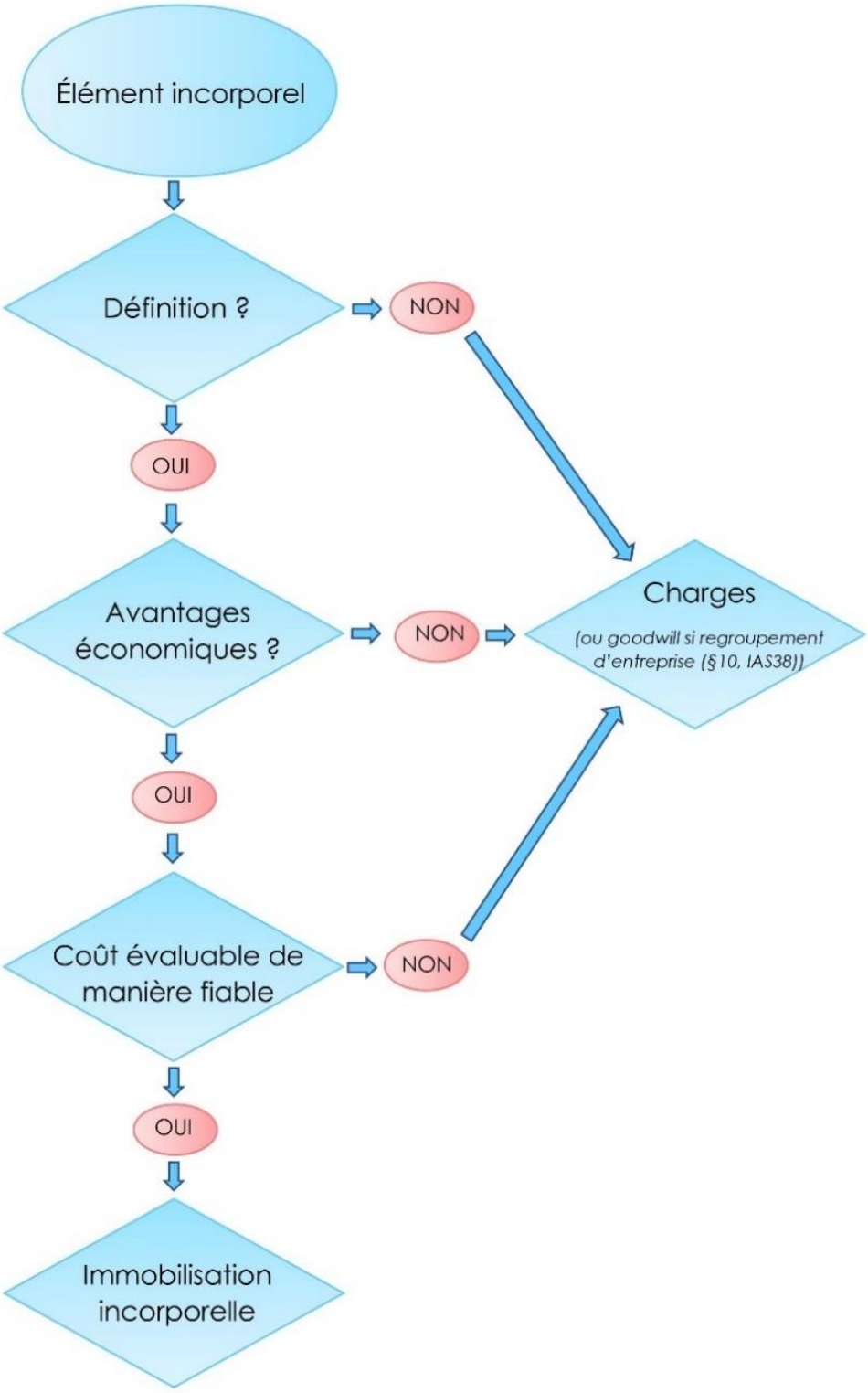
(c) For 2021, this line relates to the discontinuation of the development of sutimlimab in the treatment of Immune Thrombocytopenic Purpura (ITP), and to the termination of various research projects in Vaccines. For 2020, this line mainly comprises impairment losses taken against R&D programs within the Specialty Care GBU, and the discontinuation of certain R&D programs and collaboration agreements in Diabetes. For 2019, it relates mainly to (i) the allocation of the impairment loss recognized for the Eloctate® franchise to the BIVV001 project (see (a) above), and (ii) the termination of the development program for sotagliflozin (€275 million).

