Registered number: 01227497

MSD VACCINES LIMITED

ANNUAL REPORT AND FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

COMPANY INFORMATION

Directors	E Can Temucin M Rogers
Company secretary	A Davies
Company Number	01227497
Registered office	MSD Vaccines Limited 120 Moorgate London United Kingdom EC2M 6UR
Independent Auditors	PricewaterhouseCoopers LLP Chartered Accountants and Statutory Auditors 40 Clarendon Road Watford Hertfordshire WD17 1JJ

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STRATEGIC REPORT
FOR THE YEAR ENDED 31 DECEMBER
2020

Strategic Report for the Year Ended 31 December 2020

The directors present their strategic report for the year ended 31 December 2020.

Business review

The company ceased to trade on the 23 October 2018 when the lease for the Maidenhead property was transferred in name to Merck Sharp & Dohme UK Limited who as of this date assumed responsibility for all lease obligations. Accordingly, the financial statements have been prepared on a basis other than going concern. No adjustments were needed in these financial statements to reduce assets to their realisable values or to provide for liabilities arising from this decision.

The results for the financial year show a loss for the year of £84,039 (2019: loss of £189,738). The company is in a net asset position as at 31 December 2020 amounting to £5,360,036 (2019: net asset of £5,444,075).

No dividend was paid during the year (2019: £nil).

Principal risks and uncertainties

Amounts due from group undertakings

Credit risk, liquidity risk and cash flow risk are all related to other group undertakings being able to settle the intercompany receivable position when requested. Periodic reviews are undertaken of the carrying values of its intercompany receivables to ensure these assets are stated at their respective recoverable amounts.

Directors' indemnities

The Company maintains liability insurance for its directors and officers, this insurance was in force during the year and at the date of approval of the financial statements. The insurance is a qualifying third party indemnity provision for the purposes of the Companies Act 2006.

This report was approved by the board on 23 December 2021 and signed on its behalf.

Ebru Can Temucin
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E Can Temucin
Director

DIRECTORS' REPORT
FOR THE YEAR ENDED 31 DECEMBER 2020

The directors present their report and the audited financial statements for the year ended 31 December 2020.

Principal activities

The company ceased to trade on the 23 October 2018.

Directors

The Directors who were in office during the year and up to the date of approval of the financial statements were:

J W Phipps (resigned 1 April 2021)

D Peacock (resigned 1 April 2021)
S Nicholson (resigned 1 April 2021)
E Can Temucin
M Rogers (appointed 1 April 2021)

As permitted by the Articles of Association, the Directors have the benefit of an indemnity which is a qualifying third party indemnity provision as defined by Section 234 of the Companies Act 2006. The indemnity was in force throughout the last financial year and is currently in force. The company also purchased and maintained throughout the financial year Directors' and Officers' liability insurance in respect of itself and its directors.

Going concern and future developments

The company ceased to trade on 23 October 2018. Accordingly, the financial statements have been prepared on a basis other than going concern. No adjustments were needed in these financial statements to reduce assets to their realisable values or to provide for liabilities arising from this decision.

There were no further events occurring after the balance sheet date that required disclosure. The management intends to liquidate the company by 31 December 2023.

Results and dividends

The loss for the year from operations was £84,039 (2019 Loss £189,738). During the year no interim dividend was paid (2019 - £nil). No final dividend will be proposed or paid in relation to the year ended 31 December 2020.

Financial risk management

The Company does not trade and the principal risks and uncertainties for the period ending 31 December 2020 relate to the recoverability of it amounts owed by group undertakings. Periodic reviews are undertaken of the carrying values of intercompany receivables to ensure that these assets are stated at their respective recoverable amounts. Given the straightforward nature of the company's operations, key performance indicators are not used by the directors' members to understand the company's operations.

Credit risk

Credit risk relates to other group undertakings being able to settle the intercompany receivable position when requested. Periodic reviews are undertaken of the carrying values of the intercompany receivables to ensure that these assets are stated at their respective recoverable amounts.

Liquidity risk

Liquidity is managed by the Company's cash balances and support from fellow Merck & Co., Inc. (ultimate parent undertaking) related companies. Regular reviews are undertaken of the company's receivables and payables when considering its cash needs and funding arrangements.

Interest rate risk

The Company does not have a material exposure to interest rate risk. There are no long-term external debts, and the intercompany debts are interest free.

Foreign exchange risk

The Company undertakes transactions denominated in foreign currencies. The risk is limited to intercompany payments denominated in Euro.

Statement of directors' responsibilities in respect of the financial statements

The directors are responsible for preparing the Annual Report and Financial Statements and the financial statements in accordance with applicable law and regulation.

Company law requires the directors to prepare financial statements for each financial year. Under that law the directors have prepared the financial statements in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards, comprising FRS 101 "Reduced Disclosure Framework", and applicable law).

Under company law, directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the company and of the profit or loss of the company for that period. In preparing the financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- state whether applicable United Kingdom Accounting Standards, comprising FRS 101 have been followed, subject to any material departures disclosed and explained in the financial statements;
- make judgements and accounting estimates that are reasonable and prudent; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The directors are also responsible for keeping adequate accounting records that are sufficient to show and explain the company's transactions and disclose with reasonable accuracy at any time the financial position of the company and enable them to ensure that the financial statements comply with the Companies Act 2006.

Directors' confirmations

In the case of each director in office at the date the directors' report is approved:

- so far as the director is aware, there is no relevant audit information of which the company's auditors are unaware; and
- they have taken all the steps that they ought to have taken as a director in order to make themselves aware of any relevant audit information and to establish that the company's auditors are aware of that information.

DIRECTORS' REPORT (continued)
FOR THE YEAR ENDED 31 DECEMBER 2020

Post balance sheet events

On 14 January 2021 the registered office for MSD Vaccines Limited changed from West Hill, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU to 120 Moorgate, London, United Kingdom, EC2M 6UR.

Independent auditors

The auditors, PricewaterhouseCoopers LLP, have indicated their willingness to continue in office and a resolution concerning their re-appointment will be proposed at the Annual General Meeting.

This report was approved by the board on 23 December 2021 and signed on its behalf.

Ebru Can Temucin

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E Can Temucin
Director

Independent auditors' report to the members of MSD Vaccines Limited

Report on the audit of the financial statements

Opinion

In our opinion, MSD Vaccines Limited's financial statements:

- give a true and fair view of the state of the company's affairs as at 31 December 2020 and of its loss for the year then ended;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards, comprising FRS 101 "Reduced Disclosure Framework", and applicable law); and
- have been prepared in accordance with the requirements of the Companies Act 2006.

We have audited the financial statements, included within the Annual Report and Financial Statements (the "Annual Report"), which comprise: the balance sheet as at 31 December 2020; the statement of comprehensive income and the statement of changes in equity for the year then ended; and the notes to the financial statements, which include a description of the significant accounting policies.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) ("ISAs (UK)") and applicable law. Our responsibilities under ISAs (UK) are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Independence

We remained independent of the company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, which includes the FRC's Ethical Standard, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

Emphasis of matter - financial statements prepared on a basis other than going concern

In forming our opinion on the financial statements, which is not modified, we draw attention to note 2.1 to the financial statements which describes the directors' reasons why the financial statements have been prepared on a basis other than going concern.

Reporting on other information

The other information comprises all of the information in the Annual Report other than the financial statements and our auditors' report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except to the extent otherwise explicitly stated in this report, any form of assurance thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If we identify an apparent material inconsistency or material misstatement, we are required to perform procedures to conclude whether there is a material misstatement of the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report based on these responsibilities.

With respect to the Strategic report and Directors' Report, we also considered whether the disclosures required by the UK Companies Act 2006 have been included.

Based on our work undertaken in the course of the audit, the Companies Act 2006 requires us also to report certain opinions and matters as described below.

Strategic report and Directors' Report

In our opinion, based on the work undertaken in the course of the audit, the information given in the Strategic report and Directors' Report for the year ended 31 December 2020 is consistent with the financial statements and has been prepared in accordance with applicable legal requirements.

In light of the knowledge and understanding of the company and its environment obtained in the course of the audit, we did not identify any material misstatements in the Strategic report and Directors' Report.

Independent auditors' report to the members of MSD Vaccines Limited

Responsibilities for the financial statements and the audit

Responsibilities of the directors for the financial statements

As explained more fully in the Statement of directors' responsibilities in respect of the financial statements, the directors are responsible for the preparation of the financial statements in accordance with the applicable framework and for being satisfied that they give a true and fair view. The directors are also responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the company or to cease operations, or have no realistic alternative but to do so.

Auditors' responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud, is detailed below.

Based on our understanding of the company and industry, we identified that the principal risks of non-compliance with laws and regulations related to the Companies Act 2006, and we considered the extent to which non-compliance might have a material effect on the financial statements. We evaluated management's incentives and opportunities for fraudulent manipulation of the financial statements (including the risk of override of controls), and determined that the principal risks were related to posting of inappropriate journals. Audit procedures performed by the engagement team included:

- auditing the risk of management override of controls;
- reviewing financial statement disclosures and testing to supporting documentation to assess compliance with applicable laws and regulations;
- enquiry of management and those charged with governance around any non-compliance with laws and regulations.

There are inherent limitations in the audit procedures described above. We are less likely to become aware of instances of non-compliance with laws and regulations that are not closely related to events and transactions reflected in the financial statements. Also, the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion.

A further description of our responsibilities for the audit of the financial statements is located on the FRC's website at: www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditors' report.

Use of this report

This report, including the opinions, has been prepared for and only for the company's members as a body in accordance with Chapter 3 of Part 16 of the Companies Act 2006 and for no other purpose. We do not, in giving these opinions, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

Independent auditors' report to the members of MSD Vaccines Limited

Other required reporting

Companies Act 2006 exception reporting

Under the Companies Act 2006 we are required to report to you if, in our opinion:

- we have not obtained all the information and explanations we require for our audit; or
- adequate accounting records have not been kept by the company, or returns adequate for our audit have not been received from branches not visited by us; or
- certain disclosures of directors' remuneration specified by law are not made; or
- the financial statements are not in agreement with the accounting records and returns.

We have no exceptions to report arising from this responsibility.

R P Girdlestone

Robert Girdlestone (Senior Statutory Auditor)
for and on behalf of PricewaterhouseCoopers LLP
Chartered Accountants and Statutory Auditors
Watford
23-12-2021

STATEMENT OF COMPREHENSIVE INCOME
FOR THE YEAR ENDED 31 DECEMBER 2020

	Note	2020 £	2019 £
Administrative expenses		**(65,862)**	(58,796)
Operating loss	*4*	**(65,862)**	(58,796)
Finance Costs	*7*	(21,766)	(18,892)
Loss before income tax		(87,628)	(77,688)
Tax on loss	*8*	**3,589**	(112,050)
Loss for the financial year		**(84,039)**	(189,738)
Other comprehensive income		-	-
Total comprehensive loss for the financial year		**(84,039)**	(189,738)

BALANCE SHEET
AS AT 31 DECEMBER 2020

	Note	2020	2019
		£	£
Assets			
Current assets			
Trade and other receivables	9	**9,262,777**	*9,746,978*
		9,262,777	*9,746,978*
Total assets		**9,262,777**	*9,746,978*
Equity and liabilities			
Equity			
Called up share capital	10	**300,000**	*300,000*
Retained earnings	11	**5,060,036**	*5,144,075*
Total equity		**5,360,036**	*5,444,075*
Current liabilities			
Trade and other payables	12	**3,902,741**	*4,302,903*
Total liabilities		**3,902,741**	*4,302,903*
Total liabilities and equity		**9,262,777**	*9,746,978*

The financial statements on pages 10 to 23 were approved and authorised for issue on 23 December 2021 by the board and were signed on its behalf by:

Ebru Can Temucin

E Can Temucin
Director

Date: 23 December 2021

STATEMENT OF CHANGES IN EQUITY
FOR THE YEAR ENDED 31 DECEMBER 2020

	Called up share capital	Retained earnings	Total equity
	£	£	£
At 1 January 2019	300,000	5,333,813	5,633,813
Comprehensive expense for the year			
Loss for the financial year	-	(189,738)	(189,738)
Total comprehensive expense for the year	-	(189,738)	(189,738)
At 31 December 2019	300,000	5,144,075	5,444,075

	Called up share capital	Retained earnings	Total equity
	£	£	£
At 1 January 2020	300,000	5,144,075	5,444,075
Comprehensive expense for the year			
Loss for the financial year	-	(84,039)	(84,039)
Total comprehensive expense for the year	-	(84,039)	(84,039)
At 31 December 2020	300,000	5,060,036	5,360,036

The notes on pages 13 to 23 form part of these financial statements.

NOTES TO THE FINANCIAL STATEMENTS
FOR THE YEAR ENDED 31 DECEMBER 2020

1. General information

The Company was engaged in the marketing and selling of pharmaceutical products within the United Kingdom until 31 March 2017. From 1 April 2017 to the 23 October 2018 the company managed the lease and property at Maidenhead until the lease was transferred to Merck Sharp and Dohme Limited. The company no longer trades, and the directors intend to restructure the capital of the entity to make it dormant for the year ending 31 December 2022 and intends to liquidate by 31 December 2023.

The Company is a private company limited by shares and domiciled in the United Kingdom (registered in England and Wales). The ultimate parent company at the year-end is Merck & Co., Inc., a company incorporated in the state of New Jersey, USA. The Company's immediate parent company as at year-end is Merck Sharp & Dohme UK Limited, a company incorporated in England and Wales. The immediate parent company of MSD Vaccines Limited changed on 1 November 2020 from Organon Pharma (UK) Limited (formerly Merck Sharp & Dohme Limited) to Merck Sharp & Dohme UK Limited (formerly Merck Sharp & Dohme (Holdings) Limited).

On 14 January 2021 the registered office for MSD Vaccines Limited changed from West Hill, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU to 120 Moorgate, London, United Kingdom, EC2M 6UR.

2. Accounting policies

2.1 Basis of preparation of financial statements

The company ceased to trade on 23 October 2018. Accordingly, the financial statements have been prepared on a basis other than going concern, under the historical cost convention and in accordance with the Financial Reporting Standard 101, "Reduced Disclosure Framework" (FRS 101) and with the Companies Act 2006 for the financial year ended 31 December 2020. No adjustments were needed in these financial statements to reduce assets to their realisable values or to provide for liabilities arising from this decision.

The preparation of financial statements in conformity with FRS 101 requires the use of certain critical accounting estimates. It also requires management to exercise judgment in applying the Company's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the financial statements are disclosed in note 3.

The following exemptions from the requirements of IFRS have been applied in the preparation of these financial statements, in accordance with FRS 101:

• Paragraphs 45(b) and 46 to 52 of IFRS 2, 'Share-based payment' (details of the number and weighted average exercise prices of share options, and how the fair value of goods or services received was determined).
• IFRS 7, 'Financial instruments: Disclosures'.
• Paragraphs 91 to 99 of IFRS 13, 'Fair value measurement' (disclosure of valuation techniques and inputs used for fair value measurement of assets and liabilities).
• Paragraph 38 of IAS 1, 'Presentation of financial statements' – comparative information requirements in respect of:
iii. Paragraph 79(a)(iv) of IAS 1;
iv. Paragraph 73(e) of IAS 16, 'Property, plant and equipment'; and
v. Paragraph 118(e) of IAS 38, 'Intangible assets' (reconciliations between the carrying amount at the beginning and end of the period).

2. Accounting policies (continued)

2.1 Basis of preparation of financial statements (continued)

• The following paragraphs of IAS 1, 'Presentation of financial statements':
10(d) (statement of cash flows);
16(statement of compliance with all IFRS);
38A(requirement for minimum of two primary statements, including cash flow statements);
38B–D (additional comparative information);
111(statement of cash flows information); and
134–136 (capital management disclosures).
• IAS 7, 'Statement of cash flows'.
• Paragraphs 30 and 31 of IAS 8, 'Accounting policies, changes in accounting estimates and errors' (requirement for the disclosure of information when an entity has not applied a new IFRS that has been issued but is not yet effective).
• Paragraph 17 of IAS 24, 'Related party disclosures' (key management compensation).
• The requirements in IAS 24, 'Related party disclosures', to disclose related party transactions entered into between two or more members of a group.

New standards, amendments and IFRIC interpretations

There are no new standards, amendments and IFRIC interpretations effective for the year ended 31 December 2020 that have a material impact on the company's financial statements.

2.2 Financial instruments

The Company recognises financial instruments when it becomes a party to the contractual arrangements of the instrument. Financial instruments are de-recognised when they are discharged or when the contractual terms expire. The Company's accounting policies in respect of financial instruments transactions are explained below:

Financial assets

The Company recognises its financial assets into one of the categories discussed below, depending on the purpose for which the asset was acquired.

The Company's accounting policy for each category is as follows:

Trade and other receivables

Trade and other receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They arise principally through the provision of goods and services to customers (e.g., trade receivables), but also incorporate other types of contractual monetary asset. They are initially recognised at fair value plus transaction costs that are directly attributable to their acquisition or issue, and are subsequently carried at amortised cost using the effective interest rate method, less provision for impairment.

2. Accounting policies (continued)

Trade and other receivables (continued)

The company applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables and contract assets.To measure the expected credit losses, trade receivables and contract assets are grouped based on shared credit risk characteristics and the days past due. The contract assets relate to unbilled work in progress and have substantially the same risk characteristics as the trade receivables for the same types of contracts. The company has therefore concluded that the expected loss rates for trade receivables are a reasonable approximation of the loss rates for the contract assets. MSD Vaccines has applied the general approach where applicable as it's trade and other receivables balance predominantly relates to intercompany transactions.

2.3 Financial instruments (continued)

Financial liabilities at amortised cost

Financial liabilities at amortised cost including bank borrowings are initially recognised at fair value net of any transaction costs directly attributable to the issue of the instrument. Such interest bearing liabilities are subsequently measured at amortised cost using the effective interest rate method, which ensures that any interest expense over the period to repayment is at a constant rate on the balance of the liability carried into the Balance Sheet.

2.3 Current and non-current liabilities

Liabilities are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers.

Liabilities are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method.

2.4 Foreign currency

The company's functional and presentational currency is the pound sterling.

Foreign currency transactions are translated into the functional currency using the spot exchange rates at the dates of the transactions.

At each period end foreign currency monetary items are translated using the closing rate. Non-monetary items measured at historical cost are translated using the exchange rate at the date of the transaction and non-monetary items measured at fair value are measured using the exchange rate when fair value was determined.

Foreign exchange gains and losses resulting from the settlement of transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the statement of comprehensive income except when deferred in other comprehensive income as qualifying cash flow hedges.

2. Accounting policies (continued)

2.5 Finance costs

Finance costs are charged to the Statement of Comprehensive Income over the term of the debt using the effective interest method so that the amount charged is at a constant rate on the carrying amount. Issue costs are initially recognised as a reduction in the proceeds of the associated capital instrument.

2.6 Dividends

Equity dividends are recognised when they become legally payable. Final dividends from investments are recognised when there is a right to receive payment that has been established through the approval by the shareholders. Interim dividends are recognised once the cash has been received. Dividends on shares recognised as liabilities are recognised as expenses and classified with interest payable.

2.7 Interest income

Interest income is recognised in the Statement of Comprehensive Income using the effective interest method.

2.8 Borrowing costs

All borrowing costs are recognised in the Statement of Comprehensive Income in the year in which they are incurred.

2.9 Provisions for liabilities

Provisions are made where an event has taken place that gives the Company a legal or constructive obligation that probably requires settlement by a transfer of economic benefit, and a reliable estimate can be made of the amount of the obligation.

Provisions are charged as an expense to the Statement of Comprehensive Income in the year that the Company becomes aware of the obligation and are measured at the best estimate at the Balance Sheet date of the expenditure required to settle the obligation, taking into account relevant risks and uncertainties.

When payments are eventually made, they are charged to the provision carried in the Balance Sheet.

2. Accounting policies (continued)

2.10 Taxation

Taxation expense for the period comprises current and deferred tax recognised in the reporting period. Tax is recognised in the statement of comprehensive income, except to the extent that is relates to items recognised in other comprehensive income or directly in equity respectively.

Current or deferred taxation assets and liabilities are not discounted.

Current tax is the amount of income tax payable in respect of the taxable profit for the year or prior years. Tax is calculated on the basis of tax rates and laws that have been enacted or substantively enacted by the period.

Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred tax arises from timing differences that are differences between taxable profits and total comprehensive income as stated in the financial statements. These timing differences arise from the inclusion of income and expenses in tax assessments in periods different from those in which they are recognised in financial statements.

Deferred tax is recognised on all timing differences at the reporting date except for certain exceptions. Unrelieved tax losses and other deferred tax assets are only recognised when it is probable that they will be recovered against the reversal of deferred tax liabilities or other future taxable profits.

Deferred tax is measured using tax rates and laws that have been enacted or substantively enacted by the period end and that are expected to apply to the reversal of the timing difference.

3 Judgments in applying accounting policies and key sources of estimation uncertainty

The preparation of the financial statements requires management to make judgments, estimates and assumptions that affect the application of policies and reported amount of asset and liabilities, income and expenses. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form a basis for making the judgments about carrying value of assets and liabilities that are not readily apparent from other sources.

The directors have reviewed the estimates and assumptions used in the preparation of the financial statements. The directors do not believe that there is a significant risk which could lead to material adjustments to the carrying value of any assets and liabilities in the next financial year due to the changes on the estimates or assumption.

NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE YEAR ENDED 31 DECEMBER 2020

4 Operating Loss

The operating loss is stated after(crediting)/charging:

	2020	*2019*
	£	*£*
Exchange (gains)/losses	**(20,439)**	*16,816*
Other operating expenses	**86,301**	*41,980*
Total administrative expenses/(income)	**65,862**	*58,796*

5 Auditors' remuneration

The audit fee of £6,181 for the year ended 31 December 2020 (2019: £6,181) has been borne by a fellow group company.

No non audit service has been rendered to this company.

6 Employee and Directors' remuneration

There were no employees during the year ended 31 December 2020 (2019: nil).

The directors did not receive any remuneration for their services during the year (2019: nil).

The emoluments of the directors are paid by their employing company, another group undertaking. The directors' services to this company are chiefly of a non-executive nature and their emoluments are deemed to be wholly attributable to their services in their employing company. Accordingly, the above details include no emoluments in respect of directors.

NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE YEAR ENDED 31 DECEMBER 2020

7 Finance Costs

	2020 £	*2019 £*
Bank interest payable	21,766	*18,892*
Total finance costs	21,766	*18,892*

8 Tax on loss

	2020 £	*2019 £*
Current tax:		
Current tax on losses for the year	-	-
Adjustments in respect of prior years	(3,589)	*112,050*
Total current tax	(3,589)	*112,050*
Deferred tax:		
Current tax	-	-
Adjustments in respect of prior years	-	-
Total deferred tax	-	-
Income tax (credit)/charge	(3,589)	*112,050*

Factors affecting tax (credit)/charge for the year

The tax assessed for the year is higher than (2019 - higher than) the standard rate of corporation tax in the UK of 19% (2019 - 19%). The differences are explained below:

	2020 £	*2019 £*
Loss before income tax	(87,628)	*(77,688)*
Loss before income tax multiplied by standard rate of corporation tax in the UK 19% (2019 – 19%)	(16,649)	*(14,761)*
Effects of:		
Adjustments in respect of prior years	(3,589)	*112,050*
Losses not recognised as a deferred tax asset	16,649	*14,761*
Total tax (credit)/charge for the year	(3,589)	*112,050*

8. Tax on loss continued

Factors that may affect future tax charges

The main rate of UK corporation tax remained constant at 19%.

Finance Act 2016 had previously enacted provisions to reduce the main rate of UK corporation tax to 17% from 1 April 2020 and accordingly the deferred tax at 31 December 2019 had been calculated at this rate. In March 2020 the Government announced that the tax rate would be held at 19%. Accordingly, the revised 19% tax rate was substantively enacted in 'The Provisional Collection of Taxes Act' on 17 March 2020. Consequently, the deferred tax balances have been restated and recognised at 19% at the year end.

The March 2021 Budget announced a further increase to the main rate of corporation tax to 25% from April 2023. This rate has not been substantively enacted at the balance sheet date, as result deferred tax balances at 31 December 2020 continue to be measured at 19%.

Current taxes in the financial statements are as follows liability/(asset):

	2020	*2019*
	£	£
Total at 1 January	**112,050**	*56,489*
Current corporation income tax expense	-	*112,050*
Interest Payable to HMRC	-	-
Income tax paid	**(112,050)**	*(56,489)*
Total at 31 December	-	*112,050*

NOTES TO THE FINANCIAL STATEMENTS (CONTINUED)
FOR THE YEAR ENDED 31 DECEMBER 2020

9 Trade and other receivables

	2020	*2019*
	£	*£*
Amounts owed by group undertakings	8,944,831	*9,429,037*
Other debtors	317,946	*317,941*
	9,262,777	*9,746,978*

Amounts owed to group undertakings are unsecured, interest free and are receivable on demand.

Credit risk arises from credit exposures to customers including outstanding receivables. Credit control assesses the credit quality of the customer using independent credit ratings (where available) or taking into account the customer financial position, past experience and other factors. Individual risk limits are set based on internal and external ratings in accordance with limits set by the board. The utilisation of limits is regularly reviewed by the credit control function. Management does not expect any material losses from non-performance by these counterparties.

10 Called up share capital

	2020	*2019*
	£	*£*
Allotted, called up and fully paid		
300,000 *(2019 – 300,000)* Ordinary shares of £1 each	300,000	*300,000*

There are no restrictions of any type attached to the share issued.

11 Retained Earnings

Retained earnings represent cumulative profits and losses, net of dividends paid and other adjustments.

12 Trade and other payables

	2020	2019
	£	£
Trade payables	-	172,515
Amounts owed to group undertakings	402,429	402,429
Corporation Tax (Note 8)	-	112,050
Bank overdraft	3,500,312	3,583,026
Accruals	-	32,883
	3,902,741	4,302,903

Amounts owed to group undertakings are unsecured, interest free and are payable on demand.

13 Financial instrument by category

	Trade and other receivables	Other liabilities at amortised cost	Total
	£	£	£
31 December 2019			
Assets as per balance sheet			
Trade and other receivables	9,746,978	-	9,746,978
Total	**9,746,978**	**-**	**9,746,978**
Liabilities as per balance sheet			
Trade and other payables	-	(4,190,852)	(4,190,852)
Total	**-**	**(4,190,852)**	**(4,190,852)**
31 December 2020			
Assets as per balance sheet			
Trade and other receivables	9,262,777	-	9,262,777
Total	**9,262,777**	**-**	**9,262,777**
Liabilities as per balance sheet			
Trade and other payables	-	(3,902,741)	(3,902,741)
Total	**-**	**(3,902,741)**	**(3,902,741)**

14 Ultimate parent undertaking and controlling party

The company's immediate parent undertaking is Merck Sharp & Dohme (UK) Limited, a company incorporated in United Kingdom and ultimate parent undertaking and controlling party is Merck & Co., Inc., a company incorporated in the United States of America.

The largest and smallest group in which the results of the company are consolidated is that headed by Merck & Co., Inc. Copies of the group financial statements Merck & Co., Inc. may be obtained from 2000 Galloping Hill Road, Kenilworth, NJ 07033 USA.

15 Post balance sheet events

On 14 January 2021 the registered office for MSD Vaccines Limited changed from West Hill, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU to 120 Moorgate, London, United Kingdom, EC2M 6UR.

16 Commitments and contingent liabilities

The Company is not currently facing outstanding litigations that might have a significant adverse impact on the Company's financial position. Furthermore, at the closing date there were no commitments signed for the acquisition of property, equipment or intangible assets.

As filed with the Securities and Exchange Commission on February 25, 2021

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

FORM 10-K

(MARK ONE)

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Fiscal Year Ended December 31, 2020

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 No. 1-6571

Merck & Co., Inc.

2000 Galloping Hill Road
Kenilworth New Jersey 07033

(908) 740-4000

New Jersey	**22-1918501**
(State or other jurisdiction of incorporation)	(I.R.S Employer Identification No.)

Securities Registered pursuant to Section 12(b) of the Act:

Title of Each Class	*Trading Symbol(s)*	*Name of Each Exchange on which Registered*
Common Stock ($0.50 par value)	MRK	New York Stock Exchange
1.125% Notes due 2021	MRK/21	New York Stock Exchange
0.500% Notes due 2024	MRK 24	New York Stock Exchange
1.875% Notes due 2026	MRK/26	New York Stock Exchange
2.500% Notes due 2034	MRK/34	New York Stock Exchange
1.375% Notes due 2036	MRK 36A	New York Stock Exchange

Number of shares of Common Stock ($0.50 par value) outstanding as of January 31, 2021: 2,530,315,668.

Aggregate market value of Common Stock ($0.50 par value) held by non-affiliates on June 30, 2020 based on closing price on June 30, 2020: $195,461,000,000.

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. 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, a smaller reporting company, or an 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. (Check One).

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. ☐

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

Documents Incorporated by Reference:

Document	*Part of Form 10-K*
Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021, to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report	Part III

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PART I

Item 1. Business.

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment in the first quarter of 2020.

The Company previously had an Alliances segment that primarily included activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

All product or service marks appearing in type form different from that of the surrounding text are trademarks or service marks owned, licensed to, promoted or distributed by Merck, its subsidiaries or affiliates, except as noted. All other trademarks or services marks are those of their respective owners.

Planned Spin-Off of Women's Health, Biosimilars and Established Brands into a New Company

In February 2020, Merck announced its intention to spin-off (the Spin-Off) products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The established brands included in the transaction consist of dermatology, non-opioid pain management, respiratory, and select cardiovascular products including *Zetia* (ezetimibe) and *Vytorin* (ezetimibe/simvastatin), as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. Organon will have development capabilities initially focused on late-stage development and life-cycle management, and is expected over time to develop research capabilities in selected therapeutic areas. The Spin-Off is expected to be completed late in the second quarter of 2021, subject to market and certain other conditions. See "Risk Factors - Risks Related to the Proposed Spin-Off of Organon."

Product Sales

Total Company sales, including sales of the Company's top pharmaceutical products, as well as sales of animal health products, were as follows:

($ in millions)	2020	2019	2018
Total Sales	$ 47,994	$ 46,840	$ 42,294
Pharmaceutical	43,021	41,751	37,689
Keytruda	14,380	11,084	7,171
Januvia/Janumet	5,276	5,524	5,914
Gardasil/Gardasil 9	3,938	3,737	3,151
ProQuad/M-M-R II/Varivax	1,878	2,275	1,798
Bridion	1,198	1,131	917
Pneumovax 23	1,087	926	907
Isentress/Isentress HD	857	975	1,140
Simponi	838	830	893
RotaTeq	797	791	728
Alliance revenue - Lynparza[1]	725	444	187
Implanon/Nexplanon	680	787	703
Zetia/Vytorin	664	874	1,355
Alliance revenue - Lenvima[1]	580	404	149
Animal Health	4,703	4,393	4,212
Livestock	2,939	2,784	2,630
Companion Animals	1,764	1,609	1,582
Other Revenues[2]	270	696	393

[1] *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs.*

[2] *Other revenues are primarily comprised of third-party manufacturing sales and miscellaneous corporate revenues, including revenue hedging activities.*

Pharmaceutical

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. Certain of the products within the Company's franchises are as follows:

Oncology

Keytruda (pembrolizumab), the Company's anti-PD-1 (programmed death receptor-1) therapy, as monotherapy for the treatment of certain patients with cervical cancer, classical Hodgkin Lymphoma (cHL), cutaneous squamous cell carcinoma (cSCC), esophageal cancer, gastric or gastroesophageal junction adenocarcinoma, head and neck squamous cell carcinoma (HNSCC), hepatocellular carcinoma (HCC), non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer, including MSI-H/dMMR colorectal cancer, primary mediastinal large B-cell lymphoma (PMBCL), tumor mutational burden-high (TMB-H) cancer, and urothelial carcinoma, including non-muscle invasive bladder cancer. *Keytruda* is also approved for the treatment of certain patients in combination with chemotherapy for metastatic squamous and non-squamous NSCLC, in combination with chemotherapy for HNSCC, in combination with chemotherapy for triple-negative breast cancer, in combination with axitinib for renal cell carcinoma, and in combination with lenvatinib for endometrial carcinoma; and *Emend* (aprepitant) for the prevention of certain chemotherapy-induced nausea and vomiting. In addition, the Company recognizes alliance revenue related to sales of Lynparza (olaparib), an oral poly (ADP-ribose) polymerase (PARP) inhibitor, for certain types of advanced ovarian, breast, pancreatic, and prostate cancers; and Lenvima (lenvatinib) for certain types of thyroid cancer, hepatocellular carcinoma, in combination with everolimus for certain patients with renal cell carcinoma, and in combination with *Keytruda* for certain patients with endometrial carcinoma.

Vaccines

Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/*Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), vaccines to help prevent certain diseases caused by certain types of human papillomavirus (HPV); *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella; *M–M–R* II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella; *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella); *Pneumovax* 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease; *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children; and *Vaqta* (hepatitis A vaccine, inactivated) indicated for the prevention of disease caused by hepatitis A virus in persons 12 months of age and older.

Hospital Acute Care

Bridion (sugammadex) Injection, a medication for the reversal of two types of neuromuscular blocking agents used during surgery; *Noxafil* (posaconazole), an antifungal agent for the prevention of certain invasive fungal infections; *Prevymis* (letermovir) for the prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant; *Primaxin* (imipenem and cilastatin) for injection, an antibiotic for the treatment of certain bacterial infections; *Cancidas* (caspofungin acetate) for injection, an anti-fungal agent for the treatment of certain fungal infections; *Invanz* (ertapenem) for injection, an antibiotic for the treatment of certain bacterial infections; *Cubicin* (daptomycin for injection), an antibiotic for the treatment of certain bacterial infections; and *Zerbaxa* (ceftolozane and tazobactam) for injection, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections.

Immunology

Simponi (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases; and *Remicade* (infliximab), a treatment for inflammatory diseases, both of which the Company markets in Europe, Russia and Turkey.

Neuroscience

Belsomra (suvorexant), an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Virology

Isentress/Isentress HD (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection; and *Zepatier* (elbasvir and grazoprevir) for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection, with ribavirin in certain patient populations.

Cardiovascular

Zetia (ezetimibe) (marketed as *Ezetrol* in most countries outside the United States); *Vytorin* (ezetimibe/simvastatin) (marketed as *Inegy* outside the United States); *Atozet* (ezetimibe and atorvastatin) (marketed outside of the United States) and *Rosuzet* (ezetimibe and rosuvastatin) (marketed outside of the United States), cholesterol modifying medicines; and Adempas (riociguat), a cardiovascular drug for the treatment of pulmonary arterial hypertension.

Diabetes

Januvia (sitagliptin) and *Janumet* (sitagliptin/metformin HCl) for the treatment of type 2 diabetes.

Women's Health

Implanon (etonogestrel implant), a single-rod subdermal contraceptive implant/ *Nexplanon* (etonogestrel implant), a single, radiopaque, rod-shaped subdermal contraceptive implant; and *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product.

Animal Health

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceuticals, vaccines and health management solutions and services, as well as an extensive suite of digitally connected identification, traceability and monitoring products. Principal products in this segment include:

Livestock Products

Nuflor (Florfenicol) antibiotic range for use in cattle and swine; *Bovilis*/*Vista* vaccine lines for infectious diseases in cattle; *Banamine* (Flunixin meglumine) bovine and swine anti-inflammatory; *Estrumate* (cloprostenol sodium) for the treatment of fertility disorders in cattle; *Matrix* (altrenogest) fertility management for swine; *Resflor* (florfenicol and flunixin meglumine), a combination broad-spectrum antibiotic and non-steroidal anti-inflammatory drug for bovine respiratory disease; *Zuprevo* (Tildipirosin) for bovine respiratory disease; *Zilmax* (zilpaterol hydrochloride) and *Revalor* (trenbolone acetate and estradiol) to improve production efficiencies in beef cattle; *Safe-Guard* (fenbendazole) de-wormer for cattle; *M+Pac* (Mycoplasma Hyopneumoniae Bacterin) swine pneumonia vaccine; *Porcilis* (Lawsonia intracellularis baterin) and *Circumvent* (Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector) vaccine lines for infectious diseases in swine; *Nobilis/Innovax* (Live Marek's Disease Vector), vaccine lines for poultry; *Paracox* and *Coccivac* coccidiosis vaccines; *Exzolt*, a systemic treatment for poultry red mite infestations; *Slice* (Emamectin benzoate) parasiticide for sea lice in salmon; *Aquavac* (Avirulent Live Culture)/*Norvax* vaccines against bacterial and viral disease in fish; *Compact PD* vaccine for salmon; *Aquaflor* (Florfenicol) antibiotic for farm-raised fish; and *Allflex Livestock Intelligence* solutions for animal identification, monitoring and traceability.

Companion Animal Products

Bravecto, a line of oral and topical parasitic control products, including the original *Bravecto* (fluralaner) products for dogs and cats that last up to 12 weeks; *Bravecto* (fluralaner) *One-Month*, a monthly product for dogs, and *Bravecto Plus* (fluralaner/moxidectin), a two-month product for cats; *Sentinel*, a line of oral parasitic products for dogs including *Sentinel Spectrum* (milbemycin oxime, lufenuron, and praziquantel) and *Sentinel Flavor Tabs* (milbemycin oxime, lufenuron); *Optimmune* (cyclosporine), an ophthalmic ointment; *Nobivac* vaccine lines for flexible dog and cat vaccination; *Otomax* (Gentamicin sulfate, USP; Betamethasone valerate USP; and Clotrimazole USP ointment)/*Mometamax* (Gentamicin sulfate, USP, Mometasone Furoate Monohydrate and Clotrimazole, USP, Otic Suspension)/*Posatex* (Orbifloxacin, Mometasone Furoate Monohydrate and Posaconazole, Suspension) ear ointments for acute and chronic otitis; *Caninsulin/Vetsulin* (porcine insulin zinc suspension) diabetes mellitus treatment for dogs and cats; *Panacur* (fenbendazole)/ *Safeguard* (fenbendazole) broad-spectrum anthelmintic (de-wormer) for use in many animals; *Regumate* (altrenogest) fertility management for horses; *Prestige* vaccine line for horses; *Scalibor* (Deltamethrin)/*Exspot* for protecting against bites from fleas, ticks, mosquitoes and sandflies; and *Sure Petcare* products for companion animal identification and well-being, including the microchip and pet recovery system *Home Again*.

For a further discussion of sales of the Company's products, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" below.

2020 Product Approvals

Set forth below is a summary of significant product approvals received by the Company in 2020.

Product	Date	Approval
Dificid [(1)]	January 2020	U.S. Food and Drug Administration (FDA) approved *Dificid* as an oral suspension, and *Dificid* tablets for the treatment of Clostridioides (formerly Clostridium) difficile-associated diarrhea in children aged six months and older.
Gardasil	November 2020	China's National Medical Products Administration (NMPA) granted expanded approval for *Gardasil* for use in girls and women from 9 to 45 years of age.
Gardasil 9	December 2020	Japan's Ministry of Health, Labour and Welfare (MHLW) approved additional indication, dosage and administrations of *Gardasil 9* (marketed as *Silgard* 9) for the prevention of anal cancer (squamous cell cancer) and precursor lesions (anal intraepithelial neoplasia (AIN) grade 1/2/3) caused by HPV types 6, 11, 16 and 18 for individuals 9 years and older and for Genital Warts (condyloma acuminate) for men 9 years and older.
	July 2020	Japan's Pharmaceuticals and Medical Devices Agency (PMDA) approved *Gardasil* 9 for use in girls and women 9 years and older for the prevention of cervical cancer, certain cervical, vaginal and vulvar precancers, and genital warts caused by the HPV types covered by the vaccine.
	June 2020	FDA granted accelerated approval for an expanded indication for *Gardasil 9* for the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58.

Keytruda	December 2020	NMPA approved *Keytruda* as monotherapy for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 (Combined Positive Score CPS ≥20) as determined by a fully validated test.
	November 2020	FDA granted accelerated approval for *Keytruda* in combination with chemotherapy for patients with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumors express PD-L1 (CPS ≥10).
	October 2020	FDA approved an expanded label for *Keytruda*, as monotherapy for the treatment of adult patients with relapsed or refractory cHL.
	August 2020	PMDA approved *Keytruda* for use at an additional recommended dosage of 400 mg every six weeks (Q6W) administered as an intravenous infusion over 30 minutes across all adult indications, including *Keytruda* monotherapy and combination therapy.
	August 2020	PMDA approved *Keytruda* for the treatment of patients whose tumors are PD-L1-positive, and have radically unresectable, advanced or recurrent esophageal squamous cell carcinoma (ESCC) who have progressed after chemotherapy.
	June 2020	FDA approved *Keytruda* as monotherapy for the first-line treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer.
	June 2020	FDA approved *Keytruda* as monotherapy for the treatment of patients with recurrent or metastatic cSCC that is not curable by surgery or radiation.
	June 2020	NMPA approved *Keytruda* as monotherapy for the treatment of patients with locally advanced or metastatic ESCC whose tumors express PD-L1 (CPS ≥10) as determined by a fully validated test, following failure of one prior line of systemic therapy.
	June 2020	FDA granted accelerated approval for *Keytruda* as monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic TMB-H [≥10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.
	April 2020	FDA granted accelerated approval for *Keytruda* for use at an additional recommended dose of 400 mg every six weeks (Q6W) for all approved adult indications.
	January 2020	FDA approved *Keytruda* for patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.
Koselugo[(2)]	April 2020	FDA approved the kinase inhibitor Koselugo for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).
Lenvima	November 2020	NMPA approved Lenvima as a monotherapy for the treatment of differentiated thyroid cancer.

Lynparza[2]	December 2020	PMDA approved Lynparza for the treatment of patients with *BRCA* gene-mutated (*BRCA*m) castration-resistant prostate cancer with distant metastasis.
	December 2020	PMDA approved Lynparza as maintenance treatment after platinum-based chemotherapy for patients with *BRCA*m curatively unresectable pancreas cancer.
	December 2020	PMDA approved Lynparza as maintenance treatment after first-line chemotherapy containing bevacizumab (genetical recombination) in patients with homologous recombination repair deficient (HRD) ovarian cancer.
	November 2020	The European Commission (EC) approved Lynparza for the maintenance treatment of adult patients with advanced (FIGO stages III and IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with HRD-positive status defined by either a breast cancer susceptibility gene 1/2 (*BRCA*1/2) mutation and/or genomic instability.
	November 2020	EC approved Lynparza as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) and BRCA1/2 mutations (germline and/or somatic) who have progressed following a prior therapy that included a new hormonal agent.
	July 2020	EC approved Lynparza as a monotherapy for the maintenance treatment of adult patients with germline *BRCA*1/2 mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a minimum of 16 weeks of platinum treatment within a first-line chemotherapy regimen.
	May 2020	FDA approved Lynparza for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated mCRPC, as determined by an FDA-approved test, who have progressed following prior treatment with enzalutamide or abiraterone.
	May 2020	FDA approved Lynparza in combination with bevacizumab as a first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with HRD positive status defined by either a deleterious or suspected deleterious *BRCA* mutation, and/or genomic instability, as determined by an FDA-approved test.
Recarbrio	June 2020	FDA approved *Recarbrio* for the treatment of patients 18 years of age and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP).
Steglatro[3]	July 2020	NMPA approved *Steglatro* 5 mg tablets for the treatment of type 2 diabetes.

[1] *Dificid in the U.S. and Canada is a trademark of Cubist Pharmaceuticals LLC, an indirect wholly-owned subsidiary of Merck Sharp & Dohme Corp.*

[2] *In July 2017, Merck and AstraZeneca entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's* Lynparza *and* Koselugo.

[3] *Being commercialized and promoted in a worldwide, except Japan, collaboration with Pfizer Inc.*

Competition and the Health Care Environment

Competition

The markets in which the Company conducts its business and the pharmaceutical industry in general are highly competitive and highly regulated. The Company's competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus, generic drug manufacturers, and animal health care companies. The Company's operations may be adversely affected by generic and biosimilar competition as the Company's products mature, as well as technological advances of competitors, industry consolidation, patents granted to competitors, competitive combination products, new products of competitors, the generic availability of competitors' branded products, and new information from clinical trials of marketed products or post-marketing surveillance. In addition, patent rights are increasingly being challenged by competitors, and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products and could result in the payment of royalties or in the recognition of an impairment charge with respect to intangible assets associated with certain products.

Pharmaceutical competition involves a rigorous search for technological innovations and the ability to market these innovations effectively. With its long-standing emphasis on research and development, the Company is well-positioned to compete in the search for technological innovations. The Company is active in acquiring and marketing products through external alliances, such as licensing arrangements and collaborations and has been refining its sales and marketing efforts to address changing industry conditions. However, the introduction of new products and processes by competitors may result in price reductions and product displacements, even for products protected by patents. For example, the number of compounds available to treat a particular disease typically increases over time and can result in slowed sales growth or reduced sales for the Company's products in that therapeutic category.

The highly competitive animal health business is affected by several factors including regulatory and legislative issues, scientific and technological advances, product innovation, the quality and price of the Company's products as well as competitors' products, effective promotional efforts and the frequent introduction of generic products by competitors.

Health Care Environment and Government Regulation

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access.

United States

In the United States, federal and state governments for many years have pursued methods to reduce the cost of drugs and vaccines for which they pay. For example, federal and state laws require the Company to pay specified rebates for medicines reimbursed by Medicaid and to provide discounts for medicines purchased by certain state and federal entities such as the Department of Defense, Veterans Affairs, Public Health Service entities and hospitals serving a disproportionate share of low income or uninsured patients.

Health Care Programs

The United States enacted major health care reform legislation in 2010 (the ACA). Various insurance market reforms have since advanced and state and federal insurance exchanges were launched in 2014. With respect to the effect of the law on the pharmaceutical industry, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program. The law also requires pharmaceutical manufacturers to pay 70% of the cost of the medicine, including biosimilar products, when Medicare Part D beneficiaries are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"), which increased from 50% beginning in 2019 as a result of the Balanced Budget Act of 2018. Merck recorded approximately $700 million, $615 million and $365 million as a reduction to revenue in 2020, 2019, and 2018, respectively, related to the donut hole provision. Also, pharmaceutical manufacturers are required to pay an annual non-tax deductible health care reform fee. The total annual industry fee has been set at $2.8 billion. The fee is assessed on each company in proportion to its share of prior year branded pharmaceutical sales to certain government programs, such as Medicare and Medicaid. The Company recorded approximately $85 million, $112 million, and $124 million of costs within *Selling, general and administrative* expenses in 2020, 2019 and 2018, respectively, for the annual health care reform fee. In February 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implemented provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. More recently, although CMS previously declined to define what constitutes a product "line extension" (beyond the statutory definition), CMS issued a new rule on December 21, 2020 that will significantly expand the definition of the term "line extension" as of January 1, 2022 to include a broad range of products, including products reflecting new strengths, dosage forms, release mechanisms, and routes of administration. This expanded definition will increase the number of drugs subject to a higher Medicaid rebate. Effective January 1, 2023, this final rule also changes the way that manufacturers must calculate Best Price, in relation to certain patient support programs, including coupons, which also may result in an increase in the Company's Medicaid rebates. The impact of these and other provisions in this final rule could adversely impact the Company's business, cash flow, results of operations, financial condition and prospects.

The Patient Protection and Affordable Care Act

There is significant uncertainty about the future of the ACA in particular and health care laws in general in the United States. In December 2018, a Texas federal district court struck down the ACA on the grounds that the individual health insurance mandate is unconstitutional. The United States Supreme Court heard arguments in this case on November 10, 2020.

The Company is participating in the health care debate and monitoring how any proposed changes could affect its business. The Company is unable to predict the likelihood of changes to the ACA. Depending on the nature of any changes to the ACA, such actions could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

Other Legislative Changes

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. A number of states have passed pharmaceutical price and cost transparency laws. These laws typically require manufacturers to report certain product price information or other financial data to the state. Some laws also require manufacturers to provide advance notification of price increases. The Company expects that states will continue their focus on pharmaceutical price transparency and that this focus will continue to exert pressure on product pricing.

Drug Pricing

The Company also faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins, including, in the United States (i) practices of managed care organizations, federal and state exchanges, and institutional and governmental purchasers, and (ii) federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the ACA.

In November 2020, the Department of Health and Human Services Office of Inspector General (OIG) issued a Final Rule that would, effective January 1, 2023, eliminate the Anti-Kickback Statute safe harbor for rebates paid to Medicare Part D plans or to pharmacy benefit managers (PBMs) on behalf of such plans. While the Company cannot anticipate the effects of this change to the way it currently contracts, this new framework could significantly alter the way it does business with Part D Plan Sponsors and PBMs on behalf of such plans. This rulemaking also established, effective January 1, 2021, a new safe harbor for point of sale discounts at the pharmacy counter and a new safe harbor for certain services arrangements between pharmaceutical manufacturers and PBMs.

CMS also recently issued an Interim Final Rule (the MFN Rule) that alters how physicians will be reimbursed under the Medicare program for physician administered drugs. Pursuant to the MFN Rule, which was intended to be effective January 1, 2021, rather than use the current Average Sales Price (ASP)-based payment framework for certain physician-administered drugs, the MFN Rule would institute a new pricing system for certain prescription drugs and biologic products covered by Medicare Part B in which Medicare would reimburse no more than the "most favored nation price," meaning the lowest price after adjusting for volume and differences in gross domestic product, for the top 50 Part B reimbursed products, which includes *Keytruda*, sold in 22 member countries of the Organisation for Economic Co-operation and Development (OECD). Several organizations, including two trade groups of which Merck is a member, have filed suit challenging this regulation. Those lawsuits remain pending with a preliminary injunction having been entered in one of the cases. At this time, the Company cannot predict with any certainty if or when the MFN Rule will go into effect. Implementation of the MFN Rule could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

The FDA also recently issued rulemaking allowing the commercial importation of certain prescription drugs from Canada through FDA-authorized, time-limited programs sponsored by states or Native American tribes recognized under the rule, and, in certain future circumstances, pharmacists and wholesalers. The FDA also recently released final guidance for industry detailing procedures for drug manufacturers to import FDA-approved prescription drug, biological, and combination products that were manufactured abroad and authorized and intended for sale in a foreign country. A trade organization. in which Merck is a member, brought suit, which remains pending in federal district court, challenging the commercial importation rule. These proposed changes could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. As an example, health care reform has contributed to an increase in the number of patients in the Medicaid program under which sales of pharmaceutical products are subject to substantial rebates.

The pharmaceutical industry also could be considered a potential source of savings via other legislative and administrative proposals that have been debated but not enacted. These types of revenue generating or cost saving proposals include additional direct price controls.

There was active consideration of drug-pricing related legislation in the last Congress, and it remains very uncertain as to what proposals, if any, may be included as part of future federal legislative proposals that would directly or indirectly affect the Company.

In the U.S. private sector, consolidation and integration among health care providers is a major factor in the competitive marketplace for pharmaceutical products. Health plans and PBMs have been consolidating into fewer, larger entities, thus enhancing their purchasing strength and importance. Private third-party insurers, as well as governments, employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for Merck's products or obtaining such placement at unfavorable pricing could adversely affect revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products. Private health insurance companies also are increasingly imposing utilization management tools, such as clinical protocols, requiring prior authorization for a branded product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine. These same management tools are also used in treatment areas in which the payor has taken the position that multiple branded products are therapeutically comparable. As the U.S. payor market concentrates further and as more drugs become available in generic form, pharmaceutical companies may face greater pricing pressure from private third-party payors.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price, net price increases, and average discounts across the Company's U.S. portfolio dating back to 2010. In 2020, the Company's gross U.S. sales were reduced by 45.5% as a result of rebates, discounts and returns.

European Union

Efforts toward health care cost containment remain intense in the European Union (EU). The Company faces competitive pricing pressure resulting from generic and biosimilar drugs. In addition, a majority of countries in the EU attempt to contain drug costs by engaging in reference pricing in which authorities examine pre-determined markets for published prices of drugs. Reference pricing may either compare a product's prices in other markets (external reference pricing), or compare a product's price with those of other products in a national class (internal reference pricing). The authorities then use the price data to set new local prices for brand-name drugs, including the Company's drugs. Guidelines for examining reference pricing are usually set in local markets and can be changed pursuant to local regulations. Some EU Member States have established free-pricing systems, but regulate the pricing for drugs through profit control plans. Others seek to negotiate or set prices based on the cost-effectiveness of a product or an assessment of whether it offers a therapeutic benefit over other products in the relevant class. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In some EU Member States, cross-border imports from low-priced markets also exert competitive pressure that may reduce pricing within an EU Member State.

Additionally, EU Member States have the power to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement. In the EU, pricing and reimbursement plans vary widely from Member State to Member State. Some EU Member States provide that drug products may be marketed only after a reimbursement price has been agreed. Some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to already available therapies or so-called health technology assessments (HTA), in order to obtain reimbursement or pricing approval. The HTA of pharmaceutical products is becoming an increasingly common part of the pricing and reimbursement procedures in most EU Member States. The HTA process, which is governed by the national laws of these countries, involves the assessment of the cost-effectiveness, public health impact, therapeutic impact and/or the economic and social impact of use of a given pharmaceutical product in the national health care system of the individual country is conducted. Ultimately, HTA measures the added value of a new health technology compared to existing ones. The outcome of HTAs regarding specific pharmaceutical products will often influence the pricing and reimbursement status granted to these pharmaceutical products by the regulatory authorities of individual EU Member States. A negative HTA of one of the Company's products may mean that the product is not reimbursable or may force the Company to reduce its reimbursement price or offer discounts or rebates.

A negative HTA by a leading and recognized HTA body could also undermine the Company's ability to obtain reimbursement for the relevant product outside a jurisdiction. For example, EU Member States that have not yet developed HTA mechanisms may rely to some extent on the HTA performed in other countries with a developed HTA framework, to inform their pricing and reimbursement decisions. HTA procedures require additional data, reviews and administrative processes, all of which increase the complexity, timing and costs of obtaining product reimbursement and exert downward pressure on available reimbursement.

To obtain reimbursement or pricing approval in some EU Member States, the Company may be required to conduct studies that compare the cost-effectiveness of the Company's product candidates to other therapies that are considered the local standard of care. There can be no assurance that any EU Member State will allow favorable pricing, reimbursement and market access conditions for any of the Company's products, or that it will be feasible to conduct additional cost-effectiveness studies, if required.

Brexit

In 2016, the United Kingdom (UK) held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit." As a result of that referendum and subsequent negotiations, the UK left the EU on January 31, 2020. A transitional period applied from January 31, 2020 until December 31, 2020, and during this period the EU and UK operated as if the UK was an EU Member State, and the UK continued to participate in the EU Customs Union allowing for the freedom of movement for people and goods.

It was announced on December 24, 2020, that the EU and the UK agreed to a Trade and Cooperation Agreement (TCA). The TCA sets out the new arrangements for trade of goods, including medicines and vaccines, which allows goods to continue to flow between the EU and the UK. On December 29, 2020, the Council of the EU adopted the decision to sign the TCA and for the TCA to be provisionally applied from January 1, 2021. The UK and EU signed the TCA on December 30, 2020. In order for the TCA to be ratified and formally come into effect, the Council of the EU must unanimously approve the TCA and the European Parliament must consent to it, which the Company believes will occur. As a result of the TCA, the Company believes that its operations will not be materially adversely affected by Brexit.

Japan

In Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines. Furthermore, the government can order re-pricings for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re-pricing rules. The next government-mandated price reduction will occur in April 2021 and is expected to impact many Company products.

China

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's current in-line products, and the absence of trade impediments or adverse pricing controls. In recent years, the Chinese government has introduced and implemented a number of structural reforms to accelerate the shift to innovative products and reduce costs. Since 2017, there have been multiple new policies introduced by the government to improve access to new innovation, reduce the complexity of regulatory filings, and accelerate the review and approval process. This has led to a significant increase in the number of new products being approved each year. Additionally, in 2017, the Chinese government updated the National Reimbursement Drug List (NRDL) for the first time in eight years. While the mechanism for drugs being added to the list evolves, inclusion may require a price negotiation which could impact the outlook in the market for selected brands. In 2020, drugs were added to the NRDL through double-digit price reductions. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through volume based procurement (VBP). In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the first three rounds of VBP have had, on average, a price reduction of 50%. The Company expects VBP to be a semi-annual process that will have a significant impact on mature products moving forward.

Emerging Markets

The Company's focus on emerging markets, in addition to China, has continued. Governments in many emerging markets are also focused on constraining health care costs and have enacted price controls and measures impacting intellectual property, including in exceptional cases, threats of compulsory licenses,. that aim to put pressure on the price of innovative pharmaceuticals or result in constrained market access to innovative medicine. The Company anticipates that pricing pressures and market access challenges will continue in the future to varying degrees in the emerging markets.

Beyond pricing and market access challenges, other conditions in emerging market countries can affect the Company's efforts to continue to grow in these markets, including potential political instability, changes in trade sanctions and embargoes, significant currency fluctuation and controls, financial crises, limited or changing availability of funding for health care, credit worthiness of health care partners, such as hospitals, due to COVID-19, and other developments that may adversely impact the business environment for the Company. Further, the Company may engage third-party agents to assist in operating in emerging market countries, which may affect its ability to realize continued growth and may also increase the Company's risk exposure.

In addressing cost containment pressures, the Company engages in public policy advocacy with policymakers and continues to work to demonstrate that its medicines provide value to patients and to those who pay for health care. The Company advocates with government policymakers to encourage a long-term approach to sustainable health care financing that ensures access to innovative medicines and does not disproportionately target pharmaceuticals as a source of budget savings. In markets with historically low rates of health care spending, the Company encourages those governments to increase their investments and adopt market reforms in order to improve their citizens' access to appropriate health care, including medicines.

Operating conditions have become more challenging under the global pressures of competition, industry regulation and cost containment efforts. Although no one can predict the effect of these and other factors on the Company's business, the Company continually takes measures to evaluate, adapt and improve the organization and its business practices to better meet customer needs and believes that it is well-positioned to respond to the evolving health care environment and market forces.

Regulation

The pharmaceutical industry is also subject to regulation by regional, country, state and local agencies around the world focused on standards and processes for determining drug safety and effectiveness, as well as conditions for sale or reimbursement.

Of particular importance is the FDA in the United States, which administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling, and marketing of prescription pharmaceuticals. In some cases, the FDA requirements and practices have increased the amount of time and resources necessary to develop new products and bring them to market in the United States. At the same time, the FDA has committed to expediting the development and review of products bearing the "breakthrough therapy" designation, which has accelerated the regulatory review process for medicines with this designation. The FDA has also undertaken efforts to bring generic competition to market more efficiently and in a more timely manner.

The EU has adopted directives and other legislation concerning the classification, approval for marketing, labeling, advertising, manufacturing, wholesale distribution, integrity of the supply chain, pharmacovigilance and safety monitoring of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU member states. In particular, EU regulators may approve products subject to a number of post-authorization conditions. Examples of typical post-authorization commitments include additional pharmacovigilance, the conduct of clinical trials, the establishment of patient registries, physician or patient education and controlled distribution and prescribing arrangements. Non-compliance with post-authorization conditions, pharmacovigilance and other obligations can lead to regulatory action, including the variation, suspension or withdrawal of the marketing authorizations, or other enforcement or regulatory actions, including the imposition of financial penalties. The Company's policies and procedures are already consistent with the substance of these directives; consequently, it is believed that they will not have any material effect on the Company's business.

The Company believes that it will continue to be able to conduct its operations, including launching new drugs, in this regulatory environment. (See "Research and Development" below for a discussion of the regulatory approval process.)

Access to Medicines

As a global health care company, Merck's primary role is to discover and develop innovative medicines and vaccines. The Company also recognizes that it has an important role to play in helping to improve access to its medicines, vaccines, and to quality health care around the world. The Company's efforts in this regard are wide-ranging and include a set of principles that the Company strives to embed into its operations and business strategies to guide the Company's worldwide approach to expanding access to health care. In addition, through innovative social investments, including philanthropic programs and impact investing, Merck is also helping to strengthen health systems and build capacity, particularly in under-resourced communities. The Merck Patient Assistance Program provides medicines and adult vaccines for free to people in the United States who do not have prescription drug or health insurance coverage and who, without the Company's assistance, cannot afford their Merck medicines and vaccines. Merck has funded "Merck for Mothers," a long-term effort with global health partners to end preventable deaths from complications of pregnancy and childbirth. Merck has also provided funds to the Merck Foundation, an independent grantmaking organization, which has partnered with a variety of organizations dedicated to improving global health.

Privacy and Data Protection

The Company is subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on the Company's ability to transfer, access and use personal data across its business. The legislative and regulatory landscape for privacy and data protection continues to evolve. There has been increased attention to privacy and data protection issues in both developed and emerging markets with the potential to affect directly the Company's business, including the EU General Data Protection Regulation, (GDPR) which went into effect in May 2018 and imposes penalties of up to 4% of global revenue.

The GDPR and related implementing laws in individual EU Member States govern the collection and use of personal health data and other personal data in the EU. The GDPR increased responsibility and liability in relation to personal data that the Company processes. It also imposes a number of strict obligations and restrictions on the ability to process (which includes collection, analysis and transfer of) personal data, including health data from clinical trials and adverse event reporting. The GDPR also includes requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals prior to processing their personal data or personal health data, notification of data processing obligations to the national data protection authorities, and the security and confidentiality of the personal data. Further, the GDPR prohibits the transfer of personal data to countries outside of the EU that are not considered by the EC to provide an adequate level of data protection, including to the United States, except if the data controller meets very specific requirements. Following the Schrems II decision of the Court of Justice of the European Union on July 16, 2020, there is considerable uncertainty as to the permissibility of international data transfers under the GDPR. In light of the implications of this decision, the Company may face difficulties regarding the transfer of personal data from the EU to third countries.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines and other administrative penalties as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU. Guidance developed at both EU level and at the national level in individual EU Member States concerning implementation and compliance practices is often updated or otherwise revised.

There is, moreover, a growing trend towards required public disclosure of clinical trial data in the EU which adds to the complexity of obligations relating to processing health data from clinical trials. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against the Company, harm to its reputation, and adversely impact its business and operating results. The uncertainty regarding the interplay between different regulatory frameworks further adds to the complexity that the Company faces with regard to data protection regulation.

Additional laws and regulations enacted in the United States (such as the California Consumer Privacy Act), Europe, Asia and Latin America, have increased enforcement and litigation activity in the United States and other developed markets, as well as increased regulatory cooperation among privacy authorities globally. The Company has adopted a comprehensive global privacy program to manage these evolving risks and facilitate the transfer of personal information across international borders.

Distribution

The Company sells its human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers, such as health maintenance organizations, PBMs and other institutions. Human health vaccines are sold primarily to physicians, wholesalers, physician distributors and government entities. The Company's professional representatives communicate the effectiveness, safety and value of the Company's pharmaceutical and vaccine products to health care professionals in private practice, group practices, hospitals and managed care organizations. The Company sells its animal health products to veterinarians, distributors and animal producers.

Patents, Trademarks and Licenses

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of its products in the United States and in most major foreign markets. Patents may cover products *per se*, pharmaceutical formulations, processes for, or intermediates useful in, the manufacture of products, or the uses of products. Protection for individual products extends for varying periods in accordance with the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage.

The Food and Drug Administration Modernization Act includes a Pediatric Exclusivity Provision that may provide an additional six months of market exclusivity in the United States for indications of new or currently marketed drugs if certain agreed upon pediatric studies are completed by the applicant. Current U.S. patent law provides additional patent term for periods when the patented product was under regulatory review by the FDA. The EU also provides an additional six months of pediatric market exclusivity attached to a product's Supplementary Protection Certificate (SPC). Japan provides the additional term for pediatric studies attached to market exclusivity unrelated to patent term.

Patent portfolios developed for products introduced by the Company normally provide market exclusivity. The Company has the following key patent protection in the United States, the EU, Japan and China (including the potential for patent term extensions (PTE) and SPCs where indicated) for the following marketed products:

Product	Year of Expiration (U.S.)	Year of Expiration (EU)[1]	Year of Expiration (Japan)[2]	Year of Expiration (China)
Januvia	2023	2022	2025-2026	2022
Janumet	2023	2023	N/A	2022
Janumet XR	2023	N/A	N/A	2022
Isentress	2024	2023[3]	2022-2026	2022
Simponi	N/A[4]	2024[5]	N/A[4]	N/A[4]
Lenvima[6]	2025[3] (with pending PTE)	2021 (patents), 2026[3] (SPCs)	2026	2021
Adempas[7]	2026[3]	2028[3]	2027-2028	2023
Bridion	2026[3] (with pending PTE)	2023	2024	Expired
Nexplanon	2027 (device)	2025 (device)	N/A	2025
Bravecto	2027 (with pending PTE)	2025 (patents), 2029 (SPCs)	2029	2033
Gardasil	2028	2021[3]	Expired	N/A
Gardasil 9	2028	2025 (patents), 2030[3] (SPCs)	N/A	2025
Keytruda	2028	2028 (patents), 2030[3] (SPCs)	2032-2033	2028
Lynparza[8]	2028[3] (with pending PTE)	2024 (patents), 2029[3] (SPCs)	2028-2029	2024
Zerbaxa	2028[3]	2023 (patents), 2028[3] (SPCs)	2028 (with pending PTE)	N/A
Sivextro	2028	2024 (patents), 2029 (SPCs)	2029	2024
Belsomra	2029[3]	N/A	2031	N/A
Prevymis	2029[3] (with pending PTE)	2024 (patents), 2029[3] (SPCs)	2029	N/A
Segluromet[9]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A[10]	N/A
Steglatro[9]	2031[3] (with pending PTE)	2029 (patents), 2034[3] (SPCs)	N/A[10]	2029
Steglujan[9]	2031 (with pending PTE)	2029 (patents), 2034 (SPCs)	N/A[10]	N/A
Verquvo[7]	2031 (with pending PTE)	N/A[11]	N/A[11]	N/A[11]
Delstrigo	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	N/A	N/A
Pifeltro	2032 (with pending PTE)	2031 (patents), 2033 (SPCs)	2036	2031
Recarbrio	2033[3] (with pending PTE)	N/A	N/A	N/A

Note: Compound patent unless otherwise noted. Certain of the products listed may be the subject of patent litigation. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below.