Property, plant and equipment

Impairment losses taken against property, plant and equipment are disclosed in Note D.3.

Annexe 2 :

Critères de comptabilisation initiale d'une immobilisation incorporelle (Andernack, 2013)


Élément incorporel
Définition ?
NON
OUI
Avantages économiques ?
NON
Charges
(ou goodwill si regroupement d'entreprise (§10, IAS38))
OUI
Coût évaluable de manière fiable
NON
OUI
Immobilisation incorporelle

Annexe 3 :

Rapport annuel 2021 Johnson & Johnson : Formulaire 10-K (Johnson & Johnson, 2021)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended January 2, 2022

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from to**

Commission file number 1-3215

JOHNSON & JOHNSON

(Exact name of registrant as specified in its charter)

New Jersey	**22-1024240**
(State of incorporation)	**(I.R.S. Employer Identification No.)**
One Johnson & Johnson Plaza New Brunswick, New Jersey	**08933**
(Address of principal executive offices)	**(Zip Code)**

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)

Registrant's telephone number, including area code: (732) 524-0400

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $1.00	JNJ	New York Stock Exchange
0.650% Notes Due May 2024	JNJ24C	New York Stock Exchange
5.50% Notes Due November 2024	JNJ24BP	New York Stock Exchange
1.150% Notes Due November 2028	JNJ28	New York Stock Exchange
1.650% Notes Due May 2035	JNJ35	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes o No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes þ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☑ No o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No þ

The aggregate market value of the Common Stock held by non-affiliates computed by reference to the price at which the Common Stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $445 billion.

On February 10, 2022, there were 2,629,268,158 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Parts I and III:	Portions of registrant's proxy statement for its 2022 annual meeting of shareholders filed within 120 days after the close of the registrant's fiscal year (the "Proxy Statement"), are incorporated by reference to this report on Form 10-K (this "Report").

JOHNSON & JOHNSON AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

At January 2, 2022 and January 3, 2021
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

	2021	2020
Assets		
Current assets		
Cash and cash equivalents (Notes 1 and 2)	$14,487	13,985
Marketable securities (Notes 1 and 2)	17,121	11,200
Accounts receivable trade, less allowances for doubtful accounts $230 (2020, $293)	15,283	13,576
Inventories (Notes 1 and 3)	10,387	9,344
Prepaid expenses and other receivables	3,701	3,132
Total current assets	**60,979**	**51,237**
Property, plant and equipment, net (Notes 1 and 4)	18,962	18,766
Intangible assets, net (Notes 1 and 5)	46,392	53,402
Goodwill (Notes 1 and 5)	35,246	36,393
Deferred taxes on income (Note 8)	10,223	8,534
Other assets	10,216	6,562
Total assets	**$182,018**	**174,894**
Liabilities and Shareholders' Equity		
Current liabilities		
Loans and notes payable (Note 7)	$3,766	2,631
Accounts payable	11,055	9,505
Accrued liabilities	13,612	13,968
Accrued rebates, returns and promotions	12,095	11,513
Accrued compensation and employee related obligations	3,586	3,484
Accrued taxes on income (Note 8)	1,112	1,392
Total current liabilities	**45,226**	**42,493**
Long-term debt (Note 7)	29,985	32,635
Deferred taxes on income (Note 8)	7,487	7,214
Employee related obligations (Notes 9 and 10)	8,898	10,771
Long-term taxes payable (Note 1)	5,713	6,559
Other liabilities	10,686	11,944
Total liabilities	**107,995**	**111,616**
Commitments and Contingencies (Note 19)		
Shareholders' equity		
Preferred stock — without par value (authorized and unissued 2,000,000 shares)	—	—
Common stock — par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)	3,120	3,120
Accumulated other comprehensive income (loss) (Note 13)	(13,058)	(15,242)
Retained earnings	123,060	113,890
	113,122	101,768
Less: common stock held in treasury, at cost (Note 12) (490,878,000 shares and 487,331,000 shares)	39,099	38,490
Total shareholders' equity	**74,023**	**63,278**
Total liabilities and shareholders' equity	**$182,018**	**174,894**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF EARNINGS

(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

	2021	2020	2019
Sales to customers	$93,775	82,584	82,059
Cost of products sold	29,855	28,427	27,556
Gross profit	63,920	54,157	54,503
Selling, marketing and administrative expenses	24,659	22,084	22,178
Research and development expense	14,714	12,159	11,355
In-process research and development (Note 5)	900	181	890
Interest income	(53)	(111)	(357)
Interest expense, net of portion capitalized (Note 4)	183	201	318
Other (income) expense, net	489	2,899	2,525
Restructuring (Note 20)	252	247	266
Earnings before provision for taxes on income	22,776	16,497	17,328
Provision for taxes on income (Note 8)	1,898	1,783	2,209
Net earnings	**$20,878**	**14,714**	**15,119**
Net earnings per share (Notes 1 and 15)			
Basic	**$7.93**	**5.59**	**5.72**
Diluted	**$7.81**	**5.51**	**5.63**
Average shares outstanding (Notes 1 and 15)			
Basic	**2,632.1**	**2,632.8**	**2,645.1**
Diluted	**2,674.0**	**2,670.7**	**2,684.3**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Dollars in Millions) (Note 1)

	2021	2020	2019
Net earnings	$20,878	14,714	15,119
Other comprehensive income (loss), net of tax			
Foreign currency translation	(1,079)	(233)	164
Securities:			
Unrealized holding gain (loss) arising during period	(4)	1	—
Reclassifications to earnings	—	—	—
Net change	(4)	1	—
Employee benefit plans:			
Prior service credit (cost), net of amortization	(169)	1,298	(18)
Gain (loss), net of amortization	4,318	(1,135)	(714)
Effect of exchange rates	106	(229)	(1)
Net change	4,255	(66)	(733)
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(199)	1,000	(107)
Reclassifications to earnings	(789)	(53)	7
Net change	(988)	947	(100)
Other comprehensive income (loss)	2,184	649	(669)
Comprehensive income	**$23,062**	**15,363**	**14,450**

The tax effects in other comprehensive income for the fiscal years 2021, 2020 and 2019 respectively: Foreign Currency Translation; $346 million, $536 million and $19 million; Securities: $1 million in 2021, Employee Benefit Plans: $1,198 million, $21 million and $222 million, Derivatives & Hedges: $263 million, $252 million and $27 million.

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF EQUITY

(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 30, 2018	**$59,752**	**106,216**	**(15,222)**	**3,120**	**(34,362)**
Net earnings	15,119	15,119			
Cash dividends paid ($3.75 per share)	(9,917)	(9,917)			
Employee compensation and stock option plans	1,933	(758)			2,691
Repurchase of common stock	(6,746)				(6,746)
Other	(1)	(1)			
Other comprehensive income (loss), net of tax	(669)		(669)		
Balance, December 29, 2019	**59,471**	**110,659**	**(15,891)**	**3,120**	**(38,417)**
Net earnings	14,714	14,714			
Cash dividends paid ($3.98 per share)	(10,481)	(10,481)			
Employee compensation and stock option plans	2,217	(931)			3,148
Repurchase of common stock	(3,221)				(3,221)
Other	(71)	(71)			
Other comprehensive income (loss), net of tax	649		649		
Balance, January 3, 2021	**63,278**	**113,890**	**(15,242)**	**3,120**	**(38,490)**
Net earnings	20,878	20,878			
Cash dividends paid ($4.19 per share)	(11,032)	(11,032)			
Employee compensation and stock option plans	2,171	(676)			2,847
Repurchase of common stock	(3,456)				(3,456)
Other comprehensive income (loss), net of tax	2,184		2,184		
Balance, January 2, 2022	**$74,023**	**123,060**	**(13,058)**	**3,120**	**(39,099)**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Dollars in Millions) (Note 1)