N/A: Currently no marketing approval.

(1) *The EU date represents the expiration date for the following five countries: France, Germany, Italy, Spain and the United Kingdom (Major EU Markets). If SPC applications have been filed but have not been granted in all Major EU Markets, both the patent expiry date and the SPC expiry date are listed.*

(2) *The PTE system in Japan allows for a patent to be extended more than once provided the later approval is directed to a different indication from that of the previous approval. This may result in multiple PTE approvals for a given patent, each with its own expiration date.*

(3) *Eligible for 6 months Pediatric Exclusivity.*

(4) *The Company has no marketing rights in the U.S., Japan or China.*

(5) *Expiration of the distribution agreement with Janssen Pharmaceuticals, Inc.*

(6) *Part of a global strategic oncology collaboration with Eisai.*

(7) *Being commercialized in a worldwide collaboration with Bayer AG.*

(8) *Part of a global strategic oncology collaboration with AstraZeneca.*

(9) *Being commercialized and promoted in a worldwide, except Japan, collaboration with Pfizer Inc.*

(10) *The Company has no marketing rights in Japan.*

(11) *The Company has no marketing rights in the EU, Japan or China.*

The Company also has the following key U.S. patent protection for drug candidates under review or in Phase 3 development:

Phase 3 Drug Candidate	Currently Anticipated Year of Expiration (in the U.S.)
MK-7264 (gefapixant)	2027
V114 (pneumoconjugate vaccine)	2031 (vaccine composition)
MK-7110 (CD24Fc)	2031
MK-8591A (islatravir/doravirine)	2032
MK-6482 (belzutifan)	2034

Unless otherwise noted, the patents in the above charts are compound patents. Each patent may be subject to a future patent term restoration of up to five years and six month pediatric market exclusivity, either or both of which may be available. In addition, depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product. Also, regulatory exclusivity tied to the protection of clinical data is complementary to patent protection and, in some cases, may provide more effective or longer lasting marketing exclusivity than a compound's patent estate. In the United States, the data protection generally runs five years from first marketing approval of a new chemical entity, extended to seven years for an orphan drug indication and 12 years from first marketing approval of a biological product.

While the expiration of a product patent normally results in a loss of market exclusivity for the covered pharmaceutical product, commercial benefits may continue to be derived from: (i) later granted patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in the United States and certain other countries, market exclusivity that may be available under relevant law. The effect of product patent expiration on pharmaceutical products also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

Additions to market exclusivity are sought in the United States and other countries through all relevant laws, including laws increasing patent life. Some of the benefits of increases in patent life have been partially offset by an increase in the number of incentives for and use of generic products. Additionally, improvements in intellectual property laws are sought in the United States and other countries through reform of patent and other relevant laws and implementation of international treaties.

For further information with respect to the Company's patents, see Item 1A. "Risk Factors" and Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below.

Worldwide, all of the Company's important products are sold under trademarks that are considered in the aggregate to be of material importance. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and can be renewed indefinitely.

Royalty income in 2020 on patent and know-how licenses and other rights amounted to $185 million. Merck also incurred royalty expenses amounting to $2.0 billion in 2020 under patent and know-how licenses it holds.

Research and Development

The Company's business is characterized by the introduction of new products or new uses for existing products through a strong research and development program. At December 31, 2020, approximately 16,750 people were employed in the Company's research activities. The Company prioritizes its research and development efforts and focuses on candidates that it believes represent breakthrough science that will make a difference for patients and payers.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The Company's research and development model is designed to increase productivity and improve the probability of success by prioritizing the Company's research and development resources on candidates the Company believes are capable of providing unambiguous, promotable advantages to patients and payers and delivering the maximum value of its approved medicines and vaccines through new indications and new formulations. Merck is pursuing emerging product opportunities independent of therapeutic area or modality (small molecule, biologics and vaccines) and is building its biologics capabilities. The Company is committed to ensuring that externally sourced programs remain an important component of its pipeline strategy, with a focus on supplementing its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies.

The Company's clinical pipeline includes candidates in multiple disease areas, including cancer, cardiovascular diseases, metabolic diseases, infectious diseases, neurosciences, respiratory diseases, and vaccines.

In the development of human health products, industry practice and government regulations in the United States and most foreign countries provide for the determination of effectiveness and safety of new chemical compounds through pre-clinical tests and controlled clinical evaluation. Before a new drug or vaccine may be marketed in the United States, recorded data on pre-clinical and clinical experience are included in the New Drug Application (NDA) for a drug or the Biologics License Application (BLA) for a vaccine or biologic submitted to the FDA for the required approval.

Once the Company's scientists discover a new small molecule compound or biologic that they believe has promise to treat a medical condition, the Company commences pre-clinical testing with that compound. Pre-clinical testing includes laboratory testing and animal safety studies to gather data on chemistry, pharmacology, immunogenicity and toxicology. Pending acceptable pre-clinical data, the Company will initiate clinical testing in accordance with established regulatory requirements. The clinical testing begins with Phase 1 studies, which are designed to assess safety, tolerability, pharmacokinetics, and preliminary pharmacodynamic activity of the compound in humans. If favorable, additional, larger Phase 2 studies are initiated to determine the efficacy of the compound in the affected population, define appropriate dosing for the compound, as well as identify any adverse effects that could limit the compound's usefulness. In some situations, the clinical program incorporates adaptive design methodology to use accumulating data to decide how to modify aspects of the ongoing clinical study as it continues, without undermining the validity and integrity of the trial. One type of adaptive clinical trial is an adaptive Phase 2a/2b trial design, a two-stage trial design consisting of a Phase 2a proof-of-concept stage and a Phase 2b dose-optimization finding stage. If data from the Phase 2 trials are satisfactory, the Company commences large-scale Phase 3 trials to confirm the compound's efficacy and safety. Another type of adaptive clinical trial is an adaptive Phase 2/3 trial design, a study that includes an interim analysis and an adaptation that changes the trial from having features common in a Phase 2 study (e.g. multiple dose groups) to a design similar to a Phase 3 trial. An adaptive Phase 2/3 trial design reduces timelines by eliminating activities which would be required to start a separate study. Upon completion of Phase 3 trials, if satisfactory, the Company submits regulatory filings with the appropriate regulatory agencies around the world to have the product candidate approved for marketing. There can be no assurance that a compound that is the result of any particular program will obtain the regulatory approvals necessary for it to be marketed.

Vaccine development follows the same general pathway as for drugs. Pre-clinical testing focuses on the vaccine's safety and ability to elicit a protective immune response (immunogenicity). Pre-marketing vaccine clinical trials are typically done in three phases. Initial Phase 1 clinical studies are conducted in normal subjects to evaluate the safety, tolerability and immunogenicity of the vaccine candidate. Phase 2 studies are dose-ranging studies. Finally, Phase 3 trials provide the necessary data on effectiveness and safety. If successful, the Company submits regulatory filings with the appropriate regulatory agencies.

In the United States, the FDA review process begins once a complete NDA or BLA is submitted, received and accepted for review by the agency. Within 60 days after receipt, the FDA determines if the application is sufficiently complete to permit a substantive review. The FDA also assesses, at that time, whether the application will be granted a priority review or standard review. Pursuant to the Prescription Drug User Fee Act V (PDUFA), the FDA review period target for NDAs or original BLAs is either six months, for priority review, or ten months, for a standard review, from the time the application is deemed sufficiently complete. Once the review timelines are determined, the FDA will generally act upon the application within those timelines, unless a major amendment has been submitted (either at the Company's own initiative or the FDA's request) to the pending application. If this occurs, the FDA may extend the review period to allow for review of the new information, but by no more than three months. Extensions to the review period are communicated to the Company. The FDA can act on an application either by issuing an approval letter or by issuing a Complete Response Letter (CRL) stating that the application will not be approved in its present form and describing all deficiencies that the FDA has identified. Should the Company wish to pursue an application after receiving a CRL, it can resubmit the application with information that addresses the questions or issues identified by the FDA in order to support approval. Resubmissions are subject to review period targets, which vary depending on the underlying submission type and the content of the resubmission.

The FDA has four program designations — Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review — to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions. The Fast Track designation provides pharmaceutical manufacturers with opportunities for frequent interactions with FDA reviewers during the product's development and the ability for the manufacturer to do a rolling submission of the NDA/BLA. A rolling submission allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. The Breakthrough Therapy designation provides manufacturers with all of the features of the Fast Track designation as well as intensive guidance on implementing an efficient development program for the product and a commitment by the FDA to involve senior managers and experienced staff in the review. The Accelerated Approval designation allows the FDA to approve a product based on an effect on a surrogate or intermediate endpoint that is reasonably likely to predict a product's clinical benefit and generally requires the manufacturer to conduct required post-approval confirmatory trials to verify the clinical benefit. The Priority Review designation means that the FDA's goal is to take action on the NDA/BLA within six months, compared to ten months under standard review. More than one of these special designations can be granted for a given application (i.e., a product designated as a Breakthrough Therapy may also be eligible for Priority Review).

Due to the COVID-19 public health crisis, the United States Secretary of Health and Human Services has exercised statutory authority to determine that a public health emergency exists, and declare these circumstances justify the emergency use of drugs and biological products as authorized by the FDA. While in effect, this declaration enables the FDA to issue Emergency Use Authorizations (EUAs) permitting distribution and use of specific medical products absent NDA/BLA submission or approval, including products to treat or prevent diseases or conditions caused by the SARS-CoV-2 virus, subject to the terms of any such EUAs. The FDA must make certain findings to grant an EUA, including that it is reasonable to believe based on the totality of evidence that the drug or biologic may be effective, and that known or potential benefits when used under the terms of the EUA outweigh known or potential risks. Additionally, the FDA must find that there is no adequate, approved and available alternative to the emergency use.

The primary method the Company uses to obtain marketing authorization of pharmaceutical products in the EU is through the "centralized procedure." This procedure is compulsory for certain pharmaceutical products, in particular those using biotechnological processes, and is also available for certain new chemical compounds and products. A company seeking to market an innovative pharmaceutical product through the centralized procedure must file a complete set of safety data and efficacy data as part of a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). After the EMA evaluates the MAA, it provides a recommendation to the EC and the EC then approves or denies the MAA. It is also possible for new chemical products to obtain marketing authorization in the EU through a "mutual recognition procedure" in which an application is made to a single member state and, if the member state approves the pharmaceutical product under a national procedure, the applicant may submit that approval to the mutual recognition procedure of some or all other EU member states.

Outside of the United States and the EU, the Company submits marketing applications to national regulatory authorities. Examples of such are the Ministry of Health, Labour and Welfare in Japan, the National Medical Products Administration in China, Health Canada, Agência Nacional de Vigilância Sanatária in Brazil, Korea Food and Drug Administration in South Korea, and the Therapeutic Goods Administration in Australia. Each country has a separate and independent review process and timeline. In many markets, approval times can be longer as the regulatory authority requires approval in a major market, such as the United States or the EU, and issuance of a Certificate of Pharmaceutical Product from that market before initiating their local review process.

Research and Development Update

The Company currently has several candidates under regulatory review in the United States and internationally or in late-stage clinical development.

MK-7655A is combination of relebactum, a beta-lactamase inhibitor, and imipenem/cilastatin (a carbapenem antibiotic) under review in Japan for the treatment of bacterial infection. MK-7655A was approved by the FDA in 2019 and is marketed in the United States as *Recarbrio*.

MK-1242, vericiguat, is an orally administered soluble guanylate cyclase (sGC) stimulator under review in the EU and in Japan to reduce the risk of cardiovascular death and heart failure hospitalization following a worsening heart failure event in patients with symptomatic chronic heart failure with reduced ejection fraction, in combination with other heart failure therapies. The applications are based on results from the Phase 3 VICTORIA trial. Vericiguat was approved by the FDA in January 2021 and will be marketed in the United States as Verquvo. Vericiguat is being jointly developed with Bayer. Bayer will commercialize vericiguat in territories outside the United States, if approved.

MK-5618, selumetinib, is under review in the EU for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN) based on positive results from the National Cancer Institute Cancer Therapy Evaluation Program-sponsored Phase 2 SPRINT Stratum 1 trial. Selumetinib was approved by the FDA in April 2020 and is marketed in the United States as Koselugo. Selumetinib is being jointly developed and commercialized with AstraZeneca globally.

V114 is an investigational 15-valent pneumococcal conjugate vaccine under priority review by the FDA for the prevention of invasive pneumococcal disease in adults 18 years of age and older. The FDA set a PDUFA date of July 18, 2021. The EMA is also reviewing an application for licensure of V114 in adults. Additionally, the Company has several ongoing Phase 3 trials evaluating V114 in pediatric patients. V114 previously received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease in pediatric patients 6 weeks to 18 years of age and adults 18 years of age and older. The Company is involved in litigation challenging the validity of several Pfizer Inc. patents that relate to pneumococcal vaccine technology in the United States and several foreign jurisdictions.

Keytruda is an anti-PD-1 therapy approved for the treatment of many cancers that is in clinical development for expanded indications. These approvals were the result of a broad clinical development program that currently consists of more than 1,400 clinical trials, including more than 1,000 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: biliary tract, cervical, colorectal, cutaneous squamous cell, endometrial, esophageal, estrogen receptor positive breast cancer, gastric, glioblastoma, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, non-small-cell lung, small-cell lung, melanoma, mesothelioma, ovarian, prostate, renal, triple-negative breast, and urothelial, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Keytruda in combination with chemotherapy is under review in the EU for the treatment of locally recurrent unresectable or metastatic triple negative breast cancer (TNBC) in adults whose tumors express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease based on the results of the KEYNOTE-355 trial. *Keytruda* was approved for this indication under accelerated approval based on progression-free survival (PFS) by the FDA in November 2020. *Keytruda* in combination with chemotherapy is also under review in Japan for the treatment of patients with locally recurrent unresectable or metastatic TNBC based on data from the KEYNOTE-355 trial.

In July 2020, the FDA accepted for standard review a supplemental BLA for *Keytruda* for the treatment of patients with high-risk, early-stage TNBC in combination with chemotherapy as neoadjuvant (pre-operative) treatment, and then as a single agent as adjuvant (post-operative) treatment after surgery. The application was based on data from the first and second interim analyses of the KEYNOTE-522 trial. In February 2021, the FDA's Oncologic Drugs Advisory Committee (ODAC), which discussed the Company's supplemental BLA for *Keytruda*, voted that a regulatory decision should be deferred until further data are available from the Phase 3 KEYNOTE-522 trial. The study met one of the dual primary endpoints of pathological complete response and is continuing to evaluate event-free survival. The ODAC provides the FDA with independent, expert advice and recommendations on marketed and investigational medicines for use in the treatment of cancer. The FDA is not bound by the committee's guidance but takes its advice into consideration. The PDUFA date for this application is March 29, 2021. The next interim analysis is calendar-driven, and data is expected in the third quarter of 2021.

In February 2021, Merck announced that the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion recommending approval of an expanded label for *Keytruda* as monotherapy for the treatment of adult and pediatric patients aged 3 years and older with relapsed or refractory cHL who have failed an earlier line of therapy. This recommendation is based on results from the pivotal Phase 3 KEYNOTE-204 trial, in which *Keytruda* monotherapy demonstrated a significant improvement in PFS compared with brentuximab vedotin, a commonly used treatment. The recommendation is also based on supportive data from an updated analysis of the KEYNOTE-087 trial, which supported EC approval of *Keytruda* for the treatment of adult patients with relapsed or refractory cHL. The CHMP's recommendation will now be reviewed by the EC for marketing authorization in the EU. *Keytruda* was approved for this indication by the FDA in October 2020.

Keytruda is also under review as monotherapy for the first-line treatment of adult patients with metastatic MSI-H or dMMR colorectal cancer in Japan based on the result of the KEYNOTE-177 trial. *Keytruda* was approved for this indication by the FDA in June 2020 and by the EU in January 2021.

In January 2021, the FDA accepted a supplemental BLA seeking use of *Keytruda* for the treatment of patients with locally advanced cSCC that is not curable by surgery or radiation based on the results of the KEYNOTE-629 trial. The FDA set a PDUFA date of September 9, 2021.

In December 2020, the FDA accepted and granted priority review for a supplemental BLA for *Keytruda* in combination with chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus and gastroesophageal junction. This supplemental BLA is based on data from the pivotal Phase 3 KEYNOTE-590 trial, in which *Keytruda* plus chemotherapy demonstrated significant improvements in the primary endpoints of overall survival (OS) and PFS versus chemotherapy in these patients regardless of PD-L1 expression status and tumor histology. These data were presented at the European Society of Medical Oncology (ESMO) Virtual Congress 2020. The FDA set a PDUFA date of April 13, 2021. In December 2020, the CHMP of the EMA announced the start of a procedure to extend the indication to include in combination with chemotherapy, first-line treatment of locally advanced unresectable or metastatic carcinoma of the esophagus or HER-2 negative gastroesophageal junction adenocarcinoma in adults for *Keytruda*, based on the results from KEYNOTE-590. *Keytruda* is also under review for this indication in Japan.

Keytruda also received Breakthrough Therapy designation from the FDA in February 2020 for the combination of *Keytruda* with Padcev (enfortumab vedotin-ejfv), in the first line setting for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In January 2021, Merck announced first-time data from the Phase 3 KEYNOTE-598 study evaluating *Keytruda* in combination with ipilimumab (Yervoy) compared with *Keytruda* monotherapy as first-line treatment for patients with metastatic NSCLC without EGFR or ALK genomic tumor aberrations and whose tumors express PD-L1 (tumor proportion score ≥50%). Results of the study showed that the addition of ipilimumab to *Keytruda* did not improve OS or PFS but added toxicity compared with *Keytruda* monotherapy in these patients. These results were presented in the Presidential Symposium at the IASLC 2020 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer in January 2021 and published in the Journal of Clinical Oncology. As previously announced in November 2020, the study was discontinued due to futility based on the recommendation of an independent Data Monitoring Committee (DMC), which determined the benefit/risk profile of *Keytruda* in combination with ipilimumab did not support continuing the trial. The DMC also advised that patients in the study discontinue treatment with ipilimumab/placebo.

In February 2021, Merck's announced that the Phase 3 KEYNOTE-122 trial evaluating *Keytruda* versus standard of care treatment (capecitabine, gemcitabine, or docetaxel) for the treatment of recurrent or metastatic nasopharyngeal cancer did not meet its primary endpoint of OS. Full results will be presented at a future medical meeting.

In May 2020, Merck and Eisai presented data from analyses of two Phase 2 trials evaluating *Keytruda* plus Lenvima at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting in which the *Keytruda* plus Lenvima combination demonstrated clinically meaningful objective response rates (ORR): the KEYNOTE-524/Study 116 trial in patients with unresectable HCC with no prior systemic therapy; and the KEYNOTE-146/Study 111 trial in patients with metastatic clear cell renal cell carcinoma (ccRCC) who progressed following immune checkpoint inhibitor therapy.

In July 2020, Merck and Eisai announced that the FDA issued a CRL regarding Merck's and Eisai's applications seeking accelerated approval for the first-line treatment of patients with unresectable HCC based on this trial, which showed clinically meaningful efficacy in the single-arm setting. These data supported a Breakthrough Therapy designation granted by the FDA in July 2019. Ahead of the PDUFA action dates of Merck's and Eisai's applications, another combination therapy was approved based on a randomized, controlled trial that demonstrated improvement in OS versus standard-of-care treatment. Consequently, the CRL stated that Merck's and Eisai's applications do not provide evidence that *Keytruda* in combination with Lenvima represents a meaningful advantage over available therapies for the treatment of unresectable or metastatic HCC with no prior systemic therapy for advanced disease. Since the applications for KEYNOTE-524/Study 116 no longer meet the criteria for accelerated approval, both companies plan to work with the FDA to take appropriate next steps, which include conducting a well-controlled clinical trial that demonstrates substantial evidence of effectiveness and the clinical benefit of the combination. As such, LEAP-002, the Phase 3 trial evaluating the *Keytruda* plus Lenvima combination as a first-line treatment for advanced HCC, is currently underway and fully enrolled. The CRL does not impact the current approved indications for *Keytruda* or for Lenvima.

In February 2021, Merck and Eisai announced the first presentation of new investigational data from the pivotal Phase 3 CLEAR study (KEYNOTE-581/Study 307) at the 2021 Genitourinary Cancers Symposium (ASCO GU) and published simultaneously in the *New England Journal of Medicine*. The trial evaluated the combinations of *Keytruda* plus Lenvima, and Lenvima plus everolimus versus sunitinib for the first-line treatment of patients with advanced RCC. *Keytruda* plus Lenvima demonstrated statistically significant and clinically meaningful improvements in PFS, OS and ORR versus sunitinib. Lenvima plus everolimus also showed significant improvements in PFS and ORR versus sunitinib. Merck and Eisai will discuss these data with regulatory authorities worldwide, with the intent to submit marketing authorization applications based on these results.

In December 2020, Merck and Eisai announced that the pivotal Phase 3 KEYNOTE-775/Study 309 trial evaluating the investigational use of *Keytruda* plus Lenvima met its dual primary endpoints of OS and PFS and its secondary efficacy endpoint of ORR in patients with advanced endometrial cancer following at least one prior platinum-based regimen. These positive results were observed in the mismatch repair proficient (pMMR) subgroup and the ITT study population, which includes both patients with endometrial carcinoma that is pMMR as well as patients whose disease is MSI-H/dMMR. Based on an analysis conducted by an independent DMC, *Keytruda* plus Lenvima demonstrated a statistically significant and clinically meaningful improvement in OS, PFS and ORR versus chemotherapy. Merck and Eisai will discuss these data with regulatory authorities worldwide, with the intent to submit marketing authorization applications based on these results, and plan to present these results at an upcoming medical meeting. KEYNOTE-775/Study 309 is the confirmatory trial for KEYNOTE-146/Study 111, which supported accelerated approval by the FDA in 2019 of the *Keytruda* plus Lenvima combination for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.

Merck and Eisai are continuing to study the *Keytruda* plus Lenvima combination through the LEAP (LEnvatinib And Pembrolizumab) clinical program across 19 trials in 13 different tumor types (endometrial carcinoma, HCC, melanoma, NSCLC, RCC, squamous cell carcinoma of the head and neck, urothelial cancer, biliary tract cancer, colorectal cancer, gastric cancer, glioblastoma, ovarian cancer, and TNBC).

MK-6482, belzutifan, is an investigational hypoxia-inducible factor-2α (HIF-2α) inhibitor being evaluated for the treatment of patients with von Hippel-Lindau (VHL) disease-associated RCC with nonmetastatic RCC tumors less than three centimeters in size, unless immediate surgery is required. In July 2020, the FDA granted Breakthrough Therapy designation to belzutifan and has also granted orphan drug designation to belzutifan for VHL disease. These designations are based on data from a Phase 2 trial evaluating belzutifan in patients with VHL-associated ccRCC, which were presented at the 2020 ASCO Annual Meeting. Additionally, Phase 2 data showing anti-tumor responses in VHL disease patients with ccRCC and other tumors were presented at the ESMO Virtual Congress 2020.

In February 2021, Merck and Eisai began a Phase 3 trial examining Lenvima in combination with belzutifan in previously treated patients with metastatic RCC.

MK-7119, Tukysa, is a small molecule tyrosine kinase inhibitor, for the treatment of HER2-positive cancers. In September 2020, Seagen granted Merck an exclusive license and entered into a co-development agreement with Merck to accelerate the global reach of Tukysa. Merck and Seagen also announced a collaboration to globally develop and commercialize Seagen's ladiratuzumab vedotin (MK-6440), an investigational antibody-drug conjugate targeting LIV-1, which is currently in Phase 2 clinical trials for breast cancer and other solid tumors. The collaboration will pursue a broad joint development program evaluating ladiratuzumab vedotin as monotherapy and in combination with *Keytruda* in TNBC, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors.

MK-7339, Lynparza, is an oral PARP inhibitor currently approved for certain types of advanced ovarian, breast, pancreatic and prostate cancers being co-developed for multiple cancer types as part of a collaboration with AstraZeneca.

MK-7264, gefapixant, is an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory or unexplained chronic cough. In September 2020, Merck announced the results from two ongoing pivotal Phase 3 trials (COUGH-1 and COUGH-2) evaluating the efficacy and safety of gefapixant. In these studies, adult patients treated with gefapixant 45 mg twice daily demonstrated a statistically significant reduction in 24-hour cough frequency versus placebo at 12 weeks (COUGH-1) and 24 weeks (COUGH-2). The gefapixant 15 mg twice daily treatment arms did not meet the primary efficacy endpoint in either Phase 3 study. These results were presented at the Virtual European Respiratory Society International Congress 2020. Merck plans to share data from COUGH-1 and COUGH-2 with regulatory authorities worldwide.

MK-7110 (also known as CD24Fc) is an investigational treatment for patients hospitalized with COVID-19. Merck obtained MK-7110 through the acquisition of OncoImmune. In September 2020, OncoImmune reported topline findings from an interim efficacy analysis of a Phase 3 study evaluating MK-7110. An interim analysis of data from 203 participants (75% of the planned enrollment) indicated that selected hospitalized patients with COVID-19 treated with a single dose of MK-7110 showed a 60% higher probability of improvement in clinical status compared to placebo, as defined by the protocol. The risk of death or respiratory failure was reduced by more than 50%. Full results from this Phase 3 study, which were consistent with the topline results, were received in February 2021 and will be submitted for publication in the future. MK-7110 is also being studied in a Phase 3 trial for the treatment of graft versus host disease.

Molnupiravir (also known as MK-4482) is an orally available antiviral candidate for the treatment of COVID-19 being developed in collaboration with Ridgeback Biotherapeutics LP. It is currently being evaluated in

Phase 2/3 clinical trials in both the hospital and outpatient settings. The primary completion date for the Phase 2/3 studies is June 2021. The Company anticipates interim efficacy data in the first quarter of 2021.

MK-8591A is a combination of islatravir, the company's investigational oral nucleoside reverse transcriptase translocation inhibitor (NRTTI), and doravirine (*Pifeltro*) being evaluated for the treatment of HIV-1 infection. In October 2020, Merck announced Week 96 data from the Phase 2b trial (NCT03272347) evaluating the efficacy and safety of MK-8591A in treatment-naïve adults with HIV-1 infection. Week 96 findings demonstrated that the combination of islatravir and doravirine maintained virologic suppression similar to *Delstrigo* (doravirine/lamivudine/tenofovir disoproxil fumarate), and the findings were consistent with Week 48 results. Additional Week 96 data from the study show low rates of participants meeting the definition of protocol-defined virologic failure in both the islatravir plus doravirine and the *Delstrigo* treatment arms, and no participants in either arm met the criteria for resistance testing. These data were presented at the virtual 2020 International Congress on Drug Therapy in HIV Infection (HIV Glasgow).

In November 2020, Merck announced a collaboration with the Bill & Melinda Gates Foundation (the foundation) where the foundation is committing to provide funding to support a pivotal Phase 3 study investigating a once-monthly oral pre-exposure prophylaxis (PrEP) option in women and adolescent girls at high risk for acquiring HIV-1 infection in sub-Saharan Africa. The study, IMPOWER 22, will evaluate the efficacy and safety of once-monthly islatravir and is anticipated to begin in early 2021. Merck will be funding the IMPOWER 22 clinical trial in the United States. Merck also plans to conduct additional studies in HIV prevention with islatravir in once-monthly oral PrEP. These studies will include IMPOWER 24, a global Phase 3 clinical trial to evaluate islatravir as a once-monthly oral agent for PrEP at sites across the world and among other key populations impacted by the epidemic, including men who have sex with men and transgender women.

In January 2021, the FDA accepted for standard review a supplemental NDA for Steglatro (ertugliflozin) to incorporate the results of the Phase 3 VERTIS cardiovascular (CV) outcomes trial in the product labeling. The VERTIS CV trial evaluated Steglatro, an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor, versus placebo, added to background standard of care treatment, in patients with type 2 diabetes and atherosclerotic CV disease. The study met the primary endpoint of non-inferiority on major adverse CV events (MACE), which is a composite of CV death, nonfatal myocardial infarction or nonfatal stroke, compared to placebo. The key secondary endpoints of superiority for Steglatro versus placebo for time to the first occurrence of the composite of CV death or hospitalization for heart failure, time to CV death alone and time to the first occurrence of the composite of renal death, dialysis/transplant or doubling of serum creatinine from baseline were not met. While not a pre-specified hypothesis for statistical testing, a reduction in hospitalization for heart failure was observed with Steglatro. A supplemental application was also submitted to the EMA and is currently under review.

In January 2021, the Company announced the discontinuation of the clinical development programs for its COVID-19 vaccine candidates, V590 and V591, following Merck's review of findings from Phase 1 clinical studies for the vaccines. In these studies, both V590 and V591 were generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/COVID-19 vaccines.

The chart below reflects the Company's research pipeline as of February 22, 2021. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to cancer) and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2	Phase 3 (Phase 3 entry date)	Under Review
Antiviral COVID-19 MK-4482 (molnupiravir)[1] **Cancer** MK-1026 Hematological Malignancies MK-1308 (quavonlimab)[2] Melanoma Non-Small-Cell Lung Solid Tumors MK-1454[2] Head and Neck MK-2140 Advanced Solid Tumors MK-3475 *Keytruda* Advanced Solid Tumors MK-4280[2] Hematological Malignancies Non-Small-Cell Lung MK-4830 Non-Small-Cell Lung MK-5890[2] Non-Small-Cell Lung MK-6440 (ladiratuzumab vedotin)[1][3] Advanced Solid Tumors Breast MK-7119 Tukysa[1] Advanced Solid Tumors Colorectal Gastric MK-7339 Lynparza[1][3] Advanced Solid Tumors MK-7684 (vibostolimab)[2] Melanoma Non-Small-Cell Lung MK-7902 Lenvima[1][2] Advanced Solid Tumors Biliary Tract Colorectal Glioblastoma V937 Breast Cutaneous Squamous Cell Head and Neck Melanoma Solid Tumors **Chikungunya virus** V184 **Cytomegalovirus** V160 **HIV-1 Prevention** MK-8591 (islatravir) **Nonalcoholic Steatohepatitis NASH** MK-3655 **Overgrowth Syndrome** MK-7075 (miransertib) **Pneumococcal Vaccine Adult** V116 **Respiratory Syncytial Virus** MK-1654 **Schizophrenia** MK-8189	**Cancer** MK-3475 *Keytruda* Biliary Tract (September 2019) Cervical (October 2018) (EU) Cutaneous Squamous Cell (August 2019) (EU) Endometrial (August 2019) (EU) Gastric (May 2015) (EU) Hepatocellular (May 2016) (EU) Mesothelioma (May 2018) Ovarian (December 2018) Prostate (May 2019) Small-Cell Lung (May 2017) (EU) MK-6482 (belzutifan) Renal Cell (February 2020) MK-7119 Tukysa[1] Breast (October 2019) MK-7339 Lynparza[1][2] Colorectal[1] (August 2020) Non-Small-Cell Lung[2] (June 2019) Small-Cell Lung[2] (December 2020) MK-7902 Lenvima[1][2] Bladder (May 2019) Endometrial (June 2018) (EU) Gastric (December 2020) Head and Neck (February 2020) Melanoma (March 2019) Non-Small-Cell Lung (March 2019) **Cough** MK-7264 (gefapixant) (March 2018) **COVID-19** MK-7110 (December 2020) **HIV-1 Infection** MK-8591A (doravirine/islatravir) (February 2020)	**New Molecular Entities/Vaccines** **Bacterial Infection** MK-7655A (relebactam+imipenem/cilastatin) (JPN) **Heart Failure** MK-1242 (vericiguat)[1] (EU) (JPN) **Pediatric Neurofibromatosis Type 1** MK-5618 (selumetinib)[1] (EU) **Pneumococcal Infection Adult** V-114 (U.S.) (EU) **Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • Metastatic Triple-Negative Breast Cancer (KEYNOTE-355) (EU) (JPN) • Early-Stage Triple-Negative Breast Cancer (KEYNOTE-522) (U.S.) • Refractory Classical Hodgkin Lymphoma (KEYNOTE-204) (EU) • Unresectable or Metastatic MSI-H or dMMR Colorectal Cancer (KEYNOTE-177) (JPN) • Cutaneous Squamous Cell Cancer (KEYNOTE-629) (U.S.) • Advanced Unresectable Metastatic Esophageal Cancer (KEYNOTE-590) (U.S.) (EU) (JPN) • First-Line Metastatic HER2+ Gastric Cancer (KEYNOTE-811) (U.S.) MK-7902 Lenvima[1] • First-Line Metastatic Hepatocellular Carcinoma (KEYNOTE-524) (U.S.)[2][4] • Thymic Carcinoma (NCCH1508/REMORA) (JPN)

Footnotes:

[1] Being developed in a collaboration.

[2] Being developed in combination with *Keytruda*.

[3] Being developed as monotherapy and in combination with *Keytruda*.

[4] In July 2020, the FDA issued a CRL for Merck's and Eisai's applications. Merck and Eisai intend to submit additional data when available to the FDA.

Human Capital

As of December 31, 2020, the Company had approximately 74,000 employees worldwide, with approximately 27,000 employed in the United States, including Puerto Rico, and approximately 26,000 third-party contractors globally. Approximately 73,000 of the Company's employees are full time-employees. Women and individuals with ethnically diverse backgrounds comprise approximately 50% and 31% of its workforce in the United States, respectively. Women comprise 46% of the members of the Board of Directors. Additionally, the Company's executive team, which includes individuals up to two structural levels below the Chief Executive

Officer, is made up of 34% women. Approximately 30% of the Company's employees are represented by various collective bargaining groups.

The Company recognizes that its employees are critical to meet the needs of its patients and customers and that its ability to excel depends on the integrity, skill, and diversity of its employees.

Talent Acquisition

The Company uses a comprehensive approach to ensure recruiting, retention and leadership development goals are systematically executed throughout the Company and that it hires talented leaders to achieve improved gender parity and representation across all dimensions of diversity. The Company provides training to its managers and external recruiting organizations on strategies to mitigate unconscious bias in the candidate selection and hiring process. In addition, the Company utilizes a comprehensive communications strategy, marketing outreach, social media and strategic alliance partnerships to reach a broad pool of talent in its critical business areas. In 2020, the Company hired approximately 10,000 employees across the globe through various channels including the Company's external career site, diversity partnerships, employee referrals, universities and other external sources.

Global Diversity and Inclusion

Diversity and inclusion are fundamental to the Company's success and core to future innovation. The Company fosters a globally diverse and inclusive workforce for its employees by creating an environment of belonging, engagement, equity, and empowerment. The Company is proactive and intentional about diversity hiring and development programs to advance talent. The Company creates competitive advantages by leveraging diversity and inclusion to accelerate business performance. This includes fostering global supplier diversity, integrating diversity and inclusion into the Company's commercialization strategies and leveraging employee insights to improve performance. In addition to these efforts, the Company has ten Employee Business Resource Groups, that provide opportunities for employees to take an active part in contributing to the Company's inclusive culture through their work in talent acquisition and development, business and customer insights and social and community outreach.

Gender and Ethnicity Performance Data[(1)]	**2020**	**2019**	**2018**
Women in the workforce	49%	49%	49%
Women in the workforce in the U.S.	50%	50%	NR
Women on the Board of Directors	46%	33%	23%
Women in executive roles[(2)]	34%	36%	32%
Women in management roles[(3)]	43%	43%	41%
Members of underrepresented ethnic groups on the Board of Directors	23%	17%	15%
Members of underrepresented ethnic groups in executive roles (U.S.)	22%	26%	21%
Members of underrepresented ethnic groups in the workforce (U.S.)	31%	29%	27%
Members of underrepresented ethnic groups in management roles (U.S.)	29%	27%	25%
New hires that were female	50%	50%	51%
New hires that were members of underrepresented ethnic groups (U.S.)	42%	33%	36%

NR: Not reported.

[(1)] As of 12/31.
[(2)] "Executive" is defined as the chief executive officer and two structural levels below.
[(3)] "Management role" is defined as all managers with direct reports other than executives defined in note 2.

Compensation and Benefits

The Company provides a valuable total rewards package reflecting its commitment to attract, retain and motivate its talent, and to supporting its employees and their families in every stage of life. The Company continuously monitors and adjusts its compensation and benefit programs to ensure they are competitive, contemporary, helpful and engaging, and that they support strategic imperatives such as diversity and inclusion, equity, flexibility, quality, security and affordability. For example, in 2020, the Company added a personal health care concierge service to assist U.S. employees participating in the Company medical plan with their health care needs. Aligned with its business and in support of its cancer care strategy, the Company also improved cancer screening benefits, added resources and provided immediate access to a leading cancer center of excellence for U.S. employees. Globally, the Company implemented a minimum standard of 12 weeks of paid parental leave, which inclusively applies to all parents. In the United States, the Company's benefits rank in the top quartile of Fortune 100 companies under the Aon Hewitt 2019 Benefits Index. The Company has been included in the Working Mother 100 Best Companies ranking for 34 consecutive years and was named a Working Mother Best Company for Dads in 2020.

Employee Wellbeing

The Company is committed to helping its employees and their families improve their own health and wellbeing. The Company's culture of wellbeing is referred to as "*Live it*", which includes programs to support preventive health, emotional and financial wellbeing, physical fitness and nutrition. It is designed to inspire all employees to pursue, enjoy, and share healthy lifestyles. *Live it* was launched in the United States in 2011 and today is available in every country in which the Company has employees. In addition, many of the Company's larger sites offer onsite health clinics that provide an array of services to help its employees stay or get well, including vaccinations, cancer and biometric screenings, travel medicine and advice, diagnosis and treatment of non-occupational illnesses or injuries, health counseling and referrals. The Company's overall employee wellbeing program was recognized for excellence in health and wellbeing by receiving the highest-level awards from the Business Group on Health (2019 and 2020), and the American Heart Association (2018-2020).

COVID-19 Response

The Company recognizes that it has a unique responsibility to help in response to the COVID-19 pandemic and is committed to supporting and protecting its employees and their families, ensuring that its supply of medicines and vaccines reaches its patients, contributing its scientific expertise to the development of antiviral approaches and supporting its health care providers and the communities in which they serve. The Company continues to provide employees with easy and regular access to information, including details regarding the Company's tracking process, guidance around hygiene measures and travel and best practices for working from home. Examples of pandemic support resources and programs available to the Company's employees include pay continuation for workers who have been sick or exposed, volunteer policy adjustment to enable employees with medical backgrounds to volunteer in SARS-CoV-2-related activities, resources to prioritize physical and mental wellness, adjustments to medical plans to cover 100% of a COVID-19-related diagnosis, testing and treatment, backup childcare and more.

Engaging Employees

The Company strives to foster employee engagement by promoting a safe, positive, diverse and inclusive work environment that provides numerous opportunities for two-way communication with employees. Some of the Company's key programs and initiatives include promoting global employee engagement surveys, ongoing pulse checks to the organization for interim feedback on specific topics, fostering professional networking and collaboration, identifying and providing opportunities for volunteering and establishing positive, cooperative business relations with designated employee representatives.

Talent Management and Development

As the Company pursues its goal of becoming the world's premier research-based biopharmaceutical company, it needs to continuously develop its diverse and talented people. The Company's current talent management system supports company-wide performance management, development, talent reviews and succession planning. Annual performance reviews help further the professional development of the Company's employees and ensure that the Company's workforce is aligned with the Company's objectives. The Company seeks to continuously build the skills and capabilities of its workforce to accelerate talent, improve performance and mitigate risk through relevant continuous learning experiences. This includes, but is not limited to, building leadership and management skills, as well as providing technical and functional training to all employees.

Environmental Matters

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were $11 million in 2020 and are estimated at $46 million in the aggregate for the years 2021 through 2025. These amounts do not consider potential recoveries from other parties. The Company has taken an active role in identifying and accruing for these costs and, in management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million at both December 31, 2020 and 2019. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation. management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately $65 million in the aggregate. Management also does not believe that these expenditures should have a material adverse effect on the Company's financial condition, results of operations, liquidity or capital resources for any year.

Merck believes that climate change could present risks to its business. Some of the potential impacts of climate change to its business include increased operating costs due to additional regulatory requirements, physical risks to the Company's facilities, water limitations and disruptions to its supply chain. These potential risks are integrated into the Company's business planning including investment in reducing energy usage, water use and greenhouse gas emissions. The Company does not believe these risks are material to its business at this time.

Geographic Area Information

The Company's operations outside the United States are conducted primarily through subsidiaries. Sales worldwide by subsidiaries outside the United States as a percentage of total Company sales were 56% in both 2020 and 2019 and were 57% in 2018.

The Company's worldwide business is subject to risks of currency fluctuations, governmental actions and other governmental proceedings abroad. The Company does not regard these risks as a deterrent to further expansion of its operations abroad. However, the Company closely reviews its methods of operations and adopts strategies responsive to changing economic and political conditions.

Merck has operations in countries located in Latin America, the Middle East, Africa, Eastern Europe and Asia Pacific. Business in these developing areas, while sometimes less stable, offers important opportunities for growth over time.

Available Information

The Company's Internet website address is *www.merck.com*. The Company will make available, free of charge at the "Investors" portion of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC). The address of that website is www.sec.gov. In addition, the Company will provide without charge a copy of its Annual Report on Form 10-K, including financial statements and schedules, upon the written request of any shareholder to the Office of the Secretary, Merck & Co., Inc., 2000 Galloping Hill Road, K1-4157, Kenilworth, NJ 07033 U.S.A.

The Company's corporate governance guidelines and the charters of the Board of Directors' four standing committees are available on the Company's website at *www.merck.com/company-overview/leadership* and all such information is available in print to any shareholder who requests it from the Company.

Item 1A. Risk Factors.

Summary Risk Factors

The Company is subject to a number of risks that if realized could materially adversely affect its business, results of operations, cash flow, financial condition or prospects. The following is a summary of the principal risk factors facing the Company:

- The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business could be materially adversely affected.
- As the Company's products lose market exclusivity, the Company generally experiences a significant and rapid loss of sales from those products.

- Key products generate a significant amount of the Company's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material adverse effect on the Company's results of operations and financial condition.
- The Company's research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; in consequence, the Company may not be able to replace sales of successful products that lose patent protection.
- The Company's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.
- The Company faces continued pricing pressure with respect to its products.
- The uncertainty in global economic conditions together with cost-reduction measures being taken by certain governments could negatively affect the Company's operating results.
- The Company faces intense competition from lower cost generic products.
- The Company faces intense competition from competitors' products.
- The global COVID-19 pandemic is having an adverse impact on the Company's business, operations and financial performance. The Company is unable to predict the full extent to which the COVID-19 pandemic or any future pandemic, epidemic or similar public health threat will adversely impact its business, operations, financial performance, results of operations, and financial condition.
- The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material adverse effect on the Company's results of operations and financial condition.
- Failure to attract and retain highly qualified personnel could affect the Company's ability to successfully develop and commercialize products.
- In the past, the Company has experienced difficulties and delays in manufacturing certain of its products, including vaccines.
- The Company may not be able to realize the expected benefits of its investments in emerging markets.
- The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates.
- Pharmaceutical products can develop unexpected safety or efficacy concerns.
- Reliance on third-party relationships and outsourcing arrangements could materially adversely affect the Company's business.
- Negative events in the animal health industry could have a material adverse effect on future results of operations and financial condition.
- Biologics and vaccines carry unique risks and uncertainties, which could have a material adverse effect on the Company's future results of operations and financial condition.
- The health care industry in the United States has been, and will continue to be, subject to increasing regulation and political action.
- The Company's products, including products in development, cannot be marketed unless the Company obtains and maintains regulatory approval.
- Developments following regulatory approval may adversely affect sales of the Company's products.
- The Company is subject to a variety of U.S. and international laws and regulations.

- The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations and financial condition.
- Product liability insurance for products may be limited, cost prohibitive or unavailable.
- The Company is increasingly dependent on sophisticated software applications, computing infrastructure and cloud service providers. In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. The Company could be a target of future cyber-attacks.
- Social media platforms present risks and challenges.
- The proposed Spin-Off of Organon may not be completed on the terms or timeline currently contemplated, if at all, and may not achieve the expected results.
- The costs to complete the proposed Spin-Off will be significant. In addition, the Company may be unable to achieve some or all of the strategic and financial benefits that it expects to achieve from the Spin-Off of Organon.
- Following the Spin-Off, the price of shares of the Company's common stock may fluctuate significantly.
- There could be significant income tax liability if the Spin-Off or certain related transactions are determined to be taxable for U.S. federal income tax purposes.

The above list is not exhaustive, and the Company faces additional challenges and risks. Investors should carefully consider all of the information set forth in this Form 10-K, including the following risk factors, before deciding to invest in any of the Company's securities.

Risk Factors

The risks below are not the only ones the Company faces. Additional risks not currently known to the Company or that the Company presently deems immaterial may also impair its business operations. The Company's business, financial condition, results of operations, cash flow or prospects could be materially adversely affected by any of these risks. This Form 10-K also contains forward-looking statements that involve risks and uncertainties. The Company's results could materially differ from those anticipated in these forward-looking statements as a result of certain factors, including the risks it faces described below and elsewhere. See "Cautionary Factors that May Affect Future Results" below.

Risks Related to the Company's Business

The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business could be materially adversely affected.

Patent protection is considered, in the aggregate, to be of material importance to the Company's marketing of human health and animal health products in the United States and in most major foreign markets. Patents covering products that it has introduced normally provide market exclusivity, which is important for the successful marketing and sale of its products. The Company seeks patents covering each of its products in each of the markets where it intends to sell the products and where meaningful patent protection is available.

Even if the Company succeeds in obtaining patents covering its products, third parties or government authorities may challenge or seek to invalidate or circumvent its patents and patent applications. It is important for the Company's business to defend successfully the patent rights that provide market exclusivity for its products. The Company is often involved in patent disputes relating to challenges to its patents or claims by third parties of infringement against the Company. The Company defends its patents both within and outside the United States, including by filing claims of infringement against other parties. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below. In particular, manufacturers of generic pharmaceutical products from time to time file abbreviated NDAs with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned or licensed by the Company. The Company normally responds by defending its patent, including by filing lawsuits alleging patent infringement. Patent litigation and other challenges to the Company's patents are costly and unpredictable and may deprive the Company of market exclusivity for a patented product or, in some cases, third-party patents may prevent the Company from marketing and selling a product in a particular geographic area.

Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies or in other circumstances, which could diminish or eliminate sales and profits from those regions and negatively affect the Company's results of operations. Further, court decisions relating to other companies' patents, potential legislation in both the United States and certain foreign markets relating to patents, as well as regulatory initiatives may result in a more general weakening of intellectual property protection.

If one or more important products lose patent protection in profitable markets, sales of those products are likely to decline significantly as a result of generic versions of those products becoming available. The Company's results of operations may be adversely affected by the lost sales unless and until the Company has launched commercially successful products that replace the lost sales. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively affect product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products.

A chart listing the patent protection for certain of the Company's marketed products, and U.S. patent protection for candidates in Phase 3 clinical development is set forth above in Item 1. "Business — Patents, Trademarks and Licenses."

As the Company's products lose market exclusivity, the Company generally experiences a significant and rapid loss of sales from those products.

The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. Loss of patent protection for one of the Company's products typically leads to a significant and rapid loss of sales for that product as lower priced generic versions of that drug become available. In the case of products that contribute significantly to the Company's sales, the loss of market exclusivity can have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects. For example, the patent that provided U.S. market exclusivity for *NuvaRing* expired in April 2018 and generic competition began in December 2019. The Company experienced a rapid and substantial decline in U.S. *NuvaRing* sales in 2020 as a result of this generic competition. In addition, *Januvia* and *Janumet* will lose market exclusivity in the United States in January 2023. *Januvia* will lose market exclusivity in the EU in September 2022. Finally, the SPC that provides market exclusivity for *Janumet* in the EU expires in April 2023. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after the loss of market exclusivity.

Key products generate a significant amount of the Company's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material adverse effect on the Company's results of operations and financial condition.

The Company's ability to generate profits and operating cash flow depends largely upon the continued profitability of the Company's key products, such as *Keytruda, Gardasil/Gardasil 9, Januvia, Janumet*, and *Bridion*. In particular, in 2020, the Company's oncology portfolio, led by *Keytruda*, represented the vast majority of the Company's revenue growth. As a result of the Company's dependence on key products, any event that adversely affects any of these products or the markets for any of these products could have a significant adverse impact on results of operations and cash flows. These events could include loss of patent protection, increased costs associated with manufacturing, generic or over-the-counter availability of the Company's product or a competitive product, the discovery of previously unknown side effects, results of post-approval trials, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason. Such events could have a material adverse effect on the sales of any such products.

The Company's research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; in consequence, the Company may not be able to replace sales of successful products that lose patent protection.

In order to remain competitive, the Company, like other major pharmaceutical companies, must continue to launch new products. Expected declines in sales of products after the loss of market exclusivity mean that the Company's future success is dependent on its pipeline of new products, including new products that it may develop through collaborations and joint ventures and products that it is able to obtain through license or acquisition. To accomplish this, the Company commits substantial effort, funds and other resources to research and development, both through its own dedicated resources and through various collaborations with third parties. There is a high rate of failure inherent in the research and development process for new drugs and vaccines. As a result, there is a high risk that funds invested by the Company in research programs will not generate financial returns. This risk profile is compounded by the fact that this research has a long investment cycle. To bring a pharmaceutical compound from the discovery phase to market may take a decade or more and failure can occur at any point in the process, including later in the process after significant funds have been invested.

For a description of the research and development process, see Item 1. "Business — Research and Development" above. Each phase of testing is highly regulated and during each phase there is a substantial risk that the Company will encounter serious obstacles or will not achieve its goals. Therefore, the Company may abandon a product in which it has invested substantial amounts of time and resources. Some of the risks encountered in the research and development process include the following: pre-clinical testing of a new compound may yield disappointing results; competing products from other manufacturers may reach the market first; clinical trials of a new drug may not be successful; a new drug may not be effective or may have harmful side effects; a new drug may not be approved by the regulators for its intended use; it may not be possible to obtain a patent for a new drug; payers may refuse to cover or reimburse the new product; or sales of a new product may be disappointing.

The Company cannot state with certainty when or whether any of its products now under development will be approved or launched; whether it will be able to develop, license or otherwise acquire compounds, product candidates or products; or whether any products, once launched, will be commercially successful. The Company must maintain a continuous flow of successful new products and successful new indications for existing products sufficient both to cover its substantial research and development costs and to replace sales that are lost as profitable products lose market exclusivity or are displaced by competing products or therapies. Failure to do so in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial condition and prospects.

The Company's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.

Products that appear promising in development may fail to reach the market or fail to succeed for numerous reasons, including the following:

- findings of ineffectiveness, superior safety or efficacy of competing products, or harmful side effects in clinical or pre-clinical testing;
- failure to receive the necessary regulatory approvals, including delays in the approval of new products and new indications, or the anticipated labeling, and uncertainties about the time required to obtain regulatory approvals and the benefit/risk standards applied by regulatory agencies in determining whether to grant approvals;
- failure in certain markets to obtain reimbursement commensurate with the level of innovation and clinical benefit presented by the product;
- lack of economic feasibility due to manufacturing costs or other factors; and
- preclusion from commercialization by the proprietary rights of others.

In the future, if certain pipeline programs are cancelled or if the Company believes that their commercial prospects have been reduced, the Company may recognize material non-cash impairment charges for those programs that were measured at fair value and capitalized in connection with acquisitions or certain collaborations.

Failure to successfully develop and market new products in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial condition and prospects.

The Company faces continued pricing pressure with respect to its products.

The Company faces continued pricing pressure globally and, particularly in mature markets, from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. In the United States, these include (i) practices of managed care groups and institutional and governmental purchasers, (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the ACA, and (iii) state activities aimed at increasing price transparency, including new laws as noted above in Item 1. "Competition and the Health Care Environment." Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. In addition, in the United States, larger customers have received higher rebates on drugs in certain highly competitive categories. The Company must also compete to be placed on formularies of managed care organizations. Exclusion of a product from a formulary can lead to reduced usage in the managed care organization.

In order to provide information about the Company's pricing practices, the Company annually posts on its website its Pricing Transparency Report for the United States. The report provides the Company's average annual list price and net price increases across the Company's U.S. portfolio dating back to 2010. In 2020, the Company's gross U.S. sales were reduced by 45.5% as a result of rebates, discounts and returns.

Outside the United States, numerous major markets, including the EU, Japan and China have pervasive government involvement in funding health care and, in that regard, fix the pricing and reimbursement of pharmaceutical and vaccine products. Consequently, in those markets, the Company is subject to government decision making and budgetary actions with respect to its products. In Japan, the pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products and certain vaccines. Furthermore, the government can order re-pricing for specific products if it determines that use of such product will exceed certain thresholds defined under applicable re-pricing rules. The next government-mandated price reduction will occur in April 2021 and is expected to impact many Company products.

The Company expects pricing pressures to continue in the future.

The uncertainty in global economic conditions together with cost-reduction measures being taken by certain governments could negatively affect the Company's operating results.

Uncertainty in global economic and geopolitical conditions may result in a slowdown to the global economy that could affect the Company's business by reducing the prices that drug wholesalers and retailers, hospitals, government agencies and managed health care providers may be able or willing to pay for the Company's products or by reducing the demand for the Company's products, which could in turn negatively impact the Company's sales and result in a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

As discussed above in "Competition and the Health Care Environment," global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2020 was negatively affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions, and additional actions in the future, will continue to negatively affect revenue performance.

If credit and economic conditions worsen, the resulting economic and currency impacts in the affected markets and globally could have a material adverse effect on the Company's results.

The Company faces intense competition from lower cost generic products.

In general, the Company faces increasing competition from lower-cost generic products. The patent rights that protect its products are of varying strengths and durations. In addition, in some countries, patent protection is significantly weaker than in the United States or in the EU. In the United States and the EU, political pressure to reduce spending on prescription drugs has led to legislation and other measures that encourage the use of generic and biosimilar products. Although it is the Company's policy to actively protect its patent rights, generic challenges to the Company's products can arise at any time, and the Company's patents may not prevent the emergence of generic competition for its products.

Loss of patent protection for a product typically is followed promptly by generic substitutes, reducing the Company's sales of that product. Availability of generic substitutes for the Company's drugs may adversely affect its results of operations and cash flow. In addition, proposals emerge from time to time in the United States and other countries for legislation to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could worsen this substantial negative effect on the Company's sales and, potentially, its business, cash flow, results of operations, financial condition and prospects.

The Company faces intense competition from competitors' products.

The Company's products face intense competition from competitors' products. This competition may increase as new products enter the market. In such an event, the competitors' products may be safer or more effective, more convenient to use, have better insurance coverage or reimbursement levels or be more effectively marketed and sold than the Company's products. Alternatively, in the case of generic competition, including the generic availability of competitors' branded products, they may be equally safe and effective products that are sold at a substantially lower price than the Company's products. As a result, if the Company fails to maintain its competitive position, this could have a material adverse effect on its business, cash flow, results of operations, financial condition and prospects. In addition, if products that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively impact product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products.

The global COVID-19 pandemic is having an adverse impact on the Company's business, operations and financial performance. The Company is unable to predict the full extent to which the COVID-19 pandemic or any future pandemic, epidemic or similar public health threat will adversely impact its business, operations, financial performance, results of operations, and financial condition.

The Company's business and financial results were negatively impacted by the outbreak of COVID-19 in 2020. The continued duration and severity of the COVID-19 pandemic is uncertain, rapidly changing and difficult to predict. The degree to which COVID-19 impacts the Company's results in 2021 will depend on future developments, beyond the Company's knowledge or control, including, but not limited to, the duration of the outbreak, its severity, the success of actions taken to contain or prevent the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume.

In 2020, the COVID-19 pandemic impacted the Company's business in numerous ways. As expected, within the Company's human health business, revenue was negatively impacted by reduced access to health care providers given social distancing measures, which negatively affected vaccine and oncology sales in particular. The estimated overall negative impact of the COVID-19 pandemic to Merck's revenue for the full year 2020 was approximately $2.5 billion, largely attributable to the Pharmaceutical segment, with approximately $50 million attributable to the Animal Health segment.

Roughly two-thirds of Merck's Pharmaceutical segment revenue is comprised of physician-administered products, which, despite strong underlying demand, have been affected by social distancing measures, fewer well visits and delays in elective surgeries due to the COVID-19 pandemic. These impacts, as well as the prioritization of COVID-19 patients at health care providers, have resulted in reduced administration of many of the Company's human health products, in particular for its vaccines, including *Gardasil* 9, as well as for *Keytruda* and *Implanon/*

Nexplanon. In addition, declines in elective surgeries negatively affected the demand for *Bridion*. However, sales of *Pneumovax* 23 have increased due to heightened awareness of pneumococcal vaccination.

Merck believes that global health systems and patients have largely adapted to the impacts of COVID-19, but the Company's assumption is that ongoing residual negative impacts will persist, particularly during the first half of 2021 and most notably with respect to vaccine sales, with the impact expected to be more acute in the United States. For the full year of 2021, Merck assumes an unfavorable impact to revenue of approximately 2% due to the COVID-19 pandemic, all of which relates to Pharmaceutical segment sales. In addition, for the full year of 2021, with respect to the COVID-19 pandemic, Merck expects a net negative impact to operating expenses, as spending on the development of its COVID-19 antiviral programs is expected to exceed the favorable impact of lower spending in other areas due to the COVID-19 pandemic. Despite the Company's efforts to manage these impacts, their ultimate impact will also depend on factors beyond the Company's knowledge or control, including the duration of the COVID-19 virus as well as governmental and third-party actions taken to contain or prevent its spread, treat the virus and mitigate its public health and economic effects. In addition, any future pandemic, epidemic or similar public health threat could present similar risks to the Company's business, cash flow, results of operations, financial condition and prospects.

The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material adverse effect on the Company's results of operations and financial condition.

The extent of the Company's operations outside the United States is significant. Risks inherent in conducting a global business include:

- changes in medical reimbursement policies and programs and pricing restrictions in key markets;
- multiple regulatory requirements that could restrict the Company's ability to manufacture and sell its products in key markets;
- trade protection measures and import or export licensing requirements, including the imposition of trade sanctions or similar restrictions by the United States or other governments;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- possible nationalization and expropriation.

In addition, there may be changes to the Company's business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease.

Failure to attract and retain highly qualified personnel could affect the Company's ability to successfully develop and commercialize products.

The Company's success is largely dependent on its continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical research and development, governmental regulation and commercialization. Competition for qualified personnel in the pharmaceutical industry is intense. The Company cannot be sure that it will be able to attract and retain quality personnel or that the costs of doing so will not materially increase.

In the past, the Company has experienced difficulties and delays in manufacturing certain of its products, including vaccines.

Merck has, in the past, experienced difficulties in manufacturing certain of its products, including vaccines. For example, in 2020 the Company issued a product recall for *Zerbaxa* following the identification of product sterility issues. The Company may, in the future, experience other difficulties and delays in manufacturing its products, such as (i) failure of the Company or any of its vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable regulations and quality assurance guidelines that could lead to manufacturing shutdowns, product shortages and delays in product manufacturing; (ii) delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for the Company's products; and (iii) other manufacturing or distribution problems including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, or physical limitations that could impact continuous supply. In addition, the Company could experience difficulties or delays in manufacturing its products caused by natural disasters, such as hurricanes. Manufacturing difficulties can result in product shortages, leading to lost sales and reputational harm to the Company.

The Company may not be able to realize the expected benefits of its investments in emerging markets.

The Company has been taking steps to increase its sales in emerging markets. However, there is no guarantee that the Company's efforts to expand sales in these markets will succeed. Some countries within emerging markets may be especially vulnerable to periods of global financial instability or may have very limited resources to spend on health care. In order for the Company to successfully implement its emerging markets strategy, it must attract and retain qualified personnel. The Company may also be required to increase its reliance on third-party agents within less developed markets. In addition, many of these countries have currencies that fluctuate substantially and, if such currencies devalue and the Company cannot offset the devaluations, the Company's financial performance within such countries could be adversely affected.

The Company's business in China has grown rapidly in the past few years, and the importance of China to the Company's overall pharmaceutical and vaccines business outside the United States has increased accordingly. Continued growth of the Company's business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products and vaccines, sustained access for the Company's currently marketed products, and the absence of trade impediments or adverse pricing controls. As noted above in "Competition and the Health Care Environment," pricing pressure in China has increased as the Chinese government has been taking steps to reduce costs, including implementing health care reform that has led to the acceleration of generic substitution, where available. In 2017, the Chinese government updated the NRDL for the first time in eight years. While the mechanism for drugs being added to the list evolves, inclusion may require a price negotiation which could impact the outlook in the market for selected brands. In 2020, drugs were added to the NRDL through double-digit price reductions. While pricing pressure has always existed in China, health care reform has increased this pressure in part due to the acceleration of generic substitution through the government's VBP program. In 2019, the government implemented the VBP program through a tendering process for mature products which have generic substitutes with a Generic Quality Consistency Evaluation approval. Mature products that have entered into the first three rounds of VBP had, on average, a price reduction of 50%. The Company expects VBP to be a semi-annual process that will have a significant impact on mature products moving forward. In addition, the Company anticipates that the reported inquiries made by various governmental authorities involving multinational pharmaceutical companies in China may continue.

For all these reasons, sales within emerging markets carry significant risks. However, at the same time macro-economic growth of selected emerging markets is expected to outpace Europe and even the United States, leading to significant increased headcount spending in those countries and access to innovative medicines for patients. A failure to maintain the Company's presence in emerging markets could therefore have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates.

The Company operates in multiple jurisdictions and virtually all sales are denominated in currencies of the local jurisdiction. Additionally, the Company has entered and will enter into business development transactions, borrowings or other financial transactions that may give rise to currency and interest rate exposure.

Since the Company cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange rates, interest rates and inflation could negatively affect the Company's business, cash flow, results of operations, financial condition and prospects.

In order to mitigate against the adverse impact of these market fluctuations, the Company will from time to time enter into hedging agreements. While hedging agreements, such as currency options and forwards and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful.

Certain of the Company's interest rate derivatives and investments are based on the London Interbank Offered Rate (LIBOR), and a portion of Merck's indebtedness bears interest at variable interest rates, primarily based on LIBOR. LIBOR is the subject of recent national, international and other regulatory guidance and proposals for reform, which will cause LIBOR to cease to exist entirely in the future. While the Company expects that reasonable alternatives to LIBOR will be implemented prior to its termination, the Company cannot predict the consequences and timing of these developments, which could include an increase in interest expense and may also require the amendment of contracts that reference LIBOR.

Pharmaceutical products can develop unexpected safety or efficacy concerns.

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and/or other claims, including potential civil or criminal governmental actions.

Reliance on third-party relationships and outsourcing arrangements could materially adversely affect the Company's business.

The Company depends on third parties, including suppliers, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for key aspects of its business including development, manufacture and commercialization of its products and support for its information technology (IT) systems. Failure of these third parties to meet their contractual, regulatory and other obligations to the Company or the development of factors that materially disrupt the relationships between the Company and these third parties could have a material adverse effect on the Company's business.

Negative events in the animal health industry could have a material adverse effect on future results of operations and financial condition.

Future sales of key animal health products could be adversely affected by a number of risk factors including certain risks that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as African Swine Fever, could lead to their widespread death and precautionary destruction as well as the reduced consumption and demand for animals, which could adversely affect the Company's results of operations. Also, the outbreak of any highly contagious diseases near the Company's main production sites could require the Company to immediately halt the manufacture of its animal health products at such sites or force the Company to incur substantial expenses in procuring raw materials or products elsewhere. Other risks specific to animal health include epidemics and pandemics, government procurement and pricing practices, weather and global agribusiness economic events. As the Animal Health segment of the Company's business becomes more significant, the impact of any such events on future results of operations would also become more significant.

Biologics and vaccines carry unique risks and uncertainties, which could have a material adverse effect on the Company's future results of operations and financial condition.

The successful development, testing, manufacturing and commercialization of biologics and vaccines, particularly human and animal health vaccines, is a long, complex, expensive and uncertain process. There are unique risks and uncertainties related to biologics and vaccines, including:

- There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States and the EU, could result in restricted access to, or transport or use of, such materials. If the Company loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research activities as planned and may incur additional development costs.