	2021	2020	2019
Cash flows from operating activities			
Net earnings	$20,878	14,714	15,119
Adjustments to reconcile net earnings to cash flows from operating activities:			
Depreciation and amortization of property and intangibles	7,390	7,231	7,009
Stock based compensation	1,135	1,005	977
Asset write-downs	989	233	1,096
Contingent consideration reversal	—	(1,148)	—
Net gain on sale of assets/businesses	(617)	(111)	(2,154)
Deferred tax provision	(2,079)	(1,141)	(2,476)
Credit losses and accounts receivable allowances	(48)	63	(20)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:			
(Increase)/Decrease in accounts receivable	(2,402)	774	(289)
Increase in inventories	(1,248)	(265)	(277)
Increase in accounts payable and accrued liabilities	2,437	5,141	4,060
Increase in other current and non-current assets	(1,964)	(3,704)	(1,054)
(Decrease)/Increase in other current and non-current liabilities	(1,061)	744	1,425
Net cash flows from operating activities	**23,410**	**23,536**	**23,416**
Cash flows from investing activities			
Additions to property, plant and equipment	(3,652)	(3,347)	(3,498)
Proceeds from the disposal of assets/businesses, net	711	305	3,265
Acquisitions, net of cash acquired (Note 18)	(60)	(7,323)	(5,810)
Purchases of investments	(30,394)	(21,089)	(3,920)
Sales of investments	25,006	12,137	3,387
Credit support agreements activity, net	214	(987)	338
Other (primarily licenses and milestones)	(508)	(521)	44
Net cash used by investing activities	**(8,683)**	**(20,825)**	**(6,194)**
Cash flows from financing activities			
Dividends to shareholders	(11,032)	(10,481)	(9,917)
Repurchase of common stock	(3,456)	(3,221)	(6,746)
Proceeds from short-term debt	1,997	3,391	39
Repayment of short-term debt	(1,190)	(2,663)	(100)
Proceeds from long-term debt, net of issuance costs	5	7,431	3
Repayment of long-term debt	(1,802)	(1,064)	(2,823)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	1,036	1,114	954
Credit support agreements activity, net	281	(333)	100
Other	114	(294)	475
Net cash used by financing activities	**(14,047)**	**(6,120)**	**(18,015)**
Effect of exchange rate changes on cash and cash equivalents	**(178)**	**89**	**(9)**
Increase/(Decrease) in cash and cash equivalents	502	(3,320)	(802)
Cash and cash equivalents, beginning of year (Note 1)	13,985	17,305	18,107
Cash and cash equivalents, end of year (Note 1)	**$14,487**	**13,985**	**17,305**
Supplemental cash flow data			
Cash paid during the year for:			
Interest	$990	904	995
Interest, net of amount capitalized	941	841	925
Income taxes	4,768	4,619	4,191
Supplemental schedule of non-cash investing and financing activities			
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds/ employee withholding tax on stock awards	$1,811	1,937	1,736
Conversion of debt	—	27	1
Acquisitions			
Fair value of assets acquired	$61	7,755	7,228
Fair value of liabilities assumed and noncontrolling interests	(1)	(432)	(1,418)
Net cash paid for acquisitions (Note 18)	$60	7,323	5,810

See Notes to Consolidated Financial Statements

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including consideration of competitor pricing. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. A significant portion of the liability related to rebates is from the sale of the Company's pharmaceutical products within the U.S., primarily the Managed Care, Medicare and Medicaid programs, which amounted to $7.7 billion and $7.2 billion as of January 2, 2022 and January 3, 2021, respectively. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales return accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The sales returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer Health and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual net trade sales during each of the fiscal years 2021, 2020 and 2019.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the same period as related sales. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue. The Company also earns profit-share payments through collaborative arrangements for certain products, which are included in sales to customers. For all years presented, profit-share payments were less than 3.0% of the total revenues and are included in sales to customers.

See Note 17 to the Consolidated Financial Statements for further disaggregation of revenue.

Shipping and Handling

Shipping and handling costs incurred were $1.1 billion, $1.0 billion and $1.0 billion in fiscal years 2021, 2020 and 2019, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories

Inventories are stated at the lower of cost or net realizable value determined by the first-in, first-out method.

Intangible Assets and Goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed its annual impairment test for 2021 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial Instruments

As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement

determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure's impact on the Company's financial performance; (2) protect the Company's cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Leases

The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Right of Use (ROU) Assets and Lease Liabilities for operating leases are included in Other assets, Accrued liabilities, and Other liabilities on the consolidated balance sheet. The ROU Assets represent the right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Commitments under finance leases are not significant, and are included in Property, plant and equipment, Loans and notes payable, and Long-term debt on the consolidated balance sheet.

ROU Assets and Lease Liabilities are recognized at the lease commencement date based on the present value of all minimum lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, when the implicit rate is not readily determinable. Lease terms may include options to extend or terminate the lease. These options are included in the lease term when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term. The Company has elected the following policy elections on adoption: use of portfolio approach on leases of assets under master service agreements, exclusion of short term leases on the balance sheet, and not separating lease and non-lease components.

The Company primarily has operating lease for space, vehicles, manufacturing equipment and data processing equipment. The ROU asset pertaining to operating leases was $0.9 billion and $1.0 billion in 2021 and 2020, respectively. The lease liability was $1.0 billion and $1.1 billion in 2021and 2020, respectively. The operating lease costs were $0.3 billion, $0.3 billion and $0.3 billion in 2021, 2020 and 2019, respectively. Cash paid for amounts included in the measurement of lease liabilities were $0.3 billion, $0.3 billion and $0.3 billion in 2021, 2020 and 2019, respectively.

Product Liability

Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated.

Research and Development

Research and development expenses are expensed as incurred in accordance with ASC 730, Research and Development. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product & profit share payments received	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner or government entity	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of products sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO®, co-developed with Bayer HealthCare AG and IMBRUVICA®, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

Separately, the Company has a number of licensing arrangements for products and compounds including DARZALEX®, licensed from Genmab A/S.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.7 billion, $2.1 billion and $2.2 billion in fiscal years 2021, 2020 and 2019, respectively.

Income Taxes

Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

In 2017, the United States enacted into law new U.S. tax legislation, the U.S. Tax Cuts and Jobs Act (TCJA). This law included provisions for a comprehensive overhaul of the corporate income tax code, including a reduction of the statutory corporate tax rate from 35% to 21%, effective on January 1, 2018. The TCJA included a provision for a tax on all

5. Intangible Assets and Goodwill

At the end of fiscal years 2021 and 2020, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2021	2020
Intangible assets with definite lives:		
Patents and trademarks — gross	$38,572	39,990
Less accumulated amortization	(20,088)	(17,618)
Patents and trademarks — net	**$18,484**	**22,372**
Customer relationships and other intangibles — gross	$23,011	22,898
Less accumulated amortization	(11,925)	(10,912)
Customer relationships and other intangibles — net[1]	**$11,086**	**11,986**
Intangible assets with indefinite lives:		
Trademarks	$6,985	7,195
Purchased in-process research and development[2]	9,837	11,849
Total intangible assets with indefinite lives	**$16,822**	**19,044**
Total intangible assets — net	**$46,392**	**53,402**

(1) The majority is comprised of customer relationships

(2) In fiscal 2021, the Company recorded a partial IPR&D impairment charge of $0.9 billion primarily related to expected development delays in the general surgery digital robotics platform (Ottava) acquired with the Auris Health acquisition in 2019. The impairment charge was calculated based on revisions to the discounted cash flow valuation model reflecting a delay of first in human procedures of approximately two years from the initial acquisition model assumption of the second half of 2022. The remaining reduction was driven by assets that reached commercialization and are now classified as having definite lives.

Goodwill as of January 2, 2022 and January 3, 2021, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer Health	Pharmaceutical	Medical Devices	Total
Goodwill at December 29, 2019	$9,736	9,169	14,734	33,639
Goodwill, related to acquisitions	—	1,222	238	1,460
Currency translation/other	600	618	76	1,294
Goodwill at January 3, 2021	$10,336	11,009	15,048	36,393
Goodwill, related to acquisitions	—	—	—	—
Goodwill, related to divestitures	(9)	—	—	(9)
Currency translation/other	(517)	(429)	(192)	(1,138)
Goodwill at January 2, 2022	**$9,810**	**10,580**	**14,856**	**35,246**

The weighted average amortization period for patents and trademarks is 12 years. The weighted average amortization period for customer relationships and other intangible assets is 21 years. The amortization expense of amortizable assets included in Cost of products sold was $4.7 billion, $4.7 billion and $4.5 billion before tax, for the fiscal years ended January 2, 2022, January 3, 2021 and December 29, 2019, respectively. Intangible asset write-downs are included in Other (income) expense, net.