- The development, manufacturing and marketing of biologics and vaccines are subject to regulation by the FDA, the EMA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both pre-clinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot.
- Manufacturing biologics and vaccines, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic and vaccine must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, the Company may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.
- Biologics and vaccines are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.
- The use of biologically derived ingredients can lead to variability in the manufacturing process and could lead to allegations of harm, including infections or allergic reactions, which allegations would be reviewed through a standard investigation process that could lead to closure of product facilities due to possible contamination. Any of these events could result in substantial costs.

Risks Relating to Government Regulation and Legal Proceedings

The health care industry in the United States has been, and will continue to be, subject to increasing regulation and political action.

As discussed above "Competition and the Health Care Environment," the Company believes that the health care industry will continue to be subject to increasing regulation as well as political and legal action, as future proposals to reform the health care system are considered by the Executive branch, Congress and state legislatures.

In 2010, the United States enacted major health care reform legislation in the form of the ACA. Various insurance market reforms have advanced and state and federal insurance exchanges were launched in 2014. The ACA increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program.

The ACA also requires pharmaceutical manufacturers to pay 70% of the cost of medicine, including biosimilar products, when Medicare Part D beneficiaries are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). In 2020, the Company's revenue was reduced by approximately $700 million due to this requirement. Also, pharmaceutical manufacturers are required to pay an annual non-tax deductible health care reform fee. In 2020, the Company recorded $85 million of costs for this annual fee.

In February 2016, the Centers for Medicare & Medicaid Services (CMS) issued the Medicaid rebate final rule that implemented provisions of the ACA effective April 1, 2016. The rule provides comprehensive guidance on the calculation of Average Manufacturer Price and Best Price; two metrics utilized to determine the rebates drug manufacturers are required to pay to state Medicaid programs. More recently, although CMS previously declined to define what constitutes a product "line extension" (beyond the statutory definition), CMS issued a new rule on December 21, 2020 that will significantly expand the definition of the term "line extension" as of January 1, 2022 to include a broad range of products, including products reflecting new strengths, dosage forms, release mechanisms, and routes of administration. This expanded definition will increase the number of drugs subject to a higher Medicaid rebate. Effective January 1, 2023, this final rule also changes the way that manufacturers must calculate Best Price, in relation to certain patient support programs, including coupons, which also may result in an increase in the Company's Medicaid rebates. The impact of these and other provisions in this final rule could adversely impact the Company's business, cash flow, results of operations, financial condition and prospects.

As discussed above in "Competition and the Health Care Environment," in November 2020, the Department of Health and Human Services Office of Inspector General (OIG) issued a Final Rule that would, effective January 1. 2023, eliminate the Anti-Kickback Statute safe harbor for rebates paid to Medicare Part D plans or to PBMs on behalf of such plans. While the Company cannot anticipate the effects of this change to the way it currently contracts, this new framework could significantly alter the way it does business with Part D Plan Sponsors and PBMs on behalf of such plans.

On November 20, 2020, CMS also issued the MFN Rule, which was intended to be effective January 1, 2021, to institute a new pricing system for certain prescription drugs and biologic products covered by Medicare Part B in which Medicare would reimburse no more than the "most favored nation price," meaning the lowest price after adjusting for volume and differences in gross domestic product, for the top fifty Part B reimbursed products, which includes *Keytruda*, sold in 22 member countries of the OECD, rather than use the current Average Sales Price ("ASP")-based payment framework for certain physician-administered drugs. Implementation of the MFN Rule could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

The FDA also recently issued rulemaking allowing the commercial importation of certain prescription drugs from Canada through FDA-authorized, time-limited programs sponsored by states or Native American tribes recognized under the rule, and, in certain future circumstances, pharmacists and wholesalers. The FDA also recently released a final guidance for industry detailing procedures for drug manufacturers to import FDA-approved prescription drug, biological, and combination products that were manufactured abroad and authorized and intended for sale in a foreign country. These changes, if they become effective, could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

Several organizations, including two trade groups of which Merck is a member, have filed suit challenging the MFN Rule. Those lawsuits remain pending with a preliminary injunction having been entered in one of the cases. A trade organization in which Merck is a member brought suit, which is pending, in federal district court challenging the commercial importation rule.

The Company cannot predict the likelihood of these regulations becoming effective or what additional future changes in the health care industry in general, or the pharmaceutical industry in particular. will occur, however, these changes could have a material adverse effect on the Company's business, cash flow, results of operations, financial condition and prospects.

The Company's products, including products in development, cannot be marketed unless the Company obtains and maintains regulatory approval.

The Company's activities, including research, pre-clinical testing, clinical trials and the manufacturing and marketing of its products, are subject to extensive regulation by numerous federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory authorities, including in the EU, Japan and China. In the United States, the FDA administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals. In many cases, the FDA requirements have increased the amount of time and money necessary to develop new products and bring them to market in the United States. Regulation outside the United States also is primarily focused on drug safety and effectiveness and, in many cases, reduction in the cost of drugs. The FDA and foreign regulatory authorities. including in Japan and China, have substantial discretion to require additional testing. to delay or withhold registration and marketing approval and to otherwise preclude distribution and sale of a product.

Even if the Company is successful in developing new products, it will not be able to market any of those products unless and until it has obtained all required regulatory approvals in each jurisdiction where it proposes to market the new products. Once obtained, the Company must maintain approval as long as it plans to market its new products in each jurisdiction where approval is required. The Company's failure to obtain approval. significant delays in the approval process, or its failure to maintain approval in any jurisdiction will prevent it from selling the products in that jurisdiction. The Company would not be able to realize revenues for those new products in any jurisdiction where it does not have approval.

Developments following regulatory approval may adversely affect sales of the Company's products.

Even after a product reaches the market, certain developments following regulatory approval may decrease demand for the Company's products, including the following:

- results in post-approval Phase 4 trials or other studies;
- the re-review of products that are already marketed;
- the recall or loss of marketing approval of products that are already marketed;
- changing government standards or public expectations regarding safety, efficacy, quality or labeling changes; and
- scrutiny of advertising and promotion.

In the past, clinical trials and post-marketing surveillance of certain marketed drugs of the Company and of competitors within the industry have raised concerns that have led to recalls, withdrawals or adverse labeling of marketed products. Clinical trials and post-marketing surveillance of certain marketed drugs also have raised concerns among some prescribers and patients relating to the safety or efficacy of pharmaceutical products in general that have negatively affected the sales of such products. In addition, increased scrutiny of the outcomes of clinical trials has led to increased volatility in market reaction. Further, these matters often attract litigation and, even where the basis for the litigation is groundless, considerable resources may be needed to respond.

In addition, following in the wake of product withdrawals and other significant safety issues, health authorities such as the FDA, the EMA, Japan's PMDA and China's NMPA have increased their focus on safety when assessing the benefit/risk balance of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products or indications.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of the Company's products, it could significantly reduce demand for the product or require the Company to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. Further, in the current environment in which all pharmaceutical companies operate, the Company is at risk for product liability and consumer protection claims and civil and criminal governmental actions related to its products, research and/or marketing activities. In addition, dissemination of promotional materials through evolving digital channels serves to increase visibility and scrutiny in the marketplace.

The Company is subject to a variety of U.S. and international laws and regulations.

The Company is currently subject to a number of government laws and regulations and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect the business, cash flow, results of operations, financial condition and prospects of the Company; these laws and regulations include (i) additional health care reform initiatives in the United States or in other countries, including additional mandatory discounts or fees; (ii) the U.S. Foreign Corrupt Practices Act or other anti-bribery and corruption laws; (iii) new laws, regulations and judicial or other governmental decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; (iv) changes in intellectual property laws; (v) changes in accounting standards; (vi) new and increasing data privacy regulations and enforcement, particularly in the EU and the United States; (vii) legislative mandates or preferences for local manufacturing of pharmaceutical or vaccine products; (viii) emerging and new global regulatory requirements for reporting payments and other value transfers to health care professionals; (ix) environmental regulations; and (x) the potential impact of importation restrictions, embargoes, trade sanctions and legislative and/or other regulatory changes.

The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations and financial condition.

The Company is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining the Company's tax liabilities, and the Company's tax returns are periodically examined by various tax authorities. The Company believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued. In addition, the Company may be negatively affected by changes in tax laws, or new tax laws, affecting, for example, tax rates, and/or revised tax law interpretations in domestic or foreign jurisdictions.

Product liability insurance for products may be limited, cost prohibitive or unavailable.

As a result of a number of factors, product liability insurance has become less available while the cost of such insurance has increased significantly. The Company is subject to a substantial number of product liability claims. See Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities" below for more information on the Company's current product liability litigation. With respect to product liability, the Company self-insures substantially all of its risk, as the availability of commercial insurance has become more restrictive. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities. The Company will continually assess the most efficient means to address its risk; however, there can be no guarantee that insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise.

Risks Related to Technology

The Company is increasingly dependent on sophisticated software applications and computing infrastructure. In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. The Company could be a target of future cyber-attacks.

The Company is increasingly dependent on sophisticated software applications, complex information technology systems, computing infrastructure, and cloud service providers (collectively, IT systems) to conduct critical operations. Certain of these systems are managed, hosted, provided or used by third parties to assist in conducting the Company's business. Disruption, degradation, or manipulation of these IT systems through intentional or accidental means by the Company's employees, third parties with authorized access or unauthorized third parties could adversely affect key business processes. Cyber-attacks against the Company's IT systems or third-party providers' IT systems, such as cloud-based systems, could result in exposure of confidential information, the modification of critical data, and/or the failure of critical operations. Misuse of any of these IT systems could result in the disclosure of sensitive personal information or the theft of trade secrets, intellectual property, or other confidential business information. The Company continues to leverage new and innovative technologies across the enterprise to improve the efficacy and efficiency of its business processes; the use of which can create new risks.

In 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations, and resulting losses.

The Company has implemented a variety of measures to further enhance and modernize its systems to guard against similar attacks in the future, and also is pursuing an enterprise-wide effort to enhance the Company's resiliency against future cyber-attacks, including incidents similar to the 2017 attack. The objective of these efforts is not only to protect against future cyber-attacks, but also to improve the speed of the Company's recovery from such attacks and enable continued business operations to the greatest extent possible during any recovery period.

Although the aggregate impact of cyber-attacks and network disruptions, including the 2017 cyber-attack, on the Company's operations and financial condition has not been material to date, the Company continues to be a target of events of this nature and expects them to continue. The Company monitors its data, information technology and personnel usage of Company IT systems to reduce these risks and continues to do so on an ongoing basis for any current or potential threats. There can be no assurance that the Company's efforts to protect its data and IT systems or the efforts of third-party providers to protect their IT systems will be successful in preventing disruptions to the Company's operations, including its manufacturing, research and sales operations. Such disruptions have in the past and could in the future result in loss of revenue, or the loss of critical or sensitive information from the Company's or the Company's third-party providers' databases or IT systems and have in the past and could in the future also result in financial, legal, business or reputational harm to the Company and substantial remediation costs.

Social media platforms present risks and challenges.

The inappropriate and/or unauthorized use of certain social media channels could cause brand damage or information leakage or could lead to legal implications, including from the improper collection and/or dissemination of personally identifiable information. In addition, negative or inaccurate posts or comments about the Company or its products on any social networking platforms could damage the Company's reputation, brand image and goodwill. Further, the disclosure of non-public Company-sensitive information by the Company's workforce or others through external media channels could lead to information loss. Although there is an internal Company Social Media Policy that guides employees on appropriate personal and professional use of social media about the Company, the processes in place may not completely secure and protect information. Identifying new points of entry as social media continues to expand also presents new challenges.

Risks Related to the Proposed Spin-Off of Organon

The proposed Spin-Off of Organon may not be completed on the terms or timeline currently contemplated, if at all, and may not achieve the expected results.

In February 2020, the Company announced its intention to Spin-Off products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company, which has been named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The transaction is expected to be completed late in the second quarter of 2021. Completion of the Spin-Off will be subject to a number of factors and conditions, and there can be no assurances that the Company will be able to complete the Spin-Off on the terms or on the timeline that was announced, if at all. Unanticipated developments could delay, prevent or otherwise adversely affect the proposed Spin-Off, including but not limited to disruptions in general or financial market conditions or potential problems or delays in obtaining various regulatory and tax approvals or clearances. In addition, consummation of the proposed Spin-Off will require final approval from the Company's Board of Directors.

The costs to complete the proposed Spin-Off will be significant. In addition, the Company may be unable to achieve some or all of the strategic and financial benefits that it expects to achieve from the Spin-Off of Organon.

The Company will incur significant expenses in connection with the Spin-Off. In addition, the Company may not be able to achieve the full strategic and financial benefits that are expected to result from the Spin-Off. The anticipated benefits of the Spin-Off are based on a number of assumptions, some of which may prove incorrect.

Following the Spin-Off, the price of shares of the Company's common stock may fluctuate significantly.

The Company cannot predict the effect of the Spin-Off on the trading price of shares of its common stock, and the market value of shares of its common stock may be less than, equal to or greater than the market value of shares of its common stock prior to the Spin-Off. In addition, the price of Merck's common stock may be more volatile around the time of the Spin-Off.

There could be significant income tax liability if the Spin-Off or certain related transactions are determined to be taxable for U.S. federal income tax purposes.

The Company expects that prior to completion of the Spin-Off it will receive an opinion from its U.S. tax counsel that concludes, among other things, that the Spin-Off of all of the outstanding Organon shares to Merck shareholders and certain related transactions will qualify as tax-free to Merck and its shareholders under Sections 355 and 368 of the U.S. Internal Revenue Code, except to the extent of any cash received in lieu of fractional shares of Organon common stock. Any such opinion is not binding on the Internal Revenue Service (IRS). Accordingly, while the Company believes the risk is low, the IRS may reach conclusions with respect to the Spin-Off that are different from the conclusions reached in the opinion. The opinion will rely on certain facts, assumptions, representations and undertakings from Merck and Organon regarding the past and future conduct of the companies' respective businesses and other matters, which, if incomplete, incorrect or not satisfied, could alter the conclusions of the party giving such opinion.

If the proposed Spin-Off ultimately is determined to be taxable, which the Company believes is unlikely, the Spin-Off could be treated as a taxable dividend to Merck's shareholders for U.S. federal income tax purposes, and Merck's shareholders could incur significant U.S. federal income tax liabilities. In addition, Merck would recognize a taxable gain to the extent that the fair market value of Organon common stock exceeds Merck's tax basis in such stock on the date of the Spin-Off.

Cautionary Factors that May Affect Future Results

(Cautionary Statements Under the Private Securities Litigation Reform Act of 1995)

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product approvals, product potential, development programs and include statements related to the expected impact of the COVID-19 pandemic. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially. The Company does not assume the obligation to update any forward-looking statement. The Company cautions you not to place undue reliance on these forward-looking statements. Although it is not possible to predict or identify all such factors, they may include the following:

- Competition from generic and/or biosimilar products as the Company's products lose patent protection.
- Increased "brand" competition in therapeutic areas important to the Company's long-term business performance.
- The difficulties and uncertainties inherent in new product development. The outcome of the lengthy and complex process of new product development is inherently uncertain. A drug candidate can fail at any stage of the process and one or more late-stage product candidates could fail to receive regulatory approval. New product candidates may appear promising in development but fail to reach the market because of efficacy or safety concerns, the inability to obtain necessary regulatory approvals, the difficulty or excessive cost to manufacture and/or the infringement of patents or intellectual property rights of others. Furthermore, the sales of new products may prove to be disappointing and fail to reach anticipated levels.
- Pricing pressures, both in the United States and abroad, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general.
- The impact of the global COVID-19 pandemic and any future pandemic, epidemic, or similar public health threat, on the Company's business, operations and financial performance.
- Changes in government laws and regulations, including laws governing intellectual property, and the enforcement thereof affecting the Company's business.

- Efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales.
- Significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage.
- Legal factors, including product liability claims, antitrust litigation and governmental investigations, including tax disputes, environmental concerns and patent disputes with branded and generic competitors, any of which could preclude commercialization of products or negatively affect the profitability of existing products.
- Cyber-attacks on the Company's or third-party providers' information technology systems, which could disrupt the Company's operations.
- Lost market opportunity resulting from delays and uncertainties in the approval process of the FDA and foreign regulatory authorities.
- Increased focus on privacy issues in countries around the world, including the United States and the EU. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws in a majority of states in the United States requiring security breach notification.
- Changes in tax laws including changes related to the taxation of foreign earnings.
- Changes in accounting pronouncements promulgated by standard-setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to the Company.
- Economic factors over which the Company has no control, including changes in inflation, interest rates and foreign currency exchange rates.
- The proposed Spin-Off might be delayed or the costs to complete the Spin-Off might be more significant than expected.

This list should not be considered an exhaustive statement of all potential risks and uncertainties. See "Risk Factors" above.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company's corporate headquarters is currently located in Kenilworth, New Jersey. The Company has previously announced that it intends to consolidate its New Jersey campuses into a single corporate headquarters location in Rahway, New Jersey by the end of 2023. The Company also maintains operational or divisional headquarters in Kenilworth, New Jersey; Madison, New Jersey and Upper Gwynedd, Pennsylvania. Principal U.S. research facilities are located in Rahway and Kenilworth, New Jersey; West Point, Pennsylvania; Boston, Massachusetts; South San Francisco, California; and Elkhorn, Nebraska (Animal Health). Principal research facilities outside the United States are located in the United Kingdom, Switzerland and China. Merck's manufacturing operations are currently headquartered in Whitehouse Station, New Jersey. The Company also has production facilities for human health products at nine locations in the United States and Puerto Rico. Outside the United States, through subsidiaries, the Company owns or has an interest in manufacturing plants or other properties in Japan, Singapore, South Africa, and other countries in Western Europe, Central and South America, and Asia. A number of properties will be transferred to Organon in the Spin-Off.

Capital expenditures were $4.7 billion in 2020, $3.5 billion in 2019 and $2.6 billion in 2018. In the United States, these amounted to $2.7 billion in 2020, $1.9 billion in 2019 and $1.5 billion in 2018. Abroad, such expenditures amounted to $2.0 billion in 2020, $1.6 billion in 2019, and $1.1 billion in 2018.

The Company and its subsidiaries own their principal facilities and manufacturing plants under titles that they consider to be satisfactory. The Company believes that its properties are in good operating condition and that its machinery and equipment have been well maintained. The Company believes that its plants for the manufacture of products are suitable for their intended purposes and have capacities and projected capacities, including previously-disclosed capital expansion projects, that will be adequate for current and projected needs for existing Company products. Some capacity of the plants is being converted, with any needed modification, to the requirements of newly introduced and future products.

Item 3. Legal Proceedings.

The information called for by this Item is incorporated herein by reference to Item 8. "Financial Statements and Supplementary Data," Note 10. "Contingencies and Environmental Liabilities".

Item 4. Mine Safety Disclosures.

Not Applicable.

Executive Officers of the Registrant (ages as of February 1, 2021)

All officers listed below serve at the pleasure of the Board of Directors. None of these officers was elected pursuant to any arrangement or understanding between the officer and any other person(s).

Name	Age	Offices and Business Experience
Kenneth C. Frazier	66	Chairman, President and Chief Executive Officer (since December 2011)
Sanat Chattopadhyay	61	Executive Vice President and President, Merck Manufacturing Division (since March 2016)
Frank Clyburn	56	Executive Vice President, Chief Commercial Officer (since January 2019); President, Global Oncology Business Unit (October 2013-December 2018)
Robert M. Davis	54	Executive Vice President, Global Services, and Chief Financial Officer (since April 2016); Executive Vice President and Chief Financial Officer (April 2014-April 2016)
Richard R. DeLuca, Jr.	58	Executive Vice President and President, Merck Animal Health (since September 2011)
Michael W. Fleming	62	Senior Vice President, Chief Ethics and Compliance Officer (since March 2019); Senior Vice President, International Legal and Compliance (January 2017-March 2019); Vice President, International Legal and Compliance (July 2008-January 2017)
Julie L. Gerberding	65	Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health (since July 2016); Executive Vice President for Strategic Communications, Global Public Policy and Population Health (January 2015-July 2016)
Rita A. Karachun	57	Senior Vice President Finance - Global Controller (since March 2014)
Dean Li	58	President, Merck Research Laboratories (since January 2021); Senior Vice President, Discovery Sciences and Translational Medicine, Merck Research Laboratories (November 2017-January 2020); Vice President, Translational Medicine (March 2017-November 2017); Prior to that, Chief Scientific Officer and Associate Vice President, University of Utah Health Sciences
Steven C. Mizell	60	Executive Vice President, Chief Human Resources Officer (since December 2016); Executive Vice President, Human Resources, Monsanto Company (August 2011-December 2016)
Michael T. Nally	45	Executive Vice President, Chief Marketing Officer (since January 2019); President, Global Vaccines, Global Human Health (September 2016-January 2019); Managing Director, United Kingdom and Ireland, Global Human Health (January 2014-September 2016)
Jennifer Zachary	43	Executive Vice President, General Counsel and Corporate Secretary (since January 2020); Executive Vice President and General Counsel (April 2018-January 2020); Partner, Covington & Burling LLP (January 2013-March 2018)

In February 2021, Merck announced that Kenneth C. Frazier, chairman and chief executive officer, will retire as chief executive officer, effective June 30, 2021. Mr. Frazier will continue to serve on Merck's Board of Directors as executive chairman, for a transition period to be determined by the board. The Merck Board of Directors has unanimously elected Robert M. Davis, Merck's current executive vice president, global services and chief financial officer, as chief executive officer, as well as a member of the board, effective July 1, 2021. Mr. Davis will become president of Merck, effective April 1, 2021, at which time the Company's operating divisions—Human Health, Animal Health, Manufacturing, and Merck Research Laboratories—will begin reporting to Mr. Davis.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

The principal market for trading of the Company's Common Stock is the New York Stock Exchange (NYSE) under the symbol MRK.

As of January 31, 2021, there were approximately 104,900 shareholders of record of the Company's Common Stock.

Issuer purchases of equity securities for the three months ended December 31, 2020 were as follows:

Issuer Purchases of Equity Securities

			($ in millions)
Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs[1]
October 1 — October 31	—	$0.00	$5,888
November 1 — November 30	—	$0.00	$5,888
December 1 — December 31	—	$0.00	$5,888
Total	—	$0.00	$5,888

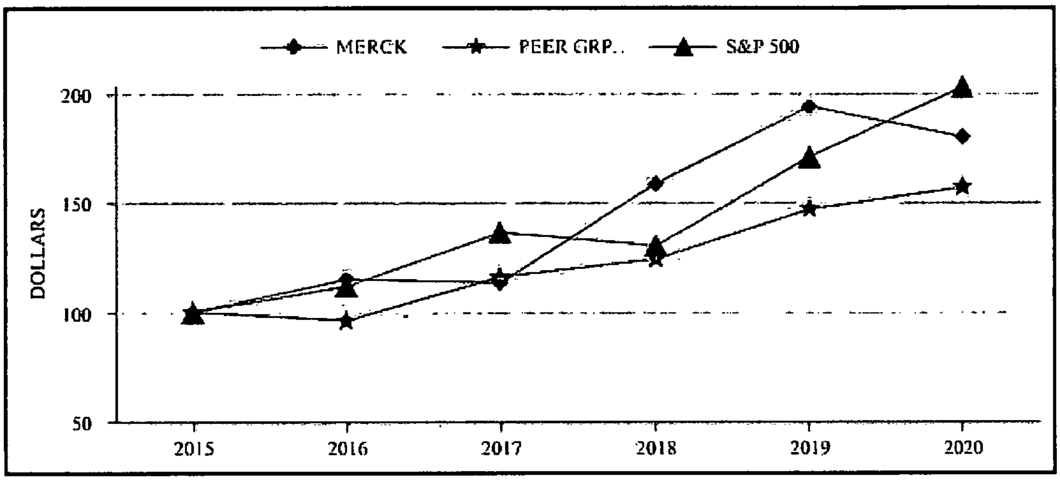
[1] *The Company did not purchase any shares during the three months ended December 31, 2020 under the plan approved by the Board of Directors in October 2018 to purchase up to $10 billion in Merck shares for its treasury.*

Performance Graph

The following graph assumes a $100 investment on December 31, 2015, and reinvestment of all dividends, in each of the Company's Common Shares, the S&P 500 Index, and a composite peer group of major U.S. and European-based pharmaceutical companies, which are: AbbVie Inc., Amgen Inc., AstraZeneca plc. Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, GlaxoSmithKline plc, Novartis AG, Pfizer Inc., Roche Holding AG, and Sanofi SA.

Comparison of Five-Year Cumulative Total Return*
Merck & Co., Inc., Composite Peer Group and S&P 500 Index

	End of Period Value	2020/2015 CAGR*
MERCK	$180	12%
PEER GRP.**	157	9%
S&P 500	203	15%



	2015	2016	2017	2018	2019	2020
MERCK	100.0	115.1	113.4	158.9	194.3	180.1
PEER GRP.	100.0	96.9	116.1	124.1	147.2	157.2
S&P 500	100.0	112.0	136.4	130.4	171.4	203.0

* *Compound Annual Growth Rate*
** *Peer group average was calculated on a market cap weighted basis.*

This Performance Graph will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference. In addition, the Performance Graph will not be deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C, other than as provided in Regulation S-K, or to the liabilities of section 18 of the Securities Exchange Act of 1934, except to the extent that the Company specifically requests that such information be treated as soliciting material or specifically incorporates it by reference into a filing under the Securities Act or the Exchange Act.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following section of this Form 10-K generally discusses 2020 and 2019 results and year-to-year comparisons between 2020 and 2019. Discussion of 2018 results and year-to-year comparisons between 2019 and 2018 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 filed on February 26, 2020.

Description of Merck's Business

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment in the first quarter of 2020.

The Company previously had an Alliances segment that primarily included activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Planned Spin-Off of Women's Health, Biosimilars and Established Brands into a New Company

In February 2020, Merck announced its intention to spin-off products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The established brands included in the transaction consist of dermatology, non-opioid pain management, respiratory, and select cardiovascular products including *Zetia* and *Vytorin*, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. Organon will have development capabilities initially focused on late-stage development and life-cycle management and is expected over time to develop research capabilities in selected therapeutic areas. The spin-off is expected to be completed late in the second quarter of 2021, subject to market and certain other conditions.

Overview

Financial Highlights

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019
Sales	$ 47,994	2 %	4 %	$ 46,840
Net Income Attributable to Merck & Co., Inc.	7,067	(28)%	(25) %	9,843
Non-GAAP Net Income Attributable to Merck & Co., Inc. [(1)]	**15,082**	**13 %**	**16 %**	13,382
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	**$2.78**	**(27)%**	**(24) %**	$3.81
Non-GAAP Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders [(1)]	**$5.94**	**14 %**	**17 %**	$5.19

[(1)] Non-GAAP net income and non-GAAP earnings per share (EPS) exclude acquisition and divestiture-related costs, restructuring costs and certain other items. For further discussion and a reconciliation of GAAP to non-GAAP net income and EPS (see "Non-GAAP Income and Non-GAAP EPS" below).

Executive Summary

Worldwide sales were $48.0 billion in 2020, an increase of 2% compared with 2019, or 4% excluding the unfavorable effect from foreign exchange. The sales increase was driven primarily by oncology, certain hospital acute care products and animal health. Growth in these areas was largely offset by the negative effects of the coronavirus disease 2019 (COVID-19) pandemic as discussed below, the effects of generic competition, particularly in the diversified brands and women's health franchises, competitive pressure in the virology franchise and pricing pressure in the diabetes franchise.

During 2020, Merck continued executing on its strategic priorities reporting year-over-year sales growth despite the business challenges posed by the COVID-19 pandemic. Roughly two-thirds of Merck's Pharmaceutical segment revenue is comprised of physician-administered products, sales of which were negatively affected in 2020 by patients' inability to access health care providers, fewer well visits, and social distancing measures. However, in the latter part of the year, the Company experienced a partial recovery in the underlying demand for products across its key growth pillars. Despite the pandemic, Merck employees across the organization continued their important work, enrolling and maintaining clinical studies, progressing the pipeline and ensuring the supply of and patient access to the Company's portfolio of medically important medicines and vaccines. The Company also executed on Merck's capital allocation priorities by completing business development transactions and investing in its pipeline. Additionally, the Company remains on track to complete the spin-off of Organon late in the second quarter of 2021 thereby creating two companies, each focused on their strengths and portfolios allowing them to pursue their respective market opportunities and business strategies. In 2020, the products that will comprise Organon had total sales of $6.5 billion.

Merck actively monitors the business development landscape for growth opportunities that meet the Company's strategic criteria. To expand its oncology presence, Merck completed the acquisitions of ArQule, Inc. (ArQule), a biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of cancer and other diseases; and VelosBio Inc. (VelosBio), a clinical-stage biopharmaceutical company committed to developing first-in-class cancer therapies targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1) currently being evaluated for the treatment of patients with hematologic malignancies and solid tumors. Additionally, Merck entered into strategic collaboration agreements with Seagen to gain access to ladiratuzumab vedotin, an investigational antibody-drug conjugate targeting LIV-1, and Tukysa (tucatinib), a small molecule tyrosine kinase inhibitor for the treatment of human epidermal growth factor receptor 2 (HER2)-positive cancers. To augment Merck's animal health business, the Company acquired the U.S. rights to Sentinel Flavor Tabs and Sentinel Spectrum Chews.

As part of industry-wide efforts to develop solutions to the pandemic, the Company acquired OncoImmune, a company developing a therapeutic candidate for the treatment of patients hospitalized with COVID-19; and Themis Bioscience GmbH (Themis), a company focused on vaccines and immune-modulation therapies for infectious diseases, including a COVID-19 vaccine candidate. Additionally, Merck entered into strategic collaborations with Ridgeback Biotherapeutics LP (Ridgeback Bio) to develop an orally available antiviral candidate in clinical development for the treatment of patients with COVID-19; and with the International AIDS Vaccine Initiative, Inc. (IAVI) to develop an investigational vaccine against SARS-CoV-2 being studied for the prevention of COVID-19. In January 2021, the Company announced it was discontinuing development of the COVID-19 vaccine candidates (see Note 3 to the consolidated financial statements).

During 2020, the Company received numerous regulatory approvals within oncology. *Keytruda* received approval in the United States as monotherapy in the therapeutic areas of cutaneous squamous cell carcinoma (cSCC), metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer, non-muscle invasive bladder cancer (NMIBC) and tumor mutational burden-high (TMB-H) solid tumors, as well as in combination with chemotherapy for the treatment of triple-negative breast cancer (TNBC). Merck also received approval in the United States for an every six weeks (Q6W) dosing regimen across all adult indications. Additionally, *Keytruda* received approval in China for the treatment of certain patients with head and neck squamous cell carcinoma (HNSCC) and in both China and Japan for the treatment of certain patients with esophageal squamous cell carcinoma (ESCC). Lynparza, which is being developed in collaboration with AstraZeneca PLC (AstraZeneca), received approval in the United States: in combination with bevacizumab as a first-line maintenance treatment of certain adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy; and for the treatment of certain adult patients with metastatic castration-resistant prostate cancer (mCRPC) following progression on prior treatment. Additionally, Lynparza was approved in the European Union (EU): as monotherapy for the treatment of adult patients with mCRPC and *BRCA*1/2 mutations who have progressed following a prior therapy; and for the maintenance treatment of certain adult patients with metastatic adenocarcinoma of the pancreas. Lynparza was also approved in Japan for the treatment of three types of advanced cancer: ovarian, prostate and pancreatic cancer. Lenvima, which is being developed in collaboration with Eisai Co., Ltd. (Eisai), received approval in China as monotherapy for the treatment of differentiated thyroid cancer.

Also in 2020, *Gardasil* 9 was approved for use in women and girls in Japan where it is marketed as *Silgard* 9. Additionally, in 2020, the U.S. Food and Drug Administration (FDA) granted accelerated approval for an expanded indication for *Gardasil* 9 for the prevention of oropharyngeal and other head and neck cancers caused by certain HPV types. In January 2021, the Company received FDA approval for Verquvo (vericiguat), to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults. Verquvo is being jointly developed with Bayer AG (Bayer).

In addition to the recent regulatory approvals discussed above, the Company advanced its late-stage pipeline with several regulatory submissions. *Keytruda* is under review in United States and/or internationally for the treatment of certain patients with TNBC, classical Hodgkin Lymphoma (cHL), colorectal cancer, cSCC, esophageal and gastric cancer. Lenvima is under review in Japan as monotherapy for the treatment of thymic cancer. V114, an investigational 15-valent pneumococcal conjugate vaccine, is under priority review by the FDA for the prevention of invasive pneumococcal disease in adults 18 years of age and older. The European Medicines Agency (EMA) is also reviewing an application for licensure of V114 in adults. The Company is involved in litigation challenging the validity of several Pfizer Inc. patents that relate to pneumococcal vaccine technology in the United States and several foreign jurisdictions.

The Company's Phase 3 oncology programs include *Keytruda* in the therapeutic areas of biliary tract, cervical, cutaneous squamous cell, endometrial, gastric, hepatocellular, mesothelioma, ovarian, prostate and small-cell lung cancers; Lynparza as monotherapy for colorectal cancer and in combination with *Keytruda* for non-small-cell lung and small-cell lung cancers; and Lenvima in combination with *Keytruda* for bladder, endometrial, gastric, head and neck, melanoma and non-small-cell lung cancers. Also within oncology, MK-6482, belzutifan, an investigational hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor being evaluated for the treatment of patients with von Hippel-Lindau disease-associated renal cell carcinoma (RCC), received Breakthrough Therapy designation from the FDA. Additionally, the Company has candidates in Phase 3 clinical development in several other therapeutic areas, including MK-7264, gefapixant, a selective, non-narcotic, orally-administered, investigational P2X3-receptor antagonist being developed for the treatment of refractory, chronic cough; MK-7110, an investigational treatment for patients hospitalized with COVID-19; MK-8591A, islatravir, an investigational nucleoside reverse transcriptase translocation inhibitor (NRTTI) in combination with doravirine for the treatment of HIV-1 infection; and V114, which is being evaluated for the prevention of pneumococcal disease in pediatric patients.

The Company is allocating resources to support its commercial opportunities in the near term while making the necessary investments to support long-term growth. Research and development expenses in 2020 reflect higher costs related to business development activity, higher clinical development spending and increased investment in discovery research and early drug development.

In November 2020, Merck's Board of Directors approved an increase to the Company's quarterly dividend, raising it to $0.65 per share from $0.61 per share on the Company's outstanding common stock. During 2020, the Company returned $7.5 billion to shareholders through dividends and share repurchases.

Management

In February 2021, Merck announced that Kenneth C. Frazier, chairman and chief executive officer, will retire as chief executive officer, effective June 30, 2021. Mr. Frazier will continue to serve on Merck's Board of Directors as executive chairman, for a transition period to be determined by the board. The Merck Board of Directors has unanimously elected Robert M. Davis, Merck's current executive vice president, global services and chief financial officer, as chief executive officer, as well as a member of the board, effective July 1, 2021. Mr. Davis will become president of Merck, effective April 1, 2021, at which time the Company's operating divisions—Human Health, Animal Health, Manufacturing, and Merck Research Laboratories (MRL)—will begin reporting to Mr. Davis.

COVID-19

Overall, in response to the COVID-19 pandemic, Merck remains focused on protecting the safety of its employees, ensuring that its supply of medicines and vaccines reaches its patients, contributing its scientific expertise to the development of antiviral approaches, and supporting health care providers and Merck's communities. Although COVID-19-related disruptions to patients' ability to access health care providers negatively affected results in 2020, Merck remains confident in the fundamental underlying demand for its products and its prospects for long-term growth.

In 2020, the estimated negative impact of the COVID-19 pandemic to Merck's sales was approximately $2.5 billion, largely attributable to the Pharmaceutical segment, with approximately $50 million attributable to the Animal Health segment. Roughly two-thirds of Merck's Pharmaceutical segment revenue is comprised of physician-administered products, which, despite strong underlying demand, have been affected by social distancing measures, fewer well visits and delays in elective surgeries due to the COVID-19 pandemic. These impacts, as well as the prioritization of COVID-19 patients at health care providers, have resulted in reduced administration of many of the Company's human health products, in particular for its vaccines, including *Gardasil* 9, as well as for *Keytruda* and *Implanon/Nexplanon*. In addition, declines in elective surgeries negatively affected the demand for *Bridion*. However, sales of *Pneumovax* 23 increased due to heightened awareness of pneumococcal vaccination.

Operating expenses were positively affected in 2020 by approximately $600 million primarily due to lower promotional and selling costs, as well as lower research and development expenses, net of investments in COVID-19-related antiviral and vaccine research programs.

Merck believes that global health systems and patients have largely adapted to the impacts of COVID-19, but the Company's assumption is that ongoing residual negative impacts will persist, particularly during the first half of 2021 and most notably with respect to vaccine sales, with the impact expected to be more acute in the United States. For the full year of 2021, Merck assumes an unfavorable impact to revenue of approximately 2% due to the COVID-19 pandemic, all of which relates to Pharmaceutical segment sales. In addition, for the full year of 2021, with respect to the COVID-19 pandemic, Merck expects a net negative impact to operating expenses, as spending on the development of its COVID-19 antiviral programs is expected to exceed the favorable impact of lower spending in other areas due to the COVID-19 pandemic.

Pricing

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's revenue performance in 2020 was negatively affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions and additional actions in the future will continue to negatively affect revenue performance.

Operating Results

Sales

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
United States	$ 21,027	2 %	2 %	$ 20,519	12 %	12 %	$ 18,346
International	26,967	2 %	5 %	26,321	10 %	13 %	23,949
Total	$ 47,994	2 %	4 %	$ 46,840	11 %	13 %	$ 42,294

U.S. plus international may not equal total due to rounding.

Worldwide sales grew 2% in 2020 due to higher sales in the oncology franchise reflecting strong growth of *Keytruda*, as well as increased alliance revenue from Lynparza and Lenvima. Also contributing to revenue growth were higher sales of certain vaccines, including *Gardasil/Gardasil* 9 and *Pneumovax* 23, as well as increased sales of certain hospital acute care products, including *Prevymis* and *Bridion*. Higher sales of animal health products also drove revenue growth in 2020.

Sales growth in 2020 was partially offset by the effects of generic competition for certain products including women's health product *NuvaRing*, hospital acute care products *Noxafil* and *Cubicin*, oncology products *Emend/Emend* for Injection, cardiovascular products *Zetia* and *Vytorin*, and products within the diversified brands franchise, particularly *Singulair*. The diversified brands franchise includes certain products that are approaching the expiration of their marketing exclusivity or that are no longer protected by patents in developed markets. Lower sales of pediatric vaccines, including *ProQuad*, *M-M-R* II, and *Varivax*, as well as lower sales of diabetes products *Januvia* and *Janumet*, and virology products *Zepatier* and *Isentress/Isentress HD* also partially offset revenue growth in 2020. As discussed above, the COVID-19 pandemic negatively affected sales in 2020.

Sales in the United States grew 2% in 2020 primarily driven by higher sales of *Keytruda*, increased alliance revenue from Lynparza and Lenvima, and higher sales of animal health products. Revenue growth was largely offset by lower sales of *NuvaRing*, *Januvia*, *Noxafil*, *Emend/Emend* for Injection, *M-M-R* II, *Janumet*, *Varivax* and *Implanon/Nexplanon*.

International sales grew 2% in 2020. The increase in international sales primarily reflects growth in *Keytruda*, *Gardasil/Gardasil* 9, increased alliance revenue from Lynparza, as well as higher sales of *Pneumovax* 23, *Prevymis*, *Januvia* and animal health products. Sales growth was partially offset by lower sales of *Zepatier*, *Vytorin*, *Noxafil*, *Zetia*, *Remicade*, *Emend/Emend* for Injection and products within the diversified brands franchise, particularly *Singulair* and *Nasonex*. International sales represented 56% of total sales in both 2020 and 2019.

See Note 18 to the consolidated financial statements for details on sales of the Company's products. A discussion of performance for select products in the franchises follows.

Pharmaceutical Segment

Oncology

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Keytruda	$ 14,380	30 %	30 %	$ 11,084	55 %	58 %	$ 7,171
Alliance Revenue - Lynparza [1]	725	63 %	62 %	444	137 %	141 %	187
Alliance Revenue - Lenvima [1]	580	44 %	43 %	404	171 %	173 %	149
Emend	145	(63) %	(62) %	388	(26)%	(24) %	522

[1] *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 4 to the consolidated financial statements).*

Keytruda is an anti-PD-1 (programmed death receptor-1) therapy that has been approved as monotherapy for the treatment of certain patients with cervical cancer, cHL, cSCC, ESCC, gastric or gastroesophageal junction adenocarcinoma, HNSCC, hepatocellular carcinoma (HCC), non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), melanoma, Merkel cell carcinoma, MSI-H or dMMR cancer including MSI-H/dMMR colorectal cancer, primary mediastinal large B-cell lymphoma (PMBCL), TMB-H cancer, and urothelial carcinoma including NMIBC. *Keytruda* is also approved for the treatment of certain patients: in combination with chemotherapy for metastatic squamous and nonsquamous NSCLC, in combination with chemotherapy for HNSCC, in combination with chemotherapy for TNBC, in combination with axitinib for RCC, and in combination with Lenvima for endometrial carcinoma. The *Keytruda* clinical development program includes studies across a broad range of cancer types.

Global sales of *Keytruda* grew 30% in 2020 driven by higher demand as the Company continues to launch *Keytruda* with multiple new indications globally, although the COVID-19 pandemic had a dampening effect on growing demand. Sales in the United States continue to build across the multiple approved indications, in particular for the treatment of advanced NSCLC as monotherapy, and in combination with chemotherapy for both nonsquamous and squamous metastatic NSCLC, along with uptake in the RCC, adjuvant melanoma, HNSCC, bladder cancer and endometrial carcinoma indications. Uptake of the every six weeks (Q6W) adult dosing regimen in the United States benefited sales in 2020. *Keytruda* sales growth in international markets was driven by continued uptake in approved indications, particularly in the EU. Sales growth was partially offset by declines in Japan due to pricing. Pursuant to a re-pricing rule, the Japanese government reduced the price of *Keytruda* by 17.5% effective February 2020. Additionally, *Keytruda* was subject to another price reduction of 20.9% in April 2020 under a provision of the Japanese pricing rules.

In January 2020, the FDA approved *Keytruda* as monotherapy for the treatment of certain patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, NMIBC based on the results of the KEYNOTE-057 trial.

In April 2020, the FDA granted accelerated approval for an additional recommended dosage of 400 mg every six weeks (Q6W) for *Keytruda* across all adult indications, including monotherapy and combination therapy. This new dosage option is available in addition to the current dose of 200 mg every three weeks (Q3W).

In June 2020, the FDA granted accelerated approval for *Keytruda* as monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic TMB-H solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options based in part on the results of the KEYNOTE-158 trial.

Also in June 2020, the FDA approved *Keytruda* as monotherapy for the treatment of patients with recurrent or metastatic cSCC that is not curable by surgery or radiation based on data from the KEYNOTE-629 trial.

Additionally in June 2020, the FDA approved *Keytruda* as monotherapy for the first-line treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer based on results from the KEYNOTE-177 trial.

In October 2020, the FDA approved an expanded label for *Keytruda* as monotherapy for the treatment of adult patients with relapsed or refractory cHL based on results from the KEYNOTE-204 trial. The FDA also approved an updated pediatric indication for *Keytruda* for the treatment of pediatric patients with refractory cHL or cHL that has relapsed after two or more lines of therapy. *Keytruda* was previously approved under the FDA's accelerated approval process for the treatment of adult and pediatric patients with refractory cHL, or who have relapsed after three or more prior lines of therapy based on data from the KEYNOTE-087 trial. In accordance with accelerated approval regulations, continued approval was contingent upon verification and description of clinical benefit; these accelerated approval requirements have been fulfilled with the data from KEYNOTE-204.

In November 2020, the FDA granted accelerated approval for *Keytruda* in combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (Combined Positive Score [CPS] $\geq$10) as determined by an FDA-approved test. The approval is based on results from the KEYNOTE-355 trial.

In June 2020, *Keytruda* was approved by the National Medical Products Administration (NMPA) in China as monotherapy for the second-line treatment of patients with locally advanced or metastatic ESCC whose tumors express PD-L1 (CPS ≥10). This indication was granted based on the KEYNOTE-181 trial, including data from an extension of the global study in Chinese patients. In December 2020, China's NMPA approved *Keytruda* as monotherapy for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 (CPS ≥20) as determined by a fully validated test.

In August 2020, *Keytruda* was approved by Japan's Pharmaceuticals and Medical Devices Agency (PMDA) as monotherapy for the treatment of patients whose tumors are PD-L1-positive, and have radically unresectable, advanced or recurrent ESCC who have progressed after chemotherapy. The approval was based on results from the KEYNOTE-181 trial. Additionally, *Keytruda* was approved by Japan's PMDA for use at an additional recommended dosage of 400 mg Q6W, including monotherapy and combination therapy. This new dosage option is available in addition to the current dose of 200 mg Q3W.

In January 2021, *Keytruda* was approved by the European Commission (EC) as a first-line treatment in adult patients with MSI-H or dMMR colorectal cancer based on the results of the KEYNOTE-177 study.

The Company is a party to certain third-party license agreements pursuant to which the Company pays royalties on sales of *Keytruda*. Under the terms of the more significant of these agreements, Merck pays a royalty of 6.5% on worldwide sales of *Keytruda* through 2023 to one third party; this royalty will decline to 2.5% for 2024 through 2026 and will terminate thereafter. The Company pays an additional 2% royalty on worldwide sales of *Keytruda* to another third party, the termination date of which varies by country; this royalty will expire in the United States in 2024 and in major European markets in 2025. The royalties are included in *Cost of sales*.

Lynparza, an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca (see Note 4 to the consolidated financial statements), is approved for the treatment of certain types of advanced ovarian, breast, pancreatic and prostate cancers. Alliance revenue related to Lynparza grew 63% in 2020 due to continued uptake across the multiple approved indications in the United States, the EU, China and Japan.

In May 2020, the FDA approved Lynparza in combination with bevacizumab as a first-line maintenance treatment of certain adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. In November 2020, Lynparza was approved in the EU for the maintenance treatment of adult patients with advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response following completion of first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD)-positive status. These approvals were based on the results from the PAOLA-1 trial.

Also in May 2020, the FDA approved Lynparza for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated mCRPC who have progressed following prior treatment. In November 2020, Lynparza was approved in the EU as monotherapy for the treatment of adult patients with mCRPC and *BRCA*1/2 mutations (germline and/or somatic) who have progressed following a prior therapy. These approvals were based on the results from the PROfound trial.

In July 2020, Lynparza was approved in the EU as a monotherapy for the maintenance treatment of adult patients with germline *BRCA*1/2 mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a first-line chemotherapy regimen. This approval was based on the results from the POLO trial.

In December 2020, Lynparza was approved in Japan for the treatment of three types of advanced cancer: ovarian, prostate and pancreatic cancer. The three approvals authorize Lynparza for use as maintenance treatment after first-line chemotherapy containing bevacizumab (genetical recombination) in patients with HRD ovarian cancer; the treatment of patients with *BRCA* gene-mutated (*BRCA*m) mCRPC; and maintenance treatment after platinum-based chemotherapy for patients with *BRCA*m curatively unresectable pancreas cancer. The concurrent approvals by the Japanese Ministry of Health, Labor, and Welfare are based on results from the PAOLA-1, PROfound and POLO trials.

Lenvima, an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai (see Note 4 to the consolidated financial statements), is approved for the treatment of certain types of thyroid cancer, HCC, in combination with everolimus for certain patients with RCC, and in combination with *Keytruda* for the treatment of certain patients with endometrial carcinoma. Alliance revenue related to Lenvima grew 44% in 2020 due to higher demand in the United States, China and the EU.

In November 2020, China's NMPA approved Lenvima as a monotherapy for the treatment of differentiated thyroid cancer.

Global sales of *Emend,* for the prevention of certain chemotherapy-induced nausea and vomiting, declined 63% in 2020 primarily due to lower demand and pricing in the United States due to generic competition for *Emend* for Injection following U.S. patent expiry in September 2019. Also contributing to the *Emend* sales decline was lower demand in the EU and Japan as a result of generic competition for the oral formulation of *Emend* following loss of market exclusivity in May 2019 and December 2019, respectively. U.S. market exclusivity for the oral formulation of *Emend* previously expired in 2015.

In April 2020, the FDA approved Koselugo (selumetinib) for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN). The FDA approval is based on positive results from the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP)-sponsored Phase 2 SPRINT Stratum 1 trial coordinated by the NCI's Center for Cancer Research, Pediatric Oncology Branch. This is the first regulatory approval of a medicine for the treatment of NF1 PN, a rare and debilitating genetic condition. Koselugo is being jointly developed and commercialized with AstraZeneca globally (see Note 4 to the consolidated financial statements).

Vaccines

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Gardasil/Gardasil 9	**$ 3,938**	**5 %**	**6 %**	$ 3,737	19 %	21 %	$ 3,151
ProQuad	**678**	**(10) %**	**(10) %**	756	27 %	29 %	593
M-M-R II	**378**	**(31) %**	**(31) %**	549	28 %	29 %	430
Varivax	**823**	**(15) %**	**(15) %**	970	25 %	28 %	774
Pneumovax 23	**1,087**	**17 %**	**18 %**	926	2 %	3 %	907

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of HPV, grew 5% in 2020 primarily due to higher volumes in China and the replenishment in 2020 of doses borrowed from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile in 2019. The replenishment resulted in the recognition of sales of $120 million in 2020, which, when combined with the reduction of sales of $120 million in 2019 due to the borrowing, resulted in a favorable impact to sales of $240 million in 2020. Lower demand in the United States and Hong Kong, SAR, PRC attributable to the COVID-19 pandemic partially offset the increase in sales of *Gardasil/Gardasil* 9.

In June 2020, the FDA approved an expanded indication for *Gardasil* 9 for the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58. The oropharyngeal and head and neck cancer indication was approved under accelerated approval based on effectiveness in preventing HPV-related anogenital disease.

In July 2020, *Gardasil* 9 was approved by the PMDA in Japan for use in women and girls nine years and older for the prevention of cervical cancer, certain cervical, vaginal and vulvar precancers, and genital warts caused by the HPV types covered by the vaccine. In December 2020, *Silgard* 9 was also approved in Japan for the prevention of anal cancer and precursor lesions caused by HPV types 6, 11, 16 and 18 for individuals nine years and older and for genital warts for men nine years and older. *Gardasil* 9 is marketed in Japan as *Silgard* 9.

The Company is a party to certain third-party license agreements pursuant to which the Company pays royalties on sales of *Gardasil/Gardasil* 9. Under the terms of the more significant of these agreements, Merck pays a 7% royalty on worldwide sales of *Gardasil/Gardasil* 9 to one third party (royalty obligations under this agreement expire in December 2023) and an additional 7% royalty on sales of *Gardasil/Gardasil* 9 in the United States to another third party (these royalty obligations expire in December 2028). The royalties are included in *Cost of sales.*

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, declined 10% in 2020 driven primarily by lower demand in the United States resulting from fewer measles outbreaks in 2020 compared with 2019, coupled with the unfavorable impact of the COVID-19 pandemic, partially offset by higher pricing.

Worldwide sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, declined 31% in 2020 driven primarily by lower demand in the United States resulting from fewer measles outbreaks in 2020 compared with 2019, coupled with the unfavorable impact of the COVID-19 pandemic. Lower demand in Brazil also contributed to the *M-M-R* II sales decline in 2020.

Global sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), declined 15% in 2020 driven primarily by lower demand in the United States resulting from the COVID-19 pandemic, partially offset by higher pricing. The *Varivax* sales decline was also attributable to lower government tenders in Brazil.

Worldwide sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, grew 17% in 2020 primarily due to higher volumes in the EU and in the United States attributable in part to heightened awareness of pneumococcal vaccination. Higher pricing in the United States also contributed to *Pneumovax* 23 sales growth in 2020.

Hospital Acute Care

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Bridion	$ 1,198	6 %	7 %	$ 1,131	23 %	26 %	$ 917
Noxafil	329	(50) %	(50) %	662	(11)%	(7) %	742
Prevymis	281	70 %	69 %	165	128 %	131 %	72
Cubicin	152	(41) %	(40) %	257	(30)%	(28) %	367
Zerbaxa	130	8 %	10 %	121	39 %	42 %	87

Global sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 6% in 2020 due to higher demand globally, particularly in the United States. However, fewer elective surgeries as a result of the COVID-19 pandemic unfavorably affected demand in 2020.

Worldwide sales of *Noxafil*, an antifungal agent for the prevention of certain invasive fungal infections, declined 50% in 2020 due to generic competition in the United States and in the EU. The patent that provided U.S. market exclusivity for certain forms of *Noxafil* representing the majority of U.S. *Noxafil* sales expired in July 2019. Additionally, the patent for *Noxafil* expired in a number of major European markets in December 2019. As a result, the Company is experiencing volume and pricing declines in *Noxafil* sales in these markets as a result of generic competition and expects the declines to continue.

Worldwide sales of *Prevymis*, a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogenic hematopoietic stem cell transplant, grew 70% in 2020 due to continued uptake since launch in the EU and in the United States. *Prevymis* was approved by the EC in January 2018 and by the FDA in November 2017.

Global sales of *Cubicin* for injection, an antibiotic for the treatment of certain bacterial infections, declined 41% in 2020 primarily due to ongoing generic competition in the EU and in the United States.

In December 2020, the Company temporarily suspended sales of *Zerbaxa*, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections, and subsequently issued a product recall, following the identification of product sterility issues. As a result, the Company recorded an intangible asset impairment charge related to *Zerbaxa* (see Note 8 to the consolidated financial statements). The Company does not anticipate that *Zerbaxa* will return to the market before 2022.

In June 2020, the FDA approved a supplemental New Drug Application (NDA) for *Recarbrio* (imipenem, cilastatin, and relebactam) for the treatment of patients 18 years of age and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by certain susceptible Gram-negative microorganisms.

Immunology

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Simponi	$ 838	1 %	1 %	$ 830	(7)%	(2) %	$ 893
Remicade	330	(20) %	(20) %	411	(29)%	(25) %	582

Sales of *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were nearly flat in 2020. Sales of *Simponi* are being unfavorably affected by the launch of biosimilars for a competing product. The Company expects this competition will continue to unfavorably affect sales of *Simponi*.

Sales of *Remicade*, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 20% in 2020 driven by ongoing biosimilar competition in the Company's marketing territories in Europe. The Company lost market exclusivity for *Remicade* in major European markets in 2015 and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

The Company's marketing rights with respect to these products will revert to Janssen Pharmaceuticals, Inc. in the second half of 2024.

Virology

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Isentress/Isentress HD	$ 857	(12) %	(11) %	$ 975	(15)%	(10) %	$ 1,140
Zepatier	167	(55) %	(54) %	370	(19)%	(16) %	455

Worldwide sales of *Isentress/Isentress HD*, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, declined 12% in 2020 primarily due to competitive pressure in the United States and in the EU. The Company expects competitive pressures for *Isentress/Isentress HD* to continue.

Global sales of *Zepatier*, a treatment for adult patients with chronic hepatitis C virus genotype (GT) 1 or GT4 infection, declined 55% in 2020 driven by lower demand globally due to competition and declining patient volumes, coupled with the impact of the COVID-19 pandemic.

Cardiovascular

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Zetia/Vytorin	$ 664	(24) %	(24) %	$ 874	(35)%	(34) %	$ 1,355
Atozet	453	16 %	16 %	391	13 %	18 %	347
Rosuzet	130	8 %	9 %	120	107 %	115 %	58
Alliance revenue - Adempas [1]	281	38 %	38 %	204	47 %	47 %	139
Adempas	220	3 %	2 %	215	13 %	17 %	190

[1] *Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 4 to the consolidated financial statements).*

Combined global sales of *Zetia* (marketed in most countries outside the United States as *Ezetrol*) and *Vytorin* (marketed outside the United States as *Inegy*), medicines for lowering LDL cholesterol, declined 24% in 2020 driven primarily by lower sales of *Ezetrol* in Japan and *Ezetrol* and *Inegy* in the EU. The patent that provided market exclusivity for *Ezetrol* in Japan expired in September 2019 and generic competition began in June 2020. The

EU patents for *Ezetrol* and *Inegy* expired in April 2018 and April 2019, respectively. Accordingly, the Company is experiencing sales declines in these markets as a result of generic competition and expects the declines to continue. The sales decline in 2020 was also attributable to lower pricing following loss of exclusivity in Australia. Higher demand for *Ezetrol* in China partially offset the sales decline in 2020. Merck lost market exclusivity in the United States for *Zetia* in 2016 and *Vytorin* in 2017 and subsequently lost nearly all U.S. sales of these products as a result of generic competition.

Sales of *Atozet* (marketed outside of the United States), a medicine for lowering LDL cholesterol, grew 16% in 2020, primarily driven by higher demand in most markets, particularly in the EU, Japan and other countries in the Asia Pacific region.

Zetia, Vytorin, Atozet and *Rosuzet* will be contributed to Organon in connection with the spin-off (see Note 1 to the consolidated financial statements).

Adempas, a cardiovascular drug for the treatment of pulmonary arterial hypertension, is part of a worldwide collaboration with Bayer to market and develop soluble guanylate cyclase (sGC) modulators including Adempas (see Note 4 to the consolidated financial statements). Revenue from Adempas includes Merck's share of profits from the sale of Adempas in Bayer's marketing territories, which grew 38% in 2020, as well as sales in Merck's marketing territories, which grew 3% in 2020.

In January 2021, the FDA approved Verquvo (vericiguat), an sGC stimulator, to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults with symptomatic chronic heart failure and reduced ejection fraction. The approval was based on the results of the pivotal Phase 3 VICTORIA trial and follows a priority regulatory review. Verquvo is part of the same worldwide clinical development collaboration with Bayer that includes Adempas referenced above.

Diabetes

($ in millions)	**2020**	**% Change**	**% Change Excluding Foreign Exchange**	2019	% Change	% Change Excluding Foreign Exchange	2018
Januvia/Janumet	**$ 5,276**	**(4) %**	**(4) %**	$ 5,524	(7) %	(4) %	$ 5,914

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 4% in 2020 as a result of continued pricing pressure in the United States, partially offset by higher demand in certain international markets, particularly in China. The Company expects U.S. pricing pressure to continue. *Januvia* and *Janumet* will lose market exclusivity in the United States in January 2023. The supplementary patent certificates that provide market exclusivity for *Januvia* and *Janumet* in the EU expire in September 2022 and April 2023, respectively. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after loss of market exclusivity.

Women's Health

($ in millions)	**2020**	**% Change**	**% Change Excluding Foreign Exchange**	2019	% Change	% Change Excluding Foreign Exchange	2018
Implanon/Nexplanon	**680**	**(14) %**	**(13) %**	787	12 %	14 %	703
NuvaRing	**236**	**(73) %**	**(73) %**	879	(3) %	(2) %	902

Worldwide sales of *Implanon/Nexplanon*, a single-rod subdermal contraceptive implant, declined 14% in 2020, primarily driven by lower demand in the United States and in the EU resulting from the COVID-19 pandemic.

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 73% in 2020 due to generic competition in the United States. The patent that provided U.S. market exclusivity for *NuvaRing* expired in April 2018 and generic competition began in December 2019. Accordingly, the Company is experiencing a rapid and substantial decline in U.S. *NuvaRing* sales and expects the decline to continue.

Implanon/Nexplanon and *NuvaRing* will be contributed to Organon in connection with the spin-off (see Note 1 to the consolidated financial statements).

Biosimilars

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Biosimilars	$ 330	31 %	31 %	$ 252	*	*	$ 64

* *Calculation not meaningful.*

Biosimilar products are marketed by the Company pursuant to an agreement with Samsung Bioepis Co., Ltd. (Samsung) to develop and commercialize multiple pre-specified biosimilar candidates. Currently, the Company markets Renflexis (infliximab-abda), a biosimilar to Remicade (infliximab) for the treatment of certain inflammatory diseases; Ontruzant (trastuzumab-dttb), a biosimilar to Herceptin (trastuzumab) for the treatment of HER2-positive breast cancer and HER2 overexpressing gastric cancer; Brenzys (etanercept biosimilar), a biosimilar to Enbrel for the treatment of certain inflammatory diseases; and Aybintio (bevacizumab) for the treatment of certain types of cancer. Merck's commercialization territories under the agreement vary by product. Sales growth of biosimilars in 2020 was primarily due to continued post-launch uptake of Renflexis in the United States and Canada and the launch of Ontruzant in Brazil in 2020.

In August 2020, the EC granted marketing authorization for Aybintio for the treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer, NSCLC, advanced and/or metastatic RCC, epithelial ovarian, fallopian tube and primary peritoneal cancer and cervical cancer. An application seeking approval of Aybintio in the United States was filed in September 2019.

The above biosimilar products will be contributed to Organon in connection with the spin-off (see Note 1 to the consolidated financial statements).

Animal Health Segment

($ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Livestock	$ 2,939	6 %	9 %	$ 2,784	6 %	11 %	$ 2,630
Companion Animal	1,764	10 %	11 %	1,609	2 %	5 %	1,582

Sales of livestock products grew 6% in 2020 predominantly due to an additional five months of sales in 2020 related to the April 2019 acquisition of Antelliq, a leader in digital animal identification, traceability and monitoring solutions (see Note 3 to the consolidated financial statements). Sales of companion animal products grew 10% in 2020 driven primarily by higher demand for the *Bravecto* line of products for parasitic control, as well as higher demand for companion animal vaccines.

Costs, Expenses and Other

($ in millions)	2020	% Change	2019	% Change	2018
Cost of sales	$ 15,485	10 %	$ 14,112	4 %	$ 13,509
Selling, general and administrative	10,468	(1) %	10,615	5 %	10,102
Research and development	13,558	37 %	9,872	1 %	9,752
Restructuring costs	578	(9) %	638	1 %	632
Other (income) expense, net	(886)	*	139	*	(402)
	$ 39,203	11 %	$ 35,376	5 %	$ 33,593

* *Calculation not meaningful.*

Cost of Sales

Cost of sales was $15.5 billion in 2020 compared with $14.1 billion in 2019. Cost of sales includes the amortization of intangible assets recorded in connection with acquisitions, collaborations, and licensing arrangements, which totaled $1.8 billion in 2020 compared with $2.0 billion in 2019, respectively. Additionally, costs in 2020 and 2019 include intangible asset impairment charges of $1.6 billion and $705 million related to marketed products and other intangibles (see Note 8 to the consolidated financial statements). The Company may recognize additional impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Costs in 2020 also include a charge of $260 million in connection with the discontinuation of COVID-19 vaccine development programs (see Note 3 to the consolidated financial statements) and inventory write-offs of $120 million related to a recall for *Zerbaxa* (see Note 8 to the consolidated financial statements). Also included in cost of sales are expenses associated with restructuring activities which amounted to $175 million in 2020 compared with $251 million in 2019, primarily reflecting accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Gross margin was 67.7% in 2020 compared with 69.9% in 2019. The gross margin decline in 2020 reflects the unfavorable effects of higher impairment charges (noted above), pricing pressure, a charge related to the discontinuation of COVID-19 vaccine development programs, and higher inventory write-offs related to the recall of *Zerbaxa* (noted above), partially offset by the favorable effects of product mix, lower amortization of intangible assets and lower restructuring costs.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses were $10.5 billion in 2020, a decline of 1% compared with 2019. The decline was driven primarily by lower administrative, selling and promotional costs, including lower travel and meeting expenses, due in part to the COVID-19 pandemic, and the favorable effect of foreign exchange, partially offset by higher costs related to the spin-off of Organon and a contribution to the Merck Foundation. SG&A expenses in 2020 include $710 million of costs related to the spin-off of Organon. SG&A expenses in 2020 and 2019 include restructuring costs of $47 million and $34 million, respectively, related primarily to accelerated depreciation for facilities to be closed or divested. Separation costs associated with sales force reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Research and Development

Research and development (R&D) expenses were $13.6 billion in 2020, an increase of 37% compared with 2019. The increase was driven primarily by higher upfront payments related to acquisitions and collaborations, including a $2.7 billion charge in 2020 related to the acquisition of VelosBio (see Note 3 to the consolidated financial statements), as well as higher expenses related to clinical development and increased investment in discovery research and early drug development. Higher restructuring costs also contributed to the increase in R&D expenses in 2020. The increase in R&D expenses in 2020 was partially offset by lower in-process research and development (IPR&D) impairment charges and lower costs resulting from the COVID-19 pandemic, net of spending on COVID-19-related vaccine and antiviral research programs.

R&D expenses are comprised of the costs directly incurred by MRL, the Company's research and development division that focuses on human health-related activities, which were $6.6 billion in 2020 compared with $6.1 billion in 2019. Also included in R&D expenses are Animal Health research costs, licensing costs and costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, which in the aggregate were $2.7 billion in 2020 and $2.6 billion in 2019. Additionally, R&D expenses in 2020 include a $2.7 billion charge for the acquisition of VelosBio (noted above), a $462 million charge for the acquisition of OncoImmune and charges of $826 million related to transactions with Seagen. R&D expenses in 2019 include a $993 million charge for the acquisition of Peloton. See Note 3 to the consolidated financial statements for more information on these transactions. R&D expenses also include IPR&D impairment charges of $90 million and $172 million in 2020 and 2019, respectively (see Note 8 to the consolidated financial statements). The Company may recognize additional impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. In addition, R&D expenses in 2020 include $83 million of costs associated with restructuring activities, primarily relating to accelerated depreciation. R&D expenses also include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with business acquisitions. During 2020 and 2019, the Company recorded a net reduction in expenses of $95 million and $39 million, respectively, related to changes in these estimates.

Restructuring Costs

In early 2019, Merck approved a new global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization, builds on prior restructuring programs and does not include any actions associated with the planned spin-off of Organon. As the Company continues to evaluate its global footprint and overall operating model, it subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program now estimated to be approximately $3.0 billion. The Company expects to record charges of approximately $700 million in 2021 related to the Restructuring Program. The Company anticipates the actions under the Restructuring Program to result in annual net cost savings of approximately $900 million by the end of 2023. Actions under previous global restructuring programs have been substantially completed.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $578 million in 2020 and $638 million in 2019. Separation costs incurred were associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Also included in restructuring costs are asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company's restructuring activities are included in *Cost of sales, Selling, general and administrative* expenses and *Research and development* costs. The Company recorded aggregate pretax costs of $883 million in 2020 and $927 million in 2019 related to restructuring program activities (see Note 5 to the consolidated financial statements).

Other (Income) Expense, Net

Other (income) expense, net, was $886 million of income in 2020 compared with $139 million of expense in 2019, primarily due to higher income from investments in equity securities, net, largely related to Moderna, Inc. For details on the components of Other (income) expense, net, see Note 14 to the consolidated financial statements.

Segment Profits

($ in millions)	**2020**	2019	2018
Pharmaceutical segment profits	$ **29,722**	$ 28,324	$ 24,871
Animal Health segment profits	**1,650**	1,609	1,659
Other non-reportable segment profits	**1**	(7)	103
Other	**(22,582)**	(18,462)	(17,932)
Income Before Taxes	$ **8,791**	$ 11,464	$ 8,701

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as SG&A expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as SG&A and R&D expenses directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred by MRL, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are costs related to restructuring activities and acquisition and divestiture-related costs, including the amortization of purchase accounting adjustments, intangible asset impairment charges, and changes in the estimated fair value measurement of liabilities for contingent consideration. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Pharmaceutical segment profits grew 5% in 2020 compared with 2019 driven primarily by higher sales, as well as lower selling and promotional costs. Animal Health segment profits grew 3% in 2020 driven primarily by higher sales and lower promotional and selling costs, partially offset by higher R&D costs and the unfavorable effect of foreign exchange.

Taxes on Income

The effective income tax rates of 19.4% in 2020 and 14.7% in 2019 reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings, including product mix. The effective income tax rate in 2020 reflects the unfavorable impact of a charge for the acquisition of VelosBio for which no tax benefit was recognized. The effective income tax rate in 2019 reflects the favorable impact of a $364 million net tax benefit related to the settlement of certain federal income tax matters (see Note 15 to the consolidated financial statements) and the reversal of tax reserves established in connection with the 2014 divestiture of Merck's Consumer Care (MCC) business due to the lapse in the statute of limitations. In addition, the effective income tax rate in 2019 reflects the unfavorable impacts of a charge for the acquisition of Peloton for which no tax benefit was recognized and charges of $117 million related to the finalization of treasury regulations for the transition tax associated with the 2017 enactment of U.S. tax legislation known as the Tax Cuts and Jobs Act (TCJA) (see Note 15 to the consolidated financial statements).

Net Income (Loss) Attributable to Noncontrolling Interests

Net income (loss) attributable to noncontrolling interests was $15 million in 2020 compared with $(66) million in 2019. The loss in 2019 was driven primarily by the portion of goodwill impairment charges related to certain businesses in the Healthcare Services segment that were attributable to noncontrolling interests.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $7.1 billion in 2020 and $9.8 billion in 2019. EPS was $2.78 in 2020 and $3.81 in 2019.

Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance that Merck is providing because management believes this information enhances investors' understanding of the Company's results as it permits investors to understand how management assesses performance. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items (which should not be considered non-recurring) consist of acquisition and divestiture-related costs, restructuring costs and certain other items. These excluded items are significant components in understanding and assessing financial performance.

Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes non-GAAP EPS. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the Company along with other metrics. In addition, senior management's annual compensation is derived in part using non-GAAP pretax income. Since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP).

A reconciliation between GAAP financial measures and non-GAAP financial measures is as follows:

($ in millions except per share amounts)	**2020**	2019	2018
Income before taxes as reported under GAAP	$ **8,791**	$ 11,464	$ 8,701
Increase (decrease) for excluded items:			
Acquisition and divestiture-related costs [1]	**3,704**	2,681	3,066
Restructuring costs	**883**	927	658
Other items:			
Charge for the acquisition of VelosBio	**2,660**	—	—
Charges for the formation of collaborations [2]	**1,076**	—	1,400
Charge for the acquisition of OncoImmune	**462**	—	—
Charge for the discontinuation of COVID-19 vaccine development programs	**305**	—	—
Charge for the acquisition of Peloton	—	993	—
Charge related to the termination of a collaboration with Samsung	—	—	423
Charge for the acquisition of Viralytics Limited	—	—	344
Other	**(20)**	55	(57)
Non-GAAP income before taxes	**17,861**	16,120	14,535
Taxes on income as reported under GAAP	**1,709**	1,687	2,508
Estimated tax benefit on excluded items [3]	**1,122**	695	535
Adjustment to tax benefits recorded in conjunction with the 2015 Cubist Pharmaceuticals, Inc. acquisition	**(67)**	—	—
Net tax benefit from the settlement of certain federal income tax matters	—	364	—
Tax benefit from the reversal of tax reserves related to the divestiture of MCC	—	86	—
Net tax charge related to the finalization of treasury regulations related to the enactment of the TCJA	—	(117)	(160)
Non-GAAP taxes on income	**2,764**	2,715	2,883
Non-GAAP net income	**15,097**	13,405	11,652
Less: Net income (loss) attributable to noncontrolling interests as reported under GAAP	**15**	(66)	(27)
Acquisition and divestiture-related costs attributable to noncontrolling interests	—	(89)	(58)
Non-GAAP net income attributable to noncontrolling interests	**15**	23	31
Non-GAAP net income attributable to Merck & Co., Inc.	$ **15,082**	$ 13,382	$ 11,621
EPS assuming dilution as reported under GAAP	$ **2.78**	$ 3.81	$ 2.32
EPS difference	**3.16**	1.38	2.02
Non-GAAP EPS assuming dilution	$ **5.94**	$ 5.19	$ 4.34

[1] *Amount in 2020 includes a $1.6 billion intangible asset impairment charge related to* Zerbaxa. *Amount in 2019 includes a $612 million intangible asset impairment charge related to* Sivextro. *See Note 8 to the consolidated financial statements.*

[2] *Amount in 2020 includes $826 million related to transactions with Seagen (see Note 3 to the consolidated financial statements). Amount in 2018 represents charge for the formation of a collaboration with Eisai (see Note 4 to the consolidated financial statements).*

[3] *The estimated tax impact on the excluded items is determined by applying the statutory rate of the originating territory of the non-GAAP adjustments.*

Acquisition and Divestiture-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with business acquisitions and divestitures. These amounts include the amortization of intangible assets and amortization of purchase accounting adjustments to inventories, as well as intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Also excluded are integration, transaction, and certain other costs associated with business acquisitions and divestitures.

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 5 to the consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Certain Other Items

These items are adjusted for after evaluating them on an individual basis considering their quantitative and qualitative aspects. Typically, these consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 2020 are charges for the acquisitions of VelosBio and OncoImmune, charges related to collaborations, including transactions with Seagen (see Note 3 to the consolidated financial statements), a charge for the discontinuation of COVID-19 vaccine development programs, and an adjustment to tax benefits recorded in conjunction with the 2015 Cubist Pharmaceuticals, Inc. acquisition. Excluded from non-GAAP income and non-GAAP EPS in 2019 is a charge for the acquisition of Peloton (see Note 3 to the consolidated financial statements), tax charges related to the finalization of U.S. treasury regulations related to the TCJA, a net tax benefit related to the settlement of certain federal income tax matters, and a tax benefit related to the reversal of tax reserves established in connection with the 2014 divestiture of MCC (see Note 15 to the consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2018 is a charge related to the formation of a collaboration with Eisai (see Note 4 to the consolidated financial statements), a charge related to the termination of a collaboration agreement with Samsung for insulin glargine (see Note 3 to the consolidated financial statements), a charge for the acquisition of Viralytics (see Note 3 to the consolidated financial statements), and measurement-period adjustments related to the provisional amounts recorded for the TCJA (see Note 15 to the consolidated financial statements).

Beginning in 2021, the Company will be changing the treatment of certain items for the purposes of its non-GAAP reporting. Historically, Merck's non-GAAP results excluded the amortization of intangible assets recognized in connection with business acquisitions (reflected as part of acquisition and divestiture-related costs) but did not exclude the amortization of intangibles originating from collaborations, asset acquisitions or licensing arrangements. Beginning in 2021, Merck's non-GAAP results will no longer differentiate between the nature of the intangible assets being amortized and will exclude all amortization of intangible assets. Also, beginning in 2021, Merck's non-GAAP results will exclude gains and losses on investments in equity securities. Prior period amounts will be recast to conform to the new presentation.

Research and Development

Research Pipeline

The Company currently has several candidates under regulatory review in the United States and internationally, as well as in late-stage clinical development. A chart reflecting the Company's current research pipeline as of February 22, 2021 and related discussion is set forth in Item 1. "Business — Research and Development" above.

Acquired In-Process Research and Development

In connection with business acquisitions, the Company has recorded the fair value of in-process research projects which, at the time of acquisition, had not yet reached technological feasibility. At December 31, 2020, the balance of IPR&D was $3.2 billion (see Note 8 to the consolidated financial statements).

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty. Significant delays in the approval process, or the Company's failure to obtain approval at all, would delay or prevent the Company from realizing revenues from these products. Additionally, if certain of the IPR&D programs fail or are abandoned during development, then the Company will not realize the future cash flows it has estimated and recorded as IPR&D as of the acquisition date. If such circumstances were to occur, the Company's future operating results could be adversely affected and the Company may recognize impairment charges and such charges could be material.

In 2020, 2019, and 2018 the Company recorded IPR&D impairment charges within *Research and development* expenses of $90 million, $172 million and $152 million, respectively (see Note 8 to the consolidated financial statements).

Additional research and development will be required before any of the remaining programs reach technological feasibility. The costs to complete the research projects will depend on whether the projects are brought to their final stages of development and are ultimately submitted to the FDA or other regulatory agencies for approval.

Acquisitions, Research Collaborations and License Agreements

Merck continues to remain focused on pursuing opportunities that have the potential to drive both near- and long-term growth. Certain recent transactions are summarized below; additional details are included in Note 3 to the consolidated financial statements. Merck is actively monitoring the landscape for growth opportunities that meet the Company's strategic criteria.

In January 2020, Merck acquired ArQule, a publicly traded biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of patients with cancer and other diseases for $2.7 billion. ArQule's lead investigational candidate, MK-1026 (formerly ARQ 531), is a novel, oral Bruton's tyrosine kinase (BTK) inhibitor currently being evaluated for the treatment of B-cell malignancies. The transaction was accounted for as an acquisition of a business. The Company recorded IPR&D of $2.3 billion (related to MK-1026), goodwill of $512 million and other net liabilities of $102 million.

In July 2020, Merck and Ridgeback Bio, a closely held biotechnology company, closed a collaboration agreement to develop molnupiravir (MK-4482, also known as EIDD-2801), an orally available antiviral candidate in clinical development for the treatment of patients with COVID-19. Merck gained exclusive worldwide rights to develop and commercialize molnupiravir and related molecules. Under the terms of the agreement, Ridgeback Bio received an upfront payment and also is eligible to receive future contingent payments dependent upon the achievement of certain developmental and regulatory approval milestones, as well as a share of the net profits of molnupiravir and related molecules, if approved. Molnupiravir is currently being evaluated in Phase 2/3 clinical trials in both the hospital and outpatient settings. The primary completion date for the Phase 2/3 studies is June 2021. The Company anticipates interim efficacy data in the first quarter of 2021.

In September 2020, Merck and Seagen announced an oncology collaboration to globally develop and commercialize Seagen's ladiratuzumab vedotin (MK-6440), an investigational antibody-drug conjugate targeting LIV-1, which is currently in Phase 2 clinical trials for breast cancer and other solid tumors. Under the terms of the agreement, Merck made an upfront payment of $600 million and a $1.0 billion equity investment in 5 million shares of Seagen common stock at a price of $200 per share. Merck recorded $616 million in *Research and development* expenses in 2020 related to this transaction. Seagen is also eligible to receive future contingent milestone payments dependent upon the achievement of certain developmental and sales-based milestones.

Concurrent with the above transaction, Seagen granted Merck an exclusive license to commercialize Tukysa (tucatinib), a small molecule tyrosine kinase inhibitor, for the treatment of HER2-positive cancers, in Asia, the Middle East and Latin America and other regions outside of the United States, Canada and Europe. Under the terms of the agreement, Merck made upfront payments aggregating $210 million, which were recorded as *Research and development* expenses in 2020. Seagen is also eligible to receive future contingent regulatory approval milestones and tiered royalties based on annual sales levels of Tukysa in Merck's territories.

In December 2020, Merck acquired OncoImmune, a privately held, clinical-stage biopharmaceutical company, for an upfront payment of $423 million. In addition, OncoImmune shareholders will be eligible to receive future contingent regulatory approval milestone payments and tiered royalties. OncoImmune's lead therapeutic candidate MK-7110 (also known as CD24Fc) is being evaluated for the treatment of patients hospitalized with COVID-19. Topline results from a pre-planned interim efficacy analysis from a Phase 3 study of MK-7110 were released in September 2020. Full results from this Phase 3 study, which were consistent with the topline results, were received in February 2021 and will be submitted for publication in the future. The transaction was accounted for as an acquisition of an asset. Under the agreement, prior to the completion of the acquisition, OncoImmune spun-out certain rights and assets unrelated to the MK-7110 program to a new entity owned by the existing shareholders of OncoImmune. In connection with the closing of the acquisition, Merck invested $50 million for a 20% ownership interest in the new entity, which was valued at $33 million resulting in a $17 million premium. Merck also recognized other net liabilities of $22 million. The Company recorded *Research and development* expenses of $462 million in 2020 related to this transaction.

In December 2020, Merck announced it had entered into an agreement with the U.S. Government to support the development, manufacture and initial distribution of MK-7110 upon approval or Emergency Use Authorization (EUA) from the FDA by June 30, 2021. Under the agreement, Merck was to receive up to approximately $356 million for manufacturing and supply of approximately 60,000-100,000 doses of MK-7110 to the U.S. government by June 30, 2021 to help meet the government's pandemic response goals. Following the execution of this agreement, Merck received feedback from the FDA that additional data, beyond the study conducted by OncoImmune, would be needed to support a potential EUA application. Based on this FDA feedback, Merck no longer expects to supply the U.S. government with MK-7110 in the first half of 2021. Merck is actively working with FDA to address the agency's comments.

In December 2020, Merck acquired VelosBio, a privately held clinical-stage biopharmaceutical company, for $2.8 billion. VelosBio's lead investigational candidate is MK-2140 (formerly known as VLS-101), an antibody-drug conjugate targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1) that is currently being evaluated for the treatment of patients with hematologic malignancies and solid tumors. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $180 million (primarily cash) and *Research and development* expenses of $2.7 billion in 2020 related to the transaction.

In February 2021, Merck and Pandion Therapeutics, Inc. (Pandion) entered into a definitive agreement under which Merck will acquire Pandion, a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases, for $60 per share in cash representing an approximate total equity value of $1.85 billion. Pandion is advancing a pipeline of precision immune modulators targeting critical immune control nodes. Under the terms of the acquisition agreement, Merck, through a subsidiary, will initiate a tender offer to acquire all outstanding shares of Pandion. The closing of the tender offer is subject to certain conditions, including the tender of shares representing at least a majority of the total number of Pandion's shares of fully-diluted common stock, the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. The transaction is expected to close in the first half of 2021.

Capital Expenditures

Capital expenditures were $4.7 billion in 2020, $3.5 billion in 2019 and $2.6 billion in 2018. Expenditures in the United States were $2.7 billion in 2020, $1.9 billion in 2019 and $1.5 billion in 2018. The increased capital expenditures in 2020 and 2019 reflect investment in new capital projects focused primarily on increasing manufacturing capacity for Merck's key products. The increased capital expenditures in 2020 also reflect the purchase of a manufacturing facility in Dunboyne, Ireland to support upcoming product launches (see Note 3 to the consolidated financial statements). The Company plans to invest more than $20 billion in new capital projects from 2020-2024.

Depreciation expense was $1.7 billion in 2020, $1.7 billion in 2019 and $1.4 billion in 2018, of which $1.2 billion in 2020, $1.2 billion in 2019 and $1.0 billion in 2018, related to locations in the United States. Total depreciation expense in 2020 and 2019 included accelerated depreciation of $268 million and $233 million, respectively, associated with restructuring activities (see Note 5 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

Merck's strong financial profile enables it to fund research and development, focus on external alliances, support in-line products and maximize upcoming launches while providing significant cash returns to shareholders.

Selected Data

($ in millions)	**2020**	2019	2018
Working capital	**$ 437**	$ 5,263	$ 3,669
Total debt to total liabilities and equity	**34.7 %**	31.2 %	30.4 %
Cash provided by operations to total debt	**0.3:1**	0.5:1	0.4:1

The decline in working capital in 2020 compared with 2019 is primarily related to increased short-term debt supporting the funding of business development activities and capital expenditures.

Cash provided by operating activities was $10.3 billion in 2020 compared with $13.4 billion in 2019, reflecting higher payments related to collaborations which were $2.9 billion in 2020 compared with $805 million in 2019. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

Cash used in investing activities was $9.4 billion in 2020 compared with $2.6 billion in 2019. The increase was driven primarily by lower proceeds from the sales of securities and other investments, higher use of cash for acquisitions and higher capital expenditures, partially offset by lower purchases of securities and other investments.

Cash used in financing activities was $2.8 billion in 2020 compared with $8.9 billion in 2019. The lower use of cash in financing activities was driven primarily by a net increase in short-term borrowings in 2020 compared with a net decrease in short-term borrowing in 2019, as well as lower purchases of treasury stock, partially offset by higher payments on debt (see below), lower proceeds from the issuance of debt (see below), higher dividends paid to shareholders and lower proceeds from the exercise of stock options.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable (see Note 6 to the consolidated financial statements). The Company factored $2.3 billion and $2.7 billion of accounts receivable in the fourth quarter of 2020 and 2019, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. At December 31, 2020 and 2019 the Company had collected $102 million and $256 million, respectively, on behalf of the financial institutions, which was remitted to them in January 2021 and 2020, respectively. The net cash flows from these collections are reported as financing activities in the Consolidated Statement of Cash Flows.

The Company's contractual obligations as of December 31, 2020 are as follows:

Payments Due by Period

($ in millions)	Total	2021	2022—2023	2024—2025	Thereafter
Purchase obligations [1]	$ 3,458	$ 977	$ 1,232	$ 668	$ 581
Loans payable and current portion of long-term debt	6,432	6,432	—	—	—
Long-term debt	25,437	—	4,000	3,863	17,574
Interest related to debt obligations	10,779	759	1,431	1,254	7,335
Unrecognized tax benefits [2]	305	305	—	—	—
Transition tax related to the enactment of the TCJA [3]	3,006	390	736	1,880	—
Milestone payments related to collaborations [4]	200	200	—	—	—
Leases [5]	1,778	335	521	342	580
	$ 51,395	$ 9,398	$ 7,920	$ 8,007	$ 26,070

[1] *Includes future inventory purchases the Company has committed to in connection with certain divestitures.*

[2] *As of December 31, 2020, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, including interest and penalties, of $1.8 billion, including $305 million reflected as a current liability. Due to the high degree of uncertainty regarding the timing of future cash outflows of liabilities for unrecognized tax benefits beyond one year, a reasonable estimate of the period of cash settlement for years beyond 2021 cannot be made.*

[3] *In connection with the enactment of the TCJA, the Company is required to pay a one-time transition tax, which the Company has elected to pay over a period of eight years through 2025 as permitted under the TCJA (see Note 15 to the consolidated financial statements).*

[4] *Reflects payments under collaborative agreements for sales-based milestones that were achieved in 2020 (and therefore deemed to be contractual obligations) but not paid until 2021 (see Note 4 to the consolidated financial statements).*

[5] *Amounts exclude reasonably certain lease renewals that have not yet been executed (see Note 9 to the consolidated financial statements).*

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services including minimum inventory contracts, research and development and advertising. Amounts do not include contingent milestone payments related to collaborative arrangements or acquisitions as they are not considered contractual obligations until the successful achievement of developmental, regulatory approval or commercial milestones. At December 31, 2020, the Company has recognized liabilities for contingent sales-based milestone payments related to collaborations with AstraZeneca and Eisai where payment remains subject to the achievement of the related sales milestone aggregating $1.0 billion (see Note 4 to the consolidated financial statements). Excluded from research and development obligations are potential future funding commitments of up to approximately $52 million for investments in research venture capital funds. Loans payable and current portion of long-term debt reflects $73 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2021 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing approximately $300 million to its U.S. pension plans, $170 million to its international pension plans and $35 million to its other postretirement benefit plans during 2021.

In June 2020, the Company issued $4.5 billion principal amount of senior unsecured notes consisting of $1.0 billion of 0.75% notes due 2026, $1.25 billion of 1.45% notes due 2030, $1.0 billion of 2.35% notes due 2040 and $1.25 billion of 2.45% notes due 2050. Merck used the net proceeds from the offering for general corporate purposes, including without limitation the repayment of outstanding commercial paper borrowings and other indebtedness with upcoming maturities.

In March 2019, the Company issued $5.0 billion principal amount of senior unsecured notes consisting of $750 million of 2.90% notes due 2024, $1.75 billion of 3.40% notes due 2029, $1.0 billion of 3.90% notes due 2039, and $1.5 billion of 4.00% notes due 2049. The Company used the net proceeds from the offering for general corporate purposes, including the repayment of outstanding commercial paper borrowings.

The Company has a $6.0 billion credit facility that matures in June 2024. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

In March 2018, the Company filed a securities registration statement with the U.S. Securities and Exchange Commission (SEC) under the automatic shelf registration process available to "well-known seasoned issuers" which is effective for three years.

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

The Company continues to maintain a conservative financial profile. The Company places its cash and investments in instruments that meet high credit quality standards, as specified in its investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issuer. The Company does not participate in any off-balance sheet arrangements involving unconsolidated subsidiaries that provide financing or potentially expose the Company to unrecorded financial obligations.

In November 2020, Merck's Board of Directors declared a quarterly dividend of $0.65 per share on the Company's outstanding common stock that was paid in January 2021. In January 2021, the Board of Directors declared a quarterly dividend of $0.65 per share on the Company's common stock for the second quarter of 2021 payable in April 2021.

In October 2018, Merck's Board of Directors authorized purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions, on or off an exchange, or in privately negotiated transactions. The Company spent $1.3 billion to purchase 16 million shares of its common stock for its treasury during 2020 under this program. In March 2020, the Company temporarily suspended its share repurchase program. As of December 31, 2020, the Company's remaining share repurchase authorization was $5.9 billion. The Company purchased $4.8 billion and $9.1 billion of its common stock during 2019 and 2018, respectively, under authorized share repurchase programs.

In 2018, the Company entered into accelerated share repurchase (ASR) agreements with two third-party financial institutions (the Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers in 2018, which were funded with existing cash and investments, as well as short-term borrowings. Upon settlement of the ASR agreements in 2019, Merck received an additional 7.7 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount, bringing the total shares received by Merck under this program to 64.4 million.

Financial Instruments Market Risk Disclosures

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives of the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management, and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by changes in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro, Japanese yen and Chinese renminbi. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *Other Comprehensive Income (Loss) (OCI)*, depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the unrealized gains or losses on these contracts are recorded in *Accumulated Other Comprehensive Income (Loss) (AOCI)* and reclassified into *Sales* when the hedged anticipated revenue is recognized. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

Because Merck principally sells foreign currency in its revenue hedging program, a uniform weakening of the U.S. dollar would yield the largest overall potential loss in the market value of these hedge instruments. The market value of Merck's hedges would have declined by an estimated $593 million and $456 million at December 31, 2020 and 2019, respectively, from a uniform 10% weakening of the U.S. dollar. The market value was determined using a foreign exchange option pricing model and holding all factors except exchange rates constant. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

A sensitivity analysis to changes in the value of the U.S. dollar on foreign currency denominated derivatives, investments and monetary assets and liabilities indicated that if the U.S. dollar uniformly weakened by 10% against all currency exposures of the Company at December 31, 2020 and 2019, *Income before taxes* would have declined by approximately $99 million and $110 million in 2020 and 2019, respectively. Because the Company was in a net short (payable) position relative to its major foreign currencies after consideration of forward contracts, a uniform weakening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. This measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The economy of Argentina was determined to be hyperinflationary in 2018; consequently, in accordance with U.S. GAAP, the Company began remeasuring its monetary assets and liabilities for those operations in earnings. The impact to the Company's results was immaterial.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *OCI*, and remain in *AOCI* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

At December 31, 2020, the Company was a party to 14 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

($ in millions)	2020		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
3.875% notes due 2021 [(1)]	$ 1,150	5	$ 1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

[(1)] These interest rate swaps matured in January 2021.

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company's investment portfolio includes cash equivalents and short-term investments, the market values of which are not significantly affected by changes in interest rates. The market value of the Company's medium- to long-term fixed-rate investments is modestly affected by changes in U.S. interest rates. Changes in medium- to long-term U.S. interest rates have a more significant impact on the market value of the Company's fixed-rate borrowings, which generally have longer maturities. A sensitivity analysis to measure potential changes in the market value of Merck's investments and debt from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2020 and 2019 would have positively affected the net aggregate market value of these instruments by $2.6 billion and $2.0 billion, respectively. A one percentage point decrease at December 31, 2020 and 2019 would have negatively affected the net aggregate market value by $3.1 billion and $2.2 billion, respectively. The fair value of Merck's debt was determined using pricing models reflecting one percentage point shifts in the appropriate yield curves. The fair values of Merck's investments were determined using a combination of pricing and duration models.

Critical Accounting Estimates

The Company's consolidated financial statements are prepared in conformity with GAAP and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities (primarily IPR&D, other intangible assets and contingent consideration), as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities, accruals for contingent sales-based milestone payments and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates. Application of the following accounting policies result in accounting estimates having the potential for the most significant impact on the financial statements.

Acquisitions and Dispositions

To determine whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses, the Company makes certain judgments, which include assessment of the inputs, processes, and outputs associated with the acquired set of activities. If the Company determines that substantially all of the fair value of gross assets included in a transaction is concentrated in a single asset (or a group of similar assets), the assets would not represent a business. To be considered a business, the assets in a transaction need to include an input and a substantive process that together significantly contribute to the ability to create outputs.

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. The fair values of intangible assets, including acquired IPR&D, are determined utilizing information available near the acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. Certain of the Company's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period until the contingency is resolved, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings. Changes in any of the inputs may result in a significantly different fair value adjustment.

The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect the Company's results of operations.

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an income approach through which fair value is estimated based on each asset's discounted projected net cash flows. The Company's estimates of market participant net cash flows consider historical and projected pricing, margins and expense levels; the performance of competing products where applicable: relevant industry and therapeutic area growth drivers and factors; current and expected trends in technology and product life cycles; the time and investment that will be required to develop products and technologies; the ability to obtain marketing and regulatory approvals; the ability to manufacture and commercialize the products; the extent and timing of potential new product introductions by the Company's competitors; and the life of each asset's underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to IPR&D are also determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate.

If the Company determines the transaction will not be accounted for as an acquisition of a business, the transaction will be accounted for as an asset acquisition rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired IPR&D with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date. In these instances, product development milestones are recognized upon achievement and sales-based milestones are recognized when the milestone is deemed probable by the Company of being achieved.

Revenue Recognition

Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. Merck acts as the principal in substantially all of its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts related to the Pharmaceutical and Animal Health segments have a single performance obligation - the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation.

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. For certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts.

In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

The U.S. provision for aggregate customer discounts covers chargebacks and rebates. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued.

The Company continually monitors its provision for aggregate customer discounts. There were no material adjustments to estimates associated with the aggregate customer discount provision in 2020, 2019 or 2018.

Summarized information about changes in the aggregate customer discount accrual related to U.S. sales is as follows:

($ in millions)	**2020**	2019
Balance January 1	**$ 2,436**	$ 2,630
Current provision	**13,144**	11,999
Adjustments to prior years	**(16)**	(230)
Payments	**(12,454)**	(11,963)
Balance December 31	**$ 3,110**	$ 2,436

Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates as current liabilities. The accrued balances relative to these provisions included in *Accounts receivable* and *Accrued and other current liabilities* were $249 million and $2.9 billion, respectively, at December 31, 2020 and were $233 million and $2.2 billion, respectively, at December 31, 2019.

Outside of the United States, variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and the Company's specific payback obligation. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others. The product returns provision for U.S. pharmaceutical sales as a percentage of U.S. net pharmaceutical sales was 0.6% in 2020, 1.1% in 2019 and 1.6% in 2018. Outside of the United States, returns are only allowed in certain countries on a limited basis.

Merck's payment terms for U.S. pharmaceutical customers are typically 36 days from receipt of invoice and for U.S. animal health customers are typically 30 days from receipt of invoice; however, certain products, including *Keytruda*, have longer payment terms, some of which are up to 90 days. Outside of the United States, payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

Through its distribution programs with U.S. wholesalers, the Company encourages wholesalers to align purchases with underlying demand and maintain inventories below specified levels. The terms of the programs allow the wholesalers to earn fees upon providing visibility into their inventory levels, as well as by achieving certain performance parameters such as inventory management, customer service levels, reducing shortage claims and reducing product returns. Information provided through the wholesaler distribution programs includes items such as sales trends, inventory on-hand, on-order quantity and product returns.

Wholesalers generally provide only the above-mentioned data to the Company, as there is no regulatory requirement to report lot level information to manufacturers, which is the level of information needed to determine the remaining shelf life and original sale date of inventory. Given current wholesaler inventory levels, which are generally less than a month, the Company believes that collection of order lot information across all wholesale customers would have limited use in estimating sales discounts and returns.

Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory does not begin until the related product candidates are in Phase 3 clinical trials and are considered to have a high probability of regulatory approval. The Company monitors the status of each respective product within the regulatory approval process; however, the Company generally does not disclose specific timing for regulatory approval. If the Company is aware of any specific risks or contingencies other than the normal regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized. Expiry dates of the inventory are affected by the stage of completion. The Company manages the levels of inventory at each stage to optimize the shelf life of the inventory in relation to anticipated market demand in order to avoid product expiry issues. For inventories that are capitalized, anticipated future sales and shelf lives support the realization of the inventory value as the inventory shelf life is sufficient to meet initial product launch requirements. Inventories produced in preparation for product launches capitalized at December 31, 2020 and 2019 were $279 million and $168 million, respectively.

Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property and commercial litigation, as well as certain additional matters including governmental and environmental matters (see Note 10 to the consolidated financial statements). The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable.

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2020 and 2019 of approximately $250 million and $240 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. When a legitimate claim for contribution is asserted, a liability is initially accrued based upon the estimated transaction costs to manage the site. Accruals are adjusted as site investigations, feasibility studies and related cost assessments of remedial techniques are completed, and as the extent to which other potentially responsible parties who may be jointly and severally liable can be expected to contribute is determined.

The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites and takes an active role in identifying and accruing for these costs. In the past, Merck performed a worldwide survey to assess all sites for potential contamination resulting from past industrial activities. Where assessment indicated that physical investigation was warranted, such investigation was performed, providing a better evaluation of the need for remedial action. Where such need was identified, remedial action was then initiated. As definitive information became available during the course of investigations and/or remedial efforts at each site, estimates were refined and accruals were established or adjusted accordingly. These estimates and related accruals continue to be refined annually.

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. Expenditures for remediation and environmental liabilities were $11 million in 2020 and are estimated at $46 million in the aggregate for the years 2021 through 2025. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million at both December 31, 2020 and 2019. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately $65 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

Share-Based Compensation

The Company expenses all share-based payment awards to employees, including grants of stock options, over the requisite service period based on the grant date fair value of the awards. The Company determines the fair value of certain share-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. Total pretax share-based compensation expense was $475 million in 2020, $417 million in 2019 and $348 million in 2018. At December 31, 2020, there was $678 million of total pretax unrecognized compensation expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be recognized over a weighted-average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

Pensions and Other Postretirement Benefit Plans

Net periodic benefit cost for pension plans totaled $454 million in 2020, $137 million in 2019 and $195 million in 2018. Net periodic benefit (credit) for other postretirement benefit plans was $(59) million in 2020, $(49) million in 2019 and $(45) million in 2018. Pension and other postretirement benefit plan information for financial reporting purposes is calculated using actuarial assumptions including a discount rate for plan benefit obligations and an expected rate of return on plan assets. The changes in net periodic benefit cost year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 2.10% to 2.80% at December 31, 2020, compared with a range of 3.20% to 3.50% at December 31, 2019.

The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid. In developing the expected rate of return, the Company considers long-term compound annualized returns of historical market data, current market conditions and actual returns on the Company's plan assets. Using this reference information, the Company develops forward-looking return expectations for each asset category and a weighted-average expected long-term rate of return for a target portfolio allocated across these investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2021, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 6.50% to 6.70%, compared to a range of 7.00% to 7.30% in 2020.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 45% in U.S. equities, 15% to 30% in international equities, 35% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio,.which approximates 11%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For non-U.S. pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Actuarial assumptions are based upon management's best estimates and judgment. A reasonably possible change of plus (minus) 25 basis points in the discount rate assumption, with other assumptions held constant, would have had an estimated $80 million favorable (unfavorable) impact on the Company's net periodic benefit cost in 2020. A reasonably possible change of plus (minus) 25 basis points in the expected rate of return assumption, with other assumptions held constant, would have had an estimated $40 million favorable (unfavorable) impact on Merck's net periodic benefit cost in 2020. Required funding obligations for 2021 relating to the Company's pension and other postretirement benefit plans are not expected to be material. The preceding hypothetical changes in the discount rate and expected rate of return assumptions would not impact the Company's funding requirements.

Net loss amounts, which primarily reflect differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions, are recorded as a component of *AOCI*. Expected returns for pension plans are based on a calculated market-related value of assets. Net loss amounts in *AOCI* in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees.

Restructuring Costs

Restructuring costs have been recorded in connection with restructuring programs designed to streamline the Company's cost structure. As a result, the Company has made estimates and judgments regarding its future plans, including future termination benefits and other exit costs to be incurred when the restructuring actions take place. When accruing termination costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. In connection with these actions, management also assesses the recoverability of long-lived assets employed in the business. In certain instances, asset lives have been shortened based on changes in the expected useful lives of the affected assets. Severance and other related costs are reflected within *Restructuring costs*. Asset-related charges are reflected within *Cost of sales*, *Selling, general and administrative* expenses and *Research and development* expenses depending upon the nature of the asset.

Impairments of Long-Lived Assets

The Company assesses changes in economic, regulatory and legal conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and other intangible assets.

The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its long-lived assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows approach.

Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. Some of the factors considered in the assessment include general macroeconomic conditions, conditions specific to the industry and market, cost factors which could have a significant effect on earnings or cash flows, the overall financial performance of the reporting unit, and whether there have been sustained declines in the Company's share price. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

Other acquired intangible assets (excluding IPR&D) are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. When events or circumstances warrant a review, the Company will assess recoverability from future operations using pretax undiscounted cash flows derived from the lowest appropriate asset groupings. Impairments are recognized in operating results to the extent that the carrying value of the intangible asset exceeds its fair value, which is determined based on the net present value of estimated future cash flows.

IPR&D that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. The Company evaluates IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by performing a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value. For impairment testing purposes, the Company may combine separately recorded IPR&D intangible assets into one unit of account based on the relevant facts and circumstances. Generally, the Company will combine IPR&D intangible assets for testing purposes if they operate as a single asset and are essentially inseparable. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

The judgments made in evaluating impairment of long-lived intangibles can materially affect the Company's results of operations.

Impairments of Investments

The Company reviews its investments in marketable debt securities for impairments based on the determination of whether the decline in market value of the investment below the carrying value is other-than-temporary. The Company considers available evidence in evaluating potential impairments of its investments in marketable debt securities, including the duration and extent to which fair value is less than cost. Changes in fair value that are considered temporary are reported net of tax in *OCI*. An other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in *Other (income) expense, net*, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*.

Investments in publicly traded equity securities are reported at fair value determined using quoted market prices in active markets for identical assets or quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data. Changes in fair value are included in *Other (income) expense, net*. Investments in equity securities without readily determinable fair values are recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, minus impairments. Such adjustments are recognized in *Other (income) expense, net*. Realized gains and losses for equity securities are included in *Other (income) expense, net*.

Taxes on Income

The Company's effective tax rate is based on pretax income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates. An estimated effective tax rate for a year is applied to the Company's quarterly operating results. In the event that there is a significant unusual or one-time item recognized, or expected to be recognized, in the Company's quarterly operating results, the tax attributable to that item would be separately calculated and recorded at the same time as the unusual or one-time item. The Company considers the resolution of prior year tax matters to be such items. Significant judgment is required in determining the Company's tax provision and in evaluating its tax positions. The recognition and measurement of a tax position is based on management's best judgment given the facts, circumstances and information available at the reporting date. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. If the more likely than not threshold is not met in the period for which a tax position is taken, the Company may subsequently recognize the benefit of that tax position if the tax matter is effectively settled, the statute of limitations expires, or if the more likely than not threshold is met in a subsequent period (see Note 15 to the consolidated financial statements).

Tax regulations require items to be included in the tax return at different times than the items are reflected in the financial statements. Timing differences create deferred tax assets and liabilities. Deferred tax assets generally represent items that can be used as a tax deduction or credit in the tax return in future years for which the Company has already recorded the tax benefit in the financial statements. The Company establishes valuation allowances for its deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities generally represent tax expense recognized in the financial statements for which payment has been deferred or expense for which the Company has already taken a deduction on the tax return, but has not yet recognized as expense in the financial statements.

Recently Issued Accounting Standards

For a discussion of recently issued accounting standards, see Note 2 to the consolidated financial statements.

Cautionary Factors That May Affect Future Results

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product approvals, product potential, development programs and include statements related to the expected impact of the COVID-19 pandemic. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company's filings with the Securities and Exchange Commission, especially on this Form 10-K and Forms 10-Q and 8-K. In Item 1A. "Risk Factors" of this annual report on Form 10-K the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

The information required by this Item is incorporated by reference to the discussion under "Financial Instruments Market Risk Disclosures" in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Item 8. Financial Statements and Supplementary Data.

(a) Financial Statements

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2020 and 2019, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2020, the notes to consolidated financial statements, and the report dated February 25, 2021 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

Consolidated Statement of Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	2020	2019	2018
Sales	$ 47,994	$ 46,840	$ 42,294
Costs, Expenses and Other			
Cost of sales	15,485	14,112	13,509
Selling, general and administrative	10,468	10,615	10,102
Research and development	13,558	9,872	9,752
Restructuring costs	578	638	632
Other (income) expense, net	(886)	139	(402)
	39,203	35,376	33,593
Income Before Taxes	8,791	11,464	8,701
Taxes on Income	1,709	1,687	2,508
Net Income	7,082	9,777	6,193
Less: Net Income (Loss) Attributable to Noncontrolling Interests	15	(66)	(27)
Net Income Attributable to Merck & Co., Inc.	$ 7,067	$ 9,843	$ 6,220
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$ 2.79	$ 3.84	$ 2.34
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$ 2.78	$ 3.81	$ 2.32

Consolidated Statement of Comprehensive Income
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2020	2019	2018
Net Income Attributable to Merck & Co., Inc.	$ 7,067	$ 9,843	$ 6,220
Other Comprehensive Loss Net of Taxes:			
Net unrealized (loss) gain on derivatives, net of reclassifications	(297)	(135)	297
Net unrealized (loss) gain on investments, net of reclassifications	(18)	96	(10)
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(279)	(705)	(425)
Cumulative translation adjustment	153	96	(223)
	(441)	(648)	(361)
Comprehensive Income Attributable to Merck & Co., Inc.	$ 6,626	$ 9,195	$ 5,859

The accompanying notes are an integral part of these consolidated financial statements.

Consolidated Balance Sheet
Merck & Co., Inc. and Subsidiaries
December 31
($ in millions except per share amounts)

	2020	2019
Assets		
Current Assets		
Cash and cash equivalents	$ 8,062	$ 9,676
Short-term investments	—	774
Accounts receivable (net of allowance for doubtful accounts of $85 in 2020 and $86 in 2019)	7,851	6,778
Inventories (excludes inventories of $2,197 in 2020 and $1,480 in 2019 classified in Other assets - see Note 7)	6,310	5,978
Other current assets	5,541	4,277
Total current assets	27,764	27,483
Investments	785	1,469
Property, Plant and Equipment (at cost)		
Land	350	343
Buildings	12,645	11,989
Machinery, equipment and office furnishings	16,649	15,394
Construction in progress	7,324	5,013
	36,968	32,739
Less: accumulated depreciation	18,982	17,686
	17,986	15,053
Goodwill	20,238	19,425
Other Intangibles, Net	14,604	14,196
Other Assets	10,211	6,771
	$ 91,588	$ 84,397
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$ 6,431	$ 3,610
Trade accounts payable	4,594	3,738
Accrued and other current liabilities	13,053	12,549
Income taxes payable	1,575	736
Dividends payable	1,674	1,587
Total current liabilities	27,327	22,220
Long-Term Debt	25,360	22,736
Deferred Income Taxes	1,015	1,470
Other Noncurrent Liabilities	12,482	11,970
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2020 and 2019	1,788	1,788
Other paid-in capital	39,588	39,660
Retained earnings	47,362	46,602
Accumulated other comprehensive loss	(6,634)	(6,193)
	82,104	81,857
Less treasury stock, at cost: 1,046,877,695 shares in 2020 and 1,038,087,496 shares in 2019	56,787	55,950
Total Merck & Co., Inc. stockholders' equity	25,317	25,907
Noncontrolling Interests	87	94
Total equity	25,404	26,001
	$ 91,588	$ 84,397

The accompanying notes are an integral part of this consolidated financial statement.

Consolidated Statement of Equity
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	Common Stock	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock	Non-controlling Interests	Total
Balance January 1, 2018	$1,788	$ 39,902	$ 41,350	$ (4,910)	$ (43,794)	$ 233	$ 34,569
Net income attributable to Merck & Co., Inc.	—	—	6,220	—	—	—	6,220
Adoption of new accounting standards	—	—	322	(274)	—	—	48
Other comprehensive loss, net of taxes	—	—	—	(361)	—	—	(361)
Cash dividends declared on common stock ($1.99 per share)	—	—	(5,313)	—	—	—	(5,313)
Treasury stock shares purchased	—	(1,000)	—	—	(8,091)	—	(9,091)
Net loss attributable to noncontrolling interests	—	—	—	—	—	(27)	(27)
Distributions attributable to noncontrolling interests	—	—	—	—	—	(25)	(25)
Share-based compensation plans and other	—	(94)	—	—	956	—	862
Balance December 31, 2018	1,788	38,808	42,579	(5,545)	(50,929)	181	26,882
Net income attributable to Merck & Co., Inc.	—	—	9,843	—	—	—	9,843
Other comprehensive loss, net of taxes	—	—	—	(648)	—	—	(648)
Cash dividends declared on common stock ($2.26 per share)	—	—	(5,820)	—	—	—	(5,820)
Treasury stock shares purchased	—	1,000	—	—	(5,780)	—	(4,780)
Net loss attributable to noncontrolling interests	—	—	—	—	—	(66)	(66)
Distributions attributable to noncontrolling interests	—	—	—	—	—	(21)	(21)
Share-based compensation plans and other	—	(148)	—	—	759	—	611
Balance December 31, 2019	1,788	39,660	46,602	(6,193)	(55,950)	94	26,001
Net income attributable to Merck & Co., Inc.	—	—	7,067	—	—	—	7,067
Other comprehensive loss, net of taxes	—	—	—	(441)	—	—	(441)
Cash dividends declared on common stock ($2.48 per share)	—	—	(6,307)	—	—	—	(6,307)
Treasury stock shares purchased	—	—	—	—	(1,281)	—	(1,281)
Net income attributable to noncontrolling interests	—	—	—	—	—	15	15
Distributions attributable to noncontrolling interests	—	—	—	—	—	(22)	(22)
Share-based compensation plans and other	—	(72)	—	—	444	—	372
Balance December 31, 2020	$ 1,788	$ 39,588	$ 47,362	$ (6,634)	$ (56,787)	$ 87	$ 25,404

The accompanying notes are an integral part of this consolidated financial statement.

Consolidated Statement of Cash Flows
Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2020	2019	2018
Cash Flows from Operating Activities			
Net income	$ 7,082	$ 9,777	$ 6,193
Adjustments to reconcile net income to net cash provided by operating activities:			
Amortization	1,899	1,973	3,103
Depreciation	1,726	1,679	1,416
Intangible asset impairment charges	1,718	1,040	296
Charge for the acquisition of VelosBio Inc.	2,660	—	—
Charge for the acquisition of Peloton Therapeutics, Inc.	—	993	—
Charge for future payments related to collaboration license options	—	—	650
Deferred income taxes	(668)	(556)	(509)
Share-based compensation	475	417	348
Other	(49)	184	978
Net changes in assets and liabilities:			
Accounts receivable	(1,002)	294	(418)
Inventories	(855)	(508)	(911)
Trade accounts payable	724	399	230
Accrued and other current liabilities	(1,138)	376	(341)
Income taxes payable	560	(2,359)	827
Noncurrent liabilities	(453)	(237)	(266)
Other	(2,426)	(32)	(674)
Net Cash Provided by Operating Activities	10,253	13,440	10,922
Cash Flows from Investing Activities			
Capital expenditures	(4,684)	(3,473)	(2,615)
Purchase of Seagen Inc. common stock	(1,000)	—	—
Purchases of securities and other investments	(95)	(3,202)	(7,994)
Proceeds from sales of securities and other investments	2,812	8,622	15,252
Acquisition of VelosBio Inc., net of cash acquired	(2,696)	—	—
Acquisition of ArQule, Inc., net of cash acquired	(2,545)	—	—
Acquisition of Antelliq Corporation, net of cash acquired	—	(3,620)	—
Acquisition of Peloton Therapeutics, Inc., net of cash acquired	—	(1,040)	—
Other acquisitions, net of cash acquired	(1,365)	(294)	(431)
Other	130	378	102
Net Cash (Used in) Provided by Investing Activities	(9,443)	(2,629)	4,314
Cash Flows from Financing Activities			
Net change in short-term borrowings	2,549	(3,710)	5,124
Payments on debt	(1,957)	—	(4,287)
Proceeds from issuance of debt	4,419	4,958	—
Purchases of treasury stock	(1,281)	(4,780)	(9,091)
Dividends paid to stockholders	(6,215)	(5,695)	(5,172)
Proceeds from exercise of stock options	89	361	591
Other	(436)	5	(325)
Net Cash Used in Financing Activities	(2,832)	(8,861)	(13,160)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	253	17	(205)
Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash	(1,769)	1,967	1,871
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes $258 of restricted cash at January 1, 2020 included in Other Assets - see Note 6)	9,934	7,967	6,096
Cash, Cash Equivalents and Restricted Cash at End of Year (includes $103 of restricted cash at December 31, 2020 included in Other Assets - see Note 6)	$ 8,165	$ 9,934	$ 7,967

The accompanying notes are an integral part of this consolidated financial statement.

Notes to Consolidated Financial Statements
Merck & Co., Inc. and Subsidiaries
($ in millions except per share amounts)

1. Nature of Operations

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment in the first quarter of 2020.

The Company previously had an Alliances segment that primarily included activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Planned Spin-Off of Women's Health, Biosimilars and Established Brands into a New Company

In February 2020, Merck announced its intention to spin-off products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The established brands included in the transaction consist of dermatology, non-opioid pain management, respiratory, and select cardiovascular products including *Zetia* and *Vytorin*, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. Organon will have development capabilities initially focused on late-stage development and life-cycle management and is expected over time to develop research capabilities in selected therapeutic areas. The spin-off is expected to be completed late in the second quarter of 2021, subject to market and certain other conditions. Subsequent to the spin-off, the historical results of the women's health, biosimilars and established brands businesses will be reflected as discontinued operations in the Company's consolidated financial statements.

2. Summary of Accounting Policies

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. Intercompany balances and transactions are eliminated. Controlling interest is determined by majority ownership interest and the absence of substantive third-party participating rights or, in the case of variable interest entities, by majority exposure to expected losses, residual returns or both. For those consolidated subsidiaries where Merck ownership is less than 100%, the outside shareholders' interests are shown as *Noncontrolling interests* in equity. Investments in affiliates over which the Company has significant influence but not a controlling interest, such as interests in entities owned equally by the Company and a third party that are under shared control, are carried on the equity basis.

Acquisitions — In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded. In an asset acquisition, acquired in-process research and development (IPR&D) with no alternative future use is charged to expense and contingent consideration is not recognized at the acquisition date.

Foreign Currency Translation — The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recorded in the foreign currency translation account, which is included in *Accumulated other comprehensive income (loss)* (*AOCI*) and reflected as a separate component of equity. For those subsidiaries that operate in highly inflationary economies and for those subsidiaries where the U.S. dollar has been determined to be the functional currency, non-monetary foreign currency assets and liabilities are translated using historical rates, while monetary assets and liabilities are translated at current rates, with the U.S. dollar effects of rate changes included in *Other (income) expense, net.*

Cash Equivalents — Cash equivalents are comprised of certain highly liquid investments with original maturities of less than three months.

Inventories — Inventories are valued at the lower of cost or net realizable value. The cost of a substantial majority of U.S. pharmaceutical and vaccine inventories is determined using the last-in, first-out (LIFO) method for both financial reporting and tax purposes. The cost of all other inventories is determined using the first-in, first-out (FIFO) method. Inventories consist of currently marketed products, as well as certain inventories produced in preparation for product launches that are considered to have a high probability of regulatory approval. In evaluating the recoverability of inventories produced in preparation for product launches, the Company considers the likelihood that revenue will be obtained from the future sale of the related inventory together with the status of the product within the regulatory approval process.

Investments — Investments in marketable debt securities classified as available-for-sale are reported at fair value. Fair values of the Company's investments in marketable debt securities are determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Changes in fair value that are considered temporary are reported net of tax in *Other Comprehensive Income* (*OCI*). The Company considers available evidence in evaluating potential impairments of its investments in marketable debt securities, including the duration and extent to which fair value is less than cost. An other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the marketable debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in *Other (income) expense, net*, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*. Realized gains and losses for debt securities are included in *Other (income) expense, net*.

Investments in publicly traded equity securities are reported at fair value determined using quoted market prices in active markets for identical assets or quoted prices for similar assets or other inputs that are observable or can be corroborated by observable market data. Changes in fair value are included in *Other (income) expense, net*. Investments in equity securities without readily determinable fair values are recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, minus impairments. Such adjustments are recognized in *Other (income) expense, net*. Realized gains and losses for equity securities are included in *Other (income) expense, net*.

Revenue Recognition — Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. Merck acts as the principal in substantially all of its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts related to the Pharmaceutical and Animal Health segments have a single performance obligation - the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation.

The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership transfer to the customer and the Company is entitled to payment. The Company recognizes revenue from the sales of vaccines to the Federal government for placement into vaccine stockpiles in accordance with Securities and Exchange Commission (SEC) Interpretation, *Commission Guidance Regarding Accounting for Sales of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*. This interpretation allows companies to recognize revenue for sales of vaccines into U.S. government stockpiles even though these sales might not meet the criteria for revenue recognition under other accounting guidance. For certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided. These service revenues are not material.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is used for prompt pay discounts.

In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

The U.S. provision for aggregate customer discounts covering chargebacks and rebates was $13.1 billion in 2020, $11.8 billion in 2019 and $10.7 billion in 2018. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. The accrued balances relative to the provisions for chargebacks and rebates included in *Accounts receivable* and *Accrued and other current liabilities* were $249 million and $2.9 billion, respectively, at December 31, 2020 and were $233 million and $2.2 billion, respectively, at December 31, 2019.

Outside of the United States, variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and the Company's specific payback obligation. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others. Outside of the United States, returns are only allowed in certain countries on a limited basis.

Merck's payment terms for U.S. pharmaceutical customers are typically 36 days from receipt of invoice and for U.S. animal health customers are typically 30 days from receipt of invoice; however, certain products, including *Keytruda*, have longer payment terms, some of which are up to 90 days. Outside of the United States, payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

See Note 18 for disaggregated revenue disclosures.

Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated tax methods are used. The estimated useful lives primarily range from 25 to 45 years for *Buildings*, and from 3 to 15 years for *Machinery, equipment and office furnishings*. Depreciation expense was $1.7 billion in 2020, $1.7 billion in 2019 and $1.4 billion in 2018.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of $2.0 billion in 2020, $2.1 billion in 2019 and $2.1 billion in 2018.

Software Capitalization — The Company capitalizes certain costs incurred in connection with obtaining or developing internal-use software including external direct costs of material and services, and payroll costs for employees directly involved with the software development. These costs are included in *Property, plant and equipment*. In addition, the Company capitalizes certain costs incurred to implement a cloud computing arrangement that is considered a service agreement, which are included in *Other Assets*. Capitalized software costs are being amortized over periods ranging from 3 to 10 years, with the longer lives generally associated with enterprise-wide projects implemented over multiple years. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

Goodwill — Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. If the carrying value of a reporting unit is greater than its fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill).

Acquired Intangibles — Acquired intangibles include products and product rights, licenses, trade names and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives ranging from 2 to 24 years (see Note 8). The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its acquired intangibles may not be recoverable. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the carrying value of the intangible asset and its fair value, which is determined based on the net present value of estimated future cash flows.

Acquired In-Process Research and Development — IPR&D that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a determination as to the then useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. The Company evaluates IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by performing a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

Contingent Consideration — Certain of the Company's acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of performance milestones, including product development milestones and royalty payments on future product sales. If the transaction is accounted for as an acquisition of a business, the fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability weighted cash flows. Subsequent to the acquisition date, at each reporting period until the contingency is resolved, the contingent consideration liability is remeasured at current fair value with changes (either expense or income) recorded in earnings. Significant events that increase or decrease the probability of achieving development and regulatory milestones or that increase or decrease projected cash flows will result in corresponding increases or decreases in the fair values of the related contingent consideration obligations. If the transaction is accounted for as an acquisition of an asset rather than a business, contingent consideration is not recognized at the acquisition date. In these instances, product development milestones are recognized upon achievement and sales-based milestones are recognized when the milestone is deemed probable by the Company of being achieved.

Research and Development — Research and development is expensed as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Research and development expenses include restructuring costs and IPR&D impairment charges. In addition, research and development expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Research and development expenses also include upfront and milestone payments related to asset acquisitions and licensing transactions involving clinical development programs that have not yet received regulatory approval.

Collaborative Arrangements — Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. When Merck is the principal on sales transactions with third parties, the Company recognizes sales, cost of sales and selling, general and administrative expenses on a gross basis. Profit sharing amounts it pays to its collaborative partners are recorded within *Cost of sales*. When the collaborative partner is the principal on sales transactions with third parties, the Company records profit sharing amounts received from its collaborative partners as alliance revenue (within *Sales*). Alliance revenue is recorded net of cost of sales and includes an adjustment to share commercialization costs between the partners in accordance with the collaboration agreement. The adjustment is determined by comparing the commercialization costs Merck has incurred directly and reported within *Selling, general and administrative* expenses with the costs the collaborative partner has incurred. Research and development costs Merck incurs related to collaborations are recorded within *Research and development* expenses. Cost reimbursements to the collaborative partner or payments received from the collaborative partner to share these costs pursuant to the terms of the collaboration agreements are recorded as increases or decreases to *Research and development* expenses.

In addition, the terms of the collaboration agreements may require the Company to make payments based upon the achievement of certain developmental, regulatory approval or commercial milestones. Upfront and milestone payments payable by Merck to collaborative partners prior to regulatory approval are expensed as incurred and included in *Research and development* expenses. Payments due to collaborative partners upon or subsequent to regulatory approval are capitalized and amortized over the estimated useful life of the corresponding intangible asset to *Cost of sales* provided that future cash flows support the amounts capitalized. Sales-based milestones payable by Merck to collaborative partners are accrued and capitalized, subject to cumulative amortization catch-up, when probable of being achieved. The amortization catch-up is calculated either from the time of the first regulatory approval for indications that were unapproved at the time the collaboration was formed, or from time of the formation of the collaboration for approved products. The related intangible asset that is recognized is amortized to *Cost of sales* over its remaining useful life, subject to impairment testing.

Share-Based Compensation — The Company expenses all share-based payments to employees over the requisite service period based on the grant-date fair value of the awards.

Restructuring Costs — The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. In accordance with existing benefit arrangements, employee termination costs are accrued when the restructuring actions are probable and estimable. When accruing these costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period.

Contingencies and Legal Defense Costs — The Company records accruals for contingencies and legal defense costs expected to be incurred in connection with a loss contingency when it is probable that a liability has been incurred and the amount can be reasonably estimated.

Taxes on Income — Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. The Company recognizes interest and penalties associated with uncertain tax positions as a component of *Taxes on income*. The Company accounts for the tax effects of the tax on global intangible low-taxed income (GILTI) of certain foreign subsidiaries in the income tax provision in the period the tax arises.

Use of Estimates — The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States (GAAP) and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities (primarily IPR&D, other intangible assets and contingent consideration), as well as subsequent fair value measurements. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities, accruals for contingent sales-based milestone payments and other reserves, pension and other postretirement benefit plan assumptions, share-based compensation assumptions, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

Reclassifications — Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

Recently Adopted Accounting Standards — In June 2016, the Financial Accounting Standards Board (FASB) issued new guidance on the accounting for credit losses on financial instruments. The new guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The Company adopted the new guidance effective January 1, 2020. There was no impact to the Company's consolidated financial statements upon adoption.

In November 2018, the FASB issued new guidance for collaborative arrangements intended to reduce diversity in practice by clarifying whether certain transactions between collaborative arrangement participants should be accounted for under revenue recognition guidance (ASC 606). The Company retrospectively adopted the new guidance effective January 1, 2020, which resulted in minor changes to the presentation of information related to the Company's collaborative arrangements (see Note 4 and Note 18).

In December 2019, the FASB issued amended guidance on the accounting and reporting of income taxes. The guidance is intended to simplify the accounting for income taxes by removing exceptions related to certain intraperiod tax allocations and deferred tax liabilities; clarifying guidance primarily related to evaluating the step-up tax basis for goodwill in a business combination; and reflecting enacted changes in tax laws or rates in the annual effective tax rate. The Company adopted the new guidance effective January 1, 2021. There was no impact to the Company's consolidated financial statements upon adoption.

In January 2020, the FASB issued new guidance intended to clarify certain interactions between accounting standards related to equity securities, equity method investments and certain derivatives. The guidance addresses accounting for the transition into and out of the equity method of accounting and measuring certain purchased options and forward contracts to acquire investments. The Company adopted the new guidance effective January 1, 2021. There was no impact to the Company's consolidated financial statements upon adoption.

Recently Issued Accounting Standard Not Yet Adopted — In March 2020, the FASB issued optional guidance to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting and subsequently issued clarifying amendments. The guidance provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate (LIBOR) or another reference rate expected to be discontinued because of reference rate reform. The optional guidance is effective upon issuance and can be applied on a prospective basis at any time between January 1, 2020 through December 31, 2022. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

3. Acquisitions, Divestitures, Research Collaborations and License Agreements

The Company continues to pursue acquisitions and the establishment of external alliances such as research collaborations and licensing agreements to complement its internal research capabilities. These arrangements often include upfront payments, as well as expense reimbursements or payments to the third party, and milestone, royalty or profit share arrangements, contingent upon the occurrence of certain future events linked to the success of the asset in development. The Company also reviews its marketed products and pipeline to examine candidates which may provide more value through out-licensing and, as part of its portfolio assessment process, may also divest certain assets. Pro forma financial information for acquired businesses is not presented if the historical financial results of the acquired entity are not significant when compared with the Company's financial results.

2020 Transactions

In December 2020, Merck acquired OncoImmune, a privately held, clinical-stage biopharmaceutical company, for an upfront payment of $423 million. In addition, OncoImmune shareholders will be eligible to receive up to $255 million of future contingent regulatory approval milestone payments and tiered royalties ranging from 10% to 20%. OncoImmune's lead therapeutic candidate MK-7110 (also known as CD24Fc) is being evaluated for the treatment of patients hospitalized with coronavirus disease 2019 (COVID-19). The transaction was accounted for as an acquisition of an asset. Under the agreement, prior to the completion of the acquisition, OncoImmune spun-out certain rights and assets unrelated to the MK-7110 program to a new entity owned by the existing shareholders of OncoImmune. In connection with the closing of the acquisition, Merck invested $50 million for a 20% ownership interest in the new entity, which was valued at $33 million resulting in a $17 million premium. Merck also recognized other net liabilities of $22 million. The Company recorded *Research and development* expenses of $462 million in 2020 related to this transaction.

Also in December 2020, Merck acquired VelosBio Inc. (VelosBio), a privately held, clinical-stage biopharmaceutical company, for $2.8 billion. VelosBio's lead investigational candidate is MK-2140 (formerly known as VLS-101), an antibody-drug conjugate targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1) that is currently being evaluated for the treatment of patients with hematologic malignancies and solid tumors. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $180 million (primarily cash) and *Research and development* expenses of $2.7 billion in 2020 related to the transaction.

In September 2020, Merck and Seagen Inc. (Seagen, formerly known as Seattle Genetics, Inc.) announced an oncology collaboration to globally develop and commercialize Seagen's ladiratuzumab vedotin (MK-6440), an investigational antibody-drug conjugate targeting LIV-1, which is currently in Phase 2 clinical trials for breast cancer and other solid tumors. The collaboration will pursue a broad joint development program evaluating ladiratuzumab vedotin as monotherapy and in combination with *Keytruda* (pembrolizumab) in triple-negative breast cancer, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors. The companies will equally share profits worldwide. Under the terms of the agreement, Merck made an upfront payment of $600 million and a $1.0 billion equity investment in 5 million shares of Seagen common stock at a price of $200 per share. Merck recorded $616 million in *Research and development* expenses in 2020 related to this transaction reflecting the upfront payment as well as a $16 million premium relating to the equity shares based on the price of Seagen common stock on the closing date. Seagen is also eligible to receive future contingent milestone payments of up to $2.6 billion, including $850 million in development milestones and $1.75 billion in sales-based milestones.

Concurrent with the above transaction, Seagen granted Merck an exclusive license to commercialize Tukysa (tucatinib), a small molecule tyrosine kinase inhibitor, for the treatment of HER2-positive cancers, in Asia, the Middle East and Latin America and other regions outside of the United States, Canada and Europe. Merck will be responsible for marketing applications seeking approval in its territories, supported by the positive results from the HER2CLIMB clinical trial. Merck will also co-fund a portion of the Tukysa global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers, including breast, colorectal, gastric and other cancers set forth in a global product development plan. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territories. Under the terms of the agreement, Merck made upfront payments aggregating $210 million, which were recorded as *Research and development* expenses in 2020. Seagen is also eligible to receive future contingent regulatory approval milestones of up to $65 million and will receive tiered royalties ranging from 20% to 33% based on annual sales levels of Tukysa in Merck's territories.

Additionally in September 2020, Merck acquired a biologics manufacturing facility located in Dunboyne, Ireland from Takeda Pharmaceutical Company Limited for €256 million ($302 million). The transaction was accounted for as an acquisition of an asset. Merck recorded property, plant and equipment of $289 million and other net assets of $13 million. There are no future contingent payments associated with the acquisition.

In July 2020, Merck acquired the U.S. rights to Sentinel Flavor Tabs and Sentinel Spectrum Chews from Virbac Corporation for $410 million. Sentinel products provide protection against common parasites in dogs. The transaction was accounted for as an acquisition of an asset. Merck recognized intangible assets of $401 million related to currently marketed products and inventory of $9 million at the acquisition date. The estimated fair values of the identifiable intangible assets related to currently marketed products were determined using an income approach. Actual cash flows are likely to be different than those assumed. The intangible assets related to currently marketed products will be amortized over their estimated useful lives of 15 years. There are no future contingent payments associated with the acquisition.

Also in July 2020, Merck and Ridgeback Biotherapeutics LP (Ridgeback Bio), a closely held biotechnology company, closed a collaboration agreement to develop molnupiravir (MK-4482, also known as EIDD-2801), an orally available antiviral candidate in clinical development for the treatment of patients with COVID-19. Merck gained exclusive worldwide rights to develop and commercialize molnupiravir and related molecules. Under the terms of the agreement, Ridgeback Bio received an upfront payment and also is eligible to receive future contingent payments dependent upon the achievement of certain developmental and regulatory approval milestones, as well as a share of the net profits of molnupiravir and related molecules, if approved. Merck and Ridgeback are committed to ensure that any medicines developed for SARS-CoV-2 (the causative agent of COVID-19) will be accessible and affordable globally.

In June 2020, Merck acquired privately held Themis Bioscience GmbH (Themis), a company focused on vaccines (including a COVID-19 vaccine candidate, V591) and immune-modulation therapies for infectious diseases and cancer for $366 million. The acquisition originally provided for Merck to make additional contingent payments of up to $740 million. The transaction was accounted for as an acquisition of a business. The Company determined the fair value of the contingent consideration was $97 million at the acquisition date utilizing a probability-weighted estimated cash flow stream using an appropriate discount rate dependent on the nature and timing of the milestone payments. Merck recognized intangible assets for IPR&D of $136 million, cash of $59 million, deferred tax assets of $70 million and other net liabilities of $32 million. The excess of the consideration transferred over the fair value of net assets acquired of $230 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed. In January 2021, the Company announced it was discontinuing development of V591 as discussed below. As a result, in 2020, the Company recorded an IPR&D impairment charge of $90 million within *Research and development* expenses. The Company also recorded a reduction in *Research and development* expenses resulting from a decrease in the related liability for contingent consideration of $45 million since future contingent milestone payments have been reduced to $450 million in the aggregate, including up to $60 million for development milestones, up to $196 million for regulatory approval milestones, and up to $194 million for commercial milestones.

In May 2020, Merck and the International AIDS Vaccine Initiative, Inc. (IAVI), a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges, announced a collaboration to develop V590, an investigational vaccine against SARS-CoV-2 being studied for the prevention of COVID-19. The agreement provided for an upfront payment by Merck of $6.5 million and also provided for future contingent payments based on sales. Merck also signed an agreement with the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response within an agency of the United States Department of Health and Human Services, to provide initial funding support to Merck for this effort. In January 2021, the Company announced it was discontinuing development of V590 as discussed below.

In January 2021, the Company announced the discontinuation of the development programs for its COVID-19 vaccine candidates, V590 and V591, following Merck's review of findings from Phase 1 clinical studies for the vaccines. In these studies, both V590 and V591 were generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/COVID-19 vaccines. Due to the discontinuation, the Company recorded a charge of $305 million in 2020, of which $260 million was reflected in *Cost of sales* and related to fixed-asset and materials write-offs, as well as the recognition of liabilities for purchase commitments. The remaining $45 million of costs were reflected in *Research and development* expenses and represent amounts related to the Themis acquisition noted above (an IPR&D impairment charge, partially offset by a reduction in the related liability for contingent consideration).

In January 2020, Merck acquired ArQule, Inc. (ArQule), a publicly traded biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of patients with cancer and other diseases. Total consideration paid of $2.7 billion included $138 million of share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of ArQule. The Company incurred $95 million of transaction costs directly related to the acquisition of ArQule, consisting almost entirely of share-based compensation payments to settle non-vested equity awards attributable to postcombination service. These costs were included in *Selling, general and administrative* expenses in 2020. ArQule's lead investigational candidate, MK-1026 (formerly known as ARQ 531), is a novel, oral Bruton's tyrosine kinase (BTK) inhibitor currently being evaluated for the treatment of B-cell malignancies. The transaction was accounted for as an acquisition of a business.

The estimated fair value of assets acquired and liabilities assumed from ArQule is as follows:

($ in millions)		January 16, 2020
Cash and cash equivalents	$	145
IPR&D MK-1026 (formerly ARQ 531) [1]		2,280
Licensing arrangement for ARQ 087		80
Deferred income tax liabilities		(361)
Other assets and liabilities, net		34
Total identifiable net assets		2,178
Goodwill [2]		512
Consideration transferred	$	2,690

[1] *The estimated fair value of the identifiable intangible asset related to IPR&D was determined using an income approach. The future net cash flows were discounted to present value utilizing a discount rate of 12.5%. Actual cash flows are likely to be different than those assumed.*

[2] *The goodwill was allocated to the Pharmaceutical segment and is not deductible for tax purposes.*

2019 Transactions

In July 2019, Merck acquired Peloton Therapeutics, Inc. (Peloton), a clinical-stage biopharmaceutical company focused on the development of novel small molecule therapeutic candidates targeting hypoxia-inducible factor-2α (HIF-2α) for the treatment of patients with cancer and other non-oncology diseases. Peloton's lead candidate, MK-6482 (formerly known as PT2977), is a novel investigational oral HIF-2α inhibitor in late-stage development for renal cell carcinoma. Merck made an upfront payment of $1.2 billion; additionally, former Peloton shareholders will be eligible to receive $50 million upon U.S. regulatory approval, $50 million upon first commercial sale in the United States, and up to $1.05 billion of sales-based milestones. The transaction was accounted for as an acquisition of an asset. Merck recorded cash of $157 million, deferred tax liabilities of $52 million, and other net liabilities of $4 million at the acquisition date, as well as *Research and development* expenses of $993 million in 2019 related to the transaction.

On April 1, 2019, Merck acquired Antelliq Corporation (Antelliq), a leader in digital animal identification, traceability and monitoring solutions. These solutions help veterinarians, farmers and pet owners gather critical data to improve management, health and well-being of livestock and pets. Merck paid $2.3 billion to acquire all outstanding shares of Antelliq and spent $1.3 billion to repay Antelliq's debt. The transaction was accounted for as an acquisition of a business.

The estimated fair value of assets acquired and liabilities assumed from Antelliq is as follows:

($ in millions)		April 1, 2019
Cash and cash equivalents	$	31
Accounts receivable		73
Inventories		93
Property, plant and equipment		60
Identifiable intangible assets (useful lives ranging from 18-24 years) [1]		2,689
Deferred income tax liabilities		(589)
Other assets and liabilities, net		(82)
Total identifiable net assets		2,275
Goodwill [2]		1,376
Consideration transferred	$	3,651

[1] *The estimated fair values of identifiable intangible assets relate primarily to trade names and were determined using an income approach. The future net cash flows were discounted to present value utilizing a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed.*

[2] *The goodwill recognized is largely attributable to anticipated synergies expected to arise after the acquisition and was allocated to the Animal Health segment. The goodwill is not deductible for tax purposes.*

The Company's results for 2019 include eight months of activity for Antelliq, while the Company's results in 2020 include 13 months of activity. The Company incurred $47 million of transaction costs directly related to the acquisition of Antelliq, consisting largely of advisory fees, which are reflected in *Selling, general and administrative* expenses in 2019.

Also in April 2019, Merck acquired Immune Design, a late-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease, for $301 million in cash. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of $156 million, cash of $83 million and other net assets of $42 million. The excess of the consideration transferred over the fair value of net assets acquired of $20 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed.

2018 Transactions

In 2018, the Company recorded an aggregate charge of $423 million within *Cost of sales* in conjunction with the termination of a collaboration agreement entered into in 2014 with Samsung Bioepis Co., Ltd. (Samsung) for insulin glargine. The charge reflects a termination payment of $155 million, which represents the reimbursement of all fees previously paid by Samsung to Merck under the agreement, plus interest, as well as the release of Merck's ongoing obligations under the agreement. The charge also included fixed asset abandonment charges of $137 million, inventory write-offs of $122 million, as well as other related costs of $9 million. The termination of this agreement had no impact on the Company's other collaboration with Samsung.

In June 2018, Merck acquired Viralytics Limited (Viralytics), an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 502 million ($378 million). The transaction provided Merck with full rights to V937 (formerly known as CVA21), an investigational oncolytic immunotherapy. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $34 million (primarily cash) at the acquisition date and *Research and development* expenses of $344 million in 2018 related to the transaction. There are no future contingent payments associated with the acquisition.

In March 2018, Merck and Eisai Co., Ltd. (Eisai) entered into a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai (see Note 4).

Remicade/Simponi

In 1998, a subsidiary of Schering-Plough entered into a licensing agreement with Centocor Ortho Biotech Inc. (Centocor), a Johnson & Johnson (J&J) company, to market *Remicade*, which is prescribed for the treatment of inflammatory diseases. In 2005, Schering-Plough's subsidiary exercised an option under its contract with Centocor for license rights to develop and commercialize *Simponi*, a fully human monoclonal antibody. The Company has marketing rights to both products throughout Europe, Russia and Turkey. *Remicade* lost market exclusivity in major European markets in 2015 and the Company no longer has market exclusivity in any of its marketing territories. The Company continues to have market exclusivity for *Simponi* in all of its marketing territories. All profits derived from Merck's distribution of the two products in these countries are equally divided between Merck and J&J. The Company's marketing rights with respect to these products will revert to Janssen Pharmaceuticals, Inc. in the second half of 2024.

4. Collaborative Arrangements

Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. Both parties in these arrangements are active participants and exposed to significant risks and rewards dependent on the commercial success of the activities of the collaboration. Merck's more significant collaborative arrangements are discussed below.

AstraZeneca

In July 2017, Merck and AstraZeneca PLC (AstraZeneca) entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types. Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor currently approved for certain types of advanced ovarian, breast, pancreatic and prostate cancers. The companies are jointly developing and commercializing Lynparza, both as monotherapy and in combination trials with other potential medicines. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* and Imfinzi. The companies are also jointly developing and commercializing AstraZeneca's Koselugo (selumetinib), an oral, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, for multiple indications. In April 2020, Koselugo was approved by the U.S. Food and Drug Administration (FDA) for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for Lynparza and Koselugo monotherapy and non-PD-L1/PD-1 combination therapy opportunities.

Profits from Lynparza and Koselugo product sales generated through monotherapies or combination therapies are shared equally. Merck will fund all development and commercialization costs of *Keytruda* in combination with Lynparza or Koselugo. AstraZeneca will fund all development and commercialization costs of Imfinzi in combination with Lynparza or Koselugo. AstraZeneca is the principal on Lynparza and Koselugo sales transactions. Merck records its share of Lynparza and Koselugo product sales, net of cost of sales and commercialization costs, as alliance revenue and its share of development costs associated with the collaboration as part of *Research and development* expenses. Reimbursements received from AstraZeneca for research and development expenses are recognized as reductions to *Research and development* costs.

As part of the agreement, Merck made an upfront payment to AstraZeneca of $1.6 billion in 2017 and made payments of $750 million over a multi-year period for certain license options (of which $250 million was paid in December 2017, $400 million was paid in December 2018 and $100 million was paid in December 2019). The upfront payment and license option payments were reflected in *Research and development* expenses in 2017. In addition, the agreement provides for additional contingent payments from Merck to AstraZeneca related to the successful achievement of sales-based and regulatory milestones.

In 2020, Merck determined it was probable that sales of Lynparza in the future would trigger $400 million of sales-based milestone payments from Merck to AstraZeneca. Accordingly, Merck recorded $400 million of liabilities and corresponding increases to the intangible asset related to Lynparza. Prior to 2020, Merck accrued sales-based milestone payments aggregating $1.0 billion related to Lynparza, of which $550 million, $200 million and $250 million was paid to AstraZeneca in 2020, 2019 and 2018, respectively. Potential future sales-based milestone payments of $2.7 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2020, 2019 and 2018, Lynparza received regulatory approvals triggering capitalized milestone payments of $160 million, $60 million and $140 million, respectively, in the aggregate from Merck to AstraZeneca. Potential future regulatory milestone payments of $1.4 billion remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $1.3 billion at December 31, 2020 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2028 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	2020	2019	2018
Alliance revenue - Lynparza	$ 725	$ 444	$ 187
Alliance revenue - Koselugo	8	—	—
Total alliance revenue	$ 733	$ 444	$ 187
Cost of sales [(1)]	247	148	93
Selling, general and administrative	160	138	48
Research and development	133	168	152

December 31	2020	2019
Receivables from AstraZeneca included in *Other current assets*	$ 215	$ 128
Payables to AstraZeneca included in *Accrued and other current liabilities* [(2)]	423	577

[(1)] *Represents amortization of capitalized milestone payments.*

[(2)] *Includes accrued milestone payments.*

Eisai

In March 2018, Merck and Eisai Co., Ltd. (Eisai) announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima (lenvatinib), an orally available tyrosine kinase inhibitor discovered by Eisai. Lenvima is currently approved for the treatment of certain types of thyroid cancer, hepatocellular carcinoma, in combination with everolimus for certain patients with renal cell carcinoma, and in combination with *Keytruda* for the treatment of certain patients with endometrial carcinoma. Under the agreement. Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with *Keytruda*. Eisai records Lenvima product sales globally (Eisai is the principal on Lenvima sales transactions), and Merck and Eisai share applicable profits equally. Merck records its share of Lenvima product sales, net of cost of sales and commercialization costs, as alliance revenue. Expenses incurred during co-development are shared by the two companies in accordance with the collaboration agreement and reflected in *Research and development* expenses. Certain expenses incurred solely by Merck or Eisai are not shareable under the collaboration agreement, including costs incurred in excess of agreed upon caps and costs related to certain combination studies of *Keytruda* and Lenvima.

Under the agreement, Merck made an upfront payment to Eisai of $750 million in 2018 and agreed to make payments of up to $650 million for certain option rights through 2021 (of which $325 million was paid in March 2019, $200 million was paid in March 2020 and $125 million is expected to be paid in March 2021). The Company recorded an aggregate charge of $1.4 billion in *Research and development* expenses in 2018 related to the upfront payment and future option payments. In addition, the agreement provides for additional contingent payments from Merck to Eisai related to the successful achievement of sales-based and regulatory milestones.

In 2020, Merck determined it was probable that sales of Lenvima in the future would trigger sales-based milestone payments aggregating $400 million from Merck to Eisai. Accordingly, Merck recorded liabilities of $400 million and corresponding increases to the intangible asset related to Lenvima. Prior to 2020, Merck accrued sales-based milestone payments aggregating $950 million related to Lenvima, of which $500 million and $50 million was paid to Eisai in 2020 and 2019, respectively. Potential future sales-based milestone payments of $2.6 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In 2020 and 2018, Lenvima received regulatory approvals triggering capitalized milestone payments of $10 million and $250 million, respectively, from Merck to Eisai. Potential future regulatory milestone payments of $125 million remain under the agreement.

The intangible asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $1.1 billion at December 31, 2020 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31	2020	2019	2018
Alliance revenue - Lenvima	$ 580	$ 404	$ 149
Cost of sales [1]	271	206	39
Selling, general and administrative	73	80	13
Research and development [2]	185	189	1,489

December 31	2020	2019
Receivables from Eisai included in *Other current assets*	$ 157	$ 150
Payables to Eisai included in *Accrued and other current liabilities* [3]	335	700
Payables to Eisai included in *Other Noncurrent Liabilities* [4]	600	525

[1] Represents amortization of capitalized milestone payments.

[2] Amount for 2018 includes $1.4 billion related to the upfront payment and option payments.

[3] Includes accrued milestone and future option payments.

[4] Includes accrued milestone payments.

Bayer AG

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas (riociguat), which is approved to treat pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. The two companies have implemented a joint development and commercialization strategy. The collaboration also includes clinical development of Bayer's Verquvo (vericiguat), which was approved by the FDA in January 2021 to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults. Verquvo is under review by regulatory authorities in other territories including the EU and Japan. Under the agreement, Bayer commercializes Adempas in the Americas, while Merck commercializes in the rest of the world. For Verquvo, Merck will commercialize in the United States and Bayer will commercialize in the rest of the world. Both companies share in development costs and profits on sales. Merck records sales of Adempas (and will record sales of Verquvo) in its marketing territories, as well as alliance revenue. Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs. In addition, the agreement provides for contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones.

Prior to 2020, Merck accrued $725 million of sales-based milestone payments for this collaboration, of which $375 million and $350 million was paid to Bayer in 2020 and 2018, respectively. Following the 2021 FDA approval of Verquvo noted above, Merck determined it was probable that sales of Adempas and Verquvo in the future would trigger the remaining $400 million sales-based milestone payment. Accordingly, Merck will record a liability of $400 million and a corresponding increase in intangible assets related to this collaboration in the first quarter of 2021.

The intangible asset balance related to this collaboration (which includes the acquired intangible asset balance, as well as capitalized sales-based milestone payments) was $849 million at December 31, 2020 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2027 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

Years Ended December 31		2020		2019		2018
Alliance revenue - Adempas	$	**281**	$	204	$	139
Net sales of Adempas recorded by Merck		**220**		215		190
Total sales	$	**501**	$	419	$	329
Cost of sales [(1)]		**115**		113		216
Selling, general and administrative		**61**		41		35
Research and development		**63**		126		127

December 31		2020		2019
Receivables from Bayer included in *Other current assets*	$	**65**	$	49
Payables to Bayer included in *Other Noncurrent Liabilities* [(2)]		**—**		375

[(1)] Includes amortization of intangible assets.
[(2)] Represents accrued milestone payment.

5. Restructuring

In early 2019, Merck approved a new global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization, builds on prior restructuring programs and does not include any actions associated with the planned spin-off of Organon. As the Company continues to evaluate its global footprint and overall operating model, it subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program now estimated to be approximately $3.0 billion. The Company estimates that approximately 70% of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 30% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The Company expects to record charges of approximately $700 million in 2021 related to the Restructuring Program. Actions under previous global restructuring programs have been substantially completed.

The Company recorded total pretax costs of $883 million in 2020, $927 million in 2019 and $658 million in 2018 related to restructuring program activities. Since inception of the Restructuring Program through December 31, 2020, Merck has recorded total pretax accumulated costs of approximately $1.8 billion. For segment reporting, restructuring charges are unallocated expenses.

The following table summarizes the charges related to restructuring program activities by type of cost:

	Separation Costs	Accelerated Depreciation	Other	Total
Year Ended December 31, 2020				
Cost of sales	**$ —**	**$ 143**	**$ 32**	**$ 175**
Selling, general and administrative	**—**	**44**	**3**	**47**
Research and development	**—**	**81**	**2**	**83**
Restructuring costs	**385**	**—**	**193**	**578**
	$ 385	**$ 268**	**$ 230**	**$ 883**
Year Ended December 31, 2019				
Cost of sales	$ —	$ 198	$ 53	$ 251
Selling, general and administrative	—	33	1	34
Research and development	—	2	2	4
Restructuring costs	572	—	66	638
	$ 572	$ 233	$ 122	$ 927
Year Ended December 31, 2018				
Cost of sales	$ —	$ 10	$ 11	$ 21
Selling, general and administrative	—	2	1	3
Research and development	—	(13)	15	2
Restructuring costs	473	—	159	632
	$ 473	$ (1)	$ 186	$ 658

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated.

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the programs. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. All the sites have and will continue to operate up through the respective closure dates and, since future undiscounted cash flows are sufficient to recover the respective book values, Merck is recording accelerated depreciation over the revised useful life of the site assets. Anticipated site closure dates, particularly related to manufacturing locations, have been and may continue to be adjusted to reflect changes resulting from regulatory or other factors.

Other activity in 2020, 2019 and 2018 includes asset abandonment, facility shut-down and other related costs, as well as pretax gains and losses resulting from the sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 13) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities:

	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2019	$ 443	$ —	$ 91	$ 534
Expenses	572	233	122	927
(Payments) receipts, net	(325)	—	(136)	(461)
Non-cash activity	—	(233)	(8)	(241)
Restructuring reserves December 31, 2019	690	—	69	759
Expenses	**385**	**268**	**230**	**883**
(Payments) receipts, net	**(508)**	**—**	**(301)**	**(809)**
Non-cash activity	**—**	**(268)**	**38**	**(230)**
Restructuring reserves December 31, 2020 (1)	**$ 567**	**$ —**	**$ 36**	**$ 603**

(1) *The remaining cash outlays are expected to be substantially completed by the end of 2023.*

6. Financial Instruments

Derivative Instruments and Hedging Activities

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by changes in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro, Japanese yen and Chinese renminbi. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *OCI*, depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the unrealized gains or losses on these contracts are recorded in *AOCI* and reclassified into *Sales* when the hedged anticipated revenue is recognized. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Other (income) expense, net*. The forward contracts are not designated as hedges and are marked to market through *Other (income) expense, net*. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *OCI*, and remain in *AOCI* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

The effects of the Company's net investment hedges on *OCI* and the Consolidated Statement of Income are shown below:

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income [1]			Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing		
Years Ended December 31	**2020**	2019	2018	**2020**	2019	2018
Net Investment Hedging Relationships						
Foreign exchange contracts	**$ 26**	$ (10)	$ (18)	**$ (19)**	$ (31)	$ (11)
Euro-denominated notes	**385**	(75)	(183)	**—**	—	—

[1] *No amounts were reclassified from AOCI into income related to the sale of a subsidiary.*

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

In February 2020, five interest rate swaps with notional amounts of $250 million each matured. These swaps effectively converted the Company's $1.25 billion, 1.85% fixed-rate notes due 2020 to variable rate debt. At December 31, 2020, the Company was a party to 14 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below:

	2020		
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
3.875% notes due 2021 [1]	$ 1,150	5	$ 1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

[1] *These interest rate swaps matured in January 2021.*

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark LIBOR swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The table below presents the location of amounts recorded on the Consolidated Balance Sheet related to cumulative basis adjustments for fair value hedges as of December 31:

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
	2020	2019	2020	2019
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	$ 1,150	$ 1,249	$ —	$ (1)
Long-Term Debt	2,301	3,409	53	14

Presented in the table below is the fair value of derivatives on a gross basis segregated between those derivatives that are designated as hedging instruments and those that are not designated as hedging instruments as of December 31:

		2020			2019		
		Fair Value of Derivative			Fair Value of Derivative		
	Balance Sheet Caption	Asset	Liability	U.S. Dollar Notional	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts	Other current assets	$ 1	$ —	$ 1,150	$ —	$ —	$ —
Interest rate swap contracts	Other Assets	54	—	2,250	15	—	3,400
Interest rate swap contracts	Accrued and other current liabilities	—	—	—	—	1	1,250
Foreign exchange contracts	Other current assets	12	—	3,183	152	—	6,117
Foreign exchange contracts	Other Assets	45	—	2,030	55	—	2,160
Foreign exchange contracts	Accrued and other current liabilities	—	217	5,049	—	22	1,748
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	52	—	1	53
		$ 112	$ 218	$ 13,714	$ 222	$ 24	$ 14,728
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	$ 70	$ —	$ 7,260	$ 66	$ —	$ 7,245
Foreign exchange contracts	Accrued and other current liabilities	—	307	11,810	—	73	8,693
		$ 70	$ 307	$ 19,070	$ 66	$ 73	$ 15,938
		$ 182	$ 525	$ 32,784	$ 288	$ 97	$ 30,666

As noted above, the Company records its derivatives on a gross basis in the Consolidated Balance Sheet. The Company has master netting agreements with several of its financial institution counterparties (see *Concentrations of Credit Risk* below). The following table provides information on the Company's derivative positions subject to these master netting arrangements as if they were presented on a net basis, allowing for the right of offset by counterparty and cash collateral exchanged per the master agreements and related credit support annexes at December 31:

	2020		2019	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	$ 182	$ 525	$ 288	$ 97
Gross amounts subject to offset in master netting arrangements not offset in the consolidated balance sheet	(156)	(156)	(84)	(84)
Cash collateral posted/received	—	(36)	(34)	—
Net amounts	$ 26	$ 333	$ 170	$ 13

The table below provides information regarding the location and amount of pretax (gains) losses of derivatives designated in fair value or cash flow hedging relationships:

	Sales			Other (income) expense, net [1]			Other comprehensive income (loss)		
Years Ended December 31	2020	2019	2018	2020	2019	2018	2020	2019	2018
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	$ 47,994	$ 46,840	$ 42,294	$ (886)	139	(402)	$ (441)	$ (648)	$ (361)
(Gain) loss on fair value hedging relationships									
Interest rate swap contracts									
Hedged items	—	—	—	40	95	(27)	—	—	—
Derivatives designated as hedging instruments	—	—	—	(76)	(65)	50	—	—	—
Impact of cash flow hedging relationships									
Foreign exchange contracts									
Amount of (loss) gain recognized in *OCI* on derivatives	—	—	—	—	—	—	(383)	87	228
(Decrease) increase in *Sales* as a result of *AOCI* reclassifications	(6)	255	(160)	—	—	—	6	(255)	160
Interest rate contracts									
Amount of gain recognized in *Other (income) expense, net* on derivatives	—	—	—	(4)	(4)	(4)	—	—	—
Amount of loss recognized in *OCI* on derivatives	—	—	—	—	—	—	(4)	(6)	(4)

[1] *Interest expense is a component of* Other (income) expense, net.

The table below provides information regarding the income statement effects of derivatives not designated as hedging instruments:

		Amount of Derivative Pretax (Gain) Loss Recognized in Income		
Years Ended December 31		2020	2019	2018
Derivatives Not Designated as Hedging Instruments	*Income Statement Caption*			
Foreign exchange contracts [1]	Other (income) expense, net	$ (12)	$ 174	$ (260)
Foreign exchange contracts [2]	Sales	13	1	(8)
Interest rate contracts [3]	Other (income) expense, net	9	—	—
Forward contract related to Seagen common stock	Research and development expenses	15	—	—

[1] *These derivative contracts mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.*

[2] *These derivative contracts serve as economic hedges of forecasted transactions.*

[3] *These derivatives serve as economic hedges against rising treasury rates.*

At December 31, 2020, the Company estimates $331 million of pretax net unrealized losses on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

Information on investments in debt and equity securities at December 31 is as follows:

	2020				2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 84	$ —	$ —	$ 84	$ 266	$ 3	$ —	$ 269
Foreign government bonds	5	—	—	5	—	—	—	—
Commercial paper	—	—	—	—	668	—	—	668
Corporate notes and bonds	—	—	—	—	608	13	—	621
Asset-backed securities	—	—	—	—	226	1	—	227
Total debt securities	89	—	—	89	1,768	17	—	1,785
Publicly traded equity securities [(1)]				1,787				838
Total debt and publicly traded equity securities				$ 1,876				$ 2,623

[(1)] *Unrealized net gains recognized in* Other (income) expense, net *on equity securities still held at December 31, 2020 were $163 million during 2020. Unrealized net gains recognized in* Other (income) expense, net *on equity securities still held at December 31, 2019 were $160 million during 2019.*

At December 31, 2020 and 2019, the Company also had $586 million and $420 million, respectively, of equity investments without readily determinable fair values included in *Other Assets*. During 2020 and 2019, the Company recognized unrealized gains of $62 million and $20 million, respectively, in *Other (income) expense, net*, on certain of these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee. In addition, during 2020 and 2019, the Company recognized unrealized losses of $3 million and $13 million, respectively, in *Other (income) expense, net*, related to certain of these investments based on unfavorable observable price changes. Cumulative unrealized gains and cumulative unrealized losses based on observable prices changes for investments in equity investments without readily determinable fair values were $169 million and $24 million, respectively.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Financial assets and liabilities measured at fair value on a recurring basis at December 31 are summarized below:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
	2020				2019			
Assets								
Investments								
Foreign government bonds	$ —	$ 5	$ —	$ 5	$ —	$ —	$ —	$ —
Commercial paper	—	—	—	—	—	668	—	668
Corporate notes and bonds	—	—	—	—	—	621	—	621
Asset-backed securities	—	—	—	—	—	227	—	227
U.S. government and agency securities	—	—	—	—	—	209	—	209
Publicly traded equity securities	780	—	—	780	518	—	—	518
	780	5	—	785	518	1,725	—	2,243
Other assets [1]								
U.S. government and agency securities	84	—	—	84	60	—	—	60
Publicly traded equity securities	1,007	—	—	1,007	320	—	—	320
	1,091	—	—	1,091	380	—	—	380
Derivative assets [2]								
Forward exchange contracts	—	90	—	90	—	169	—	169
Interest rate swaps	—	55	—	55	—	15	—	15
Purchased currency options	—	37	—	37	—	104	—	104
	—	182	—	182	—	288	—	288
Total assets	$ 1,871	$ 187	$ —	$ 2,058	$ 898	$ 2,013	$ —	$ 2,911
Liabilities								
Other liabilities								
Contingent consideration	$ —	$ —	$ 841	$ 841	$ —	$ —	$ 767	$ 767
Derivative liabilities [2]								
Forward exchange contracts	—	505	—	505	—	95	—	95
Written currency options	—	20	—	20	—	1	—	1
Interest rate swaps	—	—	—	—	—	1	—	1
	—	525	—	525	—	97	—	97
Total liabilities	$ —	$ 525	$ 841	$ 1,366	$ —	$ 97	$ 767	$ 864

(1) *Investments included in other assets are restricted as to use, including for the payment of benefits under employee benefit plans.*

(2) *The fair value determination of derivatives includes the impact of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.*

As of December 31, 2020 and 2019, *Cash and cash equivalents* include $6.8 billion and $8.9 billion, respectively, of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

Summarized information about the changes in liabilities for contingent consideration associated with business acquisitions is as follows:

	2020	2019
Fair value January 1	$ 767	$ 788
Additions	97	—
Changes in estimated fair value [(1)]	83	64
Payments	(106)	(85)
Fair value December 31 [(2)(3)]	$ 841	$ 767

[(1)] *Recorded in* Cost of sales, Research and development *expenses, and* Other (income) expense, net. *Includes cumulative translation adjustments.*

[(2)] *Balance at December 31, 2020 includes $148 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

[(3)] *At December 31, 2020 and 2019, $711 million and $625 million, respectively, of the liabilities relate to the termination of the Sanofi Pasteur MSD joint venture in 2016. As part of the termination, Merck recorded a liability for contingent future royalty payments of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024. The fair value of this liability is determined utilizing the estimated amount and timing of projected cash flows and a risk-adjusted discount rate of 8% to present value the cash flows.*

The additions to contingent consideration in 2020 relate to the acquisition of Themis. The changes in the estimated fair value of liabilities for contingent consideration in 2020 and 2019 were largely attributable to increases in the liabilities recorded in connection with the termination of the Sanofi Pasteur MSD (SPMSD) joint venture in 2016. In 2020, the increase was partially offset by a decline related to the discontinuation of a COVID-19 vaccine program obtained through the acquisition of Themis. The payments of contingent consideration in both years relate to the SPMSD liabilities described above.

Other Fair Value Measurements

Some of the Company's financial instruments, such as cash and cash equivalents, receivables and payables, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

The estimated fair value of loans payable and long-term debt (including current portion) at December 31, 2020, was $36.0 billion compared with a carrying value of $31.8 billion and at December 31, 2019, was $28.8 billion compared with a carrying value of $26.3 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate and government issuers of securities and financial institutions with which it conducts business. Credit exposure limits are established to limit a concentration with any single issuer or institution. Cash and investments are placed in instruments that meet high credit quality standards, as specified in the Company's investment policy guidelines.

The majority of the Company's accounts receivable arise from product sales in the United States, Europe and China and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company also continues to monitor global economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and its business.

The Company's customers with the largest accounts receivable balances are: McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which represented, in aggregate, approximately 45% of total accounts receivable at December 31, 2020. The Company monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored $2.3 billion and $2.7 billion of accounts receivable in the fourth quarter of 2020 and 2019, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the

Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. At December 31, 2020 and 2019, the Company had collected $102 million and $256 million, respectively, on behalf of the financial institutions, which is reflected as restricted cash in *Other current assets* and the related obligation to remit the cash within *Accrued and other current liabilities*. The Company remitted the cash to the financial institutions in January 2021 and 2020, respectively. The net cash flows relating to these collections are reported as financing activities in the Consolidated Statement of Cash Flows. The cost of factoring such accounts receivable was *de minimis*.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. Cash collateral advanced by the Company to counterparties was $36 million at December 31, 2020. Cash collateral received by the Company from various counterparties was $34 million at December 31, 2019. The obligation to return such collateral is recorded in *Accrued and other current liabilities*.

7. Inventories

Inventories at December 31 consisted of:

	2020	2019
Finished goods	$ 1,963	$ 1,772
Raw materials and work in process	6,420	5,650
Supplies	206	207
Total (approximates current cost)	8,589	7,629
Decrease to LIFO cost	(82)	(171)
	$ 8,507	$ 7,458
Recognized as:		
Inventories	$ 6,310	$ 5,978
Other assets	2,197	1,480

Inventories valued under the LIFO method comprised approximately $2.9 billion and $2.6 billion at December 31, 2020 and 2019, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2020 and 2019, these amounts included $1.9 billion and $1.3 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $279 million and $168 million at December 31, 2020 and 2019, respectively, of inventories produced in preparation for product launches.

8. Goodwill and Other Intangibles

The following table summarizes goodwill activity by segment:

	Pharmaceutical	Animal Health	All Other	Total
Balance January 1, 2019	$ 16,162	$ 1,870	$ 221	$ 18,253
Acquisitions	19	1,322	—	1,341
Impairments	—	—	(162)	(162)
Other [(1)]	—	—	(7)	(7)
Balance December 31, 2019 [(2)]	16,181	3,192	52	19,425
Acquisitions	**742**	**105**	**—**	**847**
Divestitures	**—**	**—**	**(54)**	**(54)**
Other [(1)]	**47**	**(29)**	**2**	**20**
Balance December 31, 2020 [(2)]	**$ 16,970**	**$ 3,268**	**$ —**	**$ 20,238**

[(1)] Other includes cumulative translation adjustments on goodwill balances and certain other adjustments.

[(2)] Accumulated goodwill impairment losses were $531 million at both December 31, 2020 and 2019.

The additions to goodwill in the Pharmaceutical segment in 2020 were primarily related to the acquisitions of ArQule and Themis (see Note 3). The additions to goodwill within the Animal Health segment in 2019 primarily relate to the acquisition of Antelliq (see Note 3). The impairments of goodwill within other non-reportable segments in 2019 relate to certain businesses within the Healthcare Services segment. The Healthcare Services segment was fully divested in the first quarter of 2020.

Other intangibles at December 31 consisted of:

	2020			2019		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	$ 45,087	$ 39,925	$ 5,162	$ 45,947	$ 38,852	$ 7,095
Licenses	4,177	1,387	2,790	3,185	824	2,361
IPR&D	3,228	—	3,228	1,032	—	1,032
Trade names	2,882	352	2,530	2,899	217	2,682
Other	2,223	1,329	894	2,261	1,235	1,026
	$ 57,597	$ 42,993	$ 14,604	$ 55,324	$ 41,128	$ 14,196

Acquired intangibles include products and product rights, licenses, trade names and patents, which are initially recorded at fair value, assigned an estimated useful life, and amortized primarily on a straight-line basis over their estimated useful lives. Some of the Company's more significant acquired intangibles, on a net basis, related to human health marketed products (included in products and product rights above) at December 31, 2020 include *Zerbaxa*, $551 million; *Implanon/Nexplanon*, $354 million; *Gardasil/Gardasil* 9, $276 million; *Dificid*, $228 million; *Bridion*, $185 million; *Sivextro*, $154 million; and *Simponi*, $132 million. Additionally, the Company had $5.4 billion of net acquired intangibles related to animal health marketed products at December 31, 2020, of which $2.5 billion relate primarily to trade names obtained through the 2019 acquisition of Antelliq (see Note 3). Some of the Company's more significant net intangible assets included in licenses above at December 31, 2020 include Lynparza, $1.3 billion and Lenvima, $1.1 billion as a result of collaborations with AstraZeneca and Eisai (see Note 4). At December 31, 2020, IPR&D primarily relates to MK-1026 obtained through the acquisition of ArQule in 2020 (see Note 3) and MK-7264 (gefapixant) obtained through the acquisition of Afferent Pharmaceuticals in 2016. The Company has an intangible asset related to a collaboration with Bayer (see Note 4) that had a carrying value of $849 million at December 31, 2020 reflected in "Other" in the table above.

In 2020, the Company recorded an impairment charge of $1.6 billion within *Cost of sales* related to *Zerbaxa* for injection, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections. In December 2020, the Company temporarily suspended sales of *Zerbaxa*, and subsequently issued a product recall, following the identification of product sterility issues. The recall constituted a triggering event requiring the evaluation of the *Zerbaxa* intangible asset for impairment. The Company revised its cash flow forecasts for *Zerbaxa* utilizing certain assumptions around the return to market timeline and anticipated uptake in sales thereafter. These revised cash flow forecasts indicated that the *Zerbaxa* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Zerbaxa* that, when compared with its related carrying value, resulted in the impairment charge noted above. The Company also wrote-off inventory of $120 million to *Cost of sales* in 2020 related to the *Zerbaxa* recall. The remaining intangible asset balance related to *Zerbaxa* was $551 million at December 31, 2020.

In 2019, the Company recorded impairment charges related to marketed products and other intangibles of $705 million. Of this amount, $612 million related to *Sivextro*, a product for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible Gram-positive organisms. As part of a reorganization and reprioritization of its internal sales force, the Company made the decision to cease promotion of *Sivextro* in the U.S. market by the end of 2019. This decision resulted in reduced cash flow projections for *Sivextro*, which indicated that the *Sivextro* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Sivextro* that, when compared with its related carrying value, resulted in the impairment charge noted above.

IPR&D that the Company acquires through business combinations represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized as IPR&D are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, the Company will make a separate determination as to the then useful life of the asset and begin amortization.

In 2020, the Company recorded a $90 million IPR&D impairment charge within *Research and development* expenses related to a decision to discontinue the development program for COVID-19 vaccine candidate V591 following Merck's review of findings from a Phase 1 clinical study for the vaccine. In the study, V591 was generally well tolerated, but the immune responses were inferior to those seen following natural infection and those reported for other SARS-CoV-2/COVID-19 vaccines. The discontinuation of this development program also resulted in a reversal of the related liability for contingent consideration of $45 million (see Note 6).

In 2019, the Company recorded $172 million of IPR&D impairment charges. Of this amount, $155 million relates to the write-off of the intangible asset balance for programs obtained in connection with the acquisition of IOmet Pharma Ltd following a review of clinical trial results conducted by Merck, along with external clinical trial results for similar compounds. The discontinuation of this clinical development program also resulted in a reversal of the related liability for contingent consideration of $11 million.

In 2018, the Company recorded $152 million of IPR&D impairment charges. Of this amount, $139 million relates to the write-off of the remaining intangible asset balance for a program obtained in connection with the SmartCells acquisition following a decision to terminate the program due to product development issues. The discontinuation of this clinical development program also resulted in a reversal of the related liability for contingent consideration of $60 million.

The IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates.

The Company may recognize additional non-cash impairment charges in the future related to other marketed products or pipeline programs and such charges could be material.

Aggregate amortization expense primarily recorded within *Cost of sales* was $1.9 billion in 2020, $2.0 billion in 2019 and $3.1 billion in 2018. The estimated aggregate amortization expense for each of the next five years is as follows: 2021, $1.5 billion; 2022, $1.5 billion; 2023, $1.4 billion; 2024, $1.3 billion; 2025, $1.2 billion.

9. Loans Payable, Long-Term Debt and Leases

Loans Payable

Loans payable at December 31, 2020 included $2.3 billion of notes due in 2021, $4.0 billion of commercial paper and $73 million of long-dated notes that are subject to repayment at the option of the holders. Loans payable at December 31, 2019 included $1.9 billion of notes due in 2020, $1.4 billion of commercial paper and $226 million of long-dated notes that are subject to repayment at the option of the holders. The weighted-average interest rate of commercial paper borrowings was 0.79% and 2.23% for the years ended December 31, 2020 and 2019, respectively.

Long-Term Debt

Long-term debt at December 31 consisted of:

	2020	2019
2.75% notes due 2025	$ 2,493	$ 2,492
3.70% notes due 2045	1,976	1,975
2.80% notes due 2023	1,748	1,747
3.40% notes due 2029	1,734	1,732
4.00% notes due 2049	1,469	1,468
2.35% notes due 2022	1,269	1,248
4.15% notes due 2043	1,238	1,238
1.45% notes due 2030	1,233	—
1.875% euro-denominated notes due 2026	1,218	1,107
2.45% notes due 2050	1,211	—
2.40% notes due 2022	1,032	1,010
0.75% notes due 2026	991	—
3.90% notes due 2039	983	982
2.35% notes due 2040	982	—
2.90% notes due 2024	746	745
6.50% notes due 2033	719	722
0.50% euro-denominated notes due 2024	611	555
1.375% euro-denominated notes due 2036	606	551
2.50% euro-denominated notes due 2034	605	550
3.60% notes due 2042	491	490
6.55% notes due 2037	411	412
5.75% notes due 2036	338	338
5.95% debentures due 2028	306	306
5.85% notes due 2039	271	271
6.40% debentures due 2028	250	250
6.30% debentures due 2026	135	135
3.875% notes due 2021	—	1,151
1.125% euro-denominated notes due 2021	—	1,113
Other	294	148
	$ 25,360	$ 22,736

Other (as presented in the table above) includes $294 million and $147 million at December 31, 2020 and 2019, respectively, of borrowings at variable rates that resulted in effective interest rates of 0.45% and 2.54% for 2020 and 2019, respectively.

With the exception of the 6.30% debentures due 2026, the notes listed in the table above are redeemable in whole or in part, at Merck's option at any time, at varying redemption prices.

In June 2020, the Company issued $4.5 billion principal amount of senior unsecured notes consisting of $1.0 billion of 0.75% notes due 2026, $1.25 billion of 1.45% notes due 2030, $1.0 billion of 2.35% notes due 2040 and $1.25 billion of 2.45% notes due 2050. Merck used the net proceeds from the offering for general corporate purposes, including without limitation the repayment of outstanding commercial paper borrowings and other indebtedness with upcoming maturities.

Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to that date.

Certain of the Company's borrowings require that Merck comply with covenants and, at December 31, 2020, the Company was in compliance with these covenants.

The aggregate maturities of long-term debt for each of the next five years are as follows: 2021, $2.3 billion; 2022, $2.3 billion; 2023, $1.7 billion; 2024, $1.4 billion; 2025, $2.5 billion.

The Company has a $6.0 billion credit facility that matures in June 2024. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Leases

The Company has operating leases primarily for manufacturing facilities, research and development facilities, corporate offices, employee housing, vehicles and certain equipment. The Company determines if an arrangement is a lease at inception. When evaluating contracts for embedded leases, the Company exercises judgment to determine if there is an explicit or implicit identified asset in the contract and if Merck controls the use of that asset. Embedded leases, primarily associated with contract manufacturing organizations, are immaterial. The lease term includes options to extend or terminate the lease when it is reasonably certain that Merck will exercise that option. Real estate leases for facilities have an average remaining lease term of eight years, which include options to extend the leases for up to four years where applicable. Vehicle leases are generally in effect for four years. The Company does not record short-term leases (leases with an initial term of 12 months or less) on the balance sheet; however, Merck currently has no short-term leases.

Lease expense for operating lease payments is recognized on a straight-line basis over the term of the lease. Operating lease assets and liabilities are recognized based on the present value of lease payments over the lease term. Since the Company's leases do not have a readily determinable implicit discount rate, the Company uses its incremental borrowing rate to calculate the present value of lease payments by asset class. On a quarterly basis, an updated incremental borrowing rate is determined based on the average remaining lease term of each asset class and the Company's pretax cost of debt for that same term. The updated rates for each asset class are applied prospectively to new leases. The Company does not separate lease components (e.g. payments for rent, real estate taxes and insurance costs) from non-lease components (e.g. common-area maintenance costs) in the event that the agreement contains both. Merck includes both the lease and non-lease components for purposes of calculating the right-of-use asset and related lease liability (if the non-lease components are fixed). For vehicle leases and employee housing, the Company applies a portfolio approach to effectively account for the operating lease assets and liabilities.

Certain of the Company's lease agreements contain variable lease payments that are adjusted periodically for inflation or for actual operating expense true-ups compared with estimated amounts; however, these amounts are immaterial. Sublease income and activity related to sale and leaseback transactions are immaterial. Merck's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Operating lease cost was $346 million in 2020 and $339 million in 2019. Rental expense under operating leases, net of sublease income, was $322 million in 2018. Cash paid for amounts included in the measurement of operating lease liabilities was $340 million in 2020 and $281 million in 2019. Operating lease assets obtained in exchange for lease obligations was $495 million in 2020 and $129 million in 2019.

Supplemental balance sheet information related to operating leases is as follows:

December 31		**2020**		2019
Assets				
Other Assets [(1)]	$	**1,725**	$	1,073
Liabilities				
Accrued and other current liabilities		**300**		236
Other Noncurrent Liabilities		**1,362**		768
	$	**1,662**	$	1,004
Weighted-average remaining lease term (years)		**8.0**		7.4
Weighted-average discount rate		**2.8 %**		3.2 %

(1) Includes prepaid leases that have no related lease liability.

Maturities of operating leases liabilities are as follows:

2021	$	336
2022		277
2023		252
2024		187
2025		162
Thereafter		665
Total lease payments		1,879
Less: Imputed interest		217
	$	1,662

At December 31, 2020, the Company had entered into additional real estate operating leases that had not yet commenced; the obligations associated with these leases total $475 million.

10. Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial condition, results of operations or cash flows.

Given the nature of the litigation discussed below and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities.

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (*Fosamax* Litigation). As of December 31, 2020, approximately 3,520 cases are pending against Merck in either federal or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of *Fosamax*.

All federal cases involving allegations of Femur Fractures have been or will be transferred to a multidistrict litigation in the District of New Jersey (Femur Fracture MDL). In the only bellwether case tried to date in the Femur Fracture MDL, *Glynn v. Merck*, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the *Glynn* case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the *Glynn* case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). In March 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. In May 2019, the U.S. Supreme Court decided that the Third Circuit had incorrectly concluded that the issue of preemption should be resolved by a jury, and accordingly vacated the judgment of the Third Circuit and remanded the proceedings back to the Third Circuit to address the issue in a manner consistent with the Supreme Court's opinion. In November 2019, the Third Circuit remanded the cases back to the District Court in order to allow that court to determine in the first instance whether the plaintiffs' state law claims are preempted by federal law under the standards described by the Supreme Court in its opinion. Briefing on the issue is closed, and the parties await the decision of the District Court.

Accordingly, as of December 31, 2020, approximately 970 cases were actively pending in the Femur Fracture MDL.

As of December 31, 2020, approximately 2,270 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge James Hyland in Middlesex County. The parties selected an initial group of cases to be reviewed through fact discovery, and Merck has continued to select additional cases to be reviewed.

As of December 31, 2020, approximately 275 cases alleging Femur Fractures have been filed and are pending in California state court. All of the Femur Fracture cases filed in California state court have been coordinated before a single judge in Orange County, California.

Additionally, there are four Femur Fracture cases pending in other state courts.

Discovery is presently stayed in the Femur Fracture MDL and in the state court in California. Merck intends to defend against these lawsuits.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Januvia* and/or *Janumet*. As of December 31, 2020, Merck is aware of approximately 1,480 product users alleging that *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries.

Most claims have been filed in multidistrict litigation before the U.S. District Court for the Southern District of California (MDL). Outside of the MDL, the majority of claims have been filed in coordinated proceedings before the Superior Court of California, County of Los Angeles (California State Court).

In November 2015, the MDL and California State Court, in separate opinions, granted summary judgment to defendants on grounds of federal preemption.

Plaintiffs appealed in both forums. In November 2017, the U.S. Court of Appeals for the Ninth Circuit vacated the judgment and remanded for further discovery. In November 2018, the California state appellate court reversed and remanded on similar grounds. In March 2019, the parties in the MDL and the California coordinated proceedings agreed to coordinate and adopt a schedule for completing discovery on general causation and preemption issues and for renewing summary judgment and expert motions. Briefing of those motions is complete and hearings before both the MDL and California State Court judges took place on October 20 and December 8, 2020, respectively.

As of December 31, 2020, six product users have claims pending against Merck in state courts other than California, including Illinois. In June 2017, the Illinois trial court denied Merck's motion for summary judgment based on federal preemption. Merck appealed, and the Illinois appellate court affirmed in December 2018. Merck filed a petition for leave to appeal to the Illinois Supreme Court in February 2019. In April 2019, the Illinois Supreme Court stayed consideration of the pending petition to appeal until the U.S. Supreme Court issued its opinion in *Merck Sharp & Dohme Corp. v. Albrecht* (relating to the *Fosamax* matter discussed above). Merck filed the opinion in *Albrecht* with the Illinois Supreme Court in June 2019. The petition for leave to appeal was decided in September 2019, in which the Illinois Supreme Court directed the intermediate appellate court to reconsider its earlier ruling. The Illinois Appellate Court issued a favorable decision concluding, consistent with *Albrecht*, that preemption presents a legal question to be resolved by the court. In May 2020, the Illinois Appellate Court issued a mandate to the state trial court, which, as of December 31, 2020, had not scheduled a case management conference.

In addition to the claims noted above, the Company has agreed to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against these lawsuits.

Vioxx

Merck reached a settlement with the Attorney General of Utah to fully resolve the state's previously disclosed civil lawsuit alleging that Merck misrepresented the safety of *Vioxx*. As part of the resolution, Merck paid the state $25 million. The settlement does not constitute an admission by Merck of any liability or wrongdoing. This agreement marks the final resolution of litigation involving *Vioxx* in the United States. There is ongoing *Vioxx* litigation in certain countries outside the United States.

Governmental Proceedings

As previously disclosed, in the fall of 2018, the Company received a records subpoena from the U.S. Attorney's Office for the District of Vermont (VT USAO) pursuant to Section 248 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) relating to an investigation of potential health care offenses. The subpoena sought information relating to any actual or potential business relationship or arrangement Merck has had with Practice Fusion, Inc. (PFI), a cloud-based, electronic health records (EHR) company that was acquired by Allscripts in January 2018. The Company cooperated with the government and responded to that subpoena. Subsequently, in May 2019, Merck received a second records subpoena from the VT USAO that broadened the government's information request by seeking information relating to Merck's relationship with any EHR company. Shortly thereafter, the VT USAO served a Civil Investigation Demand (CID) upon Merck similarly seeking information on the Company's relationships with EHR vendors. The CID explains that the government is conducting a False Claims Act investigation concerning whether Merck and/or PFI submitted claims to federal health care programs that violate the Federal Anti-Kickback Statute. Merck is cooperating with the government's investigation.

As previously disclosed, in April 2019, Merck received a set of investigative interrogatories from the California Attorney General's Office pursuant to its investigation of conduct and agreements that allegedly affected or delayed competition to Lantus in the insulin market. The interrogatories seek information concerning Merck's development of an insulin glargine product, and its subsequent termination, as well as Merck's patent litigation against Sanofi S.A. concerning Lantus and the resolution of that litigation. Merck is cooperating with the California Attorney General's investigation.

As previously disclosed, in June 2020, Merck received a CID from the U.S. Department of Justice. The CID requests answers to interrogatories, as well as various documents, regarding temperature excursions at a third party storage facility containing certain Merck products. Merck is cooperating with the government's investigation and intends to produce information and/or documents as necessary in response to the CID.

As previously disclosed, the Company's subsidiaries in China have received and may continue to receive inquiries regarding their operations from various Chinese governmental agencies. Some of these inquiries may be related to matters involving other multinational pharmaceutical companies, as well as Chinese entities doing business with such companies. The Company's policy is to cooperate with these authorities and to provide responses as appropriate.

As previously disclosed, from time to time, the Company receives inquiries and is the subject of preliminary investigation activities from competition and other governmental authorities in markets outside the United States. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to the Company, monetary fines and/or remedial undertakings may be required.

Commercial and Other Litigation

Zetia Antitrust Litigation

As previously disclosed, Merck, MSD, Schering Corporation and MSP Singapore Company LLC (collectively, the Merck Defendants) are defendants in putative class action and opt-out lawsuits filed in 2018 on behalf of direct and indirect purchasers of *Zetia* alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The cases have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Rebecca Beach Smith in the Eastern District of Virginia. In December 2018, the court denied the Merck Defendants' motions to dismiss or stay the direct purchaser putative class actions pending bilateral arbitration. In August 2019, the district court adopted in full the report and recommendation of the magistrate judge with respect to the Merck Defendants' motions to dismiss on non-arbitration issues, thereby granting in part and denying in part Merck Defendants' motions to dismiss. In addition, in June 2019, the representatives of the putative direct purchaser class filed an amended complaint and, in August 2019, retailer opt-out plaintiffs filed an amended complaint. In December 2019, the district court granted the Merck Defendants' motion to dismiss to the extent the motion sought dismissal of claims for overcharges paid by entities that purchased generic ezetimibe from Par Pharmaceutical, Inc. (Par Pharmaceutical) and dismissed any claims for such overcharges. In November 2019, the direct purchaser plaintiffs and the indirect purchaser plaintiffs filed motions for class certification. On August 21, 2020, the district court granted in part the direct purchasers' motion for class certification and certified a class of 35 direct purchasers, and on November 2, 2020, the U.S. Court of Appeals for the Fourth Circuit granted the Merck Defendants' motion for permission to appeal the district court's order. Also, on August 14, 2020, the magistrate judge recommended that the court grant the motion for class certification filed by the putative indirect purchaser class. The Merck Defendants objected to this report and recommendation and are awaiting a decision from the district court.

On August 10, 2020, the Merck Defendants filed a motion for summary judgment and other motions, and plaintiffs filed a motion for partial summary judgment, and other motions. Those motions are now fully briefed, and the court will likely hold a hearing on the competing motions. Trial in this matter has been adjourned.

On September 4, 2020, United Healthcare Services, Inc. filed a lawsuit in the United States District Court for the District of Minnesota against Merck and others (the UHC Action). The UHC Action makes similar allegations as those made in the *Zetia* class action. On September 23, 2020, the United States Judicial Panel on Multidistrict Litigation transferred the case to the Eastern District of Virginia to proceed with the multidistrict *Zetia* litigation already in progress.

On December 11, 2020, Humana Inc. filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against Merck and others, alleging defendants violated state antitrust laws in multiple states. Also, on December 11, 2020, Centene Corporation and others filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against the same defendants as Humana. Both lawsuits allege similar anticompetitive acts to those alleged in the *Zetia* class action.

Rotavirus Vaccines Antitrust Litigation

As previously disclosed, MSD is a defendant in putative class action lawsuits filed in 2018 on behalf of direct purchasers of *RotaTeq*, alleging violations of federal antitrust laws. The cases were consolidated in the Eastern District of Pennsylvania. In January 2019, the court denied MSD's motions to compel arbitration and to dismiss the consolidated complaint. In February 2019, MSD appealed the court's order on arbitration to the Third Circuit. In October 2019, the Third Circuit vacated the district court's order and remanded for limited discovery on the issue of arbitrability. On July 6, 2020, MSD filed a renewed motion to compel arbitration, and plaintiffs filed a cross motion for summary judgment as to arbitrability. On November 20, 2020, the district court denied MSD's motion and granted plaintiffs' motion. On December 4, 2020, MSD filed a notice of appeal to the Third Circuit.

Bravecto Litigation

As previously disclosed, in January 2020, the Company was served with a complaint in the United States District Court for the District of New Jersey, seeking to certify a nationwide class action of purchasers or users of *Bravecto* (fluralaner) products in the United States or its territories between May 1, 2014 and December 27, 2019. The complaint contends *Bravecto* causes neurological events and alleges violations of the New Jersey Consumer

Fraud Act, Breach of Warranty, Product Liability, and related theories. A similar case was filed in Quebec, Canada in May 2019.

Qui Tam Litigation

As previously disclosed, in June 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that had been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's *M-M-R* II vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit but notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, as previously disclosed, two putative class action lawsuits on behalf of direct purchasers of the *M-M-R* II vaccine, which charge that the Company misrepresented the efficacy of the *M-M-R* II vaccine in violation of federal antitrust laws and various state consumer protection laws, are pending in the Eastern District of Pennsylvania. In September 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending antitrust suit. As a result, both the False Claims Act suit and the antitrust suits have proceeded into discovery, which is now complete, and the parties have filed and briefed cross-motions for summary judgment, which are currently pending before the Court. The Company continues to defend against these lawsuits.

Merck KGaA Litigation

As previously disclosed, in January 2016, to protect its long-established brand rights in the United States, the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), historically operating as the EMD Group in the United States, alleging it improperly uses the name "Merck" in the United States. KGaA has filed suit against the Company in France, the UK, Germany, Switzerland, Mexico, India, Australia, Singapore, Hong Kong, and China alleging, among other things, unfair competition, trademark infringement and/or corporate name infringement. In the UK, Australia, Singapore, Hong Kong, and India, KGaA also alleges breach of the parties' coexistence agreement. The litigation is ongoing in the United States with no trial date set, and also ongoing in numerous jurisdictions outside of the United States; the Company is defending those suits in each jurisdiction.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications (NDAs) with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Similar lawsuits defending the Company's patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products and, with respect to products acquired through acquisitions, potentially significant intangible asset impairment charges.

Bridion — Between January and November 2020, the Company received multiple Paragraph IV Certification Letters under the Hatch-Waxman Act notifying the Company that generic drug companies have filed applications to the FDA seeking pre-patent expiry approval to sell generic versions of *Bridion* (sugammadex) Injection. In March, April and December 2020, the Company filed patent infringement lawsuits in the U.S. District Courts for the District of New Jersey and the Northern District of West Virginia against those generic companies. All actions in the District of New Jersey have been consolidated. These lawsuits, which assert one or more patents covering sugammadex and methods of using sugammadex, automatically stay FDA approval of the generic applications until June 2023 or until adverse court decisions, if any, whichever may occur earlier.

Mylan Pharmaceuticals Inc., Mylan API US LLC, and Mylan Inc. (Mylan) have filed motions to dismiss in the District of New Jersey for lack of venue and failure to state a claim against certain defendants, and in the Northern District of West Virginia for failure to state a claim against certain defendants. The New Jersey motion has not yet been decided, and the West Virginia action is stayed pending resolution of the New Jersey motion.

Januvia, Janumet, Janumet XR — The FDA has granted pediatric exclusivity with respect to *Januvia, Janumet,* and *Janumet XR,* which provides a further six months of exclusivity in the United States beyond the expiration of all patents listed in the FDA's Orange Book. Including this exclusivity, key patent protection extends to January 2023. The Company anticipates that sales of *Januvia* and *Janumet* in the United States will decline significantly after this loss of market exclusivity. However, *Januvia. Janumet,* and *Janumet XR* contain sitagliptin phosphate monohydrate and the Company has another patent covering certain phosphate salt and polymorphic forms of sitagliptin, which, if determined to be valid, would preclude generic manufacturers from making sitagliptin phosphate salt and polymorphic forms before that patent, inclusive of pediatric exclusivity, expires in 2027 (2027 salt/polymorph patent). In 2019, Par Pharmaceutical filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of the 2027 salt/polymorph patent. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of *Januvia, Janumet,* and *Janumet XR* following expiration of key patent protection, but prior to the expiration of the 2027 salt/polymorph patent, and a later granted patent owned by the Company covering the *Janumet* formulation which, inclusive of pediatric exclusivity, expires in 2029. The Company also filed a patent infringement lawsuit against Mylan in the Northern District of West Virginia. The Judicial Panel of Multidistrict Litigation entered an order transferring the Company's lawsuit against Mylan to the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with the other cases pending in that district. The U.S. District Court for the District of Delaware has scheduled the lawsuits for a single three-day trial on invalidity issues in October 2021. The Court has scheduled separate one-day trials on infringement issues in November 2021 through January 2022, to the extent such trials are necessary. In the Company's case against Mylan, the U.S. District Court for the Northern District of West Virginia has conditionally scheduled a three-day trial in December 2021 on all issues.

The Company has settled with nine generic companies providing that these generic companies can bring their products to the market in May 2027 or earlier under certain circumstances.

Additionally, in 2019, Mylan filed a petition for *Inter Partes* Review (IPR) at the United States Patent and Trademark Office (USPTO) seeking invalidity of some, but not all, of the claims of the 2027 salt/polymorph patent, which other manufacturers joined. The USPTO instituted IPR proceedings in May 2020, finding a reasonable likelihood that the challenged claims are not valid. A trial was held in February 2021 and a final decision is expected in May 2021. If the challenges are successful, the unchallenged claims of the 2027 salt/polymorph patent will remain valid, subject to the court proceedings described above.

In Germany, two generic companies have sought the revocation of the Supplementary Protection Certificate (SPC) for *Janumet*. If the generic companies are successful, *Janumet* could lose market exclusivity in Germany as early as July 2022. Challenges to the *Janumet* SPC have also occurred in Portugal and Finland, and could occur in other European countries.

Nexplanon — In June 2017, Microspherix LLC (Microspherix) sued the Company in the U.S District Court for the District of New Jersey asserting that the manufacturing, use, sale and importation of *Nexplanon* infringed several of Microspherix's patents that claim radio-opaque, implantable drug delivery devices. Microspherix is claiming damages from September 2014 until those patents expire in May 2021. The Company brought IPR proceedings in the USPTO and successfully stayed the district court action. The USPTO invalidated some, but not all, of the claims asserted against the Company. The Company appealed the decisions finding claims valid, and the Court of Appeals for the Federal Circuit affirmed the USPTO's decisions. The matter is no longer stayed in the district court, and the Company is currently litigating the invalidity and non-infringement of the remaining asserted claims.

Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial condition, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of December 31, 2020 and 2019 of approximately $250 million and $240 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Environmental Matters

The Company and its subsidiaries are parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is *de minimis* and for others the final costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a material adverse effect on the financial condition, results of operations or liquidity of the Company. The Company has taken an active role in identifying and accruing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled $67 million at both December 31, 2020 and 2019. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed approximately $65 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial condition, results of operations or liquidity for any year.

11. Equity

The Merck certificate of incorporation authorizes 6,500,000,000 shares of common stock and 20,000,000 shares of preferred stock.

Capital Stock

A summary of common stock and treasury stock transactions (shares in millions) is as follows:

	2020		2019		2018	
	Common Stock	**Treasury Stock**	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	**3,577**	**1,038**	3,577	985	3,577	880
Purchases of treasury stock	**—**	**16**	—	66	—	122
Issuances [(1)]	**—**	**(7)**	—	(13)	—	(17)
Balance December 31	**3,577**	**1,047**	3,577	1,038	3,577	985

[(1)] *Issuances primarily reflect activity under share-based compensation plans.*

In 2018, the Company entered into accelerated share repurchase (ASR) agreements with two third-party financial institutions (the Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers, which were funded with existing cash and investments, as well as short-term borrowings. Upon settlement of the ASR agreements in 2019, Merck received an additional 7.7 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount, bringing the total shares received by Merck under this program to 64.4 million.

12. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. These plans were approved by the Company's shareholders.

At December 31, 2020, 100 million shares collectively were authorized for future grants under the Company's share-based compensation plans. These awards are settled with treasury shares.

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. These awards generally vest one-third each year over a three-year period, with a contractual term of 7-10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and PSUs, dividends declared during the vesting period are payable to the employees only upon vesting. Over the PSU performance period, the number of shares of stock that are expected to be issued will be adjusted based on the probability of achievement of a performance target and final compensation expense will be recognized based on the ultimate number of shares issued. RSU and PSU distributions will be in shares of Company stock after the end of the vesting or performance period, subject to the terms applicable to such awards. PSU awards generally vest after three years. RSU awards generally vest one-third each year over a three-year period.

Total pretax share-based compensation cost recorded in 2020, 2019 and 2018 was $475 million, $417 million and $348 million, respectively, with related income tax benefits of $65 million, $57 million and $55 million, respectively.

The Company uses the Black-Scholes option pricing model for determining the fair value of option grants. In applying this model, the Company uses both historical data and current market data to estimate the fair value of its options. The Black-Scholes model requires several assumptions including expected dividend yield, risk-free interest rate, volatility, and term of the options. The expected dividend yield is based on historical patterns of dividend payments. The risk-free interest rate is based on the rate at grant date of zero-coupon U.S. Treasury Notes with a term equal to the expected term of the option. Expected volatility is estimated using a blend of historical and implied volatility. The historical component is based on historical monthly price changes. The implied volatility is obtained from market data on the Company's traded options. The expected life represents the amount of time that options granted are expected to be outstanding, based on historical and forecasted exercise behavior.

The weighted average exercise price of options granted in 2020, 2019 and 2018 was $77.67, $80.05 and $58.15 per option, respectively. The weighted average fair value of options granted in 2020, 2019 and 2018 was $9.93, $10.63 and $8.26 per option, respectively, and were determined using the following assumptions:

Years Ended December 31	**2020**	2019	2018
Expected dividend yield	**3.1 %**	3.2 %	3.4 %
Risk-free interest rate	**0.4 %**	2.4 %	2.9 %
Expected volatility	**22.1 %**	18.7 %	19.1 %
Expected life (years)	**5.8**	5.9	6.1

Summarized information relative to stock option plan activity (options in thousands) is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2020	17,868	$ 59.88		
Granted	**3,564**	**77.67**		
Exercised	**(1,685)**	**52.73**		
Forfeited	**(301)**	**67.73**		
Outstanding December 31, 2020	**19,446**	**$ 63.64**	**6.27**	**$ 353**
Exercisable December 31, 2020	**13,141**	**$ 58.30**	**5.13**	**$ 309**

Additional information pertaining to stock option plans is provided in the table below:

Years Ended December 31	**2020**	2019	2018
Total intrinsic value of stock options exercised	**$ 51**	$ 295	$ 348
Fair value of stock options vested	**25**	27	29
Cash received from the exercise of stock options	**89**	361	591

A summary of nonvested RSU and PSU activity (shares in thousands) is as follows:

	RSUs		PSUs	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested January 1, 2020	13,527	$ 67.58	1,972	$ 69.18
Granted	**6,627**	**77.79**	**996**	**77.82**
Vested	**(7,511)**	**65.70**	**(824)**	**64.01**
Forfeited	**(728)**	**72.06**	**(44)**	**80.06**
Nonvested December 31, 2020	**11,915**	**$ 74.17**	**2,100**	**$ 75.08**

At December 31, 2020, there was $678 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.9 years. For segment reporting, share-based compensation costs are unallocated expenses.

13. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the United States and in certain of its international subsidiaries. In addition, the Company provides medical benefits, principally to its eligible U.S. retirees and their dependents, through its other postretirement benefit plans. The Company uses December 31 as the year-end measurement date for all of its pension plans and other postretirement benefit plans.

Net Periodic Benefit Cost

The net periodic benefit cost (credit) for pension and other postretirement benefit plans consisted of the following components:

	Pension Benefits								
	U.S.			International			Other Postretirement Benefits		
Years Ended December 31	**2020**	2019	2018	**2020**	2019	2018	**2020**	2019	2018
Service cost	**$ 360**	$ 293	$ 326	**$ 301**	$ 238	$ 238	**$ 52**	$ 48	$ 57
Interest cost	**431**	458	432	**137**	177	178	**57**	69	69
Expected return on plan assets	**(774)**	(817)	(851)	**(415)**	(426)	(431)	**(75)**	(72)	(83)
Amortization of unrecognized prior service cost	**(49)**	(49)	(50)	**(18)**	(12)	(13)	**(73)**	(78)	(84)
Net loss (gain) amortization	**303**	151	232	**127**	64	84	**(18)**	(10)	1
Termination benefits	**10**	31	19	**3**	8	2	**2**	5	3
Curtailments	**10**	14	10	**—**	6	1	**(4)**	(11)	(8)
Settlements	**13**	—	5	**15**	1	13	**—**	—	—
Net periodic benefit cost (credit)	**$ 304**	$ 81	$ 123	**$ 150**	$ 56	$ 72	**$ (59)**	$ (49)	$ (45)

The changes in net periodic benefit cost year over year for pension plans are largely attributable to changes in the discount rate affecting net loss amortization.

In connection with restructuring actions (see Note 5), termination charges were recorded in 2020, 2019 and 2018 on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments were recorded on pension and other postretirement benefit plans and settlements were recorded on certain U.S. and international pension plans as reflected in the table above.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 14), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in *Restructuring costs* if the event giving rise to the termination benefits, curtailment or settlement is related to restructuring actions as noted above.

Obligations and Funded Status

Summarized information about the changes in plan assets and benefit obligations, the funded status and the amounts recorded at December 31 is as follows:

	Pension Benefits				Other Postretirement Benefits	
	U.S.		International			
	2020	2019	**2020**	2019	**2020**	2019
Fair value of plan assets January 1	$ **11,361**	$ 9,648	$ **10,163**	$ 8,580	$ **1,102**	$ 968
Actual return on plan assets	**1,908**	2,165	**1,026**	1,505	**175**	203
Company contributions	**199**	130	**387**	262	**19**	14
Effects of exchange rate changes	**—**	—	**746**	31	**—**	—
Benefits paid	**(751)**	(582)	**(215)**	(230)	**(93)**	(104)
Settlements	**(45)**	—	**(117)**	(12)	**—**	—
Other	**—**	—	**59**	27	**18**	21
Fair value of plan assets December 31	$ **12,672**	$ 11,361	$ **12,049**	$ 10,163	$ **1,221**	$ 1,102
Benefit obligation January 1	$ **13,003**	$ 10,620	$ **10,612**	$ 9,083	$ **1,673**	$ 1,615
Service cost	**360**	293	**301**	238	**52**	48
Interest cost	**431**	458	**137**	177	**57**	69
Actuarial losses (gains) [1]	**1,594**	2,165	**1,036**	1,313	**(98)**	21
Benefits paid	**(751)**	(582)	**(215)**	(230)	**(93)**	(104)
Effects of exchange rate changes	**—**	—	**794**	4	**(3)**	1
Plan amendments	**—**	—	**(64)**	1	**—**	—
Curtailments	**11**	18	**(8)**	3	**(1)**	—
Termination benefits	**10**	31	**3**	8	**2**	5
Settlements	**(45)**	—	**(117)**	(12)	**—**	—
Other	**—**	—	**55**	27	**18**	18
Benefit obligation December 31	$ **14,613**	$ 13,003	$ **12,534**	$ 10,612	$ **1,607**	$ 1,673
Funded status December 31	$ **(1,941)**	$ (1,642)	$ **(485)**	$ (449)	$ **(386)**	$ (571)
Recognized as:						
Other Assets	$ **—**	$ —	$ **941**	$ 837	$ **—**	$ —
Accrued and other current liabilities	**(82)**	(92)	**(13)**	(18)	**(9)**	(10)
Other Noncurrent Liabilities	**(1,859)**	(1,550)	**(1,413)**	(1,268)	**(377)**	(561)

[1] *Actuarial losses (gains) primarily reflect changes in discount rates.*

At December 31, 2020 and 2019, the accumulated benefit obligation was $26.4 billion and $22.8 billion, respectively, for all pension plans, of which $14.4 billion and $12.8 billion, respectively, related to U.S. pension plans.

Information related to the funded status of selected pension plans at December 31 is as follows:

	U.S.		International	
	2020	2019	**2020**	2019
Pension plans with a projected benefit obligation in excess of plan assets				
Projected benefit obligation	$ **14,613**	$ 13,003	$ **8,951**	$ 7,421
Fair value of plan assets	**12,672**	11,361	**7,626**	6,135
Pension plans with an accumulated benefit obligation in excess of plan assets				
Accumulated benefit obligation	$ **13,489**	$ 12,009	$ **4,288**	$ 2,476
Fair value of plan assets	**11,685**	10,484	**3,033**	1,501

Plan Assets

Entities are required to use a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity. The Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation. At December 31, 2020 and 2019, $942 million and $860 million, respectively, or approximately 4% of the Company's pension investments were categorized as Level 3 assets.

If the inputs used to measure the financial assets fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

The fair values of the Company's pension plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	Level 2	Level 3	NAV [1]	Total	Level 1	Level 2	Level 3	NAV [1]	Total
	2020					2019				
U.S. Pension Plans										
Cash and cash equivalents	$ 5	$ —	$ —	$ 303	$ 308	$ 3	$ —	$ —	$ 236	$ 239
Investment funds										
Developed markets equities	206	—	—	3,884	4,090	205	—	—	3,542	3,747
Emerging markets equities	169	—	—	927	1,096	165	—	—	723	888
Mortgage and asset-backed securities	—	89	—	—	89	—	—	—	—	—
Government and agency obligations	—	—	—	—	—	—	—	—	173	173
Equity securities										
Developed markets	2,819	—	—	—	2,819	2,451	—	—	—	2,451
Fixed income securities										—
Government and agency obligations	—	2,236	—	—	2,236	—	2,094	—	—	2,094
Corporate obligations	—	1,994	—	—	1,994	—	1,582	—	—	1,582
Mortgage and asset-backed securities	—	33	—	—	33	—	178	—	—	178
Other investments	—	—	7	—	7	—	—	9	—	9
Plan assets at fair value	$ 3,199	$ 4,352	$ 7	$ 5,114	$ 12,672	$ 2,824	$ 3,854	$ 9	$ 4,674	$ 11,361
International Pension Plans										
Cash and cash equivalents	$ 110	$ 1	$ —	$ 20	$ 131	$ 70	$ 1	$ —	$ 15	$ 86
Investment funds										
Developed markets equities	475	4,286	—	118	4,879	546	3,761	—	96	4,403
Government and agency obligations	1,516	2,614	—	172	4,302	462	2,534	—	207	3,203
Emerging markets equities	154	—	—	92	246	66	96	—	90	252
Corporate obligations	5	12	—	172	189	5	11	—	109	125
Other fixed income obligations	9	11	—	4	24	9	6	—	—	15
Real estate	—	1	—	15	16	—	1	—	—	1
Equity securities										
Developed markets	505	—	—	—	505	565	—	—	—	565
Fixed income securities										
Government and agency obligations	3	486	—	3	492	3	376	—	—	379
Corporate obligations	1	174	—	2	177	1	135	—	—	136
Mortgage and asset-backed securities	—	70	—	—	70	—	61	—	—	61
Other investments										
Insurance contracts [2]	—	76	935	1	1,012	—	65	851	—	916
Other	1	5	—	—	6	—	5	—	16	21
Plan assets at fair value	$ 2,779	$ 7,736	$ 935	$ 599	$ 12,049	$ 1,727	$ 7,052	$ 851	$ 533	$ 10,163

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2020 and 2019.*

[2] *The plans' Level 3 investments in insurance contracts are generally valued using a crediting rate that approximates market returns and invest in underlying securities whose market values are unobservable and determined using pricing models, discounted cash flow methodologies, or similar techniques.*

The table below provides a summary of the changes in fair value, including transfers in and/or out, of all financial assets measured at fair value using significant unobservable inputs (Level 3) for the Company's pension plan assets:

	2020				2019			
	Insurance Contracts	Real Estate	Other	Total	Insurance Contracts	Real Estate	Other	Total
U.S. Pension Plans								
Balance January 1	$ —	$ —	$ 9	$ 9	$ —	$ —	$ 13	$ 13
Actual return on plan assets:								
Relating to assets still held at December 31	—	—	(5)	(5)	—	—	(8)	(8)
Relating to assets sold during the year	—	—	5	5	—	—	8	8
Purchases and sales, net	—	—	(2)	(2)	—	—	(4)	(4)
Balance December 31	$ —	$ —	$ 7	$ 7	$ —	$ —	$ 9	$ 9
International Pension Plans								
Balance January 1	$ 851	$ —	$ —	$ 851	$ 811	$ 1	$ 1	$ 813
Actual return on plan assets:								
Relating to assets still held at December 31	103	—	—	103	54	—	—	54
Purchases and sales, net	(17)	—	—	(17)	(14)	(1)	(1)	(16)
Transfers out of Level 3	(2)	—	—	(2)	—	—	—	—
Balance December 31	$ 935	$ —	$ —	$ 935	$ 851	$ —	$ —	$ 851

The fair values of the Company's other postretirement benefit plan assets at December 31 by asset category are as follows:

	Fair Value Measurements Using					Fair Value Measurements Using				
	Level 1	Level 2	Level 3	NAV [1]	Total	Level 1	Level 2	Level 3	NAV [1]	Total
	2020					2019				
Cash and cash equivalents	$ 31	$ —	$ —	$ 28	$ 59	$ 52	$ —	$ —	$ 22	$ 74
Investment funds										
Developed markets equities	19	—	—	355	374	19	—	—	324	343
Emerging markets equities	16	—	—	85	101	15	—	—	66	81
Government and agency obligations	1	—	—	—	1	1	—	—	16	17
Mortgage and asset-backed securities	—	8	—	—	8	—	—	—	—	—
Equity securities										
Developed markets	258	—	—	—	258	225	—	—	—	225
Fixed income securities										
Government and agency obligations	—	221	—	—	221	—	196	—	—	196
Corporate obligations	—	196	—	—	196	—	149	—	—	149
Mortgage and asset-backed securities	—	3	—	—	3	—	17	—	—	17
Plan assets at fair value	$ 325	$ 428	$ —	$ 468	$ 1,221	$ 312	$ 362	$ —	$ 428	$ 1,102

[1] *Certain investments that were measured at net asset value (NAV) per share or its equivalent have not been classified in the fair value hierarchy. The NAV amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the fair value of plan assets at December 31, 2020 and 2019.*

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 30% to 45% in U.S. equities, 15% to 30% in international equities, 35% to 45% in fixed-income investments, and up to 5% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans' benefit obligations. The expected annual standard deviation of returns of the target portfolio, which approximates 11%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. For international pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Expected Contributions

Expected contributions during 2021 are approximately $300 million for U.S. pension plans, approximately $170 million for international pension plans and approximately $35 million for other postretirement benefit plans.

Expected Benefit Payments

Expected benefit payments are as follows:

	U.S. Pension Benefits	International Pension Benefits	Other Postretirement Benefits
2021	$ 816	$ 274	$ 85
2022	786	277	86
2023	781	284	87
2024	772	285	89
2025	782	287	91
2026 — 2030	4,271	1,688	474

Expected benefit payments are based on the same assumptions used to measure the benefit obligations and include estimated future employee service.

Amounts Recognized in Other Comprehensive Income

Net loss amounts reflect differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions. Net loss amounts in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees. The following amounts were reflected as components of *OCI*:

	Pension Plans						Other Postretirement Benefit Plans		
	U.S.			International					
Years Ended December 31	**2020**	2019	2018	**2020**	2019	2018	**2020**	2019	2018
Net (loss) gain arising during the period	$ **(448)**	$ (816)	$ (397)	$ **(407)**	$ (227)	$ (505)	$ **198**	$ 112	$ 186
Prior service (cost) credit arising during the period	**(1)**	(4)	(4)	**62**	(1)	(10)	**(3)**	(11)	2
	$ **(449)**	$ (820)	$ (401)	$ **(345)**	$ (228)	$ (515)	$ **195**	$ 101	$ 188
Net loss (gain) amortization included in benefit cost	$ **303**	$ 151	$ 232	$ **127**	$ 64	$ 84	$ **(18)**	$ (10)	$ 1
Prior service credit amortization included in benefit cost	**(49)**	(49)	(50)	**(18)**	(12)	(13)	**(73)**	(78)	(84)
	$ **254**	$ 102	$ 182	$ **109**	$ 52	$ 71	$ **(91)**	$ (88)	$ (83)

Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining U.S. pension and other postretirement benefit plan and international pension plan information are as follows:

	U.S. Pension and Other Postretirement Benefit Plans			International Pension Plans		
December 31	**2020**	2019	2018	**2020**	2019	2018
Net periodic benefit cost						
Discount rate	**3.40 %**	4.40 %	3.70 %	**1.50 %**	2.20 %	2.10 %
Expected rate of return on plan assets	**7.30 %**	8.10 %	8.20 %	**4.40 %**	4.90 %	5.10 %
Salary growth rate	**4.20 %**	4.30 %	4.30 %	**2.80 %**	2.80 %	2.90 %
Interest crediting rate	**4.90 %**	3.40 %	3.30 %	**2.80 %**	2.90 %	2.80 %
Benefit obligation						
Discount rate	**2.70 %**	3.40 %	4.40 %	**1.10 %**	1.50 %	2.20 %
Salary growth rate	**4.60 %**	4.20 %	4.30 %	**2.80 %**	2.80 %	2.80 %
Interest crediting rate	**4.70 %**	4.90 %	3.40 %	**3.00 %**	2.80 %	2.90 %

For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid and is determined on a plan basis. The expected rate of return for each plan is developed considering long-term historical returns data, current market conditions, and actual returns on the plan assets. Using this reference information, the long-term return expectations for each asset category and a weighted-average expected return for each plan's target portfolio is developed according to the allocation among those investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2021, the expected rate of return for the Company's U.S. pension and other postretirement benefit plans will range from 6.50% to 6.70%, as compared to a range of 7.00% to 7.30% in 2020.

The health care cost trend rate assumptions for other postretirement benefit plans are as follows:

December 31	**2020**	2019
Health care cost trend rate assumed for next year	**6.6 %**	6.8 %
Rate to which the cost trend rate is assumed to decline	**4.5 %**	4.5 %
Year that the trend rate reaches the ultimate trend rate	**2032**	2032

Savings Plans

The Company also maintains defined contribution savings plans in the United States. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total employer contributions to these plans in 2020, 2019 and 2018 were $166 million, $149 million and $136 million, respectively.

14. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

Years Ended December 31	2020	2019	2018
Interest income	$ (59)	$ (274)	$ (343)
Interest expense	831	893	772
Exchange losses	145	187	145
Income from investments in equity securities, net [1]	(1,338)	(170)	(324)
Net periodic defined benefit plan (credit) cost other than service cost	(339)	(545)	(512)
Other, net	(126)	48	(140)
	$ (886)	$ 139	$ (402)

[1] Includes net realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds. Unrealized gains and losses from investments that are directly owned are determined at the end of the reporting period, while ownership interests in investment funds are accounted for on a one quarter lag.

Other, net (as presented in the table above) in 2019 includes $162 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment (see Note 8).

Other, net in 2018 includes a gain of $115 million related to the settlement of certain patent litigation, income of $99 million related to AstraZeneca's option exercise in 2014 in connection with the termination of the Company's relationship with AstraZeneca LP (AZLP), and a gain of $85 million resulting from the receipt of a milestone payment for an out licensed migraine clinical development program. Other, net in 2018 also includes $144 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment (see Note 8), as well as $41 million of charges related to the write-down of assets held for sale to fair value in anticipation of the dissolution of the Company's joint venture with Supera Farma Laboratorios S.A. in Brazil.

Interest paid was $822 million in 2020, $841 million in 2019 and $777 million in 2018.

15. Taxes on Income

A reconciliation between the effective tax rate and the U.S. statutory rate is as follows:

	2020		2019		2018	
	Amount	**Tax Rate**	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	$ 1,846	21.0 %	$ 2,408	21.0 %	$ 1,827	21.0 %
Differential arising from:						
Foreign earnings	(1,242)	(14.1)	(1,020)	(8.9)	(245)	(2.8)
GILTI and the foreign-derived intangible income deduction	364	4.1	336	2.9	(25)	(0.3)
R&D tax credit	(110)	(1.3)	(118)	(1.0)	(96)	(1.1)
Tax settlements	(13)	(0.2)	(403)	(3.5)	(22)	(0.3)
Acquisition of VelosBio	559	6.3	—	—	—	—
Restructuring	105	1.2	39	0.3	56	0.6
Acquisition of OncoImmune	97	1.1	—	—	—	—
State taxes	67	0.8	(2)	—	201	2.3
Acquisition-related costs, including amortization	46	0.5	95	0.8	267	3.1
Valuation allowances	42	0.5	113	1.0	269	3.1
Acquisition of Peloton	—	—	209	1.8	—	—
Tax Cuts and Jobs Act of 2017	—	—	117	1.0	289	3.3
Other	(52)	(0.5)	(87)	(0.7)	(13)	(0.1)
	$ 1,709	19.4 %	$ 1,687	14.7 %	$ 2,508	28.8 %

The Tax Cuts and Jobs Act (TCJA) was enacted in December 2017 and the Company reflected the impact of the TCJA in its 2017 financial statements. However, since application of certain provisions of the TCJA remained subject to further interpretation, in certain instances the Company made reasonable estimates of the effects of the TCJA, which were since finalized and resulted in additional income tax expense in 2018 and 2019. The Company's remaining transition tax liability under the TCJA, which has been reduced by payments and the utilization of foreign tax credits, was $3.0 billion at December 31, 2020, of which $390 million is included in *Income taxes payable* and the remainder of $2.6 billion is included in *Other Noncurrent Liabilities*. As a result of the transition tax under the TCJA, the Company is no longer indefinitely reinvested with respect to its undistributed earnings from foreign subsidiaries and has provided a deferred tax liability for foreign withholding taxes that would apply. The Company remains indefinitely reinvested with respect to its financial statement basis in excess of tax basis of its foreign subsidiaries. A determination of the deferred tax liability with respect to this basis difference is not practicable.

The foreign earnings tax rate differentials in the tax rate reconciliation above primarily reflect the impacts of operations in jurisdictions with different tax rates than the United States, particularly Ireland and Switzerland, as well as Singapore and Puerto Rico which operate under tax incentive grants (which begin to expire in 2022), thereby yielding a favorable impact on the effective tax rate compared with the U.S. statutory rate of 21%. Towards the end of 2020, a new reduced tax rate arrangement was agreed to in Switzerland for certain newly active legal entities.

Income before taxes consisted of:

Years Ended December 31	2020	2019	2018
Domestic	$ (3,492)	$ 439	$ 3,717
Foreign	12,283	11,025	4,984
	$ 8,791	$ 11,464	$ 8,701

Taxes on income consisted of:

Years Ended December 31	2020	2019	2018
Current provision			
Federal	$ 962	$ 514	$ 536
Foreign	1,362	1,806	2,281
State	53	(77)	200
	2,377	2,243	3,017
Deferred provision			
Federal	(605)	(330)	(402)
Foreign	(40)	(240)	(64)
State	(23)	14	(43)
	(668)	(556)	(509)
	$ 1,709	$ 1,687	$ 2,508

Deferred income taxes at December 31 consisted of:

	2020		2019	
	Assets	Liabilities	Assets	Liabilities
Product intangibles and licenses	$ 141	$ 1,250	$ 442	$ 1,778
Inventory related	43	335	32	354
Accelerated depreciation	—	588	—	594
Equity investments	—	175	—	—
Pensions and other postretirement benefits	834	248	785	191
Compensation related	252	—	322	—
Unrecognized tax benefits	117	—	109	—
Net operating losses and other tax credit carryforwards	794	—	897	—
Other	808	81	764	84
Subtotal	2,989	2,677	3,351	3,001
Valuation allowance	(433)		(1,100)	
Total deferred taxes	$ 2,556	$ 2,677	$ 2,251	$ 3,001
Net deferred income taxes		$ 121		$ 750
Recognized as:				
Other Assets	$ 894		$ 719	
Deferred Income Taxes		$ 1,015		$ 1,470

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2020, $464 million of deferred taxes on NOL carryforwards relate to foreign jurisdictions. Valuation allowances of $433 million have been established on these foreign NOL carryforwards and other foreign deferred tax assets. In addition, the Company has $330 million of deferred tax assets relating to various U.S. tax credit carryforwards and NOL carryforwards, all of which are expected to be fully utilized prior to expiry.

Income taxes paid in 2020, 2019 and 2018 were $2.7 billion, $4.5 billion and $1.5 billion, respectively. Tax benefits relating to stock option exercises were $55 million in 2020, $65 million in 2019 and $77 million in 2018.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2020	2019	2018
Balance January 1	$ 1,225	$ 1,893	$ 1,723
Additions related to current year positions	298	199	221
Additions related to prior year positions	110	46	142
Reductions for tax positions of prior years [1]	(4)	(454)	(73)
Settlements [1]	(70)	(356)	(91)
Lapse of statute of limitations [2]	(22)	(103)	(29)
Balance December 31	$ 1,537	$ 1,225	$ 1,893

[1] *Amounts in 2019 reflects the settlement with the IRS discussed below.*

[2] *Amount in 2019 includes $78 million related to the divestiture of Merck's Consumer Care business in 2014.*

If the Company were to recognize the unrecognized tax benefits of $1.5 billion at December 31, 2020, the income tax provision would reflect a favorable net impact of $1.5 billion.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2020 could decrease by up to approximately $160 million in the next 12 months as a result of various audit closures, settlements or the expiration of the statute of limitations. The ultimate finalization of the Company's examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

Interest and penalties associated with uncertain tax positions amounted to an expense (benefit) of $27 million in 2020, $(101) million in 2019 and $51 million in 2018. These amounts reflect the beneficial impacts of various tax settlements, including the settlement discussed below. Liabilities for accrued interest and penalties were $268 million and $243 million as of December 31, 2020 and 2019, respectively.

In 2019, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2012-2014 U.S. federal income tax returns. As a result, the Company was required to make a payment of $107 million. The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $364 million net tax benefit in 2019. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for.

The IRS is currently conducting examinations of the Company's tax returns for the years 2015 and 2016. In addition, various state and foreign tax examinations are in progress and for these jurisdictions, the Company's income tax returns are open for examination for the period 2003 through 2020.

16. Earnings per Share

The calculations of earnings per share (shares in millions) are as follows:

Years Ended December 31	**2020**	2019	2018
Net income attributable to Merck & Co., Inc.	$ **7,067**	$ 9,843	$ 6,220
Average common shares outstanding	**2,530**	2,565	2,664
Common shares issuable [(1)]	**11**	15	15
Average common shares outstanding assuming dilution	**2,541**	2,580	2,679
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$ **2.79**	$ 3.84	$ 2.34
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$ **2.78**	$ 3.81	$ 2.32

[(1)] *Issuable primarily under share-based compensation plans.*

In 2020, 2019 and 2018, 5 million, 2 million and 6 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

17. Other Comprehensive Income (Loss)

Changes in *AOCI* by component are as follows:

	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2018, net of taxes	$ (108)	$ (61)	$ (2,787)	$ (1,954)	$ (4,910)
Other comprehensive income (loss) before reclassification adjustments, pretax	228	(108)	(728)	(84)	(692)
Tax	(55)	1	169	(139)	(24)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	173	(107)	(559)	(223)	(716)
Reclassification adjustments, pretax	157 [1]	97 [2]	170 [3]	—	424
Tax	(33)	—	(36)	—	(69)
Reclassification adjustments, net of taxes	124	97	134	—	355
Other comprehensive income (loss), net of taxes	297	(10)	(425)	(223)	(361)
Adoption of ASU 2018-02	(23)	1	(344)	100	(266)
Adoption of ASU 2016-01	—	(8)	—	—	(8)
Balance at December 31, 2018, net of taxes	166	(78)	(3,556)	(2,077)	(5,545)
Other comprehensive income (loss) before reclassification adjustments, pretax	86	140	(948)	112	(610)
Tax	(15)	—	192	(16)	161
Other comprehensive income (loss) before reclassification adjustments, net of taxes	71	140	(756)	96	(449)
Reclassification adjustments, pretax	(261) [1]	(44) [2]	66 [3]	—	(239)
Tax	55	—	(15)	—	40
Reclassification adjustments, net of taxes	(206)	(44)	51	—	(199)
Other comprehensive income (loss), net of taxes	(135)	96	(705)	96	(648)
Balance at December 31, 2019, net of taxes	31	18	(4,261) [4]	(1,981)	(6,193)
Other comprehensive income (loss) before reclassification adjustments, pretax	**(383)**	**3**	**(599)**	**64**	**(915)**
Tax	**84**	**—**	**111**	**89**	**284**
Other comprehensive income (loss) before reclassification adjustments, net of taxes	**(299)**	**3**	**(488)**	**153**	**(631)**
Reclassification adjustments, pretax	**2** [1]	**(21)** [2]	**272** [3]	**—**	**253**
Tax	**—**	**—**	**(63)**	**—**	**(63)**
Reclassification adjustments, net of taxes	**2**	**(21)**	**209**	**—**	**190**
Other comprehensive income (loss), net of taxes	**(297)**	**(18)**	**(279)**	**153**	**(441)**
Balance at December 31, 2020, net of taxes	**$ (266)**	**$ —**	**$ (4,540)** [4]	**$ (1,828)**	**$ (6,634)**

[1] *Relates to foreign currency cash flow hedges that were reclassified from* AOCI *to* Sales.

[2] *Represents net realized (gains) losses on the sales of available-for-sale investments that were reclassified from* AOCI *to* Other (income) expense, net.

[3] *Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 13).*

[4] *Includes pension plan net loss of $5.4 billion and $5.1 billion at December 31, 2020 and 2019, respectively, and other postretirement benefit plan net gain of $391 million and $247 million at December 31, 2020 and 2019, respectively, as well as pension plan prior service credit of $255 million and $263 million at December 31, 2020 and 2019, respectively, and other postretirement benefit plan prior service credit of $244 million and $305 million at December 31, 2020 and 2019, respectively.*

18. Segment Reporting

The Company's operations are principally managed on a products basis and include two operating segments, which are the Pharmaceutical and Animal Health segments, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors and animal producers.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment in the first quarter of 2020.

The Company previously had an Alliances segment that primarily included activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Sales of the Company's products were as follows:

Years Ended December 31	2020 U.S.	2020 Int'l	2020 Total	2019 U.S.	2019 Int'l	2019 Total	2018 U.S.	2018 Int'l	2018 Total
Pharmaceutical:									
Oncology									
Keytruda	$ 8,352	$ 6,028	$ 14,380	$ 6,305	$ 4,779	$ 11,084	$ 4,150	$ 3,021	$ 7,171
Alliance revenue - Lynparza [1]	417	308	725	269	176	444	127	61	187
Alliance revenue - Lenvima [1]	359	220	580	239	165	404	95	54	149
Emend	18	127	145	183	205	388	312	210	522
Vaccines									
Gardasil/Gardasil 9	1,755	2,184	3,938	1,831	1,905	3,737	1,873	1,279	3,151
ProQuad/M-M-R II/Varivax	1,378	500	1,878	1,683	592	2,275	1,430	368	1,798
Pneumovax 23	727	359	1,087	679	247	926	627	281	907
RotaTeq	486	311	797	506	284	791	496	232	728
Vaqta	103	67	170	130	108	238	127	112	239
Hospital Acute Care									
Bridion	583	615	1,198	533	598	1,131	386	531	917
Noxafil	42	287	329	282	380	662	353	389	742
Prevymis	119	162	281	84	81	165	46	27	72
Primaxin	2	248	251	2	271	273	7	258	265
Cancidas	7	207	213	6	242	249	12	314	326
Invanz	9	202	211	30	233	263	253	243	496
Cubicin	46	106	152	92	165	257	191	176	367
Zerbaxa	74	56	130	63	58	121	42	45	87
Immunology									
Simponi	—	838	838	—	830	830	—	893	893
Remicade	—	330	330	—	411	411	—	582	582
Neuroscience									
Belsomra	81	247	327	92	214	306	96	164	260
Virology									
Isentress/Isentress HD	326	531	857	398	576	975	513	627	1,140
Zepatier	60	107	167	118	252	370	8	447	455
Cardiovascular									
Zetia	(1)	483	482	14	575	590	45	813	857
Vytorin	12	171	182	16	269	285	10	487	497
Atozet	—	453	453	—	391	391	—	347	347
Alliance revenue - Adempas [2]	259	22	281	194	10	204	134	5	139
Adempas	—	220	220	—	215	215	—	190	190
Diabetes									
Januvia	1,470	1,836	3,306	1,724	1,758	3,482	1,969	1,718	3,686
Janumet	477	1,494	1,971	589	1,452	2,041	811	1,417	2,228
Women's Health									
Implanon/Nexplanon	488	192	680	568	219	787	495	208	703
NuvaRing	110	127	236	742	136	879	722	180	902
Diversified Brands									
Singulair	18	444	462	29	669	698	20	688	708
Cozaar/Hyzaar	21	365	386	24	418	442	23	431	453
Arcoxia	—	258	258	—	288	288	—	335	335
Nasonex	12	206	218	9	284	293	23	353	376
Follistim AQ	84	109	193	103	138	241	115	153	268
Other pharmaceutical [3]	1,555	3,152	4,709	1,416	3,204	4,615	1,231	3,308	4,546
Total Pharmaceutical segment sales	19,449	23,572	43,021	18,953	22,798	41,751	16,742	20,947	37,689
Animal Health:									
Livestock	612	2,327	2,939	582	2,201	2,784	528	2,102	2,630
Companion Animals	872	892	1,764	724	885	1,609	710	872	1,582
Total Animal Health segment sales	1,484	3,219	4,703	1,306	3,086	4,393	1,238	2,974	4,212
Other segment sales [4]	23	—	23	174	1	175	248	2	250
Total segment sales	20,956	26,791	47,747	20,433	25,885	46,319	18,228	23,923	42,151
Other [5]	71	176	247	86	436	521	118	26	143
	$ 21,027	$ 26,967	$ 47,994	$ 20,519	$ 26,321	$ 46,840	$ 18,346	$ 23,949	$ 42,294

U.S. plus international may not equal total due to rounding.

[1] *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 4).*

[2] *Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 4).*

[3] *Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.*

[4] *Represents sales for the non-reportable segments of Healthcare Services (fully divested in the first quarter of 2020) and Alliances (which concluded in 2018).*

[5] *Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales.*

Consolidated sales by geographic area where derived are as follows:

Years Ended December 31		2020		2019		2018
United States	$	**21,027**	$	20,519	$	18,346
Europe, Middle East and Africa		**13,600**		12,707		12,213
China		**3,624**		3,207		2,184
Japan		**3,376**		3,583		3,212
Asia Pacific (other than China and Japan)		**2,864**		2,943		2,909
Latin America		**2,274**		2,469		2,415
Other		**1,229**		1,412		1,015
	$	**47,994**	$	46,840	$	42,294

A reconciliation of segment profits to *Income before taxes* is as follows:

Years Ended December 31		2020		2019		2018
Segment profits:						
Pharmaceutical segment	$	**29,722**	$	28,324	$	24,871
Animal Health segment		**1,650**		1,609		1,659
Other segments		**1**		(7)		103
Total segment profits		**31,373**		29,926		26,633
Other profits		**140**		363		6
Unallocated:						
Interest income		**59**		274		343
Interest expense		**(831)**		(893)		(772)
Depreciation and amortization		**(1,602)**		(1,593)		(1,352)
Research and development		**(13,072)**		(9,499)		(9,432)
Amortization of purchase accounting adjustments		**(1,168)**		(1,406)		(2,664)
Restructuring costs		**(578)**		(638)		(632)
Charge related to the termination of a collaboration with Samsung		**—**		—		(423)
Other unallocated, net		**(5,530)**		(5,070)		(3,006)
Income Before Taxes	$	**8,791**	$	11,464	$	8,701

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as selling, general and administrative expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as selling, general and administrative expenses and research and development costs directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred in Merck Research Laboratories, the Company's research and development division that focuses on human health-related activities, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of purchase accounting adjustments are not allocated to segments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing sales.

Other unallocated, net includes expenses from corporate and manufacturing cost centers, goodwill and other intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value of liabilities for contingent consideration, and other miscellaneous income or expense items.

Equity (income) loss from affiliates and depreciation and amortization included in segment profits is as follows:

	Pharmaceutical	Animal Health	All Other	Total
Year Ended December 31, 2020				
Included in segment profits:				
Equity (income) loss from affiliates	**$ 6**	**$ —**	**$ —**	**$ 6**
Depreciation and amortization	**690**	**164**	**1**	**855**
Year Ended December 31, 2019				
Included in segment profits:				
Equity (income) loss from affiliates	$ —	$ —	$ —	$ —
Depreciation and amortization	534	109	10	653
Year Ended December 31. 2018				
Included in segment profits:				
Equity (income) loss from affiliates	$ 4	$ —	$ —	$ 4
Depreciation and amortization	411	82	10	503

Property, plant and equipment, net, by geographic area where located is as follows:

December 31	**2020**	2019	2018
United States	**$ 10,526**	$ 8,974	$ 8,306
Europe, Middle East and Africa	**6,059**	4,767	3,706
Asia Pacific (other than China and Japan)	**761**	714	684
Latin America	**252**	266	264
China	**217**	174	167
Japan	**166**	152	159
Other	**5**	6	5
	$ 17,986	$ 15,053	$ 13,291

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Merck & Co., Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheet of Merck & Co., Inc. and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2020, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Customer Discount Accruals in the U.S. - Medicaid, Managed Care and Medicare Part D Rebates

As described in Note 2 to the consolidated financial statements, the Company records certain variable consideration including discounts, which are estimated at the time of sale generally using the expected value method. Amounts accrued for aggregate customer discounts as of December 31, 2020 in the U.S. are $3.1 billion and are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. Certain of these discounts take the form of rebates, which are amounts owed based upon definitive contractual agreements or legal requirements with private sector (Managed Care) and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. Management uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision.

The principal considerations for our determination that performing procedures relating to customer discount accruals in the U.S. - Medicaid, Managed Care, and Medicare Part D rebates is a critical audit matter are the significant judgment by management due to the significant measurement uncertainty involved in developing the provisions, as the provisions include assumptions related to changes to price and historical customer segment utilization mix, pertaining to forecasted customer claims that may not be fully paid until a subsequent period. This in turn led to a high degree of auditor judgment, subjectivity and effort in applying the procedures related to those assumptions and in evaluating the evidence obtained from these procedures.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to customer discount accruals in the U.S. - Medicaid, Managed Care, and Medicare Part D rebates, including management's controls over the assumptions used to estimate the corresponding rebate accruals. These procedures also included, among others, (i) developing an independent estimate of the rebate accruals by utilizing third party data on historical customer segment utilization mix in the U.S., changes to price, the terms of the specific rebate programs, and the historical trend of actual rebate claims paid, (ii) comparing the independent estimate to the rebate accruals recorded by management and (iii) testing actual rebate claims paid, including evaluating those claims for consistency with the contractual terms of the Company's rebate agreements.

PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 25, 2021

We have served as the Company's auditor since 2002.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Act)) are effective. For the fourth quarter of 2020, there have been no changes in internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Act. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2020. PricewaterhouseCoopers LLP, an independent registered public accounting firm, has performed its own assessment of the effectiveness of the Company's internal control over financial reporting and its attestation report is included in this Form 10-K filing.

Management's Report

Management's Responsibility for Financial Statements

Responsibility for the integrity and objectivity of the Company's financial statements rests with management. The financial statements report on management's stewardship of Company assets. These statements are prepared in conformity with generally accepted accounting principles and, accordingly, include amounts that are based on management's best estimates and judgments. Nonfinancial information included in the Annual Report on Form 10-K has also been prepared by management and is consistent with the financial statements.

To assure that financial information is reliable and assets are safeguarded, management maintains an effective system of internal controls and procedures, important elements of which include: careful selection, training and development of operating and financial managers; an organization that provides appropriate division of responsibility; and communications aimed at assuring that Company policies and procedures are understood throughout the organization. A staff of internal auditors regularly monitors the adequacy and application of internal controls on a worldwide basis.

To ensure that personnel continue to understand the system of internal controls and procedures, and policies concerning good and prudent business practices, annually all employees of the Company are required to complete Code of Conduct training. This training reinforces the importance and understanding of internal controls by reviewing key corporate policies, procedures and systems. In addition, the Company has compliance programs, including an ethical business practices program to reinforce the Company's long-standing commitment to high ethical standards in the conduct of its business.

The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this Form 10-K filing.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control — Integrated*

Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2020.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2020, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Kenneth C. Frazier
Chairman, President
and Chief Executive Officer

Robert M. Davis
Executive Vice President, Global Services,
and Chief Financial Officer

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Proposal 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021. Information on executive officers is set forth in Part I of this document on page 44.

The required information on compliance with Section 16(a) of the Securities Exchange Act of 1934, if applicable, is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

The Company has a Code of Conduct — *Our Values and Standards* applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer and Controller. The Code of Conduct is available on the Company's website at www.merck.com/company-overview/culture-and-values/code-of-conduct/values-and-standards. The Company intends to disclose future amendments to certain provisions of the Code of Conduct, and waivers of the Code of Conduct granted to executive officers and directors, if any, on the website within four business days following the date of any amendment or waiver. Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior.

The required information on the identification of the audit committee and the audit committee financial expert is incorporated by reference from the discussion under the heading "Board Meetings and Committees" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

Item 11. Executive Compensation.

The information required on executive compensation is incorporated by reference from the discussion under the headings "Compensation Discussion and Analysis," "Summary Compensation Table," "All Other Compensation" table, "Grants of Plan-Based Awards" table, "Outstanding Equity Awards" table, "Option Exercises and Stock Vested" table, "Pension Benefits" table, "Nonqualified Deferred Compensation" table, "Potential Payments Upon Termination or a Change in Control", including the discussion under the subheadings "Separation" and "Change in Control," as well as all footnote information to the various tables, of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

The required information on director compensation is incorporated by reference from the discussion under the heading "Director Compensation" and related "2020 Schedule of Director Fees" table and "2020 Director Compensation" table of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

The required information under the headings "Compensation and Benefits Committee Interlocks and Insider Participation" and "Compensation and Benefits Committee Report" is incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information with respect to security ownership of certain beneficial owners and management is incorporated by reference from the discussion under the heading "Stock Ownership Information" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

Equity Compensation Plan Information

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company's equity compensation plans as of the close of business on December 31, 2020. The table does not include information about tax qualified plans such as the Merck U.S. Savings Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders[1]	19,446,307[2]	$ 63.64	100,353,680
Equity compensation plans not approved by security holders	—	—	—
Total	19,446,307	$ 63.64	100,353,680

[1] *Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck & Co., Inc. 2010 and 2019 Incentive Stock Plans, and the Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan.*

[2] *Excludes approximately 11,914,491 shares of restricted stock units and 2,099,739 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2010 and 2019 Incentive Stock Plans. Also excludes 193,746 shares of phantom stock deferred under the MSD Employee Deferral Program and 564,209 shares of phantom stock deferred under the Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation.*

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The required information on transactions with related persons is incorporated by reference from the discussion under the heading "Related Person Transactions" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

The required information on director independence is incorporated by reference from the discussion under the heading "Independence of Directors" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Proposal 3. Ratification of Appointment of Independent Registered Public Accounting Firm for 2021 beginning with the caption "Pre-Approval Policy for Services of Independent Registered Public Accounting Firm" through "Fees for Services Provided by the Independent Registered Public Accounting Firm" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2021.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K

1. **Financial Statements**

   Consolidated statement of income for the years ended December 31, 2020, 2019 and 2018

   Consolidated statement of comprehensive income for the years ended December 31, 2020, 2019 and 2018

   Consolidated balance sheet as of December 31, 2020 and 2019

   Consolidated statement of equity for the years ended December 31, 2020, 2019 and 2018

   Consolidated statement of cash flows for the years ended December 31, 2020, 2019 and 2018

   Notes to consolidated financial statements

   Report of PricewaterhouseCoopers LLP, independent registered public accounting firm

2. **Financial Statement Schedules**

   Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

3. Exhibits

Exhibit Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective July 22, 2015) — Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed July 28, 2015 (No. 1-6571)
4.1	—	Indenture, dated as of April 1, 1991, between Merck Sharp & Dohme Corp. (f/k/a Schering Corporation) and U.S. Bank Trust National Association (as successor to Morgan Guaranty Trust Company of New York), as Trustee (the 1991 Indenture) — Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349)
4.2	—	First Supplemental Indenture to the 1991 Indenture, dated as of October 1, 1997 — Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 filed September 25, 1997 (No. 333-36383)
4.3	—	Second Supplemental Indenture to the 1991 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No.1-6571)
4.4	—	Third Supplemental Indenture to the 1991 Indenture, dated May 1, 2012 — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2012 (No. 1-6571)
4.5	—	Indenture, dated November 26, 2003, between Merck & Co., Inc. (f/k/a Schering-Plough Corporation) and The Bank of New York as Trustee (the 2003 Indenture) — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.6	—	Second Supplemental Indenture to the 2003 Indenture (including Form of Note), dated November 26, 2003 — Incorporated by reference to Exhibit 4.3 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 (No. 1-6571)
4.7	—	Third Supplemental Indenture to the 2003 Indenture (including Form of Note), dated September 17, 2007 — Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 (No. 1-6571)

Exhibit Number		Description
4.8	—	Fifth Supplemental Indenture to the 2003 Indenture, dated November 3, 2009 — Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 (No. 1-6571)
4.9	—	Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee — Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 (No. 1-6571)
4.10	—	Description of the Registrant's Common Stock
4.11	—	Description of the Registrant's 1.125% Notes due 2021, 1.875% Notes due 2026, and 2.500% Notes due 2034
4.12	—	Description of the Registrant's 0.500% Notes due 2024 and 1.375% Notes due 2036
*10.1	—	Merck & Co., Inc. Executive Incentive Plan (as amended and restated effective June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.2	—	Merck & Co., Inc. Deferral Program Including the Base Salary Deferral Plan (Amended and Restated effective December 1, 2019) - Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2019 filed February 26, 2020 (No. 1-6571)
*10.3	—	Merck & Co., Inc. 2010 Incentive Stock Plan (as amended and restated June 1, 2015) — Incorporated by reference to Merck & Co., Inc.'s Schedule 14A filed April 13, 2015 (No. 1-6571)
*10.4	—	Form of stock option terms for 2011 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the period ended March 31, 2011 filed May 9, 2011 (No. 1-6571)
*10.5	—	Form of stock option terms for 2012 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2011 filed February 28, 2012 (No. 1-6571)
*10.6	—	Form of stock option terms for 2013 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2012 filed February 28, 2013 (No. 1-6571)
*10.7	—	Form of stock option terms for 2014 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.18 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2014 filed February 27, 2015 (No. 1-6571)
*10.8	—	Form of stock option terms for 2015 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.20 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2015 filed February 26, 2016 (No. 1-6571)
*10.9	—	Form of stock option terms for 2018 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by referent to Exhibit 10.12 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed February 27, 2018 (No. 1-6571)

Exhibit Number		Description
*10.10	—	Form of stock option terms for 2016 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2016 filed February 28, 2017 (No. 1-6571)
*10.11	—	Form of restricted stock unit terms for 2018 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2017 filed on February 28, 2018 (No. 1-6571)
*10.12	—	2018 Performance Share Unit Award Terms under the Merck & Co., Inc. 2010 Stock Incentive Plan — Incorporated by reference to Exhibit 10 to Merck & Co., Inc.'s Current Report on Form 10-Q Quarterly Report for the period ended March 31, 2018 filed May 8, 2018 (No. 1-6571)
*10.13	—	Merck & Co., Inc. 2019 Incentive Stock Plan - Incorporated by reference to Appendix C to Merck & Co., Inc.'s Schedule 14A filed April 8, 2019 (No. 1-6571)
*10.14	—	Merck & Co., Inc. Change in Control Separation Benefits Plan (effective as amended and restated, as of January 1, 2013) — Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 29, 2012 (No. 1-6571)
*10.15	—	Merck & Co., Inc. U.S. Separation Benefits Plan (amended and restated as of January 1, 2019) - Incorporated by reference to Exhibit 10.19 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
*10.16	—	Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan (amended and restated as of December 1, 2010) — Incorporated by reference to Exhibit 10.17 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2010 filed February 28, 2011 (No. 1-6571)
*10.17	—	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) —Incorporated by reference to Exhibit 10.C to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1996 filed August 13, 1996 (No. 1-3305)
*10.18	—	Merck & Co., Inc. Plan for Deferred Payment of Directors' Compensation (Amended and Restated effective as of January 1, 2020) - Incorporated by reference to Exhibit 10.18 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2019 filed February 26, 2020 (No. 1-6571)
10.19	—	Distribution agreement between Schering-Plough and Centocor, Inc., dated April 3, 1998 — Incorporated by reference to Exhibit 10(u) to Schering-Plough's Amended 10-K for the year ended December 31, 2003 filed May 3, 2004 (No. 1-6571)†
10.20	—	Amendment Agreement to the Distribution Agreement between Centocor, Inc., CAN Development, LLC, and Schering-Plough (Ireland) Company — Incorporated by reference to Exhibit 10.1 to Schering-Plough's Current Report on Form 8-K filed December 21, 2007 (No. 1-6571)†
10.21	—	Severance Agreement and General Release between Merck & Co., Inc. and Adam H. Schechter, dated December 1, 2018 - Incorporated by reference to Exhibit 10.27 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
10.22	—	Offer Letter between Merck & Co., Inc. and Jennifer Zachary, dated March 16, 2018 - Incorporated by reference to Exhibit 10.28 to Merck & Co., Inc.'s Form 10-K Annual Report for the fiscal year ended December 31, 2018 filed February 27, 2019 (No. 1-6571)
*10.23	—	Form of stock option terms for 2021 annual non-qualified option grants under the Merck & Co., Inc. 2019 Incentive Stock Plan.
*10.24	—	Form of restricted stock unit terms for 2021 annual grants under the Merck & Co., Inc. 2019 Incentive Stock Plan.
21	—	Subsidiaries of Merck & Co., Inc.
23	—	Consent of Independent Registered Public Accounting Firm
24.1	—	Power of Attorney
24.2	—	Certified Resolution of Board of Directors

31.1	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer

Exhibit Number		Description
101.INS	—	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	—	XBRL Taxonomy Extension Schema Document.
101.CAL	—	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	—	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	—	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	—	XBRL Taxonomy Extension Presentation Linkbase Document.
104	—	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* *Management contract or compensatory plan or arrangement.*

† *Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.*

Long-term debt instruments under which the total amount of securities authorized does not exceed 10% of Merck & Co., Inc.'s total consolidated assets are not filed as exhibits to this report. Merck & Co., Inc. will furnish a copy of these agreements to the Securities and Exchange Commission on request.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 25, 2021

MERCK & CO., INC.

By: KENNETH C. FRAZIER
(Chairman, President and Chief Executive Officer)

By: /s/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
KENNETH C. FRAZIER	Chairman, President and Chief Executive Officer; Principal Executive Officer; Director	February 25, 2021
ROBERT M. DAVIS	Executive Vice President, Global Services, and Chief Financial Officer; Principal Financial Officer	February 25, 2021
RITA A. KARACHUN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 25, 2021
LESLIE A. BRUN	Director	February 25, 2021
THOMAS R. CECH	Director	February 25, 2021
MARY ELLEN COE	Director	February 25, 2021
PAMELA J. CRAIG	Director	February 25, 2021
THOMAS H. GLOCER	Director	February 25, 2021
RISA J. LAVIZZO-MOUREY	Director	February 25, 2021
PAUL B. ROTHMAN	Director	February 25, 2021
PATRICIA F. RUSSO	Director	February 25, 2021
CHRISTINE E. SEIDMAN	Director	February 25, 2021
INGE G. THULIN	Director	February 25, 2021
KATHY J. WARDEN	Director	February 25, 2021
PETER C. WENDELL	Director	February 25, 2021

Jennifer Zachary, by signing her name hereto, does hereby sign this document pursuant to powers of attorney duly executed by the persons named, filed with the Securities and Exchange Commission as an exhibit to this document, on behalf of such persons, all in the capacities and on the date stated, such persons including a majority of the directors of the Company.

By: /S/ JENNIFER ZACHARY
Jennifer Zachary
(Attorney-in-Fact)

Exhibit 4.10

Description of the Registrant's Common Stock

Registered under Section 12 of the Securities Exchange Act of 1934

The following sets forth a description of the material terms of the common stock of Merck & Co., Inc. ("Merck"). The description is qualified in its entirety by reference to Merck's certificate of incorporation and by-laws, copies of which are included or incorporated by reference as exhibits to Merck's most recently filed Annual Report on Form 10-K. You are encouraged to read Merck's certificate of incorporation and by-laws and the applicable provisions of the New Jersey Business Corporation Act for additional information.

Under its certificate of incorporation, Merck is authorized to issue an aggregate of 6,520,000,000 shares of capital stock, divided into classes as follows:

- 6,500,000,000 shares of common stock, par value $0.50 per share; and
- 20,000,000 shares of preferred stock, par value $1.00 per share, issuable in one or more series.

Subject to the preferences, qualifications, limitations, voting and other rights and restrictions with respect to each class of Merck's capital stock having any preference or priority over Merck's common stock, the holders of the common stock shall have and possess all rights appertaining to Merck's capital stock. The holders of shares of Merck's common stock are entitled to one vote per share for each share held of record on all matters voted on by shareholders, including the election of directors.

A majority of votes cast by shares of Merck's common stock entitled to vote is required for:

- adoption of a proposed amendment to the certificate of incorporation;
- approval of a proposed plan of merger or consolidation;
- approval of a sale, lease, exchange or other disposition of all, or substantially all, of Merck's assets, not in the usual and regular course of business;
- approval of a proposed plan of exchange; and
- approval of a proposed plan of dissolution.

In addition, unless approved by the affirmative vote of holders of at least two-thirds of the shares of Merck's common stock voted thereon by disinterested shareholders, Merck is generally prohibited from purchasing shares of Merck's common stock at a price in excess of a fair market price from a person known to Merck to be the beneficial owner of more than 5% of the voting power of the then outstanding shares of Merck's common stock, subject to exceptions for certain open market transactions, certain public transactions, purchases pursuant to an offer to purchase made on the same terms and conditions to all holders of Merck's common stock and shares held by such a beneficial owner for longer than two years.

Holders of Merck's common stock are entitled to participate equally in dividends when and as such dividends may be declared by Merck's board of directors out of funds legally available therefor. As a New Jersey corporation, Merck is subject to statutory limitations on the declaration and payment of dividends. In the event of Merck's liquidation, dissolution or winding up, holders of Merck's common stock have the right to a ratable portion of assets remaining after satisfaction in full of the prior rights of creditors, including holders of Merck's indebtedness, all liabilities and the aggregate liquidation preferences of any outstanding shares of Merck's preferred stock. The holders of Merck's common stock have no conversion, redemption, preemptive or cumulative voting rights. All of the shares of Merck's common stock issued by Merck are validly issued, fully paid and non-assessable.

The transfer agent and registrar for Merck's common stock is Equinity Trust Company.

Takeover Defense

Certain provisions of Merck's certificate of incorporation and by-laws and of the New Jersey Business Corporation Act (the "NJBCA") may have anti-takeover effects and could delay, defer or prevent a tender offer or takeover attempt that a shareholder might consider to be in such shareholder's best interests, including attempts that might result in a premium over the market price for the shares held by shareholders, and may make removal of the incumbent management and directors more difficult.

Authorized Shares; Undesignated Preferred Stock. Merck's certificate of incorporation authorizes the issuance of up to 6,500,000,000 shares of common stock and 20,000,000 shares of preferred stock. These additional authorized shares may be used by Merck's board of directors, to the extent consistent with its fiduciary duty, to deter future attempts to gain control of Merck, and may discourage attempts by others to attempt to acquire control of Merck without negotiation with Merck's board of directors.

Merck's board of directors has the sole authority, subject to the rights of any outstanding series of Merck's preferred stock, to fix the numbers, designations, rights, preferences and limitations of any one or more series of preferred stock, including with respect to voting, dividends, conversion, redemption and liquidation preferences. As a result of the ability to fix voting rights for a series of preferred stock, Merck's board of directors has the power, to the extent consistent with its fiduciary duty, to issue a series of preferred stock to persons friendly to management in order to attempt to block a tender offer, merger or other transaction by which a third party seeks control of Merck, and thereby assist members of management to retain their positions.

No Shareholder Action by Written Consent. Merck's certificate of incorporation provides that shareholders may not act by written consent. Any shareholder action must be taken at a duly called annual or special meeting.

Special Meetings of Shareholders. In addition to what is provided by the NJBCA, a special meeting may be called at any time by Merck's board of directors and, subject to the rights of the holders of any class or series of preferred stock then outstanding, generally may be called at any time upon the written request, in the form prescribed in Merck's by-laws, of the holders of record of at least 15% or more of the capital stock entitled to vote in the election of directors.

Notification of Proposed Business and Nominations for Annual Meetings. Merck's by-laws require that written notice of any shareholder proposal for business at an annual meeting of shareholders, or any shareholder director nomination for an annual meeting of shareholders, be received at least 120 days but no more than 150 days prior to the anniversary date of the preceding year's annual meeting; provided, however, in the event that the date of the annual meeting is more than 30 days earlier or later than the anniversary date of the most recent annual meeting of shareholders, the shareholders' notice must be so delivered not later than the close of business on the later of (i) the 120th day prior to such annual meeting of shareholders or (ii) the 10th day following the day on which a public announcement of the annual meeting date is first made. Also, Merck's by-laws allow a shareholder or a group of no more than 20 shareholders, who or which has maintained continuous qualifying ownership of at least 3% of Merck's outstanding common stock for at least three years and has complied with the other requirements set forth in the by-laws, to include director nominees constituting up to 20% of the board of directors in Merck's proxy materials for an annual meeting of shareholders. A request to include such a nominee must be received at least 120 days but no more than 150 days prior to the anniversary of the date Merck commenced mailing of its proxy materials in connection with the most recent annual meeting of shareholders.

No Cumulative Voting. Merck's certificate of incorporation does not permit cumulative voting in the election of directors.

Business Combinations with Interested Shareholder. The NJBCA provides that no corporation organized under the laws of New Jersey (a "resident domestic corporation") may engage in any "business combination" (as defined in the NJBCA) with any interested shareholder (generally a 10% or greater shareholder) of such corporation for a period of five years following such interested shareholder's stock acquisition, unless either (i) such stock acquisition is approved by the board of directors of such corporation prior to the stock acquisition and any subsequent business combinations with the interested shareholder are approved by (A) members of the board of directors independent of the interested shareholder and (B) the holders of a majority of the voting stock not beneficially owned by the interested shareholder or (ii) such business combination is approved by the board of directors of such corporation prior to the stock acquisition.

In addition, no resident domestic corporation may engage, at any time, in any business combination with any interested shareholder of such corporation other than: (i) a business combination approved by the board of directors prior to the stock acquisition, (ii) a business combination approved by the affirmative vote of the holders of two-thirds of the voting stock not beneficially owned by such interested shareholder at a meeting called for such purpose, (iii) a business combination in which the interested shareholder pays a formula price designed to ensure that all other shareholders receive at least the highest price per share paid by such interested shareholder or (iv) a business combination approved (A) by the board of directors independent of the interested shareholder prior to the consummation of the business combination and (B) the holders of a majority of the voting stock not beneficially owned by the interested shareholder at a meeting called for such purpose if the interested shareholder's stock acquisition was approved by the board of directors prior to the consummation of such stock acquisition.

Board of Directors. Merck's certificate of incorporation provides that, subject to the rights of the holders of shares of any series of preferred stock then outstanding, the number of directors composing Merck's board of directors will not exceed eighteen, and that a director can only be removed by shareholder vote if there is cause for the director's removal. A majority of the directors then constituting Merck's board of directors are authorized to fill vacancies on the board of directors, whether created by removal for cause, resignation or otherwise.

Exhibit 4.11

Description of the Registrant's 1.125% Notes due 2021, 1.875% Notes due 2026 and 2.500% Notes due 2034

Registered under Section 12 of the Securities Exchange Act of 1934

In this description, unless the context requires otherwise:

- *"2021 notes" means the 1.125% Notes due 2021 of Merck & Co., Inc.;*
- *"2026 notes" means the 1.875% Notes due 2026 of Merck & Co., Inc.;*
- *"2034 notes" means the 2.500% Notes due 2034 of Merck & Co., Inc.;*
- *"holder" means a direct holder and not a street name or other indirect holder of notes;*
- *"notes" means the 2021 notes, 2026 notes and 2034 notes, collectively; and*
- *"we," "our" and "us" refer to Merck & Co., Inc., but not to any of Merck & Co., Inc.'s subsidiaries.*

The following sets forth a description of the material terms of the notes. The description is qualified in its entirety by reference to the indenture, dated as of January 6, 2010, between us and U.S. Bank Trust National Association, as trustee (a copy of which is included as Exhibit 4.1 to our Current Report on Form 8-K filed on December 10, 2010) and, as applicable, the officers' certificate pursuant to such indenture with respect to the 2021 notes, dated October 15, 2014, including the form of the 2021 notes (a copy of which is included as Exhibit 4.1 to our Current Report on Form 8-K filed on October 15, 2014), the officers' certificate pursuant to such indenture with respect to the 2026 notes, dated October 15, 2014, including the form of the 2026 notes (a copy of which is included as Exhibit 4.2 to our Current Report on Form 8-K filed on October 15, 2014) or the officers' certificate pursuant to such indenture with respect to the 2034 notes, dated October 15, 2014, including the form of the 2034 notes (a copy of which is included as Exhibit 4.3 to our Current Report on Form 8-K filed on October 15, 2014). You are encouraged to read such indenture and officers' certificates for additional information.

The 2021 notes, the 2026 notes and the 2034 notes are each a separate series of notes under the indenture.

The 2021 notes are initially limited to €1,000,000,000 aggregate principal amount, which amount remains outstanding as of February 24, 2021, and will mature on October 15, 2021. The 2026 notes are initially limited to €1,000,000,000 aggregate principal amount, which amount remains outstanding as of February 24, 2021, and will mature on October 15, 2026. The 2034 notes are initially limited to €500,000,000 aggregate principal amount, which amount remains outstanding as of February 24, 2021, and will mature on October 15, 2034.

The notes are unsecured and rank equally with all our other unsecured and unsubordinated indebtedness from time to time outstanding. The notes are not guaranteed by any of our subsidiaries and are therefore structurally subordinated to all liabilities of our subsidiaries from time to time outstanding, including any guarantees provided by our subsidiaries. The notes also are effectively subordinated to any secured debt we or our subsidiaries incur to the extent of the value of any assets securing such debt.

The notes were issued in denominations of €100,000 and integral multiples of €1,000 in excess thereof.

We may issue as many distinct series of debt securities under the indenture as we wish. A series of debt securities may be guaranteed by one or more of our subsidiaries. There is no limit on the amount of debt securities we may issue under the indenture and the provisions of the indenture allow us to issue debt securities with terms different from those previously issued under the indenture. Also, as discussed below under "—Further Issues," we may "reopen" a previous issue of a series of debt securities and issue additional debt securities of that series. We also may issue other debt under other indentures or documentation, containing provisions different from those included in the indenture or applicable to the notes.

The notes are listed on the New York Stock Exchange. We have no obligation to maintain such listing and we may delist the notes at any time.

The 2021 notes bear interest at a rate of 1.125% per annum, the 2026 notes bear interest at a rate of 1.875% per annum, and the 2034 notes bear interest at a rate of 2.500% per annum. Interest on the notes is payable annually on October 15 of each year to the person in whose name such notes were registered at the close of business on the fifteenth calendar day before the next interest payment date. If any payment date for the notes is not a business day, payment is made on the next business day, but we are not liable for any additional interest as a result of the delay in payment. With respect to the notes, by business day, we mean any Monday, Tuesday, Wednesday, Thursday or Friday which is not a day when banking institutions are authorized or obligated by law or executive order to be closed in The City of New York or London and, for any place of payment outside of The City of New York or London, in such place of payment, and on which the Trans-European Automated Real-time Gross Settlement Express Transfer system (the TARGET2 system), or any successor thereto, operates.

With respect to each series of notes, we compute the amount of interest payable on the basis of (i) the actual number of days in the period for which interest is being calculated and (ii) the actual number of days from (and including) the last date on which interest was paid on the notes of such series (or October 15, 2014, if no interest has been paid on the notes of such series) to (but excluding) the next scheduled interest payment date. This payment convention is referred to as ACTUAL/ACTUAL (ICMA) as defined in the rulebook of the International Capital Market Association.

Elavon Financial Services DAC, UK Branch initially acts as principal paying agent and transfer agent for the notes (the "paying agent"). Elavon Financial Services DAC initially acts as security registrar (the "security registrar") and U.S. Bank Trust National Association initially acts as trustee ("trustee") for the notes. We have entered into an issuing and paying agency agreement in relation to the notes between us, U.S. Bank Trust National Association, as trustee, Elavon Financial Services Limited, UK Branch, as principal paying agent and transfer agent and Elavon Financial Services Limited as security registrar. Payment of principal of and interest on the notes is made through the office of the principal paying agent in London. The terms "principal paying agent" and "paying agent" shall include any successors appointed from time to time in accordance with the provisions of the issuing and paying agency agreement, and any reference to an "agent" or "agents" shall mean any or all (as applicable) of such persons.

Payments in Euros

All payments of interest and principal, including payments made upon any redemption of the notes, are payable in euros. If, at any time, the euro is unavailable to us due to the imposition of exchange controls or other circumstances beyond our control or if the euro is no longer being used by the then member states of the European Monetary Union that have adopted the euro as their currency or for the settlement of transactions by public institutions of or within the international banking community, then all payments in respect of the notes will be made in U.S. dollars until the euro is again available to us or so used. In such circumstances, the amount payable on any date in euros will be converted into U.S. dollars on the basis of the most recently available market exchange rate for euros. Any payment in respect of the notes so made in U.S. dollars will not constitute an event of default under the notes or the indenture governing the notes. Neither the trustee nor the paying agent shall have any responsibility for any calculation or conversion in connection with the foregoing.

Investors are subject to foreign exchange risks as to payments of principal and interest that may have important economic and tax consequences to them.

Optional Redemption

Each series of notes is redeemable in whole or in part, at our option at any time or from time to time, at a redemption price equal to the greater of (i) 100% of the principal amount of the notes to be redeemed or (ii) the sum of the present values of the Remaining Scheduled Payments (as defined below) (not including any portion of such payment of interest accrued as of the date of redemption) discounted to the redemption date on an annual basis

(ACTUAL/ACTUAL (ICMA)) at the applicable Comparable Government Bond Rate (as defined below), plus 15 basis points with respect to the 2021 notes, the Comparable Government Bond Rate plus 15 basis points with respect to the 2026 notes and the Comparable Government Bond Rate plus 15 basis points with respect to the 2034 notes, plus, in each case, accrued and unpaid interest on the principal amount being redeemed to, but excluding, the redemption date.

On or after July 15, 2021 for the 2021 notes, July 15, 2026 for the 2026 notes and July 15, 2034 for the 2034 notes (three months prior to the maturity date of the 2021 notes, the 2026 notes or the 2034 notes, as applicable), we may redeem in whole or in part the 2021 notes, the 2026 notes or the 2034 notes, as applicable, at any time or from time to time, at our option, at a redemption price equal to 100% of the principal amount of the applicable notes being redeemed, plus accrued and unpaid interest on the principal amount being redeemed to, but excluding, the redemption date.

We are required to give notice of redemption at least 30 days, but no more than 60 days, prior to the redemption date. The notice will be mailed to the registered address of each holder of that series of notes. The principal amount of a note remaining outstanding after a redemption in part shall be €100,000 or an integral multiple of €1,000 in excess thereof.

"Comparable Government Bond Rate" means, with respect to any redemption date, the price, expressed as a percentage (rounded to three decimal places, with 0.0005 being rounded upwards), at which the gross redemption yield on the notes to be redeemed, if they were to be purchased at such price on the third business day prior to the date fixed for redemption, would be equal to the gross redemption yield on such business day of the Comparable Government Bond (as defined below) on the basis of the middle market price of the Comparable Government Bond prevailing at 11:00 a.m. (London time) on such business day as determined by an independent investment bank selected by us.

"Comparable Government Bond" means, in relation to any Comparable Government Bond Rate calculation, at the discretion of an independent investment bank selected by us, a German federal government bond whose maturity is closest to the maturity of the notes to be redeemed, or if such independent investment bank in its discretion determines that such similar bond is not in issue, such other German government bond as such independent investment bank may, with the advice of three brokers of, and/or market makers in, German government bonds selected by us, determine to be appropriate for determining the Comparable Government Bond Rate.

"Remaining Scheduled Payments" means, with respect to each note to be redeemed, the remaining scheduled payments of principal of and interest on the note that would be due after the related redemption date but for the redemption. If that redemption date is not an interest payment date with respect to a note, the amount of the next succeeding scheduled interest payment on the note will be reduced by the amount of interest accrued on the note to the redemption date.

If fewer than all of the notes of any series are to be redeemed, the trustee will select the particular notes or portions thereof for redemption from the outstanding notes not previously called, pro rata or by lot, or in such other manner as we direct each in accordance with the depositary's procedures.

Unless we default in payment of the redemption price, on and after the redemption date interest will cease to accrue on the notes or portions thereof called for redemption.

The notes are also subject to redemption if certain events occur involving United States taxation. See "—Taxation Redemption."

Additional Amounts

All payments of principal and interest in respect of the notes are made free and clear of, and without deduction or withholding for or on account of any present or future taxes, duties, assessments or other governmental charges of whatsoever nature imposed, levied, collected, withheld or assessed by the United States or any political subdivision or taxing authority of or in the United States (collectively, "Taxes"), unless such withholding or deduction is required by law.

In the event such withholding or deduction of Taxes is required by law, subject to the limitations described below, we will pay to the holder of any note that is not a U.S. Holder (as defined below) such additional amounts ("Additional Amounts") as may be necessary in order that every net payment received by such holder of principal of or interest or any other amount payable on the notes (including upon redemption), after deduction or withholding for or on account of such Taxes, will not be less than the amount provided for in such note to be then due and payable before deduction or withholding for or on account of such Taxes.

However, our obligation to pay Additional Amounts shall not apply to:

(a) any Taxes which would not have been so imposed but for:

(1) the existence of any present or former connection between such holder or beneficial owner (or between a fiduciary, settlor, beneficiary, member or shareholder or other equity owner of, or a person having a power over, such holder or beneficial owner, if such holder or beneficial owner is an estate, a trust, a limited liability company, a partnership, a corporation or other entity) and the United States, including, without limitation, such holder or beneficial owner (or such fiduciary, settlor, beneficiary, member, shareholder or other equity owner or person having such a power) being or having been a citizen or resident or treated as a resident of the United States or being or having been engaged in a trade or business in the United States or being or having been present in the United States or having or having had a permanent establishment in the United States;

(2) the failure of such holder or beneficial owner to comply with any certification, information or other reporting requirement, if compliance is required under United States tax laws and regulations to establish entitlement to a partial or complete exemption from such Taxes (including, but not limited to, the requirement to provide Internal Revenue Service Form W-8BEN, Form W-8BEN-E, Form W-8ECI, or any subsequent versions thereof or successor thereto); or

(3) such holder's or beneficial owner's present or former status as a personal holding company or a foreign personal holding company with respect to the United States, as a controlled foreign corporation with respect to the United States, as a passive foreign investment company with respect to the United States, as a foreign tax exempt organization with respect to the United States or as a corporation which accumulates earnings to avoid United States federal income tax;

(b) any Taxes imposed by reason of the holder or beneficial owner:

(1) owning or having owned, directly or indirectly, actually or constructively, 10% or more of the total combined voting power of all classes of our stock, as described in section 871(h)(3) of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"),

(2) being a bank receiving interest described in section 881(c)(3)(A) of the Internal Revenue Code, or

(3) being a controlled foreign corporation with respect to the United States that is related to us by stock ownership;

(c) any Taxes which would not have been so imposed but for the presentation by the holder or beneficial owner of such note for payment on a date more than 30 days after the date on which such payment became due and payable or the date on which payment of the note is duly provided for and notice is given to holders, whichever occurs later, except to the extent that the holder or beneficial owner would have been entitled to such Additional Amounts on presenting such note on any date during such 30-day period;

(d) any estate, inheritance, gift, sales, excise, transfer, personal property, wealth or similar Taxes;

(e) any Taxes which are payable otherwise than by withholding from a payment on such note;

(f) any Taxes which are payable by a holder that is not the beneficial owner of the note, or a portion of the note, or that is a fiduciary, partnership, limited liability company or other similar entity, but only to the extent that a beneficial owner, a beneficiary or settlor with respect to such fiduciary or member of such partnership, limited liability company or similar entity would not have been entitled to the payment of an additional amount had such beneficial owner, settlor, beneficiary or member received directly its beneficial or distributive share of the payment;

(g) any Taxes required to be withheld by any paying agent from any payment on any note, if such payment can be made without such withholding by at least one other paying agent;

(h) any Taxes required to be withheld or deducted where such withholding or deduction is imposed pursuant to European Council Directive 2003/48/EC on the taxation of savings income, or any law implementing or complying with, or introduced in order to conform to, such European Council Directive;

(i) any Taxes imposed under Sections 1471 through 1474 of the Internal Revenue Code (or any amended or successor provisions), any current or future regulations or official interpretations thereof, any agreement entered into pursuant to Section 1471(b) of the Code or any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement entered into in connection with the implementation of such sections of the Code;

(j) any combination of items (a), (b), (c), (d), (e), (f), (g), (h) and (i).

For purposes of this section, the acquisition, ownership, enforcement, or holding of or the receipt of any payment with respect to a note will not constitute a connection (1) between the holder or beneficial owner and the United States or (2) between a fiduciary, settlor, beneficiary, member or shareholder or other equity owner of, or a person having a power over, such holder or beneficial owner if such holder or beneficial owner is an estate, a trust, a limited liability company, a partnership, a corporation or other entity and the United States.

Any reference in this description, in the indenture or in the notes to principal or interest or other payment on the notes shall be deemed to refer also to Additional Amounts which may be payable under the provisions of this section.

We will pay all stamp and other duties, if any, which may be imposed by the United States or any political subdivision thereof or taxing authority therein with respect to the issuance of the notes pursuant to this offering.

Except as specifically provided under the heading "—Additional Amounts," we will not be required to make any payment with respect to any tax, duty, assessment or other governmental charge imposed by any government or any political subdivision or taxing authority of or in the United States.

In addition, we undertake that, to the extent permitted by law, we will maintain a paying agent in a Member State of the European Union (if any) that will not require withholding or deduction of tax pursuant to European Council Directive 2003/48/EC on the taxation of savings income or any law implementing or complying with, or introduced in order to conform to, such European Council Directive.

A "U.S. Holder" is a beneficial owner of a note or notes that is for U.S. federal income tax purposes:

- an individual who is citizen or resident of the United States;

- a corporation (or other entity classified as a corporation for these purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of the source of that income; or
- a trust, if (1) a U.S. court is able to exercise primary supervision over the trust's administration and one or more "United States persons" (within the meaning of the Internal Revenue Code) has the authority to control all of the trust's substantial decisions, or (2) the trust has a valid election in effect under applicable Treasury regulations to be treated as a "United States person."

Taxation Redemption

The notes may be redeemed at our option, in whole but not in part, at a redemption price equal to 100% of the principal amount of the notes to be redeemed, together with interest accrued and unpaid to the date fixed for redemption, at any time, on giving not less than 30 nor more than 60 days' notice in accordance with "Notices" below if:

(a) we have or will become obligated to pay Additional Amounts as a result of (i) any change in or amendment to the laws, regulations or rulings of the United States or any political subdivision or any taxing authority of or in the United States affecting taxation, or (ii) any change in or amendment to an official application, interpretation, administration or enforcement of such laws, regulations or rulings, which change or amendment is announced or becomes effective on or after October 6, 2014; *provided* we reasonably determine that such obligation cannot be avoided by our taking reasonable measures available to us without significant difficulty, cost or expense, or

(b) any action shall have been taken by a taxing authority, or any action has been brought in a court of competent jurisdiction, in the United States or any political subdivision or taxing authority of or in the United States, including any of those actions specified in (a) above. whether or not such action was taken or brought with respect to us, or any change, clarification, amendment, application or interpretation of such laws, regulations or rulings shall be officially proposed, in any such case on or after October 6, 2014, which results in a substantial likelihood that we will be required to pay Additional Amounts on the next interest payment date.

However, no such notice of redemption shall be given earlier than 90 days prior to the earliest date on which we would be, in the case of a redemption for the reasons specified in (a) above, or there would be a substantial likelihood that we would be, in the case of a redemption for the reasons specified in (b) above, obligated to pay such Additional Amounts if a payment in respect of the notes were then due and, at the time such notification of redemption is given, such circumstance remains in effect.

Prior to the publication of any notice of redemption pursuant to this section, in the case of a redemption for the reasons specified in (a) or (b) above, we will deliver to the trustee:

(1) a certificate signed by one of our duly authorized officers stating that we are entitled to effect such redemption and setting forth a statement of facts showing that the conditions precedent to our right so to redeem have occurred, and

(2) a written opinion of independent legal counsel of recognized standing to the effect that we have or will become obligated to pay such Additional Amounts as a result of such change or amendment or that there is a substantial likelihood that we will be required to pay such Additional Amounts as a result of such action or proposed change, clarification, amendment, application or interpretation, as the case may be.

Such notice, once delivered by us to the trustee, will be irrevocable.

Modification and Waiver

There are three types of changes we can make to the indenture and the notes.

Changes Requiring Holder Approval. First, there are changes that cannot be made to the notes of any series without specific approval by each holder of the notes of such series affected thereby. Following is a list of those types of changes:

- change the payment due date of any installment of the principal or any premium or interest on a note stated in the note;
- reduce any amounts due on a note;
- change the place or currency of payment on a note;
- impair holders' right to sue for payment;
- reduce the percentage of notes of any series, the holders of which must consent to modify or amend the indenture;
- reduce the percentage of notes of any series the holders of which must consent to waive compliance with certain provisions of the indenture or to waive certain defaults: and
- modify any other aspect of the provisions dealing with modification and waiver of the indenture except to increase any such percentage or to provide that certain other provisions of the indenture cannot be modified or waived without the consent of the holder of each outstanding security affected thereby.

Changes Requiring a Majority Vote. The second type of change to the indenture and the notes is the kind that requires a vote in favor by holders owning not less than a majority of the principal amount of the *notes of the particular series affected.* Most changes fall into this category, such as if we wish to obtain a waiver of all or part of the restrictive covenants described below, or a waiver of a past default. However, we cannot obtain a waiver of a payment default or any other aspect of the indenture or the notes listed in the first category above under "—Changes Requiring Holder Approval" unless we obtain the individual consent of each holder of the notes of such series affected thereby to the waiver.

Changes Not Requiring Approval. The third type of change does not require any vote by holders of notes. This type is limited to the addition or release of a guarantee, corrections and clarifications and other changes that would not adversely affect holders of the notes.

Further Details Concerning Voting. When taking a vote, we use the U.S. dollar equivalent to decide how much principal amount to attribute to a note.

Notes will not be considered outstanding and therefore will not carry voting rights if we have deposited or set aside in trust for the holders thereof money for their payment or redemption. Notes will also not be eligible to vote if they have been fully defeased as described under "—Defeasance—Full Defeasance."

We may set any day as a record date for the purpose of determining the holders of outstanding notes that are entitled to vote or take other action under the indenture. In some circumstances, the trustee may set a record date for action by holders.

Street name and other indirect holders should consult their banks or brokers for information on how approval may be granted or denied if we seek to change the indenture or the notes or request a waiver.

Mergers and Similar Events

We may consolidate or merge with another company or firm. We may also convey, transfer or lease all of our properties and assets substantially as an entirety to another firm, or buy or lease substantially all of the assets of another firm. However, we may not take any of these actions unless the following conditions, among others, are met:

- We are the surviving entity or, when we merge out of existence or convey, transfer or lease all of our properties and assets substantially as an entirety, the other firm must be a corporation, limited liability company, partnership or trust organized under the laws of a U.S. state or the District of Columbia or under federal law and it must agree to be legally responsible for the notes.

- The merger, sale of assets or other transaction must not cause a default on the notes, and we must not already be in default unless the merger or other transaction would cure the default. For purposes of this no-default test, a default would include an event of default, as described under "—Default and Remedies—Events of Default—What is an Event of Default," that has occurred and not been cured. A default for this purpose would also include the occurrence of any event that would be an event of default if we received the required notice of our default or if under the indenture the default would become an event of default after existing for a specific period of time.

- It is possible that the merger, sale of assets or other transaction would cause some of our property to become subject to a mortgage or other legal mechanism giving lenders preferential rights in that property over other lenders or over our general creditors if we fail to pay them back. We have promised to limit these preferential rights, as discussed under "—Restrictive Covenants." If a merger or other transaction would create any liens on any of our property, we must comply with those restrictive covenants. We would do this either by deciding that the liens were permitted, or by following the requirements of the restrictive covenants to grant an equivalent or higher-ranking lien to the holders of the notes on the same property that we own.

If the conditions described above are satisfied with respect to any series of notes, we do not need to obtain the approval of the holders of those notes in order to merge or consolidate or to sell our assets. Also, these conditions apply only if we wish to merge or consolidate with another entity or convey, transfer or lease all of our properties and assets substantially as an entirety. We do not need to satisfy these conditions if we enter into other types of transactions, including any transaction in which we acquire the stock or assets of another entity, any transaction that involves a change of control but in which we do not merge or consolidate and any transaction in which we convey, transfer or lease less than all of our properties and assets substantially as an entirety. It is possible that these other types of transactions may result in a reduction in our credit rating, may reduce our operating results or may impair our financial condition. However, the holders of notes have no approval right with respect to any transaction of this type.

Restrictive Covenants

Restrictions on Secured Debt. Some of our property may be subject to a mortgage or other legal mechanism that gives our lenders preferential rights in that property over other lenders, including the holders of the notes, or over our general creditors if we fail to pay them back. These preferential rights are called liens. Debt which is protected by these preferential rights is called secured debt. In the indenture, we promise that neither we nor our domestic subsidiaries (as defined below) will incur any new secured debt that is secured by a lien on any of our or our domestic subsidiaries' principal domestic manufacturing properties (as defined below), or on any shares of stock of any of our domestic subsidiaries that own or lease a principal domestic manufacturing property, unless we grant an equivalent or higher-ranking lien on the same property to the holders of the notes and other outstanding debt securities issued under the indenture.

We do not need to comply with this restriction if the amount of all debt that would be secured by liens on principal domestic manufacturing properties, including the new debt, the notes and other outstanding debt securities issued under the indenture which we would so secure as described in the previous sentence, and all attributable debt (as defined below) that results from a sale and leaseback transaction involving principal domestic manufacturing properties, is less than 10% of our consolidated net tangible assets (as defined below).

This restriction on secured debt does not apply to debt secured by certain types of liens, and we can disregard this secured debt when we calculate the limits imposed by this restriction. These types of liens are:

- liens on the property of any of our domestic subsidiaries, or on their shares of stock, if those liens existed at the time the corporation became our domestic subsidiary;
- with respect to any series of notes, any lien existing on the date of issuance of such notes;
- liens in favor of us or our domestic subsidiaries;
- liens in favor of U.S. governmental bodies that we granted in order to assure our payments to such bodies that we owe by law or because of a contract we entered into;
- liens in favor of any customer arising in respect of payments made by or on behalf of a customer for goods produced for, or services rendered to, customers in the ordinary course of business not exceeding the amount of those payments;
- statutory liens, liens for taxes or assessments or governmental charges or levies not yet due or delinquent or which can be paid without penalty or are being contested in good faith, landlord's liens on leased property, easements and other liens of a similar nature;
- liens on property or shares of stock that existed at the time we acquired them, including property we may acquire through a merger or similar transaction, or that we granted in order to purchase the property, which are sometimes called purchase money mortgages; and
- debt secured by liens that extend, renew or replace any of these types of liens.

We and our subsidiaries may have as much unsecured debt as we may choose.

Restrictions on Sales and Leasebacks. We promise that neither we nor any of our domestic subsidiaries will enter into any sale and leaseback transaction involving a principal domestic manufacturing property, unless we comply with this restrictive covenant. A sale and leaseback transaction generally is an arrangement between us or a domestic subsidiary and a bank, insurance company or other lender or investor where we or the domestic subsidiary sell a property to a lender or investor more than 120 days after the acquisition of the property or the completion of construction of the property and the beginning of its full operation and we lease the property back from the lender.

We can comply with this restrictive covenant in either of two ways:

- First, we will be in compliance if we or our domestic subsidiary could grant a lien on the principal domestic manufacturing property in an amount equal to the attributable debt for the sale and leaseback transaction without being required to grant an equivalent or higher-ranking lien to the holders of the notes and other outstanding debt securities issued under the indenture under the restriction on secured debt described above.
- Second, we can comply if we retire an amount of our or any domestic subsidiary's funded debt which is not subordinated in right of payment to any outstanding notes or other outstanding debt securities issued under the indenture, within 120 days of the transaction, equal to the greater of the net proceeds of the sale of the principal domestic manufacturing property that we lease in the transaction or the fair market value of that property, subject to credits for voluntary retirements of notes and other

outstanding debt securities issued under the indenture and funded debt we or the domestic subsidiary may make.

This restriction on sales and leasebacks does not apply to any sale and leaseback transaction that is between us and one of our domestic subsidiaries or between domestic subsidiaries, or that involves a lease for a period of three years or less.

Definitions Relating to our Restrictive Covenants. Following are summaries of the meanings of the terms that are important in understanding the restrictive covenants previously described:

"Attributable debt" means the total net amount of rent, discounted at 1% per annum over the weighted average yield to maturity of the outstanding notes and other outstanding debt securities issued under the indenture compounded semi-annually, that is required to be paid during the remaining term of any lease.

"Consolidated net tangible assets" is the total amount of assets, less reserves and certain other permitted deductible items, after subtracting all current liabilities and all goodwill, trade names, trademarks, patents, unamortized debt discounts and expenses and similar intangible assets, as such amounts appear on our most recent consolidated balance sheet and computed in accordance with generally accepted accounting principles.

A "domestic subsidiary" means any of our subsidiaries which transacts substantially all of its business in the United States, has substantially all of its fixed assets located in the United States, or owns or leases principal domestic manufacturing property. However, a subsidiary whose principal business is financing our operations outside of the United States is not a domestic subsidiary. A subsidiary is a corporation in which we and/or one or more of our other subsidiaries owns at least 50% of the voting stock (generally defined as stock that ordinarily permits its owners to vote for the election of directors).

"Funded debt" means all debt for borrowed money that either has a maturity of 12 months or more from the date on which the calculation of funded debt is made or has a maturity of less than 12 months from that date but is by its terms renewable or extendible beyond 12 months from that date at the option of the borrower.

A "principal domestic manufacturing property" is any building or other structure or facility, and the land on which it sits and its associated fixtures, that we use primarily for manufacturing, processing or warehousing, that is located in the United States and that has a gross book value in excess of 1% of our consolidated net tangible assets, other than a building, structure or other facility that our board of directors has determined is not of material importance to the total business that we and our subsidiaries conduct or a building or structure which is financed by obligations issued by a state, a territory, or a possession of the United States, or any political subdivision of any of the foregoing, or the District of Columbia, the interest of which is excludable from gross income of the holders under provisions of the tax code.

Further Issues

We may, without the consent of holders of any series of the notes, issue additional notes having the same ranking and the same interest rate, maturity and other terms as the notes of that series. Any additional notes of any series, together with the outstanding notes of the applicable series, will constitute a single series of notes under the indenture. No additional notes may be issued if an event of default has occurred and is continuing with respect to the applicable series of notes. Additional notes cannot be issued under the same CUSIP, ISIN or Common Code number unless the additional notes and original notes are fungible for U.S. federal income tax purposes.

Defeasance

Full Defeasance. If there is a change in federal tax law, as described below, we can legally release ourselves from any payment or other obligations on the notes of a series if we put in place other arrangements for the holders of such notes to be repaid. This is called full defeasance. In order to achieve full defeasance, we must do the following, among other things:

- We must deposit in trust for the benefit of all holders of the notes of the series any combination of money (in euros) and Federal Republic of Germany obligations (as defined below) that will generate enough cash to make interest, principal and any other payments on the notes of that series on their various due dates.

- There must be a change in current federal tax law or an IRS ruling that lets us make the above deposit without causing holders or beneficial owners of the notes of the series to be taxed on such notes any differently than if we did not make the deposit and just repaid such notes ourselves. (Under current federal tax law, the deposit and our legal release from such notes would be treated as though we took back beneficial owners' notes and gave them their share of the cash and notes or bonds deposited in trust. In that event, beneficial owners could recognize gain or loss on the notes they give back to us.)

- We must deliver to the trustee a legal opinion of our counsel confirming the tax law change described above.

If we ever did accomplish full defeasance, as described above, holders of defeased notes would have to rely solely on the trust deposit for repayment on such notes. Holders of such notes could not look to us for repayment in the unlikely event of any shortfall.

Covenant Defeasance. Under current federal tax law, we can make the same type of deposit described above and be released from some of the restrictive covenants in the notes. This is called covenant defeasance. In that event, holders of notes would lose the protection of those restrictive covenants but would gain the protection of having money and securities set aside in trust to repay the notes. In order to achieve covenant defeasance of the notes of a series, we must do the following:

- We must deposit in trust for the benefit of all holders of the notes of the series any combination of money (in euros) and Federal Republic of Germany obligations that will generate enough cash to make interest, principal and any other payments on the notes on their various due dates.

- We must deliver to the trustee a legal opinion of our counsel confirming that under current federal income tax law we may make the above deposit without causing holders or beneficial owners of the notes to be taxed on the notes any differently than if we did not make the deposit and just repaid the notes ourselves.

If we accomplish covenant defeasance, the following provisions of the indenture and the notes would no longer apply:

- Our promises regarding conduct of our business previously described under "—Restrictive Covenants."

- Restrictions regarding mergers or similar transactions, as described under "—Mergers and Similar Events."

- The events of default relating to mergers or similar transactions and either of the restrictive covenants described under "—Restrictive Covenants."

If we accomplish covenant defeasance, holders of notes can still look to us for repayment of the notes if there were a shortfall in the trust deposit. In fact, if one of the remaining events of default occurred, such as our bankruptcy, and the notes become immediately due and payable, there may be such a shortfall in the trust deposit.

"Federal Republic of Germany obligations" means (1) securities that are direct obligations of the Federal Republic of Germany for the payment of which its full faith and credit is pledged or (2) obligations of a person controlled or supervised by and acting as an agency or instrumentality of the Federal Republic of Germany, the payment of which is unconditionally guaranteed as a full faith and credit obligation by the Federal Republic of

Germany, which, in either case under clauses (1) or (2) are not callable or redeemable at the option of the issuer thereof.

Events of Default

Holders of notes have special rights if an event of default occurs and is not cured, as described later in this subsection.

The term event of default with respect to each series of notes means any of the following:

- We do not pay the principal or any premium on such series of notes on its due date.
- We do not pay interest on such series of notes within 30 days of its due date.
- We remain in breach of either of the restrictive covenants described under "—Restrictive Covenants" or any other covenant or warranty in the indenture for 90 days after we receive a notice of default stating we are in breach. The notice must be sent by either the trustee or holders of at least 25% of the principal amount of notes of the affected series.
- We file for bankruptcy or other specific events of bankruptcy, insolvency or reorganization occur.
- We do not pay Additional Amounts on such series of notes within 30 days after such payment is due.

Any payment in respect of the notes made in U.S. dollars due to the unavailability or nonuse of the euro as discussed under "—Payments in Euros" will not constitute an event of default under the notes or the indenture governing the notes.

If an event of default has occurred and has not been cured, the trustee or the holders of at least 25% in principal amount of the outstanding notes of the affected series may declare the entire principal amount of all the notes of that series to be due and immediately payable. This is called a declaration of acceleration. The holders of at least a majority in principal amount of the notes of the affected series may cancel a declaration of acceleration of maturity.

Except in cases of default, where the trustee has some special duties, the trustee is not required to take any action under the indenture at the request of any holders unless such holders offer the trustee reasonable protection, called an indemnity, against expenses and liability. If reasonable indemnity is provided, the holders of a majority in principal amount of the outstanding notes of the relevant series may direct the time, method and place of conducting any lawsuit or other formal legal action seeking any remedy available to the trustee. These majority holders may also direct the trustee in performing any other action under the indenture with respect to the notes of the applicable series.

Before a holder of notes of any series bypasses the trustee and brings its own lawsuit or other formal legal action or takes other steps to enforce its rights or protect its interests relating to the notes of such series, the following must occur:

- The holder must give the trustee written notice that an event of default has occurred and remains uncured.
- The holders of at least 25% in principal amount of all outstanding notes of the relevant series must make a written request that the trustee take action because of the default, and must offer indemnity reasonably satisfactory to the trustee against the cost and other liabilities of taking that action.
- The trustee must have not received from holders of a majority in principal amount of the outstanding notes of that series a direction inconsistent with the written notice.

- The trustee must have not taken action for 60 days after receipt of the above notice and offer of indemnity.

However, a holder of notes is entitled at any time to bring a lawsuit for the payment of money due on its notes on or after their due date.

Street name and other indirect holders should consult their banks or brokers for information on how to give notice or direction to or make a request of the trustee and to make or cancel a declaration of acceleration.

We furnish to the trustee every year a written statement of our principal executive, financial or accounting officer certifying that to the best of such signer's knowledge we are in compliance with the indenture and the notes, or else specifying any default.

Form, Exchange and Registration of Transfer

We issued the notes only in fully registered form and without interest coupons.

A holder of notes may have its notes broken into more notes of smaller denominations of not less than €100,000 or combined into fewer notes of larger denominations, as long as the total principal amount is not changed. This is called an exchange.

A holder of notes may exchange or register a transfer of notes at the office of the trustee. The trustee acts as our agent for registering notes in the names of holders and registering transfers of notes. We may change this appointment to another entity or perform it ourselves. The entity performing the role of maintaining the list of registered holders is called the security registrar. It also registers transfers. A holder of notes may also replace lost, stolen or mutilated notes at that office. The trustee's agent may require an indemnity before replacing any notes.

A holder of notes is not required to pay a service charge to register a transfer of notes or to exchange notes, but may be required to pay for any tax or other governmental charge associated with the transfer or exchange. The security registrar makes the registration of transfer or exchange only if it is satisfied with such holder's proof of ownership.

We may cancel the designation of any trustee. We may also approve a change in the office through which any trustee acts.

If we redeem less than all of the notes of a particular series, we may block the issuance of, registration of transfer or exchange of notes during the period beginning 15 days before the day we mail the notice of redemption and ending on the day of that mailing, in order to freeze the list of holders to prepare the mailing. We may also refuse to register transfers or exchanges of notes selected for redemption, except that we will continue to permit transfers and exchanges of the unredeemed portion of any note being partially redeemed.

The rules for exchange described above apply to exchange of notes for other notes of the same series and tenor.

Payment and Paying Agents

We pay interest to a holder of notes on each date interest is due if the holder is a direct holder listed in the trustee's records at the close of business on the fifteenth calendar day before the next interest payment date, even if such holder no longer owns the note on the interest due date. That particular day is called the regular record date. Holders buying and selling notes must work out between them how to compensate for the fact that we pay all the interest for an interest period to the one who is the registered holder on the regular record date.

We pay interest, principal and any other money due on the notes at the office of the trustee in London, UK. That office is currently located at 125 Old Broad Street, Fifth Floor, London EC2N 1AR United Kingdom. A holder of notes must make arrangements to have its payments picked up at or wired from that office. We may also choose to pay interest by mailing checks.

Street name and other indirect holders should consult their banks or brokers for information on how they may receive payments.

We may also arrange for additional payment offices, and may cancel or change these offices. These offices are called paying agents. We may also choose to act as our own paying agent. We must notify holders of notes of changes in the paying agents for any particular notes of the series.

Notices

We and the trustee send notices regarding the notes only to direct holders, using their addresses as listed in the trustee's records.

All paying agents must return to us upon our request all money paid by us that remains unclaimed two years after the amount is due to direct holders. After that two-year period, holders of notes may look only to us for payment and not to the trustee, any other paying agent or anyone else.

Book-Entry System

Upon issuance, the notes of each series are represented by one or more global notes. Each global note is deposited with, or on behalf of, a common depositary, and registered in the name of the nominee of the common depositary for the accounts of Clearstream and Euroclear.

Investors may elect to hold interests in the global notes held by the depository through Clearstream Banking, *société anonyme* ("Clearstream") or Euroclear Bank S.A./N.V., as operator of the Euroclear System ("Euroclear") if they are participants of such systems, or indirectly through organizations that are participants in such systems. Clearstream and Euroclear hold interests on behalf of their participants through customers' securities accounts in Clearstream's and Euroclear's names on the books of their respective depositories. Book-entry interests in the notes and all transfers relating to the notes are reflected in the book-entry records of Clearstream and Euroclear. Because holders acquire, hold and transfer security entitlements with respect to the notes through Clearstream, Euroclear and their participants, a beneficial holder's rights with respect to the notes is subject to the laws (including Article 8 of the Uniform Commercial Code) and contractual provisions governing a holder's relationship with its securities intermediary and the relationship between its securities intermediary and each other securities intermediary and between it and us, as the issuer. Except as set forth below, the global notes may be transferred, in whole and not in part, only to another nominee of the depository or to a successor of the depository or its nominee.

No global note may be exchanged in whole or in part for notes registered, and no transfer of a global note in whole or in part may be registered, in the name of any person other than the depository or any nominee of the depository unless (i) the depository has notified us that it is unwilling or unable to continue as depository for such global note or has ceased to be qualified to act as such as required by the indenture, (ii) there has occurred and is continuing an event of default with respect to the notes or (iii) we determine in our sole discretion at any time that the global note shall be so exchangeable.

Any global note that is exchangeable pursuant to the preceding sentence shall be exchangeable in whole for separate notes in registered form of any authorized denomination and of like tenor and aggregate principal amount. These notes shall be registered in the name or names of such person or persons as the depository instructs the trustee. We expect that these instructions would be based upon directions received by the depository from its participants with respect to ownership of beneficial interests in such global note.

Except in the limited circumstances referred to above, owners of beneficial interests in a global note are not entitled to have such global note registered in their names, will not receive and are not entitled to receive physical delivery of notes in exchange therefor and are not considered to be the owners or holders of such global note for any purpose under the notes or the indenture. Accordingly, each person owning a beneficial interest in the global note must rely on the procedures of the participant through which such person owns its interest to exercise any rights of a holder under the indenture.

The indenture provides that the depository. as a holder, may appoint agents and otherwise authorize participants to give or take any request. demand, authorization, direction, notice, consent, waiver, or other action which a holder is entitled to give or take under the indenture.

Governing Law

The indenture and the notes are governed by, and construed and enforced in accordance with, the laws of the State of New York applicable to agreements made or instruments entered into and performed in New York State.

Relationship with Trustee

U.S. Bank Trust National Association is the trustee under the indenture. U.S. Bank Trust National Association performs services for us in the ordinary course of business and serves as the trustee with respect to certain of our other outstanding debt securities.

Open Market Purchases

We may at any time and from time to time purchase notes in the open market or otherwise.

The Paying Agent, Transfer Agent and Security Registrar

Elavon Financial Services DAC is the security registrar with respect to the notes. Elavon Financial Services DAC, UK Branch is the paying agent and transfer agent with respect to the notes.

Exhibit 4.12

Description of the Registrant's 0.500% Notes due 2024 and 1.375% Notes due 2036

Registered under Section 12 of the Securities Exchange Act of 1934

In this description, unless the context requires otherwise:

- *"2024 notes" means the 0.500% Notes due 2024 of Merck & Co., Inc.;*
- *"2036 notes" means the 1.375% Notes due 2036 of Merck & Co., Inc.;*
- *"holder" means a direct holder and not a street name or other indirect holder of notes;*
- *"notes" means the 2024 notes and 2036 notes, collectively; and*
- *"we," "our" and "us" refer to Merck & Co., Inc., but not to any of Merck & Co., Inc.'s subsidiaries.*

The following sets forth a description of the material terms of the notes. The description is qualified in its entirety by reference to the indenture, dated as of January 6, 2010, between us and U.S. Bank Trust National Association, as trustee (a copy of which is included as Exhibit 4.1 to our Current Report on Form 8-K filed on December 10, 2010) and, as applicable, the officers' certificate pursuant to such indenture with respect to the 2024 notes, dated November 2, 2016, including the form of the 2024 notes (a copy of which is included as Exhibit 4.1 to our Current Report on Form 8-K filed on November 2, 2016) or the officers' certificate pursuant to such indenture with respect to the 2036 notes, dated November 2, 2016, including the form of the 2036 notes (a copy of which is included as Exhibit 4.2 to our Current Report on Form 8-K filed on November 2, 2016). You are encouraged to read such indenture and officers' certificates for additional information.

The 2024 notes and the 2036 notes are each a separate series of notes under the indenture.

The 2024 notes are initially limited to €500,000,000 aggregate principal amount, which amount remains outstanding as of February 24, 2021, and will mature on November 2, 2024. The 2036 notes are initially limited to €500,000,000 aggregate principal amount, which amount remains outstanding as of February 24, 2021, and will mature on November 2, 2036.

The notes are unsecured and rank equally with all our other unsecured and unsubordinated indebtedness from time to time outstanding. The notes are not guaranteed by any of our subsidiaries and are therefore structurally subordinated to all liabilities of our subsidiaries from time to time outstanding, including any guarantees provided by our subsidiaries. The notes also are effectively subordinated to any secured debt we or our subsidiaries incur to the extent of the value of any assets securing such debt.

The notes were issued in denominations of €100,000 and integral multiples of €1,000 in excess thereof.

We may issue as many distinct series of debt securities under the indenture as we wish. A series of debt securities may be guaranteed by one or more of our subsidiaries. There is no limit on the amount of debt securities we may issue under the indenture and the provisions of the indenture allow us to issue debt securities with terms different from those previously issued under the indenture. Also, as discussed below under "—Further Issues," we may "reopen" a previous issue of a series of debt securities and issue additional debt securities of that series. We also may issue other debt under other indentures or documentation, containing provisions different from those included in the indenture or applicable to the notes.

The notes are listed on the New York Stock Exchange. We have no obligation to maintain such listing and we may delist the notes at any time.

The 2024 notes bear interest at a rate of 0.500% per annum and the 2036 notes bear interest at a rate of 1.375% per annum. Interest on the notes is payable annually on November 2 of each year to the person in whose name such notes were registered at the close of business on the fifteenth calendar day before the next interest payment date. If any payment date for the notes is not a business day, payment is made on the next business day, but we are not liable for any additional interest as a result of the delay in payment. With respect to the notes, by business day, we mean any Monday, Tuesday, Wednesday, Thursday or Friday which is not a day when banking institutions are authorized or obligated by law or executive order to be closed in The City of New York or London and, for any place of payment outside of The City of New York or London, in such place of payment, and on which the Trans-European Automated Real-time Gross Settlement Express Transfer system (the TARGET2 system), or any successor thereto, operates.

With respect to each series of notes, we compute the amount of interest payable on the basis of (i) the actual number of days in the period for which interest is being calculated and (ii) the actual number of days from (and including) the last date on which interest was paid on the notes of such series (or November 2, 2016 if no interest has been paid on the notes of such series) to (but excluding) the next scheduled interest payment date. This payment convention is referred to as ACTUAL/ACTUAL (ICMA) as defined in the rulebook of the International Capital Market Association.

Elavon Financial Services DAC, UK Branch initially acts as principal paying agent for the notes (the "paying agent"). Elavon Financial Services DAC initially acts as security registrar (the "security registrar") and transfer agent and U.S. Bank Trust National Association initially acts as trustee ("trustee") for the notes. We have entered into an issuing and paying agency agreement in relation to the notes between us, U.S. Bank Trust National Association, as trustee, Elavon Financial Services DAC, UK Branch, as principal paying agent and Elavon Financial Services Limited as security registrar and transfer agent. Payment of principal of and interest on the notes is made through the office of the principal paying agent in London. The terms "principal paying agent" and "paying agent" shall include any successors appointed from time to time in accordance with the provisions of the issuing and paying agency agreement, and any reference to an "agent" or "agents" shall mean any or all (as applicable) of such persons.

Payments in Euros

All payments of interest and principal, including payments made upon any redemption of the notes, are payable in euros. If, at any time, the euro is unavailable to us due to the imposition of exchange controls or other circumstances beyond our control or if the euro is no longer being used by the then member states of the European Monetary Union that have adopted the euro as their currency or for the settlement of transactions by public institutions of or within the international banking community, then all payments in respect of the notes will be made in U.S. dollars until the euro is again available to us or so used. In such circumstances, the amount payable on any date in euros will be converted into U.S. dollars on the basis of the most recently available market exchange rate for euros. Any payment in respect of the notes so made in U.S. dollars will not constitute an event of default under the notes or the indenture governing the notes. Neither the trustee nor the paying agent shall have any responsibility for any calculation or conversion in connection with the foregoing.

Investors are subject to foreign exchange risks as to payments of principal and interest that may have important economic and tax consequences to them.

Optional Redemption

Each series of notes is redeemable in whole or in part, at our option at any time or from time to time, at a redemption price equal to the greater of (i) 100% of the principal amount of the notes to be redeemed or (ii) the sum of the present values of the Remaining Scheduled Payments (as defined below) (not including any portion of such payment of interest accrued as of the date of redemption) discounted to the redemption date on an annual basis (ACTUAL/ACTUAL (ICMA)) at the applicable Comparable Government Bond Rate (as defined below), plus 12.5 basis points with respect to the 2024 notes and the Comparable Government Bond Rate plus 15 basis points with respect to the 2036 notes, plus, in each case, accrued and unpaid interest on the principal amount being redeemed to, but excluding, the redemption date.

On or after August 2, 2024 for the 2024 notes and August 2, 2036 for the 2036 notes (three months prior to the maturity date of the 2024 notes or the 2036 notes, as applicable), we may redeem in whole or in part the 2024 notes or the 2036 notes, as applicable, at any time or from time to time, at our option, at a redemption price equal to 100% of the principal amount of the applicable notes being redeemed, plus accrued and unpaid interest on the principal amount being redeemed to, but excluding, the redemption date.

We are required to give notice of redemption at least 30 days, but no more than 60 days, prior to the redemption date. The notice will be mailed to the registered address of each holder of that series of notes. The principal amount of a note remaining outstanding after a redemption in part shall be €100,000 or an integral multiple of €1,000 in excess thereof.

"Comparable Government Bond Rate" means, with respect to any redemption date, the price, expressed as a percentage (rounded to three decimal places, with 0.0005 being rounded upwards), at which the gross redemption yield on the notes to be redeemed, if they were to be purchased at such price on the third business day prior to the date fixed for redemption, would be equal to the gross redemption yield on such business day of the Comparable Government Bond (as defined below) on the basis of the middle market price of the Comparable Government Bond prevailing at 11:00 a.m. (London time) on such business day as determined by an independent investment bank selected by us.

"Comparable Government Bond" means, in relation to any Comparable Government Bond Rate calculation, at the discretion of an independent investment bank selected by us, a German federal government bond whose maturity is closest to the maturity of the notes to be redeemed, or if such independent investment bank in its discretion determines that such similar bond is not in issue, such other German government bond as such independent investment bank may, with the advice of three brokers of, and/or market makers in, German government bonds selected by us, determine to be appropriate for determining the Comparable Government Bond Rate.

"Remaining Scheduled Payments" means, with respect to each note to be redeemed, the remaining scheduled payments of principal of and interest on the note that would be due after the related redemption date but for the redemption. If that redemption date is not an interest payment date with respect to a note, the amount of the next succeeding scheduled interest payment on the note will be reduced by the amount of interest accrued on the note to the redemption date.

If fewer than all of the notes of any series are to be redeemed, the trustee will select the particular notes or portions thereof for redemption from the outstanding notes not previously called, pro rata or by lot, or in such other manner as we direct each in accordance with the depositary's procedures.

Unless we default in payment of the redemption price, on and after the redemption date interest will cease to accrue on the notes or portions thereof called for redemption.

The notes are also subject to redemption if certain events occur involving United States taxation. See "—Taxation Redemption."

Additional Amounts

All payments of principal and interest in respect of the notes are made free and clear of, and without deduction or withholding for or on account of any present or future taxes, duties, assessments or other governmental charges of whatsoever nature imposed, levied, collected, withheld or assessed by the United States or any political subdivision or taxing authority of or in the United States (collectively, "Taxes"), unless such withholding or deduction is required by law.

In the event such withholding or deduction of Taxes is required by law, subject to the limitations described below, we will pay to the holder of any note that is not beneficially owned by a U.S. Holder (as defined below) such additional amounts ("Additional Amounts") as may be necessary in order that every net payment received by the beneficial owner of such note of principal of or interest or any other amount payable on the notes (including upon redemption), after deduction or withholding for or on account of such Taxes, will not be less than the amount provided for in such note to be then due and payable before deduction or withholding for or on account of such Taxes.

However, our obligation to pay Additional Amounts shall not apply to:

(a) any Taxes which would not have been so imposed but for:

(1) the existence of any present or former connection between such holder or beneficial owner (or between a fiduciary, settlor, beneficiary, member or shareholder or other equity owner of, or a person having a power over, such holder or beneficial owner, if such holder or beneficial owner is an estate, a trust, a limited liability company, a partnership, a corporation or other entity) and the United States, including, without limitation, such holder or beneficial owner (or such fiduciary, settlor, beneficiary, member, shareholder or other equity owner or person having such a power) being or having been a citizen or resident or treated as a resident of the United States or being or having been engaged in a trade or business in the United States or being or having been present in the United States or having or having had a permanent establishment in the United States;

(2) the failure of such holder or beneficial owner to comply with any certification, information or other reporting requirement, if compliance is required under United States tax laws and regulations to establish entitlement to a partial or complete exemption from such Taxes (including, but not limited to, the requirement to provide Internal Revenue Service Form W-8BEN, Form W-8BEN-E, Form W-8ECI, or any subsequent versions thereof or successor thereto); or

(3) such holder's or beneficial owner's present or former status as a personal holding company or a foreign personal holding company with respect to the United States, as a controlled foreign corporation with respect to the United States, as a passive foreign investment company with respect to the United States, as a foreign tax exempt organization with respect to the United States or as a corporation which accumulates earnings to avoid United States federal income tax;

(b) any Taxes imposed by reason of the holder or beneficial owner:

(1) owning or having owned, directly or indirectly, actually or constructively, 10% or more of the total combined voting power of all classes of our stock, as described in section 871(h)(3) of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"),

(2) being a bank receiving interest described in section 881(c)(3)(A) of the Internal Revenue Code, or

(3) being a controlled foreign corporation with respect to the United States that is related to us by stock ownership;

(c) any Taxes which would not have been so imposed but for the presentation by the holder or beneficial owner of such note for payment on a date more than 30 days after the date on which such payment became due and payable or the date on which payment of the note is duly provided for and notice is given to holders, whichever occurs later, except to the extent that the holder or beneficial owner would have been entitled to such Additional Amounts on presenting such note on any date during such 30-day period;

(d) any estate, inheritance, gift, sales, excise, transfer, personal property, wealth or similar Taxes;

(e) any Taxes which are payable otherwise than by withholding from a payment on such note;

(f) any Taxes which are payable by a holder that is not the beneficial owner of the note, or a portion of the note, or that is a fiduciary, partnership, limited liability company or other similar entity, but only to the extent that a beneficial owner, a beneficiary or settlor with respect to such fiduciary or member of such partnership, limited liability company or similar entity would not have been entitled to the payment of an additional amount had such beneficial owner, settlor, beneficiary or member received directly its beneficial or distributive share of the payment;

(g) any Taxes required to be withheld by any paying agent from any payment on any note, if such payment can be made without such withholding by at least one other paying agent;

(h) any Taxes imposed under Sections 1471 through 1474 of the Internal Revenue Code (or any amended or successor provisions), any current or future regulations or official interpretations thereof, any agreement entered into pursuant to Section 1471(b) of the Code or any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement entered into in connection with the implementation of such sections of the Code;

(i) any combination of items (a), (b), (c), (d), (e), (f), (g) and (h).

For purposes of this section, the acquisition, ownership, enforcement, or holding of or the receipt of any payment with respect to a note will not constitute a connection (1) between the holder or beneficial owner and the United States or (2) between a fiduciary, settlor, beneficiary, member or shareholder or other equity owner of, or a person having a power over, such holder or beneficial owner if such holder or beneficial owner is an estate, a trust, a limited liability company, a partnership, a corporation or other entity and the United States.

Any reference in this description, in the indenture or in the notes to principal or interest or other payment on the notes shall be deemed to refer also to Additional Amounts which may be payable under the provisions of this section.

We will pay all stamp and other duties, if any, which may be imposed by the United States or any political subdivision thereof or taxing authority therein with respect to the issuance of the notes pursuant to this offering.

Except as specifically provided under the heading "—Additional Amounts," we will not be required to make any payment with respect to any tax, duty, assessment or other governmental charge imposed by any government or any political subdivision or taxing authority of or in the United States.

A "U.S. Holder" is a beneficial owner of a note or notes that is for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of the source of that income; or
- a trust, if (1) a U.S. court is able to exercise primary supervision over the trust's administration and one or more "United States persons" (within the meaning of the Internal Revenue Code) have the authority

to control all of the trust's substantial decisions, or (2) the trust has a valid election in effect under applicable Treasury regulations to be treated as a "United States person."

Taxation Redemption

The notes may be redeemed at our option, in whole but not in part, at a redemption price equal to 100% of the principal amount of the notes to be redeemed, together with interest accrued and unpaid to, but excluding, the redemption date, at any time, on giving not less than 30 nor more than 60 days' notice in accordance with "Notices" below if:

(a) we have or will become obligated to pay Additional Amounts as a result of (i) any change in or amendment to the laws, regulations or rulings of the United States or any political subdivision or any taxing authority of or in the United States affecting taxation, or (ii) any change in or amendment to an official application, interpretation, administration or enforcement of such laws, regulations or rulings, which change or amendment is announced or becomes effective on or after October 26, 2016; *provided* we reasonably determine that such obligation cannot be avoided by our taking reasonable measures available to us without significant difficulty, cost or expense, or

(b) any action shall have been taken by a taxing authority, or any action has been brought in a court of competent jurisdiction, in the United States or any political subdivision or taxing authority of or in the United States, including any of those actions specified in (a) above, whether or not such action was taken or brought with respect to us, or any change, clarification, amendment, application or interpretation of such laws, regulations or rulings shall be officially proposed, in any such case on or after October 26, 2016, which results in a substantial likelihood that we will be required to pay Additional Amounts on the next interest payment date.

However, no such notice of redemption shall be given earlier than 90 days prior to the earliest date on which we would be, in the case of a redemption for the reasons specified in (a) above, or there would be a substantial likelihood that we would be, in the case of a redemption for the reasons specified in (b) above, obligated to pay such Additional Amounts if a payment in respect of the notes were then due and, at the time such notification of redemption is given, such circumstance remains in effect.

Prior to the publication of any notice of redemption pursuant to this section, in the case of a redemption for the reasons specified in (a) or (b) above, we will deliver to the trustee:

(1) a certificate signed by one of our duly authorized officers stating that we are entitled to effect such redemption and setting forth a statement of facts showing that the conditions precedent to our right so to redeem have occurred, and

(2) a written opinion of independent legal counsel of recognized standing to the effect that we have or will become obligated to pay such Additional Amounts as a result of such change or amendment or that there is a substantial likelihood that we will be required to pay such Additional Amounts as a result of such action or proposed change, clarification, amendment, application or interpretation, as the case may be.

Such notice, once delivered by us to the trustee, will be irrevocable.

Modification and Waiver

There are three types of changes we can make to the indenture and the notes.

Changes Requiring Holder Approval. First, there are changes that cannot be made to the notes of any series without specific approval by each holder of the notes of such series affected thereby. Following is a list of those types of changes:

- change the payment due date of any installment of the principal or any premium or interest on a note stated in the note;
- reduce any amounts due on a note;
- change the place or currency of payment on a note;
- impair holders' right to sue for payment;
- reduce the percentage of notes of any series, the holders of which must consent to modify or amend the indenture;
- reduce the percentage of notes of any series the holders of which must consent to waive compliance with certain provisions of the indenture or to waive certain defaults; and
- modify any other aspect of the provisions dealing with modification and waiver of the indenture except to increase any such percentage or to provide that certain other provisions of the indenture cannot be modified or waived without the consent of the holder of each outstanding security affected thereby.

Changes Requiring a Majority Vote. The second type of change to the indenture and the notes is the kind that requires a vote in favor by holders owning not less than a majority of the principal amount of the *notes of the particular series affected*. Most changes fall into this category, such as if we wish to obtain a waiver of all or part of the restrictive covenants described below, or a waiver of a past default. However, we cannot obtain a waiver of a payment default or any other aspect of the indenture or the notes listed in the first category above under "—Changes Requiring Holder Approval" unless we obtain the individual consent of each holder of the notes of such series affected thereby to the waiver.

Changes Not Requiring Approval. The third type of change does not require any vote by holders of notes. This type is limited to the addition or release of a guarantee, corrections and clarifications and other changes that would not adversely affect holders of the notes.

Further Details Concerning Voting. When taking a vote, we use the U.S. dollar equivalent to decide how much principal amount to attribute to a note.

Notes will not be considered outstanding and therefore will not carry voting rights if we have deposited or set aside in trust for the holders thereof money for their payment or redemption. Notes will also not be eligible to vote if they have been fully defeased as described under "—Defeasance—Full Defeasance."

We may set any day as a record date for the purpose of determining the holders of outstanding notes that are entitled to vote or take other action under the indenture. In some circumstances, the trustee may set a record date for action by holders.

Street name and other indirect holders should consult their banks or brokers for information on how approval may be granted or denied if we seek to change the indenture or the notes or request a waiver.

Mergers and Similar Events

We may consolidate or merge with another company or firm. We may also convey, transfer or lease all of our properties and assets substantially as an entirety to another firm, or buy or lease substantially all of the assets of another firm. However, we may not take any of these actions unless the following conditions, among others, are met:

- We are the surviving entity or, when we merge out of existence or convey, transfer or lease all of our properties and assets substantially as an entirety, the other firm must be a corporation, limited liability company, partnership or trust organized under the laws of a U.S. state or the District of Columbia or under federal law and it must agree to be legally responsible for the notes.

- The merger, sale of assets or other transaction must not cause a default on the notes, and we must not already be in default unless the merger or other transaction would cure the default. For purposes of this no-default test, a default would include an event of default, as described under "—Default and Remedies—Events of Default—What is an Event of Default," that has occurred and not been cured. A default for this purpose would also include the occurrence of any event that would be an event of default if we received the required notice of our default or if under the indenture the default would become an event of default after existing for a specific period of time.

- It is possible that the merger, sale of assets or other transaction would cause some of our property to become subject to a mortgage or other legal mechanism giving lenders preferential rights in that property over other lenders or over our general creditors if we fail to pay them back. We have promised to limit these preferential rights, as discussed under "—Restrictive Covenants." If a merger or other transaction would create any liens on any of our property, we must comply with those restrictive covenants. We would do this either by deciding that the liens were permitted, or by following the requirements of the restrictive covenants to grant an equivalent or higher-ranking lien to the holders of the notes on the same property that we own.

If the conditions described above are satisfied with respect to any series of notes, we do not need to obtain the approval of the holders of those notes in order to merge or consolidate or to sell our assets. Also, these conditions apply only if we wish to merge or consolidate with another entity or convey, transfer or lease all of our properties and assets substantially as an entirety. We do not need to satisfy these conditions if we enter into other types of transactions, including any transaction in which we acquire the stock or assets of another entity, any transaction that involves a change of control but in which we do not merge or consolidate and any transaction in which we convey, transfer or lease less than all of our properties and assets substantially as an entirety. It is possible that these other types of transactions may result in a reduction in our credit rating, may reduce our operating results or may impair our financial condition. However, the holders of notes have no approval right with respect to any transaction of this type.

Restrictive Covenants

Restrictions on Secured Debt. Some of our property may be subject to a mortgage or other legal mechanism that gives our lenders preferential rights in that property over other lenders, including the holders of the notes, or over our general creditors if we fail to pay them back. These preferential rights are called liens. Debt which is protected by these preferential rights is called secured debt. In the indenture, we promise that neither we nor our domestic subsidiaries (as defined below) will incur any new secured debt that is secured by a lien on any of our or our domestic subsidiaries' principal domestic manufacturing properties (as defined below), or on any shares of stock of any of our domestic subsidiaries that own or lease a principal domestic manufacturing property, unless we grant an equivalent or higher-ranking lien on the same property to the holders of the notes and other outstanding debt securities issued under the indenture.

We do not need to comply with this restriction if the amount of all debt that would be secured by liens on principal domestic manufacturing properties, including the new debt, the notes and other outstanding debt securities issued under the indenture which we would so secure as described in the previous sentence, and all attributable debt (as defined below) that results from a sale and leaseback transaction involving principal domestic manufacturing properties, is less than 10% of our consolidated net tangible assets (as defined below).

This restriction on secured debt does not apply to debt secured by certain types of liens, and we can disregard this secured debt when we calculate the limits imposed by this restriction. These types of liens are:

- liens on the property of any of our domestic subsidiaries, or on their shares of stock, if those liens existed at the time the corporation became our domestic subsidiary;

- with respect to any series of notes, any lien existing on the date of issuance of such notes;
- liens in favor of us or our domestic subsidiaries;
- liens in favor of U.S. governmental bodies that we granted in order to assure our payments to such bodies that we owe by law or because of a contract we entered into;
- liens in favor of any customer arising in respect of payments made by or on behalf of a customer for goods produced for, or services rendered to, customers in the ordinary course of business not exceeding the amount of those payments:
- statutory liens, liens for taxes or assessments or governmental charges or levies not yet due or delinquent or which can be paid without penalty or are being contested in good faith, landlord's liens on leased property, easements and other liens of a similar nature;
- liens on property or shares of stock that existed at the time we acquired them, including property we may acquire through a merger or similar transaction, or that we granted in order to purchase the property, which are sometimes called purchase money mortgages; and
- debt secured by liens that extend, renew or replace any of these types of liens.

We and our subsidiaries may have as much unsecured debt as we may choose.

Restrictions on Sales and Leasebacks. We promise that neither we nor any of our domestic subsidiaries will enter into any sale and leaseback transaction involving a principal domestic manufacturing property, unless we comply with this restrictive covenant. A sale and leaseback transaction generally is an arrangement between us or a domestic subsidiary and a bank, insurance company or other lender or investor where we or the domestic subsidiary sell a property to a lender or investor more than 120 days after the acquisition of the property or the completion of construction of the property and the beginning of its full operation and we lease the property back from the lender.

We can comply with this restrictive covenant in either of two ways:

- First, we will be in compliance if we or our domestic subsidiary could grant a lien on the principal domestic manufacturing property in an amount equal to the attributable debt for the sale and leaseback transaction without being required to grant an equivalent or higher-ranking lien to the holders of the notes and other outstanding debt securities issued under the indenture under the restriction on secured debt described above.
- Second, we can comply if we retire an amount of our or any domestic subsidiary's funded debt which is not subordinated in right of payment to any outstanding notes or other outstanding debt securities issued under the indenture, within 120 days of the transaction, equal to the greater of the net proceeds of the sale of the principal domestic manufacturing property that we lease in the transaction or the fair market value of that property, subject to credits for voluntary retirements of notes and other outstanding debt securities issued under the indenture and funded debt we or the domestic subsidiary may make.

This restriction on sales and leasebacks does not apply to any sale and leaseback transaction that is between us and one of our domestic subsidiaries or between domestic subsidiaries, or that involves a lease for a period of three years or less.

Definitions Relating to our Restrictive Covenants. Following are summaries of the meanings of the terms that are important in understanding the restrictive covenants previously described:

"Attributable debt" means the total net amount of rent, discounted at 1% per annum over the weighted average yield to maturity of the outstanding notes and other outstanding debt securities issued under the indenture compounded semi-annually, that is required to be paid during the remaining term of any lease.

"Consolidated net tangible assets" is the total amount of assets, less reserves and certain other permitted deductible items, after subtracting all current liabilities and all goodwill, trade names, trademarks, patents, unamortized debt discounts and expenses and similar intangible assets, as such amounts appear on our most recent consolidated balance sheet and computed in accordance with generally accepted accounting principles.

A "domestic subsidiary" means any of our subsidiaries which transacts substantially all of its business in the United States, has substantially all of its fixed assets located in the United States, or owns or leases principal domestic manufacturing property. However, a subsidiary whose principal business is financing our operations outside of the United States is not a domestic subsidiary. A subsidiary is a corporation in which we and/or one or more of our other subsidiaries owns at least 50% of the voting stock (generally defined as stock that ordinarily permits its owners to vote for the election of directors).

"Funded debt" means all debt for borrowed money that either has a maturity of 12 months or more from the date on which the calculation of funded debt is made or has a maturity of less than 12 months from that date but is by its terms renewable or extendible beyond 12 months from that date at the option of the borrower.

A "principal domestic manufacturing property" is any building or other structure or facility, and the land on which it sits and its associated fixtures, that we use primarily for manufacturing, processing or warehousing, that is located in the United States and that has a gross book value in excess of 1% of our consolidated net tangible assets, other than a building, structure or other facility that our board of directors has determined is not of material importance to the total business that we and our subsidiaries conduct or a building or structure which is financed by obligations issued by a state, a territory, or a possession of the United States, or any political subdivision of any of the foregoing, or the District of Columbia, the interest of which is excludable from gross income of the holders under provisions of the tax code.

Further Issues

We may, without the consent of holders of any series of the notes, issue additional notes having the same ranking and the same interest rate, maturity and other terms as the notes of that series. Any additional notes of any series, together with the outstanding notes of the applicable series, will constitute a single series of notes under the indenture. No additional notes may be issued if an event of default has occurred and is continuing with respect to the applicable series of notes. Additional notes cannot be issued under the same CUSIP, ISIN or Common Code number unless the additional notes and original notes are fungible for U.S. federal income tax purposes.

Defeasance

Full Defeasance. If there is a change in federal tax law, as described below, we can legally release ourselves from any payment or other obligations on the notes of a series if we put in place other arrangements for the holders of such notes to be repaid. This is called full defeasance. In order to achieve full defeasance, we must do the following, among other things:

- We must deposit in trust for the benefit of all holders of the notes of the series any combination of money (in euros) and Federal Republic of Germany obligations (as defined below) that will generate enough cash to make interest, principal and any other payments on the notes of that series on their various due dates.
- There must be a change in current federal tax law or an IRS ruling that lets us make the above deposit without causing holders or beneficial owners of the notes of the series to be taxed on such notes any differently than if we did not make the deposit and just repaid such notes ourselves. (Under current federal tax law, the deposit and our legal release from such notes would be treated as though we took

back beneficial owners' notes and gave them their share of the cash and notes or bonds deposited in trust. In that event, beneficial owners could recognize gain or loss on the notes they give back to us.)

- We must deliver to the trustee a legal opinion of our counsel confirming the tax law change described above.

If we ever did accomplish full defeasance, as described above, holders of defeased notes would have to rely solely on the trust deposit for repayment on such notes. Holders of such notes could not look to us for repayment in the unlikely event of any shortfall.

Covenant Defeasance. Under current federal tax law, we can make the same type of deposit described above and be released from some of the restrictive covenants in the notes. This is called covenant defeasance. In that event, holders of notes would lose the protection of those restrictive covenants but would gain the protection of having money and securities set aside in trust to repay the notes. In order to achieve covenant defeasance of the notes of a series, we must do the following:

- We must deposit in trust for the benefit of all holders of the notes of the series any combination of money (in euros) and Federal Republic of Germany obligations that will generate enough cash to make interest, principal and any other payments on the notes on their various due dates.

- We must deliver to the trustee a legal opinion of our counsel confirming that under current federal income tax law we may make the above deposit without causing holders or beneficial owners of the notes to be taxed on the notes any differently than if we did not make the deposit and just repaid the notes ourselves.

If we accomplish covenant defeasance, the following provisions of the indenture and the notes would no longer apply:

- Our promises regarding conduct of our business previously described under "—Restrictive Covenants."

- Restrictions regarding mergers or similar transactions, as described under "—Mergers and Similar Events."

- The events of default relating to mergers or similar transactions and either of the restrictive covenants described under "—Restrictive Covenants."

If we accomplish covenant defeasance, holders of notes can still look to us for repayment of the notes if there were a shortfall in the trust deposit. In fact, if one of the remaining events of default occurred, such as our bankruptcy, and the notes become immediately due and payable, there may be such a shortfall in the trust deposit.

"Federal Republic of Germany obligations" means (1) securities that are direct obligations of the Federal Republic of Germany for the payment of which its full faith and credit is pledged or (2) obligations of a person controlled or supervised by and acting as an agency or instrumentality of the Federal Republic of Germany, the payment of which is unconditionally guaranteed as a full faith and credit obligation by the Federal Republic of Germany, which, in either case under clauses (1) or (2) are not callable or redeemable at the option of the issuer thereof.

Events of Default

Holders of notes have special rights if an event of default occurs and is not cured, as described later in this subsection.

The term event of default with respect to each series of notes means any of the following:

- We do not pay the principal or any premium on such series of notes on its due date.
- We do not pay interest on such series of notes within 30 days of its due date.
- We remain in breach of either of the restrictive covenants described under "—Restrictive Covenants" or any other covenant or warranty in the indenture for 90 days after we receive a notice of default stating we are in breach. The notice must be sent by either the trustee or holders of at least 25% of the principal amount of notes of the affected series.
- We file for bankruptcy or other specific events of bankruptcy, insolvency or reorganization occur.
- We do not pay Additional Amounts on such series of notes within 30 days after such payment is due.

Any payment in respect of the notes made in U.S. dollars due to the unavailability or nonuse of the euro as discussed under "—Payments in Euros" will not constitute an event of default under the notes or the indenture governing the notes.

If an event of default has occurred and has not been cured, the trustee or the holders of at least 25% in principal amount of the outstanding notes of the affected series may declare the entire principal amount of all the notes of that series to be due and immediately payable. This is called a declaration of acceleration. The holders of at least a majority in principal amount of the notes of the affected series may cancel a declaration of acceleration of maturity.

Except in cases of default, where the trustee has some special duties, the trustee is not required to take any action under the indenture at the request of any holders unless such holders offer the trustee reasonable protection, called an indemnity, against expenses and liability. If reasonable indemnity is provided, the holders of a majority in principal amount of the outstanding notes of the relevant series may direct the time, method and place of conducting any lawsuit or other formal legal action seeking any remedy available to the trustee. These majority holders may also direct the trustee in performing any other action under the indenture with respect to the notes of the applicable series.

Before a holder of notes of any series bypasses the trustee and brings its own lawsuit or other formal legal action or takes other steps to enforce its rights or protect its interests relating to the notes of such series, the following must occur:

- The holder must give the trustee written notice that an event of default has occurred and remains uncured.
- The holders of at least 25% in principal amount of all outstanding notes of the relevant series must make a written request that the trustee take action because of the default, and must offer indemnity reasonably satisfactory to the trustee against the cost and other liabilities of taking that action.
- The trustee must have not received from holders of a majority in principal amount of the outstanding notes of that series a direction inconsistent with the written notice.
- The trustee must have not taken action for 60 days after receipt of the above notice and offer of indemnity.

However, a holder of notes is entitled at any time to bring a lawsuit for the payment of money due on its notes on or after their due date.

Street name and other indirect holders should consult their banks or brokers for information on how to give notice or direction to or make a request of the trustee and to make or cancel a declaration of acceleration.

We furnish to the trustee every year a written statement of our principal executive, financial or accounting officer certifying that to the best of such signer's knowledge we are in compliance with the indenture and the notes, or else specifying any default.

Form, Exchange and Registration of Transfer

We issued the notes only in fully registered form and without interest coupons.

A holder of notes may have its notes broken into more notes of smaller denominations of not less than €100,000 or combined into fewer notes of larger denominations, as long as the total principal amount is not changed. This is called an exchange.

A holder of notes may exchange or register a transfer of notes at the office of the trustee. The trustee acts as our agent for registering notes in the names of holders and registering transfers of notes. We may change this appointment to another entity or perform it ourselves. The entity performing the role of maintaining the list of registered holders is called the security registrar. It also registers transfers. A holder of notes may also replace lost, stolen or mutilated notes at that office. The trustee's agent may require an indemnity before replacing any notes.

A holder of notes is not required to pay a service charge to register a transfer of notes or to exchange notes, but may be required to pay for any tax or other governmental charge associated with the transfer or exchange. The security registrar makes the registration of transfer or exchange only if it is satisfied with such holder's proof of ownership.

We may cancel the designation of any trustee. We may also approve a change in the office through which any trustee acts.

If we redeem less than all of the notes of a particular series, we may block the issuance of, registration of transfer or exchange of notes during the period beginning 15 days before the day we mail the notice of redemption and ending on the day of that mailing, in order to freeze the list of holders to prepare the mailing. We may also refuse to register transfers or exchanges of notes selected for redemption, except that we will continue to permit transfers and exchanges of the unredeemed portion of any note being partially redeemed.

The rules for exchange described above apply to exchange of notes for other notes of the same series and tenor.

Payment and Paying Agents

We pay interest to a holder of notes on each date interest is due if the holder is a direct holder listed in the trustee's records at the close of business on the fifteenth calendar day before the next interest payment date, even if such holder no longer owns the note on the interest due date. That particular day is called the regular record date. Holders buying and selling notes must work out between them how to compensate for the fact that we pay all the interest for an interest period to the one who is the registered holder on the regular record date.

We pay interest, principal and any other money due on the notes at the office of the trustee in London, UK. That office is currently located at125 Old Broad Street, Fifth Floor, London EC2N 1AR United Kingdom. A holder of notes must make arrangements to have its payments picked up at or wired from that office. We may also choose to pay interest by mailing checks.

Street name and other indirect holders should consult their banks or brokers for information on how they may receive payments.

We may also arrange for additional payment offices, and may cancel or change these offices. These offices are called paying agents. We may also choose to act as our own paying agent. We must notify holders of notes of changes in the paying agents for any particular notes of the series.

Notices

We and the trustee send notices regarding the notes only to direct holders, using their addresses as listed in the trustee's records.

All paying agents must return to us upon our request all money paid by us that remains unclaimed two years after the amount is due to direct holders. After that two-year period, holders of notes may look only to us for payment and not to the trustee, any other paying agent or anyone else.

Book-Entry System

Upon issuance, the notes of each series are represented by one or more global notes. Each global note is deposited with, or on behalf of, a common depositary, and registered in the name of the nominee of the common depositary for the accounts of Clearstream and Euroclear.

Investors may elect to hold interests in the global notes held by the depository through Clearstream Banking, *société anonyme* ("Clearstream") or Euroclear Bank S.A./N.V., as operator of the Euroclear System, ("Euroclear") if they are participants of such systems, or indirectly through organizations that are participants in such systems. Clearstream and Euroclear hold interests on behalf of their participants through customers' securities accounts in Clearstream's and Euroclear's names on the books of their respective depositories. Book-entry interests in the notes and all transfers relating to the notes are reflected in the book-entry records of Clearstream and Euroclear. Because holders acquire, hold and transfer security entitlements with respect to the notes through Clearstream, Euroclear and their participants, a beneficial holder's rights with respect to the notes is subject to the laws (including Article 8 of the Uniform Commercial Code) and contractual provisions governing a holder's relationship with its securities intermediary and the relationship between its securities intermediary and each other securities intermediary and between it and us, as the issuer. Except as set forth below, the global notes may be transferred, in whole and not in part, only to another nominee of the depository or to a successor of the depository or its nominee.

No global note may be exchanged in whole or in part for notes registered, and no transfer of a global note in whole or in part may be registered, in the name of any person other than the depository or any nominee of the depository unless (i) the depository has notified us that it is unwilling or unable to continue as depository for such global note or has ceased to be qualified to act as such as required by the indenture, (ii) there has occurred and is continuing an event of default with respect to the notes or (iii) we determine in our sole discretion at any time that the global note shall be so exchangeable.

Any global note that is exchangeable pursuant to the preceding sentence shall be exchangeable in whole for separate notes in registered form of any authorized denomination and of like tenor and aggregate principal amount. These notes shall be registered in the name or names of such person or persons as the depository instructs the trustee. We expect that these instructions would be based upon directions received by the depository from its participants with respect to ownership of beneficial interests in such global note.

Except in the limited circumstances referred to above, owners of beneficial interests in a global note are not entitled to have such global note registered in their names, will not receive and are not entitled to receive physical delivery of notes in exchange therefor and are not considered to be the owners or holders of such global note for any purpose under the notes or the indenture. Accordingly, each person owning a beneficial interest in the global note must rely on the procedures of the participant through which such person owns its interest to exercise any rights of a holder under the indenture.

The indenture provides that the depository, as a holder, may appoint agents and otherwise authorize participants to give or take any request, demand, authorization, direction, notice, consent, waiver, or other action which a holder is entitled to give or take under the indenture.

Governing Law

The indenture and the notes are governed by, and construed and enforced in accordance with, the laws of the State of New York applicable to agreements made or instruments entered into and performed in New York State.

Relationship with Trustee

U.S. Bank Trust National Association is the trustee under the indenture. U.S. Bank Trust National Association performs services for us in the ordinary course of business and serves as the trustee with respect to certain of our other outstanding debt securities.

Open Market Purchases

We may at any time and from time to time purchase notes in the open market or otherwise.

The Paying Agent, Transfer Agent and Security Registrar

Elavon Financial Services DAC is the security registrar and transfer agent with respect to the notes. Elavon Financial Services DAC, UK Branch is the paying agent with respect to the notes.

Exhibit 10.24

TERMS FOR
2021 RESTRICTED STOCK UNIT GRANTS
UNDER THE MERCK & CO., 2019 INCENTIVE STOCK PLAN

This is a summary of the terms applicable to the Restricted Stock Unit (RSU) Award specified in this document. Different terms may apply to any prior or future RSU Awards.

Grant Type: RSU - Annual
Grant Date: May 4, 2021

Vesting Dates	Portion that Vests
May 4, 2022	First: 33.333%
May 4, 2023	Second: 33.333%
May 4, 2024	Third: Balance

Eligibility: Eligibility for grants is determined under the Merck & Co., Inc. 2019 Incentive Stock Plan for employees of the Company, its subsidiaries, its affiliates or its joint ventures if designated by the Compensation and Benefits Committee of Merck's Board of Directors, or its delegate (the "Committee").

I. GENERAL INFORMATION

IMPORTANT NOTICE: This grant requires you to affirmatively accept it. You MUST log onto the Morgan Stanley website at (http://www.morganstanley.com/spc/knowledge/managing-equity/managing-your-existing-awards/accepting-awards-grants/) to accept the grant.

Follow the procedure described on the Morgan Stanley website to accept your RSU Award within 90 days. Failure to accept the terms and conditions of your RSU Award within 90 days may result in Forfeiture of the RSU Award.

A. **Restricted Period.** The Restricted is the period during which this RSU Award is restricted and subject to forfeiture. The Restricted Period ends with respect to one-third of this RSU Award on each of the First, Second, and Third anniversaries of the Grant Date as shown in the box above, unless ended earlier under Article II below. No voting rights apply to this RSU Award. No fractional shares will be awarded: all calculations are subject to rounding.

B. **Dividend Equivalents.** During the Restricted Period, dividend equivalents will be accrued for the holder ("you") if and to the extent dividends are paid by the Company on Merck Common Stock. Payment of such dividends will be made, without interest or earnings, at the time of distribution. If any portion of this RSU award lapses, is forfeited or expires, no dividend equivalents will be credited or paid on such portion. Any payment of dividend equivalents will be reduced to the extent necessary for the Company to satisfy any tax or other withholding obligations.

C. **Distribution.** Upon the expiration of the Restricted Period if you are then employed, you will be entitled to receive a number of shares of Merck common stock equal to the number of RSUs that have become unrestricted and the dividend equivalents that accrued on that portion. Prior to distribution, you must deliver to the Company an amount the Company determines to be sufficient to satisfy any amount required to be withheld, including applicable taxes. The Company may, in its sole discretion, withhold from the RSU Award distribution a number of shares to pay applicable withholding (including taxes).

D. **409A Compliance.** Anything to the contrary notwithstanding, no distribution of RSUs may be made unless in compliance with Section 409A of the Internal Revenue Code or any successor thereto. Specifically, distributions made due to a separation from service (as defined in Section 409A) to a "Specified Employee" as defined in Treas. Reg. Sec. 1.409A-1(i) or any successor thereto, to the extent required by Section 409A of the Code will not be made until administratively feasible following the first day of the sixth month following the separation from service, in the same form as they would have been made had this restriction not applied; provided further, that dividend equivalents that otherwise would have accrued will accrue during the period during which distribution is suspended.

E. **Subject to Recoupment.** For employees in Band 600 and above, this RSU Award will be subject to recoupment in the event of certain violations of Company policy in accordance with the Company's policy for Recoupment of Compensation for Compliance Violations, as set forth in Appendix A (as may be amended from time to time).

II. TERMINATION OF EMPLOYMENT

If your employment with the Company is terminated during the Restricted Period, your right to the RSU Award will be determined according to the terms in this Section II.

A. **General Rule.** If your employment is terminated during the Restricted Period for any reason other than those specified in the following paragraphs, the unvested portion of this RSU Award (and any accrued dividend equivalents) will be forfeited on the date your employment ends. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this grant nevertheless will expire according to this paragraph notwithstanding such rehire.

B. **Sale.** If your employment is terminated during the Restricted Period and the Company determines that such termination resulted from the sale of your subsidiary, division or joint venture, the following portion of your RSU Award and accrued dividend equivalents will be distributed to you at such time as it would have been paid if your employment had continued: one-third if employment terminates on or after the Grant Date but before the first anniversary thereof; and all if employment terminates on or after the first anniversary of the Grant Date. The remainder will be forfeited on the date your employment ends. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this grant nevertheless will expire according to this paragraph notwithstanding such rehire.

C. **Involuntary Termination.** If the company determines that your employment is involuntarily terminated during the Restricted Period but on or after the First Anniversary, a pro rata portion of your unvested RSU Award and accrued dividend equivalents will be distributed to you at such time as they would have been paid if your employment had continued. The pro rata portion will equal the full amount of this RSU Award (whether or not vested) times the number of completed months during the Restricted Period and prior to the date employment terminates, divided by 36; reduced by the number of RSUs that have vested pursuant to Paragraph A. The remainder and any accrued dividends will be forfeited on the date your employment ends. An "involuntary termination" includes termination of your employment by the Company as the result of a restructuring or job elimination, but excludes non-performance of your duties and the reasons listed under paragraphs B, or D through H of this section. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this grant nevertheless will expire according to this paragraph notwithstanding such rehire.

D. **Retirement.** If your employment terminates by retirement during the Restricted Period, a pro rata portion of your unvested RSU Award and accrued dividend equivalents will be distributed to you at such time as they would have been paid if your employment had continued. The pro rata portion will equal the full amount of this RSU Award (whether or not vested) times the number of completed months during the Restricted Period and prior to the date employment terminates, divided by 36; reduced by the number of RSUs that have vested pursuant to Paragraph A. The remainder and any accrued dividends will be forfeited on the date your employment ends. For grantees who are employed in the U.S., "retirement" means a termination of employment after attaining the earliest of (a) age 55 with at least 10 years of service (b) such age and service that provides eligibility for subsidized retiree medical coverage or (c) age 65 without regard to years of service. For other grantees, "retirement" is determined by the Company. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this grant nevertheless will expire according to this paragraph notwithstanding such rehire.

E. **Death.** If your employment terminates due to your death during the Restricted Period, all of this RSU Award and accrued dividend equivalents will be distributed to your estate as soon as possible after your death. If you die during the Restricted Period, but after your employment terminates for the reasons listed under paragraphs B, C, D, G or H of this section, the remaining, non-forfeited portion of this RSU Award and accrued dividend equivalents will be distributed to your estate as soon as possible after your death.

F. **Misconduct.** If your employment is terminated as a result of your deliberate, willful or gross misconduct, this RSU Award and accrued dividend equivalents will be forfeited immediately upon your receipt of notice of such termination.

G. **Disability.** If your employment is terminated during the Restricted Period and the Company determines that such termination resulted from inability to perform the material duties of your role by reason of a physical or mental infirmity that is expected to last for at least six months or to result in your death, whether or not you are eligible for disability benefits from any applicable disability program, then this RSU Award will continue and be distributable in accordance with its terms as if employment had continued and will be distributed at the time active RSU Grantees receive distributions with respect to this RSU Award.

H. **Change in Control.** If the Company involuntarily terminates your employment during the Restricted Period without Cause before the second anniversary after the closing of any change in control, then this RSU Award will continue in accordance with its terms as if employment had continued and will be distributed at the time active RSU Grantees receive distributions with respect to this RSU Award. If this RSU does not remain outstanding following the change in control and is not converted into a successor RSU, then you will be entitled to receive cash for this RSU in an amount equal to the fair market value of the consideration paid to Merck stockholders for a share of Merck common stock in the change in control payable within 30 days of the closing of the change in control. On the second anniversary of the closing of the change in control, this paragraph shall expire. Change in control is defined in the Merck & Co., Inc. Change in Control Separation Benefits Plan (excluding an MSD Change in Control), but if RSUs are considered "deferred compensation" under Section 409A of the Internal Revenue Code, the definition of change in control will be modified to the extent necessary to comply with Section 409A.

I. **Joint Venture**. Employment with a joint venture or other entity in which the Company has a significant business or ownership interest is not considered termination of employment for purposes of this RSU Award. Such employment must be approved by, and contiguous with employment by, the Company. The terms set out in paragraphs A-H above apply to this RSU Award while you are employed by the joint venture or other entity.

III. TRANSFERABILITY

This RSU Award is not transferable and may not be assigned or otherwise transferred.

IV. ELECTRONIC ACCEPTANCE

The Company may, in its sole discretion, decide to deliver any documents related to the RSU or future RSUs that may be granted under the Plan by electronic means or request your consent to participate in the Plan by electronic means. You hereby consent to receive such documents by electronic delivery and agree to participate in the Plan through an online or electronic system established and maintained by the Company or a third party designated by the Company.

V. ADMINISTRATION

The Committee is responsible for construing and interpreting this grant, including the right to construe disputed or doubtful plan provisions, and may establish, amend and construe such rules and regulations as it may deem necessary or desirable for the proper administration of this grant. Any decision or action taken or to be taken by the Committee, arising out of or in connection with the construction, administration, interpretation and effect of this grant shall, to the maximum extent permitted by applicable law, be within its absolute discretion (except as otherwise specifically provided herein) and shall be final, binding and conclusive upon the Company, all eligible employees and any person claiming under or through any eligible employee. All determinations by the Committee including, without limitation, determinations of the eligible employees, the form, amount and timing of incentives, the terms and provisions of incentives and the writings evidencing incentives, need not be uniform and may be made selectively among eligible employees who receive, or are eligible to receive, Incentives hereunder, whether or not such eligible employees are similarly situated.

VI. GRANTS NOT PART OF THE EMPLOYMENT CONTRACT

Notwithstanding reference to grants of incentives in letters offering employment or in specific employment agreements, incentives do not constitute part of any employment contract between the Company or JV and the grantee, whether the employment contract arises as a matter of agreement or applicable law. The value of any grant or of the proceeds of any exercise of incentives are not included in calculating compensation for purposes of pension payments, separation pay, termination indemnities or other similar payments due upon termination of employment.

This RSU Award is subject to the provisions of the 2019 Incentive Stock Plan. For further information regarding the Long- Term Incentive Program, please visit the Company intranet Long-Term Incentive homepage.

Appendix A
Recoupment of Compensation for Compliance Violations

POLICIES AND PROCEDURES

Policy
It is the policy of the Compensation and Benefits Committee of the Board of Directors (the "Committee") that the Committee will exercise its discretion to determine whether to seek Recoupment of any bonus and/or other incentive compensation paid or awarded to an Affected Employee with respect to any performance period beginning after December 31, 2013, where it determines, in consultation with the Audit Committee, that: a) the Affected Employee engaged in misconduct, or failed to reasonably supervise an employee who engaged in misconduct, that resulted in a Material Policy Violation relating to the research, development, manufacturing, sales, or marketing of Company products; and b) the Committee concludes that the Material Policy Violation caused Significant Harm to the Company, as those terms are defined in this policy. The Committee's exercise of its discretion may take into account any considerations determined by the Committee to be relevant.

Definitions

1. "Recoupment" is defined to include any and all of the following actions to the extent permitted by law: (a) reducing the amount of a current or future bonus or other cash or non-cash incentive compensation award, (b) requiring reimbursement of a bonus or other cash-based incentive compensation award paid with respect to the most recently completed performance period, (c) cancelling all or a portion of a future-vesting equity award, (d) cancelling all or a portion of an equity award that vested within the previous twelve- month period, (e) requiring return of shares paid upon vesting and/or reimbursement of any proceeds received from the sale of an equity award, in each case that vested within the previous twelve-month period, and (f) any other method of reducing the total compensation paid to an employee for any prior twelve-month period or any current or future period.

2. A "Material Policy Violation" is defined as a material violation of a Company policy relating to the research, development, manufacturing, sales, or marketing of Company products.

3. An "Affected Employee" is an employee in Band 600 or higher who (i) engaged in misconduct that results in a Material Policy Violation; or (ii) failed in his or her supervisory responsibilities to reasonably manage or monitor the conduct of an employee who engaged in misconduct that results in a Material Policy Violation.

4. "Significant Harm" means a significant negative impact on the Company's financial operating results or reputation.

Procedures

1. The Committee, acting in consultation with the Audit Committee, shall administer this policy and have full discretion to interpret and to make any and all determinations under this policy, subject to the approval of the full Board of Directors in the case of a determination to seek or waive Recoupment from the Chief Executive Officer.

2. The General Counsel, in consultation with the Chief Ethics and Compliance Officer and the Executive Vice President, Human Resources, is responsible for determining whether to refer a matter to the Committee for review under this policy and for assisting the Committee with its review. The Committee may consult with other Board Committees and any external or internal advisors as it deems appropriate.

3. If the Committee, acting in consultation with the Audit Committee, determines that there is a basis for seeking Recoupment under this policy, the Committee shall exercise its discretion to determine for each Affected Employee, on an individual basis, and to what extent and in which manner, to seek Recoupment.

4. In exercising its discretion, the Committee may take into consideration, as it deems appropriate, all of the facts and circumstances of the particular matter and the general interests of the Company.

Delegation to Management for Certain Recoupment Decisions
The Committee hereby delegates to the Chief Executive Officer (who may further delegate as he deems appropriate) the authority to administer this policy and to make any and all decisions under it regarding Affected Employees who are not Section 16 Officers of the Company. Section 16 Officers are employees of the Company who are subject to Section 16 of the Securities Exchange Act of 1934. Management shall report to the Committee on any affirmative decisions to seek Recoupment pursuant to this delegation.

Disclosure of Recoupment Decisions
The Company will comply with all applicable securities laws and regulations, including Securities and Exchange Commission disclosure requirements regarding executive compensation. The Company may also, but is not obligated to, provide additional disclosure beyond that required by law when the Company deems it to be appropriate and determines that such disclosure is in the best interest of the Company and its shareholders.

Miscellaneous
Nothing in this policy shall limit or otherwise affect any of the following: 1) management's ability to take any disciplinary action with respect to any Affected Employee; 2) the Committee's ability to use its negative discretion with respect to any incentive compensation performance target at any time; or 3) the Committee's or management's ability to reduce the amount (in whole or in part) of a current or future bonus or other cash or non- cash incentive compensation award to any executive or other employee for any reason as they may deem appropriate and to the extent permitted by law. Nothing in this policy shall replace or otherwise limit or affect the Clawback Policy for EIP Awards Upon Significant Restatement of Financial Results and/or the Clawback Policy for PSUs Upon Significant Restatement of Financial Results.

Exhibit 10.23

TERMS FOR
2021 NON-QUALIFIED STOCK OPTION (NQSO) GRANTS
UNDER THE MERCK & CO., INC. 2019 INCENTIVE STOCK PLAN

This is a summary of the terms applicable to the stock option specified in this document. Different terms may apply to any prior or future stock option.

Grant Type: NQSO – Annual
Option Price: $XX.XX
Grant Date: May 4, 2021
Expiration Date: May 3, 2031

Vesting Dates	Portion that Vests
May 4, 2022	First: 33.333%
May 4, 2023	Second: 33.333%
May 4, 2024	Third: Balance

I. GENERAL INFORMATION

IMPORTANT NOTICE: This grant requires you to affirmatively accept it. You MUST log onto the Morgan Stanley website at: (http://www.morganstanley.com/spc/knowledge/managing-equity/managing-your-existing-awards/accepting-awards-grants/) to accept the grant.

Follow the procedure described on the Morgan Stanley website to accept your stock option within 90 days. Failure to accept the terms and conditions of your stock option within 90 days may result in Forfeiture of the stock option.

This stock option becomes exercisable in equal installments (subject to a rounding process) on the Vesting Dates indicated in the accompanying box. This stock option expires on its Expiration Date, which is the day before the tenth anniversary of the Grant Date. If your employment with the Company is terminated, your right to exercise this stock option will be determined according to the terms in Section II.

Eligibility: Eligibility for grants is determined under the Merck & Co., Inc. 2019 Incentive Stock Plan for employees of the Company, its subsidiaries, its affiliates or its joint ventures if designated by the Compensation and Benefits Committee of Merck's Board of Directors, or its delegate (the "Committee").

Subject to Recoupment: For employees in Band 600 and above, this Stock Option Award will be subject to recoupment in the event of certain violations of Company policy in accordance with the Company's policy for Recoupment of Compensation for Compliance Violations, as set forth in Appendix A (as may be amended from time to time).

II. TERMINATION OF EMPLOYMENT

A. **General Rule.** If your employment is terminated for any reason other than those specified in the following paragraphs, the portion of this stock option that is unvested will expire on the date your employment ends; the portion of this stock option that is vested will expire unless exercised before the New York Stock Exchange closes (the "Close of Business") on the day before the same day of the third month ("Within Three Months") after the date of the termination (but in no event after the expiration of the Option Period). Close of Business for any day on which the New York Stock Exchange is not open means the close of business prior to that date when the Exchange is open. Where there is no corresponding day of a month, the last day of the month is deemed to be the same day as a later date (e.g., November 28, 29 and 30 all correspond to February 28 in non-leap years). If you are rehired by the Company or JV, this option nevertheless will expire unless exercised Within Three Months, or the original Expiration Date if earlier.

B. **Retirement.** If you retire from service with the Company the portion of this stock option that would have become exercisable according to its original schedule within one year of the date your employment terminates will vest and become exercisable on its applicable Vesting Date and the remainder will expire immediately. Whether already vested on the date your employment terminates or vested as a result of such retirement, this option will expire on the earlier of (a) the day before the fifth anniversary of the termination date or (b) its original Expiration Date. For grantees who are employed in the U.S., "retirement" means a termination of employment after attaining the earliest of (a) age 55 with at least 10 years of service (b) such age and service that provides eligibility for subsidized retiree medical coverage or (c) age 65 without regard to years of service. For other grantees, "retirement" is determined by the Company. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this option nevertheless will expire according to this paragraph notwithstanding such rehire.

C. **Involuntary Termination.** If your employment is terminated by the Company and the Company determines that such termination was involuntary, including the result of a restructuring or job elimination, but excluding non-performance of your duties and the reasons listed under paragraphs B or D through H, the portion of this stock option that is unvested will expire on the date your employment ends; the portion of this stock option that is vested will expire on the day before the one year anniversary of the date your employment ends, but in no event later than the original Expiration Date. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this option nevertheless will expire according to this paragraph notwithstanding such rehire.

D. **Sale.** If your employment is terminated and the Company determines that such termination resulted from the sale of your subsidiary, division or joint venture, the following portion of this stock option award will vest and become exercisable immediately upon such termination: one-third if employment terminates on or after the Grant Date but before the first anniversary thereof; and all if employment terminates on or after the first anniversary of the Grant Date. Whether already vested on the date your employment terminates or vested as a result of such sale, this stock option will expire the day before the first anniversary of the date your employment with the Company ends, but in no event later than the original Expiration Date. Notwithstanding the foregoing, the Committee may determine, for purposes of this stock option grant, whether employment with an entity that is established from the Company's spin off, split off, split up or distribution of equity securities in connection with that entity constitutes a termination of employment, and may make adjustments, if any, as it deems appropriate, at the time of the distribution of such equity securities, in the kind and/or number of shares subject to this option, and/or in the option price of such option. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this option nevertheless will expire according to this paragraph notwithstanding such rehire.

E. **Misconduct.** If your employment is terminated as a result of your deliberate, willful or gross misconduct, this stock option (whether vested or unvested) will expire immediately upon your receipt of notice of such termination.

F. **Death.** If your employment terminates as a result of your death, the portion of this stock option that is unvested will vest immediately upon your death. Whether already vested on the date of your death or vested as a result of your death, this stock option will expire on the day before the second anniversary of your death, even if such date is later than the Original Expiration date. This stock option will expire on such earlier date than otherwise specified in this paragraph as may be required under applicable non-U.S. law (e.g., in France, six months from the date of death). If you die while any portion of this stock option remains outstanding, but after your employment terminates for the reasons listed under paragraphs B, C, D, G or H of this section, the portion that remains outstanding after such employment termination will become immediately exercisable and will continue to be exercisable until the expiration date prescribed in paragraph B, C, D, G or H as applicable (and at least a year from your death in those jurisdictions where such extension is required by law).

G. **Disability.** If your employment is terminated and the Company determines that such termination resulted from your inability to perform the material duties of your role by reason of a physical or mental infirmity that is expected to last for at least six months or to result in your death, whether or not you are eligible for disability benefits from any applicable disability program, then this stock option will continue to become exercisable on applicable Vesting Dates and will expire on the earlier of (a) the day before the fifth anniversary of the day your employment terminates and (b) its original Expiration Date. If your employment is terminated as described in this paragraph and you are later rehired by the Company or JV, this option nevertheless will expire according to this paragraph notwithstanding such rehire.

H. **Change in Control.** If the Company involuntarily terminates your employment without Cause before the second anniversary after the closing of a change in control, each unvested Stock Option that is outstanding immediately prior to the change in control will immediately become fully vested and exercisable. All options, including options vested prior to such time, will expire on the day before the fifth anniversary of the termination of your employment following a change in control (but not beyond the Expiration Date). This extended exercise period does not apply in the case of termination by reasons of retirement, involuntary termination, sale, misconduct, death or disability, as described in paragraphs B through G above or termination prior to a change in control. If this stock option does not remain outstanding following the change in control and is not converted into a successor stock option, then you will be entitled to receive cash for this option in an amount at least equal to the difference between the price paid to stockholders in the change in control and the Option Price of this stock option. A "change in control" has the same meaning that it has under the Merck & Co., Inc. Change in Control Separation Benefits Plan (excluding an MSD Change in Control).

I. **Joint Venture.** Employment with a joint venture or other entity in which the Company has determined that it has a significant business or ownership interest (a "JV") is not considered termination of employment for purposes of this stock option. If you transfer employment from the Company to a JV or from a JV to the Company, such employment must be approved by, and contiguous with employment by, the Company or the JV. The terms set out in paragraphs A through H above apply to this stock option while the option holder is employed by the JV.

III. TRANSFERABILITY

This stock option is not transferable and may not be assigned or otherwise transferred except, under specific terms, by executives who hold or who retired within the prior 12 months from a Section 16 officer position.

IV. ELECTRONIC ACCEPTANCE

The Company may, in its sole discretion, decide to deliver any documents related to the stock option or future options that may be granted under the Plan by electronic means or request your consent to participate in the Plan by electronic means. You hereby consent to receive such documents by electronic delivery and agree to participate in the Plan through an online or electronic system established and maintained by the Company or a third party designated by the Company.

V. ADMINISTRATION

The Committee is responsible for construing and interpreting this grant, including the right to construe disputed or doubtful plan provisions, and may establish, amend and construe such rules and regulations as it may deem necessary or desirable for the proper administration of this grant. Any decision or action taken or to be taken by the Committee, arising out of or in connection with the construction, administration, interpretation and effect of this grant shall, to the maximum extent permitted by applicable law, be within its absolute discretion (except as otherwise specifically provided herein) and shall be final, binding and conclusive upon the Company, all eligible employees and any person claiming under or through any eligible employee. All determinations by the Committee including, without limitation, determinations of the eligible employees, the form, amount and timing of incentives, the terms and provisions of incentives and the writings evidencing incentives, need not be uniform and may be made selectively among eligible employees who receive, or are eligible to receive, Incentives hereunder, whether or not such eligible employees are similarly situated.

VI. GRANTS NOT PART OF EMPLOYMENT CONTRACT

Notwithstanding reference to grants of incentives in letters offering employment or in specific employment agreements, incentives do not constitute part of any employment contract between the Company or JV and the grantee, whether the employment contract arises as a matter of agreement or applicable law. The value of any grant or of the proceeds of any exercise of Incentives are not included in calculating compensation for purposes of pension payments, separation pay, termination indemnities or other similar payments due upon termination of employment.

This stock option is subject to the provisions of the 2019 Incentive Stock Plan. For further information regarding the Long- Term Incentive Program, please visit the Company intranet Long-Term Incentive homepage.

Appendix A
Recoupment of Compensation for Compliance Violations

POLICIES AND PROCEDURES

Policy
It is the policy of the Compensation and Benefits Committee of the Board of Directors (the "Committee") that the Committee will exercise its discretion to determine whether to seek Recoupment of any bonus and/or other incentive compensation paid or awarded to an Affected Employee with respect to any performance period beginning after December 31, 2013, where it determines, in consultation with the Audit Committee, that: a) the Affected Employee engaged in misconduct, or failed to reasonably supervise an employee who engaged in misconduct, that resulted in a Material Policy Violation relating to the research, development, manufacturing, sales, or marketing of Company products; and b) the Committee concludes that the Material Policy Violation caused Significant Harm to the Company, as those terms are defined in this policy. The Committee's exercise of its discretion may take into account any considerations determined by the Committee to be relevant.

Definitions

1. "Recoupment" is defined to include any and all of the following actions to the extent permitted by law: (a) reducing the amount of a current or future bonus or other cash or non- cash incentive compensation award, (b) requiring reimbursement of a bonus or other cash-based incentive compensation award paid with respect to the most recently completed performance period, (c) cancelling all or a portion of a future-vesting equity award, (d) cancelling all or a portion of an equity award that vested within the previous twelve-month period, (e) requiring return of shares paid upon vesting and/or reimbursement of any proceeds received from the sale of an equity award, in each case that vested within the previous twelve-month period, and (f) any other method of reducing the total compensation paid to an employee for any prior twelve- month period or any current or future period.
2. A "Material Policy Violation" is defined as a material violation of a Company policy relating to the research, development, manufacturing, sales, or marketing of Company products.
3. An "Affected Employee" is an employee in Band 600 or higher who (i) engaged in misconduct that results in a Material Policy Violation; or (ii) failed in his or her supervisory responsibilities to reasonably manage or monitor the conduct of an employee who engaged in misconduct that results in a Material Policy Violation.
4. "Significant Harm" means a significant negative impact on the Company's financial operating results or reputation.

Procedures

1. The Committee, acting in consultation with the Audit Committee, shall administer this policy and have full discretion to interpret and to make any and all determinations under this policy, subject to the approval of the full Board of Directors in the case of a determination to seek or waive Recoupment from the Chief Executive Officer.
2. The General Counsel, in consultation with the Chief Ethics and Compliance Officer and the Executive Vice President, Human Resources, is responsible for determining whether to refer a matter to the Committee for review under this policy and for assisting the Committee with its review. The Committee may consult with other Board Committees and any external or internal advisors as it deems appropriate.
3. If the Committee, acting in consultation with the Audit Committee, determines that there is a basis for seeking Recoupment under this policy, the Committee shall exercise its discretion to determine for each Affected Employee, on an individual basis, whether, and to what extent and in which manner, to seek Recoupment.
4. In exercising its discretion, the Committee may take into consideration, as it deems appropriate, all of the facts and circumstances of the particular matter and the general interests of the Company.

Delegation to Management for Certain Recoupment Decisions
The Committee hereby delegates to the Chief Executive Officer (who may further delegate as he deems appropriate) the authority to administer this policy and to make any and all decisions under it regarding Affected Employees who are not Section 16 Officers of the Company. Section 16 Officers are employees of the Company who are subject to Section 16 of the Securities Exchange Act of 1934. Management shall report to the Committee on any affirmative decisions to seek Recoupment pursuant to this delegation.

Disclosure of Recoupment Decisions
The Company will comply with all applicable securities laws and regulations, including Securities and Exchange Commission disclosure requirements regarding executive compensation. The Company may also, but is not obligated to, provide additional disclosure beyond that required by law when the Company deems it to be appropriate and determines that such disclosure is in the best interest of the Company and its shareholders.

Miscellaneous
Nothing in this policy shall limit or otherwise affect any of the following: 1) management's ability to take any disciplinary action with respect to any Affected Employee; 2) the Committee's ability to use its negative discretion with respect to any incentive compensation performance target at any time; or 3) the Committee's or management's ability to reduce the amount (in whole or in part) of a current or future bonus or other cash or non-cash incentive compensation award to any executive or other employee for any reason as they may deem appropriate and to the extent permitted by law. Nothing in this policy shall replace or otherwise limit or affect the Clawback Policy for EIP Awards Upon Significant Restatement of Financial Results and/or the Clawback Policy for PSUs upon Significant Restatement of Financial Results.

Exhibit 21

MERCK & CO., INC. SUBSIDIARIES

as of 12/31/2020

The following is a list of subsidiaries of the Company, doing business under the name stated.

Name	Country or State of Incorporation
7728026 Canada Inc.	Canada
Abmaxis Inc.	Delaware
Afferent Pharmaceuticals, Inc.	Delaware
Agrident GmbH	Germany
Agro Verhen B.V.	Netherlands
Aleis Pty Ltd	Australia
Allflex Argentina S.A.	Argentina
Allflex Australia Pty. Ltd.	Australia
Allflex Avrasya Hayvan Kimlik Sistemleri Sanayi Ve Ticaret Limited Sirketi	Turkey
Allflex dan-mark ApS	Denmark
Allflex Europe S.A.S.	France
Allflex Group Germany GmbH	Germany
Allflex India Private Limited	India
Allflex International do Brasil Ltda	Brazil
Allflex Maroc S.A.R.L.	Morocco
Allflex New Zealand Limited	New Zealand
Allflex Polska Spolka z ograniczona odpowiedzialnoscia	Poland
Allflex SCR Vostok	Belarus
Allflex Services S.A.R.L.	France
Allflex UK Group Limited	United Kingdom
Allflex USA, Inc.	Delaware
Alta Plastic Muhendislik Sanayi Ve Ticaret Limited Sirketi	Turkey
Animal ID Australia Pty Ltd	Australia
Antelliq Corporation	Delaware
Antelliq Finance, Inc.	Delaware
Antelliq Holdings France S.A.S	France
Antelliq Holdings, Inc.	Delaware
Antelliq Management, Inc.	Delaware

Beijing Allflex Plastic Products Co. Ltd	China
Beijing Protection Science and Technology Co., Ltd.	People's Republic of China
Biomark, Inc.	Idaho
BRC Ltd.	Bermuda
Burgwedel Biotech GmbH	Germany
Calporta Therapeutics, Inc.	Delaware
Cambridge Resonant Technologies Ltd	United Kingdom
Canji, Inc.	Delaware
cCam Biotherapeutics Ltd.	Israel
Cherokee Pharmaceuticals LLC	Delaware
Chevillot S.A.S.	France
Continuum Professional Services Limited	United Kingdom
Controladora MSD Mexicana Sociedad de Responsabilidad Limitada de Capital Variable	Mexico
Cooper Veterinary Products (Proprietary) Limited	South Africa
Corporation Allflex, Inc.	Canada
Cosmas B.V.	Netherlands
Cubist (UK) Ltd	United Kingdom
Cubist Pharmaceuticals (UK) Ltd.	United Kingdom
Cubist Pharmaceuticals LLC	Delaware
Dashtag	United Kingdom
Desarrollos Farmaceuticos Y Cosmeticos, S.A.	Spain
Destron Fearing Corporation	Delaware
Dialstat Trading 91 Pty Ltd T/A Allflex SA	South Africa
Dieckmann Arzneimittel GmbH	Germany
Digital Angel S.A.	Digital Angel S.A.
Diosynth France S.A.S.	France
Diosynth Holding B.V.	Netherlands
Diosynth Produtos Farmo-quimicos Ltda.	Brazil
Drovers ID Pty Ltd	Australia
DSD Holding A/S	Denmark
Elastec S.R.L	Argentina
Essex Pharmaceuticals, Inc.	Philippines

Essexfarm, S.A.	Ecuador
Farmacox - Companhia Farmaceutica, Lda	Portugal
Farmasix-Produtos Farmaceuticos, Lda	Portugal
Financiere MSD	France
Fontelabor-Produtos Farmaceuticos, Lda.	Portugal

Frosst Laboratories, Inc.	Delaware
Frosst Portuguesa - Produtos Farmaceuticos, Lda.	Portugal
Fulford (India) Limited[1]	India
GlycoFi, Inc.	Delaware
GT Acquisition Sub, Inc.	Minnesota
GTS FI B.V.	Netherlands
Hangzhou MSD Pharmaceutical Co., Ltd.[1]	China
Harrisvaccines, Inc.	Iowa
Hawk and Falcon L.L.C.	Delaware
Healthcare Services and Solutions, LLC	Delaware
Heptafarma Companhia Farmaceutica, Lda	Portugal
Hydrochemie GmbH	Germany
Idenix GmbH	Switzerland
Idenix SARL	France
IdentiGEN Canada Ltd.	Canada
IdentiGEN Czech s.r.o.	Czech Republic
IdentiGEN Deutschland GmbH	Germany
IdentiGEN Limited	Ireland
IdentiGEN North America Inc.	Delaware
IdentiGEN Switzerland AG	Switzerland
Immune Design B.V.	Netherlands
Immune Design Corp.	Delaware
Insight Acquisition Holdings Limited	Ireland
International Indemnity Ltd.	Bermuda
Intervet (Ireland) Limited	Ireland
Intervet (Israel) Ltd.	Israel
Intervet (M) Sdn. Bhd.	Malaysia
Intervet (Proprietary) Limited	South Africa
Intervet (Thailand) Ltd.	Thailand
Intervet AB	Sweden
Intervet Agencies B.V.	Netherlands
Intervet Animal Health Taiwan Limited	Republic of China

Intervet Argentina S.A.	Argentina
Intervet Australia Pty Limited	Australia
Intervet Canada Corp.	Canada
Intervet Central America S. de R.L.	Panama
Intervet Deutschland GmbH	Germany
Intervet Ecuador S.A.	Ecuador

Intervet Egypt for Animal Health SAE	Egypt
Intervet GesmbH	Austria
Intervet Hellas A.E.	Greece
Intervet Holding B.V.	Netherlands
Intervet Holdings France SAS	France
Intervet Hungaria Értékesítő Kft	Hungary
Intervet Inc.	Delaware
Intervet India Pvt Limited	India
Intervet International B.V.	Netherlands
Intervet International GmbH	Germany
Intervet International Sarl	France
Intervet LLC	Russian Federation
Intervet Maroc S.A.	Morocco
Intervet Mexico S.A. de C.V.	Mexico
Intervet Middle East Limited	Cyprus
Intervet Nederland B.V.	Netherlands
Intervet Philippines, Inc.	Philippines
Intervet Productions S.A.	France
Intervet Productions S.r.l.	Italy
Intervet Romania SRL	Romania
Intervet S.A.	Peru
Intervet SAS	France
Intervet Schering-Plough Animal Health Pty. Ltd.	Australia
Intervet South Africa (Proprietary) Limited	South Africa
Intervet Sp. z.o.o.	Poland
Intervet UK Production Limited	United Kingdom
Intervet Venezolana S.A.	Venezuela
Intervet Veterinaria Chile Ltda	Chile
Intervet Veteriner Ilaclari Pazarlama ve Ticaret Ltd. Sirketi	Turkey
Intervet, s.r.o.	Czech Republic
Interveterinaria SA de CV	Mexico
IOmet Pharma Limited	United Kingdom

Laboratoires Merck Sharp & Dohme-Chibret	France
Laboratorios Abello, S.A.	Spain
Laboratorios Chibret, S.A.	Spain
Laboratorios Frosst, S.A.	Spain
Laboratorios Quimico-Farmaceuticos Chibret, Lda	Portugal
Lemifar S. A.	Uruguay

Maple Leaf Holdings GmbH	Switzerland
Maya Tibbi Urunler Ticaret Limited Sirketi	Turkey
MCM Vaccine B.V.[1]	Netherlands
Med-Nim (Proprietary) Limited	South Africa
Merck and Company, Incorporated	Delaware
Merck Canada Inc.	Canada
Merck Capital Ventures, LLC[1]	Delaware
Merck Frosst Canada & Co.	Canada
Merck Frosst Company	Canada
Merck Global Health Innovation Fund, LLC	Delaware
Merck Global Health Innovation, Private Equity, LLC	Delaware
Merck HDAC Research, LLC	Delaware
Merck Holdings II Corp.	Delaware
Merck Holdings III Corp.	Delaware
Merck Holdings IV Corp.	Delaware
Merck Holdings LLC	Delaware
Merck International Holdings Corp.	Delaware
Merck Lumira Biosciences Fund L.P.[1]	Canada
Merck Registry Holdings, Inc.	New Jersey
Merck Research Investments LLC	Delaware
Merck Research Laboratories Massachusetts, LLC	Delaware
Merck Sharp & Dohme (Argentina) LLC	Delaware
Merck Sharp & Dohme (Asia) Limited	Hong Kong
Merck Sharp & Dohme (Australia) Pty. Limited	Australia
Merck Sharp & Dohme (Chile) Ltda.	Chile
Merck Sharp & Dohme (China) Limited	Hong Kong
Merck Sharp & Dohme (Enterprises) B.V.	Netherlands
Merck Sharp & Dohme (Europe) Inc.	Delaware
Merck Sharp & Dohme (Holdings) Pty Ltd	Australia
Merck Sharp & Dohme (I.A.) LLC	Delaware
Merck Sharp & Dohme (International) Limited	Bermuda
Merck Sharp & Dohme (Israel - 1996) Company Ltd.	Israel

Merck Sharp & Dohme (Malaysia) SDN. BHD.	Malaysia
Merck Sharp & Dohme (New Zealand) Limited	New Zealand
Merck Sharp & Dohme (Sweden) A.B.	Sweden
Merck Sharp & Dohme (Switzerland) GmbH	Switzerland
Merck Sharp & Dohme (UK) Limited	United Kingdom
Merck Sharp & Dohme Animal Health, S.L.	Spain

Merck Sharp & Dohme Asia Pacific Services Pte. Ltd.	Singapore
Merck Sharp & Dohme B.V.	Netherlands
Merck Sharp & Dohme BH d.o.o.	Bosnia
Merck Sharp & Dohme Bulgaria EOOD	Bulgaria
Merck Sharp & Dohme Colombia S.A.S.	Colombia
Merck Sharp & Dohme Comercializadora, S. de R.L. de C.V.	Mexico
Merck Sharp & Dohme Corp.	New Jersey
Merck Sharp & Dohme Cyprus Limited	Cyprus
Merck Sharp & Dohme d.o.o.	Croatia
Merck Sharp & Dohme d.o.o. Belgrade	Serbia
Merck Sharp & Dohme de Espana SAU	Spain
Merck Sharp & Dohme Farmaceutica Ltda.	Brazil
Merck Sharp & Dohme Finance Europe Limited	United Kingdom
Merck Sharp & Dohme Gesellschaft m.b.H.	Austria
Merck Sharp & Dohme IDEA GmbH	Switzerland
Merck Sharp & Dohme inovativna zdravila d.o.o.	Slovenia
Merck Sharp & Dohme International Services B.V.	Netherlands
Merck Sharp & Dohme Latvija	Latvia
Merck Sharp & Dohme Limitada	Bolivia
Merck Sharp & Dohme LLC	New Jersey
Merck Sharp & Dohme Manufacturing Unlimited Company	Ireland
Merck Sharp & Dohme OU	Estonia
Merck Sharp & Dohme Peru SRL	Peru
Merck Sharp & Dohme Pharmaceutical Industrial and Commercial Societe Anonyme	Greece
Merck Sharp & Dohme Research GmbH	Switzerland
Merck Sharp & Dohme Romania SRL	Romania
Merck Sharp & Dohme S.A.	Morocco
Merck Sharp & Dohme s.r.o.	Czech Republic
Merck Sharp & Dohme Salud Animal Columbia S.A.S.	Colombia
Merck Sharp & Dohme Saude Animal Ltda.	Brazil
Merck Sharp & Dohme Singapore Trading Pte. Ltd.	Singapore
Merck Sharp & Dohme Tunisie SARL	Tunisia

Merck Sharp & Dohme, Limitada	Portugal
Merck Sharp & Dohme, S. de R.L. de C.V.	Mexico
Merck Sharp & Dohme, s.r.o.	Slovakia
Merck Sharp Dohme Ilaclari Limited Sirketi	Turkey
Merck Teknika LLC	Delaware
Merko Acquisition S.A.	Belgium

Merko B.V.	Netherlands
Merko Dalton B.V.	Netherlands
Merko N.V.	Belgium
ML Holdings (Canada) Inc.	Canada
MRL San Francisco, LLC	Delaware
MRL Ventures Fund LLC	Delaware
MSD (I.A.) B.V.	Netherlands
MSD (L-SP) Unterstützungskasse GmbH	Germany
MSD (Ningbo) Animal Health Technology Co., Ltd.	China
MSD (Nippon Holdings) B.V.	Netherlands
MSD (Norge) AS	Norway
MSD (Proprietary) Limited	South Africa
MSD (Shanghai) Pharmaceuticals Consultancy Co., Ltd.	China
MSD (Thailand) Ltd.	Thailand
MSD AH Limited	United Kingdom
MSD Animal Health (Phils.), Inc	Philippines
MSD Animal Health (Shanghai) Trading Co., Ltd.	China
MSD Animal Health A/S	Denmark
MSD Animal Health B.V.	Belgium
MSD Animal Health Danube Biotech GmbH	Austria
MSD Animal Health FZ-LLC	United Arab Emirates
MSD Animal Health GmbH	Switzerland
MSD Animal Health Innovation AS	Norway
MSD Animal Health Innovation GmbH	Germany
MSD Animal Health Innovation Pte. Ltd.	Singapore
MSD Animal Health Innovation SAS	France
MSD Animal Health K.K.	Japan
MSD Animal Health Korea Ltd.	Korea, Republic of
MSD Animal Health Norge AS	Norway
MSD Animal Health Oy	Finland
MSD Animal Health Pension Trustee Limited	United Kingdom
MSD Animal Health S.r.l.	Italy

MSD Animal Health UK Ltd.	United Kingdom
MSD Animal Health Vietnam Co. Limited	Viet Nam
MSD Animal Health, Lda.	Portugal
MSD Argentina Holdings B.V.	Netherlands
MSD Argentina SRL	Argentina
MSD Asia Holdings Pte. Ltd.	Singapore

MSD Belgium BV - SRL	Belgium
MSD Biotech B.V.	Netherlands
MSD Brazil Investments B.V.	Netherlands
MSD Central America Services S. de R.L.	Panama
MSD China (Investments) B.V.	Netherlands
MSD China B.V.	Netherlands
MSD China Holding Co., Ltd.	China
MSD Cubist Holdings Unlimited Company	Ireland
MSD Czech Republic s.r.o.	Czech Republic
MSD Danmark ApS	Denmark
MSD Egypt LLC	Egypt
MSD EIC Unlimited Company	Ireland
MSD Eurofinance	Bermuda
MSD Farmaceutica C.A.	Venezuela
MSD FI BV	Netherlands
MSD Finance 2 LLC	Delaware
MSD Finance B.V.	Netherlands
MSD Finance Company	Bermuda
MSD Finance Holdings Unlimited Company	Ireland
MSD Finland Oy	Finland
MSD France	France
MSD Global Research GmbH	Switzerland
MSD HH Vietnam Ltd	Vietnam
MSD Holdings (Ireland) Unlimited Company	Ireland
MSD Holdings 2 G.K.	Japan
MSD Holdings G.K.	Japan
MSD Human Health Holding B.V.	Netherlands
MSD Human Health Holding II B.V.	Netherlands
MSD IDEA Pharmaceuticals Nigeria Limited	Nigeria
MSD IDEA Tunisie SARL	Tunisia
MSD Idenix Holdings Unlimited Company	Ireland
MSD Innovation & Development GmbH	Switzerland

MSD International Business GmbH	Switzerland
MSD International Finance B.V.	Netherlands
MSD International Finance LLC	Delaware
MSD International GmbH	Switzerland
MSD International Holdings 2 B.V.	Netherlands
MSD International Investment Holdings Unlimited Company	Ireland

MSD International Manufacturing GmbH	Switzerland
MSD Investment Holdings (Ireland) Unlimited Company	Ireland
MSD Investments (Holdings) GmbH	Switzerland
MSD Italia s.r.l.	Italy
MSD Japan Holdings B.V.	Netherlands
MSD Japan Holdings GK	Japan
MSD K.K.	Japan
MSD Korea Co., Ltd.	Korea
MSD Laboratories India LLC	Delaware
MSD Latin America Services S. de R.L.	Panama
MSD Latin America Services S. de R.L. de C.V.	Mexico
MSD Limited	United Kingdom
MSD Luxembourg S.a.r.l.	Luxembourg
MSD Merck Sharp & Dohme AG	Switzerland
MSD NL 4 B.V.	Netherlands
MSD Overseas Manufacturing Co (Ireland) Unlimited Company	Ireland
MSD Panama International Services S. de R.L.	Panama
MSD Participations B.V.	Netherlands
MSD Pharma (Singapore) Pte. Ltd.	Singapore
MSD Pharma GmbH	Germany
MSD Pharma Hungary Korlatolt Felelossegu Tarsasag	Hungary
MSD Pharmaceuticals Holdings Unlimited Company	Ireland
MSD Pharmaceuticals Investments 1 Unlimited Company	Ireland
MSD Pharmaceuticals Investments 3 Unlimited Company	Ireland
MSD Pharmaceuticals Ireland Unlimited Company	Ireland
MSD Pharmaceuticals LLC	Russian Federation
MSD Pharmaceuticals Private Limited	India
MSD Polska Dystrybucja Sp. z.o.o.	Poland
MSD Polska Sp.z.o.o.	Poland
MSD R&D (China) Co., Ltd.	China
MSD R&D Innovation Centre Limited	United Kingdom
MSD RDC Costa Rica Sociedad de Responsabilidad Limitada	Cost Rica

MSD Regional Business Support Center GmbH	Germany
MSD Registry Holdings, Inc.	New Jersey
MSD Shared Business Services EMEA Limited	Ireland
MSD Sharp & Dohme Gesellschaft mit beschränkter Haftung	Germany
MSD Switzerland Investments 1 Unlimited Company	Ireland
MSD Switzerland Investments 4 Unlimited Company	Ireland

MSD Switzerland Investments 5 Unlimited Company	Ireland
MSD Ukraine Limited Liability Company	Ukraine
MSD Unterstutzungskasse GmbH	Germany
MSD Vaccines Limited	United Kingdom
MSD Vaccins	France
MSD Vaccins Holdings	France
MSD Venezuela Holding GmbH	Switzerland
MSD Ventures (Ireland) Unlimited Company	Ireland
MSD Verwaltungs GmbH	Germany
MSD Vietnam Company Limited	Vietnam
MSD Vietnam Holdings B.V.	Netherlands
MSD Vostok B.V.	Netherlands
MSDIG Holdings Limited	Ireland
MSDRG Holdings Unlimited Company	Switzerland
MSDRG LLC	Delaware
MSP Singapore - Sub, LLC	Delaware
MSP Singapore Company, LLC	Delaware
MSP Vaccine Company[1]	Pennsylvania
Multilan AG	Switzerland
N.V. Organon	Netherlands
Nihon MSD G.K.	Japan
Nourifarma - Produtos Quimicos e Farmaceuticos, Sociedade Unipessoal, Lda	Portugal
O.PI.VI S.R.L.	Italy
OBS Holdings B.V.	Netherlands
OBS Human Health Holding B.V.	Netherlands
OBS International 9 B.V.	Netherlands
OBS Mexico Holdings B.V.	Netherlands
Oncoethix GmbH	Switzerland
OncoImmune, Inc.	Delaware
Optimer Pharmaceuticals LLC	Delaware
Organon – Ecuador S.A.	Ecuador
Organon & Co.	Delaware

Organon (I.A.) B.V.	Bulgaria
Organon (India) Private Limited	India
Organon (Ireland) Ltd	Ireland
Organon (Philippines) Incorporated	Philippines
Organon (Shanghai) Pharmaceutical Technology Co., Ltd.	Peoples Republic of China
Organon (Thailand) Ltd.	Thailand

Organon Agencies B.V.	Netherlands
Organon Argentina Holdings B.V.	Argentina
Organon Argentina S.R.L.	Argentina
Organon Asia Holdings B.V.	Netherlands
Organon Asia Pacific Services Pte. Ltd.	Singapore
Organon Austria GmbH	Austria
Organon Belgium BV	Belgium
Organon BH d.o.o.	Bosnia and Herzegovina
Organon BioSciences International B.V.	Netherlands
Organon BioSciences Peru S.R.L.	Peru
Organon BioSciences S.R.L.	Romania
Organon BioSciences Ventures B.V.	Netherlands
Organon Canada Holdings BV	Netherlands
Organon Canada Holdings LLC	Delaware
Organon Canada Inc.	Canada
Organon Central East GmbH	Switzerland
Organon Chile SPA	Chile
Organon China B.V.	Netherlands
Organon Colombia S.A.S.	Colombia
Organon Comercializadora, S. de R.L. de C.V.	Mexico
Organon Czech Republic s.r.o.	Czech Republic
Organon Denmark ApS	Denmark
Organon Dominicana S.A.	Dominican Republic
Organon Egypt Ltd	Egypt
Organon Finance 1 LLC	Delaware
Organon Finance Inc.	Delaware
Organon Finland Oy	Finland
Organon France	France
Organon Global Inc.	Delaware
Organon GmbH	Switzerland
Organon Healthcare GmbH	Germany
Organon Holding I B.V.	Netherlands

Organon Holdings 9 B.V.	Netherlands
Organon Hong Kong Limited	Hong Kong
Organon International GmbH	Switzerland
Organon International Holdings 9 B.V.	Netherlands
Organon International Holdings B.V.	Netherlands
Organon International Services GmbH	Switzerland

Organon Ireland Holdings B.V.	Netherlands
Organon Italia S.r.l.	Italy
Organon Japan Holdings B.V.	Netherlands
Organon Japan Holdings G.K.	Japan
Organon K.K.	Japan
Organon Korea Co. Ltd.	Korea (the Republic of)
Organon KSA GmbH	Switzerland
Organon Laboratories Ltd	United Kingdom
Organon Latin America S.A.	Uruguay
Organon Latin America Services S. de R.L.	Panama
Organon Limited Liability Company	Russian Federation
Organon LLC	Delaware
Organon Malaysia Sdn. Bhd.	Malaysia
Organon Maroc S.A.R.L.	Morocco
Organon Middle East S.A.L.	Lebanon
Organon New Zealand Limited	New Zealand
Organon Norway AS	Norway
Organon Participations B.V.	Netherlands
Organon Pharma (Ireland) Limited	Ireland
Organon Pharma (UK) Limited	United Kingdom
Organon Pharma B.V.	Netherlands
Organon Pharma Costa Rica S.R.L.	Costa Rica
Organon Pharma d.o.o.	Croatia
Organon Pharma d.o.o. Beograde	Serbia
Organon Pharma FZ-LLC	United Arab Emirates
Organon Pharma Holdings LLC	Delaware
Organon Pharma Israel Ltd.	Israel
Organon Pharma Pty Ltd	Australia
Organon Pharma S. de R.L.	Panama
Organon Pharmaceutical Egypt LLC	Egypt
Organon Polska Sp. zo.o.	Poland
Organon Portugal Sociedade Unipessoal Lda	Portugal

Organon Puerto Rico LLC	Puerto Rico
Organon Salud, S.L.	Spain
Organon Singapore Pte. Ltd.	Singapore
Organon Slovakia s.r.o.	Slovakia
Organon South Africa (Pty) Ltd	South Africa
Organon Sweden AB	Sweden

Organon Trade LLC	Delaware
Organon Turkey Ilaclari Limited Sirketi	Turkey
Organon Ukraine Limited Liability Company	Ukraine
Organon USA LLC	New Jersey
OS ID AS	Norway
OS ID Hellas M.I.K.E	Greece
P.T. Merck Sharp & Dohme Indonesia	Indonesia
Parlanca Limited	Ireland
Peloton Therapeutics, Inc.	Delaware
Pentair Iceland Holdings ehf.	Iceland
Pentair Chile SpA	Chile
Peocon ehf.	Iceland
Pixobot, Inc.	Delaware
Polnet ID Spolka z ograniczona odpowiedzialnoscia	Poland
Productos Famaceuticos Organon, S. de R.L. de C.V.	Mexico
Prondil Sociedad Anónima	Uruguay
PT Intervet Indonesia	Indonesia
PT Merck Sharp Dohme Pharma Tbk [1]	Indonesia
Putexin Investments Limited	New Zealand
Rigontec GmbH	Germany
Rigontec, Inc.	Delaware
Rosetta Biosoftware UK Limited	United Kingdom
Rosetta Inpharmatics LLC	Delaware
S.C. Allflex Romania S.R.L.	Romania
S.C.R. (Engineers) Limited	Israel
Schering-Plough	France
Schering-Plough (India) Private Limited	India
Schering-Plough (Ireland) Unlimited Company	Ireland
Schering-Plough Animal Health Limited	New Zealand
Schering-Plough Bermuda Ltd.	Bermuda
Schering-Plough Canada Inc.	Canada
Schering-Plough Corporation	Philippines

Schering-Plough Corporation, U.S.A.	Delaware
Schering-Plough del Peru S.A.	Peru
Schering-Plough Holdings Limited	United Kingdom
Schering-Plough Indústria Farmacêutica Ltda.	Brazil
Schering-Plough Labo NV	Belgium
Schering-Plough Limited	United Kingdom

Schering-Plough S.A.	Panama
Schering-Plough S.A.	Paraguay
Schering-Plough S.A.	Spain
Schering-Plough S.A.	Uruguay
Schering-Plough S.A. de C.V.	Mexico
Schering-Plough Sante Animale	France
SCR Allflex Management, Ltd	Israel
SCR Dairy, Inc.	Delaware
SCR Europe S.R.L.	Italy
SCR Monitoring Mexico, S. de R.L. de C.V.	Mexico
Sentipharm AG	Switzerland
Servicios Organon S. de R.L. de C.V.	Brazil
Servicios Veterniarios Servet, Sociedad Anónima	Costa Rica
Shanghai MSD Pharmaceutical Trading Co., Ltd.	China
Sistemas de Identificacao Animal Ltda	Brazil
SmartCells, Inc.	Delaware
SOL Limited	Bermuda
S-P Ril Ltd.	United Kingdom
S-P Veterinary Holdings Limited	United Kingdom
S-P Veterinary Limited	United Kingdom
Stallmastaren AB	Sweden
SureFlap (NZ) Limited	New Zealand
SureFlap Limited	United Kingdom
SureFlap LLC	Florida
Tag ID Investments, Inc.	Delaware
Theriak B.V.	Netherlands]
Tilos Therapeutics, Inc.	Delaware
Trius Therapeutics LLC	Delaware
UAB Merck Sharp & Dohme	Lithuania
Undra, S.A. de C.V.	Mexico
Vaki A/S	Norway
Vaki Aquaculture Systems ehf.	Iceland

Vaki Chile Limitada	Chile
Vaki Scotland Ltd	United Kingdom
Vallée S.A.[1]	Brazil
VelosBio Inc.	Delaware
Venco Farmaceutica S.A.	Venezuela
Venco Holding GmbH	Switzerland

Vet Pharma Friesoythe GmbH	Germany
Veterinaria Premium, Sociedad Anonima	Guatemala
VetInvent, LLC	Delaware
Vetrex B.V.	Netherlands
Vetrex Egypt L.L.C.	Egypt
Vilsan Veteriner Ilaclari Ticaret ve Sanayi Anonim Sirketi	Turkey
Viralytics Limited	Australia
Vocaltag Ltd.	Israel
Vree Health Italia S.r.l.	Italy
Vree Health Ltd.	United Kingdom
Werthenstein Biopharma GmbH	Switzerland
Zoöpharm B.V.	Netherlands

[1] own less than 100%

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-224016 and 333-224017) and on Form S-8 (Nos. 333-173025, 333-173024, 333-162883, 333-162884, 333-162885, 333-162886, 333-121089, and 333-233226) of Merck & Co., Inc. of our report dated February 25, 2021 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 25, 2021

Exhibit 24.1

POWER OF ATTORNEY

Each of the undersigned does hereby appoint JENNIFER ZACHARY as his/her true and lawful attorney to execute on behalf of the undersigned (whether on behalf of the Company, or as an officer or director thereof, or by attesting the seal of the Company, or otherwise) the Annual Report on Form 10-K of Merck & Co., Inc. for the fiscal year ended December 31, 2020 under the Securities Exchange Act of 1934, including amendments thereto and all exhibits and other documents in connection therewith.

IN WITNESS WHEREOF, this instrument has been duly executed as of the 25th day of February 2021.

MERCK & CO., Inc.

/s/ Kenneth C. Frazier Kenneth C. Frazier	Chairman, President and Chief Executive Officer (Principal Executive Officer; Director)
/s/ Robert M. Davis Robert M. Davis	Executive Vice President, Global Services, and Chief Financial Officer (Principal Financial Officer)
/s/ Rita A. Karachun Rita A. Karachun	Senior Vice President Finance—Global Controller (Principal Accounting Officer)

DIRECTORS

/s/ Leslie A. Brun Leslie A. Brun	/s/ Paul B. Rothman Paul B. Rothman
/s/ Thomas R. Cech Thomas R. Cech	/s/ Patricia F. Russo Patricia F. Russo
/s/ Mary Ellen Coe Mary Ellen Coe	/s/ Christine E. Seidman Christine E. Seidman
/s/ Pamela J. Craig Pamela J. Craig	/s/ Inge G. Thulin Inge G. Thulin
/s/ Thomas H. Glocer Thomas H. Glocer	/s/ Kathy J. Warden Kathy J. Warden
/s/ Risa J. Lavizzo-Mourey Risa J. Lavizzo-Mourey	/s/ Peter C. Wendell Peter C. Wendell

Exhibit 24.2

I, Kelly Grez, Deputy Corporate Secretary of Merck & Co., Inc. (the "Company"), a corporation duly organized and existing under the laws of the State of New Jersey, do hereby certify that the following is a true copy of a resolution adopted by unanimous written consent of the Board of Directors of the Company on February 25, 2021 in accordance with the provisions of the By-Laws of the Company:

"Special Resolution No. 13 – 2021

RESOLVED, that the proposed form of the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2020, attached hereto, is hereby approved with such changes as the proper officers of the Company, with the advice of counsel, deem appropriate;

FURTHER RESOLVED, that each officer and director who may be required to execute the aforesaid Annual Report on Form 10-K or any amendments thereto (whether on behalf of the Company or as an officer or director thereof, or by attesting the seal of the Company, or otherwise) is hereby authorized to execute a power of attorney appointing Jennifer Zachary as his/her true and lawful attorney to execute in his/her name, place and stead (in any such capacity) such Annual Report on Form 10-K and any and all amendments thereto and any and all exhibits and other documents necessary or incidental in connection therewith and to file the same with the Securities and Exchange Commission, the attorney to have power to act and to have full power and authority to do and perform in the name and on behalf of each of said officers and directors, or both, as the case may be, every act whatsoever necessary or advisable to be done in the premises as fully and to all intents and purposes as any such officer or director might or could do in person; and

FURTHER RESOLVED that an executed copy of the Action by Unanimous Written Consent be filed with the minutes of the meetings of the Board of Directors of the Company."

IN WITNESS WHEREOF, I have hereunto subscribed my signature and affixed the seal of the Company this 25th day of February 2021.

[Corporate Seal]

/s/ Kelly Grez

Kelly Grez
Deputy Corporate Secretary

Exhibit 31.1

CERTIFICATION

I, Kenneth C. Frazier, certify that:

1. I have reviewed this annual report on Form 10-K of Merck & Co., Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

By: /s/ Kenneth C. Frazier
KENNETH C. FRAZIER
Chairman, President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Robert M. Davis, certify that:

1. I have reviewed this annual report on Form 10-K of Merck & Co., Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

By: /s/ Robert M. Davis

ROBERT M. DAVIS
Executive Vice President, Global Services,
and Chief Financial Officer

Exhibit 32.1

Section 1350
Certification of Chief Executive Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Annual Report on Form 10-K for the year ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 25, 2021

/s/ Kenneth C. Frazier

Name: KENNETH C. FRAZIER

Title: Chairman, President and Chief Executive Officer

Exhibit 32.2

Section 1350
Certification of Chief Financial Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 25, 2021

/s/ Robert M. Davis

Name: ROBERT M. DAVIS

Title: Executive Vice President, Global Services, and Chief Financial Officer