The estimated amortization expense for approved products, before tax, for the five succeeding years is approximately:

(Dollars in Millions) 2022	2023	2024	2025	2026
$4,600	4,600	4,400	3,600	3,000

See Note 18 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

Medical Devices includes:

- A gain of $2.0 billion from the divestiture of the ASP business
- A restructuring related charge of $0.4 billion
- Litigation expense of $0.4 billion
- Auris Health acquisition and integration related costs of $0.1 billion

(6) Long-lived assets include property, plant and equipment, net for fiscal years 2021, and 2020 of $18,962 and $18,766, respectively, and intangible assets and goodwill, net for fiscal years 2021 and 2020 of $81,638 and $89,795, respectively.

18. Acquisitions and Divestitures

During fiscal year 2021, the Company did not make any material acquisitions.

During fiscal year 2020, certain businesses were acquired for $7.3 billion in cash and $0.4 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $7.5 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The fiscal year 2020 acquisitions primarily included: all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc. (XBiotech), Momenta Pharmaceuticals, Inc. (Momenta), a company that discovers and develops novel therapies for immune-mediated diseases and the outstanding shares in Verb Surgical Inc., a company with significant robotics and data science capabilities.

During the fiscal first quarter of 2020, the Company completed the acquisition of all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc., for a purchase price of $0.8 billion. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets, primarily IPR&D, for $0.8 billion applying a probability of success factor that ranged from 20% to 60% to reflect inherent development, regulatory and commercial risk for the different indications. The discount rate applied was approximately 16%. XBiotech may be eligible to receive additional payments upon the receipt of certain commercialization authorizations. The transaction was accounted for as a business combination and included in the Pharmaceutical segment. On January 28, 2022, subsequent to the fiscal year 2021, additional information regarding efficacy became available which led the Company to the decision to terminate the development of bermekimab for Atopic Dermatitis (AD). The Company recorded an intangible asset impairment charge of approximately $0.6 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of AD and Hidradenitis Suppurativa (HS). The impairment charge is related to the AD indication and is a nonrecognized subsequent event and will be reflected in the first quarter 2022 financial statements. The Company acquired all rights to bermekimab from XBiotech, Inc. in fiscal year 2020.

Additionally, in the fiscal first quarter of 2020, the Company completed the acquisition of all outstanding shares in Verb Surgical Inc., a company with significant robotics and data science capabilities, including those shares previously held by Verily. The transaction was accounted for as a business combination and included in the Medical Devices segment. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets, primarily IPR&D, for $0.4 billion, goodwill for $0.2 billion, other assets of $0.2 billion and liabilities assumed of $0.3 billion. The fair value of the Company's previously held equity investment in Verb Surgical Inc. was $0.4 billion.

On October 1, 2020, the Company completed the acquisition of Momenta for a purchase price of approximately $6.1 billion, net of cash acquired. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets (IPR&D) of $6.0 billion, goodwill of $1.2 billion, other assets of $0.5 billion and liabilities of $1.6 billion. The assets acquired are intended to address substantial unmet medical need in maternal-fetal disorders, neuro-inflammatory disorders, rheumatology, dermatology and autoimmune hematology. Depending on the asset, probability of success factors ranging from 20% to 77% were used in the fair value calculation to reflect inherent development and regulatory risk of the IPR&D. The discount rate applied was approximately 13%. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes. The transaction was accounted for as a business combination and included in the Pharmaceutical segment.

During fiscal year 2019 certain businesses were acquired for $5.8 billion in cash and $1.4 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $6.8 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The fiscal year 2019 acquisitions primarily included DR. CI:LABO, a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products and Auris Health, Inc. a privately held developer of robotic technologies, initially focused in lung cancer, with an U.S. FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures.

On January 17, 2019, the Company acquired DR. CI:LABO, a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products for a total purchase price of approximately ¥230 billion, which equates to approximately $2.1 billion, using the exchange rate of 109.06 Japanese Yen to each U.S. Dollar on January 16, 2019. Additionally, in the fiscal first quarter of 2019, the Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO.

The Company treated this transaction as a business combination and included it in the Consumer Health segment. During the fiscal first quarter of 2020, the Company finalized the purchase price allocation. The final fair value of the acquisition was allocated primarily to amortizable intangible assets for $1.5 billion, goodwill for $1.2 billion and liabilities of $0.4 billion. The amortizable intangible assets were comprised of brand/trademarks and customer relationships with a weighted average life of 15.3 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes.

On April 1, 2019 the Company completed the acquisition of Auris Health, Inc. for approximately $3.4 billion, net of cash acquired. Additional contingent payments of up to $2.35 billion, in the aggregate, may be payable upon reaching certain predetermined milestones. Auris Health was a privately held developer of robotic technologies, initially focused in lung cancer, with a U.S. FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures. The Company treated this transaction as a business combination and included it in the Medical Devices segment. The fair value of the acquisition was allocated primarily to amortizable and non-amortizable intangible assets, primarily IPR&D for $3.0 billion, goodwill for $2.0 billion, marketable securities of $0.2 billion and liabilities assumed of $1.8 billion, which includes the fair value of the contingent payments mentioned above. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes. During the fiscal second quarter of 2020, the Company finalized the purchase price allocation. During fiscal 2020, the Company recorded Other income of approximately $1.1 billion for the reversal of all of the contingent consideration related to the timing of certain developmental and commercial milestones, which are not expected to be met based on the Company's current timelines. During the fiscal third quarter of 2020, the Company recorded a partial IPR&D impairment charge of $0.1 billion related to timing and progression of the digital surgery platforms. In the fiscal third quarter of 2021, the Company recorded a partial IPR&D charge of $0.9 billion primarily related to expected development delays in the general surgery digital robotics platform (Ottava). A probability of success factor ranging from 18% to 66% across Ottava sub-platforms, was used in the fair value calculation to reflect inherent regulatory and commercial risk of the contingent payments and IPR&D. The discount rate applied was approximately 9.5%.

In accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, supplemental pro forma information for fiscal years 2021, 2020 and 2019 is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

Divestitures

During fiscal year 2021, in separate transactions, the Company divested two brands outside the U.S. within the Pharmaceutical segment. The Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $0.6 billion.

During fiscal year 2020, the Company sold 11.8 million shares of Idorsia LTD (Idorsia), or its 8.3% ownership in the company at that time. The transaction resulted in gross proceeds of approximately CHF 337 million ($357 million) based on a sales price of CHF 28.55/share and resulted in an immaterial net loss. At the end of fiscal 2020, the Company had rights to approximately 38.7 million shares through a convertible loan with a principal amount of CHF 445 million (due June 2027). During fiscal year 2021, the Company converted CHF 110 million ($120 million) of this loan into approximately 9.6 million shares of Idorsia which were reflected at fair value as of January 2, 2022. During the fiscal third quarter of 2021, the Company's undrawn credit facility with Idorsia was terminated.

During fiscal year 2019, the Company divested its ASP business to Fortive Corporation for an aggregate value of approximately $2.8 billion, consisting of $2.7 billion of cash proceeds and $0.1 billion of retained net receivables. The Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $2.0 billion.

19. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability; intellectual property; commercial; indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business. Due to the ongoing impacts of the COVID-19 pandemic, certain trials have been rescheduled or delayed. The Company continues to monitor its legal proceedings as the situation evolves and in person trials resume.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred, and the amount of the loss can be reasonably estimated. As of January 2, 2022, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse awards, judgments or verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

PRODUCT LIABILITY

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. From time to time, even if it has substantial defenses, the Company considers isolated settlements based on a variety of circumstances. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include: the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; the PINNACLE® Acetabular Cup System; pelvic meshes; RISPERDAL®; XARELTO®; body powders containing talc, primarily JOHNSON'S® Baby Powder; INVOKANA®; and ETHICON PHYSIOMESH® Flexible Composite Mesh. As of January 2, 2022, in the United States there were approximately 250 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; 5,300 with respect to the PINNACLE® Acetabular Cup System; 10,100 with respect to pelvic meshes; 8,800 with respect to RISPERDAL®; 5,500 with respect to XARELTO®; 40,400 with respect to body powders containing talc; 100 with respect to INVOKANA®; and 4,700 with respect to ETHICON PHYSIOMESH® Flexible Composite Mesh. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed.