
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 2
to
Form 10

GENERAL FORM FOR REGISTRATION OF SECURITIES
Pursuant to Section 12(b) or (g) of
the Securities Exchange Act of 1934

Organon & Co.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

30 Hudson Street, Floor 33, Jersey City, NJ
(Address of principal executive offices)

85-2269702
(I.R.S. employer
Identification number)

07302
(Zip Code)

(551) 430-6900

(Registrant's telephone number, including area code)

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

Title of Each Class
to be so Registered

Name of Each Exchange on which
Each Class is to be Registered

Common Stock, par value \$0.01 per share

NYSE

Securities to be registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

Large accelerated filer

Non-accelerated filer

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.

Organon & Co.

**INFORMATION REQUIRED IN REGISTRATION STATEMENT
CROSS-REFERENCE SHEET BETWEEN INFORMATION STATEMENT
AND ITEMS OF FORM 10**

Certain information required to be included herein is incorporated by reference to specifically identified portions of the body of the information statement filed herewith as Exhibit 99.1. None of the information contained in the information statement shall be incorporated by reference herein or deemed to be a part hereof unless such information is specifically incorporated by reference.

Item 1. Business.

The information required by this item is contained under the sections of the information statement entitled “Information Statement Summary,” “Risk Factors,” “Unaudited Pro Forma Financial Information,” “Selected Historical Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Business,” “Certain Relationships and Related Party Transactions,” “Where You Can Find More Information,” and “Index to Financial Statements” and the financial statements referenced therein. Those sections are incorporated herein by reference.

Item 1A. Risk Factors.

The information required by this item is contained under the section of the information statement entitled “Risk Factors.” That section is incorporated herein by reference.

Item 2. Financial Information.

The information required by this item is contained under the sections of the information statement entitled “Unaudited Pro Forma Financial Information,” “Selected Historical Financial Data,” “Capitalization,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Those sections are incorporated herein by reference.

Item 3. Properties.

The information required by this item is contained under the section of the information statement entitled “Business—Properties” and “Business—Manufacturing Capabilities and Global Supply Chain—Internal Manufacturing Capabilities.” That section is incorporated herein by reference.

Item 4. Security Ownership of Certain Beneficial Owners and Management.

The information required by this item is contained under the section of the information statement entitled “Security Ownership of Certain Beneficial Owners and Management.” That section is incorporated herein by reference.

Item 5. Directors and Executive Officers.

The information required by this item is contained under the section of the information statement entitled “Management.” That section is incorporated herein by reference.

Item 6. Executive Compensation.

The information required by this item is contained under the section of the information statement entitled “Executive Compensation.” That section is incorporated herein by reference.

Item 7. *Certain Relationships and Related Transactions.*

The information required by this item is contained under the sections of the information statement entitled “Management” and “Certain Relationships and Related Party Transactions.” Those sections are incorporated herein by reference.

Item 8. *Legal Proceedings.*

The information required by this item is contained under the section of the information statement entitled “Business—Legal Proceedings.” That section is incorporated herein by reference.

Item 9. *Market Price of, and Dividends on, the Registrant’s Common Equity and Related Stockholder Matters.*

The information required by this item is contained under the sections of the information statement entitled “Dividend Policy,” “Capitalization,” “The Separation and Distribution,” and “Description of Capital Stock.” Those sections are incorporated herein by reference.

Item 10. *Recent Sales of Unregistered Securities.*

The information required by this item is contained under the sections of the information statement entitled “Description of Certain Indebtedness.” Those sections are incorporated herein by reference.

Item 11. *Description of Registrant’s Securities to be Registered.*

The information required by this item is contained under the sections of the information statement entitled “Dividend Policy,” “The Separation and Distribution,” and “Description of Capital Stock.” Those sections are incorporated herein by reference.

Item 12. *Indemnification of Directors and Officers.*

The information required by this item is contained under the section of the information statement entitled “Description of Capital Stock—Limitations on Liability of Directors and Indemnification of Officers and Directors.” That section is incorporated herein by reference.

Item 13. *Financial Statements and Supplementary Data.*

The information required by this item is contained under the section of the information statement entitled “Index to Financial Statements” and the financial statements referenced therein. That section is incorporated herein by reference.

Item 14. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.*

None.

Item 15. *Financial Statements and Exhibits.*

(a) Financial Statements

The information required by this item is contained under the section of the information statement entitled “Index to Financial Statements” and the financial statements referenced therein. That section is incorporated herein by reference.

(b) Exhibits

The following documents are filed as exhibits hereto:

<u>Exhibit Number</u>	<u>Exhibit Description</u>
2.1*	Form of Separation and Distribution Agreement by and between Merck & Co., Inc. and Organon & Co.
3.1*	Form of Amended and Restated Certificate of Incorporation of Organon & Co.
3.2*	Form of Amended and Restated Bylaws of Organon & Co.
10.1*	Form of Tax Matters Agreement by and between Merck & Co., Inc. and Organon & Co.
10.2	Form of Employee Matters Agreement by and between Merck & Co., Inc. and Organon & Co.
10.3*	Form of Transition Services Agreement by and between Merck & Co., Inc. and Organon & Co.
10.4*	Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated February 18, 2013+
10.5*	Amendment No. 1 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated July 21, 2014+
10.6*	Amendment No. 2 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated August 2, 2017+
10.7*	Amendment No. 3 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated October 1, 2017
10.8*	Amendment No. 4 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated September 1, 2018
10.9*	Amendment No. 5 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated October 15, 2018
10.10*	Amendment No. 6 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated December 19, 2018+
10.11*	Amendment No. 7 to Development and Commercialization Agreement by and between Samsung Bioepis Co., Ltd., and Merck Sharp & Dohme Corp., dated May 15, 2020+
10.12*	Specified Technology License Agreement (Nexplanon Rod Technology) by and between Merck Sharp & Dohme B.V. and Merck Sharp & Dohme RT B.V., dated October 28, 2020 +
10.13	Form of Organon & Co. 2021 Incentive Stock Plan**
10.14*	Form of Indemnification Agreement
10.15	Letter Agreement between Kevin Ali and Merck & Co., Inc. dated October 14, 2020**
10.16	Letter Agreement between Matthew M. Walsh and Merck Sharp & Dohme Corp. dated March 24, 2020**
21.1*	Subsidiaries of the Registrant
99.1	Information Statement of Organon & Co., preliminary and subject to completion.

* Previously filed.

** Executive Compensation Plan or Agreement.

+ Certain confidential information contained in this document, marked by [***], has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 2 to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: April 29, 2021

By: /s/ Jennifer Zachary
Name: Jennifer Zachary
Title: Vice President

EMPLOYEE MATTERS AGREEMENT

BY AND BETWEEN

MERCK & CO., INC.

AND

ORGANON & CO.

DATED AS OF JUNE 2, 2021

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This EMPLOYEE MATTERS AGREEMENT dated as of June 2, 2021, is by and between Merck & Co., Inc., a New Jersey corporation (“Merck”) and Organon & Co., a Delaware corporation (“Organon”) (each a “Party” and together, the “Parties”).

RECITALS:

WHEREAS, the board of directors of Merck has determined that it is appropriate and advisable to separate the Organon Business from the Merck Business (the “Spin-Off”);

WHEREAS, to achieve the foregoing, the Parties have executed a Separation and Distribution Agreement (the “Separation and Distribution Agreement”), which provides for, among other things, distribution, on a pro rata basis, to holders of the outstanding Merck Common Shares on the Record Date of all of the outstanding shares of Organon Common Stock, and the execution and delivery of this Agreement and certain other agreements to facilitate and provide for the foregoing, in each case subject to the terms and conditions set forth therein;

WHEREAS, the Employees of the Organon Business are currently or were previously employed by the Merck Group and are expected to or have previously become Employees of the Organon Group in connection with the Spin-Off; and

WHEREAS, this Agreement describes the principal employment, compensation and employee benefit plan arrangements between the Parties in connection with the Spin-Off.

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained in this Agreement, the Parties hereby agree as follows:

AGREEMENT

ARTICLE I

DEFINITIONS

Section 1.01 Defined Terms. Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Separation and Distribution Agreement. The following capitalized terms as used in this Agreement shall have the meaning set forth below unless otherwise specified herein:

“Adjusted Merck Award” means a Merck Option, Merck PSU Award, or Merck RSU Award, as adjusted in accordance with Section 6.01(a).

“Adjusted Merck Phantom Share” means a Merck Phantom Share, as adjusted in accordance with Section 3.04(c).

“Adjusted Organon Stock Value” means the product obtained by multiplying (i) the Organon Price by (ii) the Distribution Ratio.

“Affiliate” means any corporation, partnership, limited liability company, or entity directly or indirectly controlled by the entity in question.

“Agreement” means this Employee Matters Agreement and each of the Schedules hereto.

“Applicable Closing Date” has the meaning set forth in Section 4.01(a).

“Benefit Plan” means any (i) “employee benefit plan,” as defined in ERISA Section 3(3) (whether or not such plan is subject to ERISA); and (ii) employment, compensation, severance, salary continuation, bonus, thirteenth month, incentive, retirement, thrift, superannuation, savings, pension, workers’ compensation, termination benefit (including termination notice requirements), termination indemnity, other indemnification, supplemental unemployment benefit, redundancy pay, profit sharing, deferred compensation, stock ownership, stock purchase, stock option, stock appreciation right, restricted stock, “phantom” stock, performance share unit, restricted stock unit, other stock-based incentive, change in control, paid time off, perquisite, fringe benefit, vacation, disability, life, or other insurance, death benefit, hospitalization, medical, or other compensatory or benefit plan, program, fund, agreement, arrangement, or policy of any kind (whether written or oral, qualified or nonqualified, funded or unfunded, foreign or domestic, currently effective or terminated), and any trust, escrow or similar agreement related thereto, whether or not funded, excluding any plan, program, fund, agreement, arrangement, or policy (other than for workers’ compensation Liabilities) that is mandated by and maintained solely pursuant to applicable Law.

“COBRA” means the U.S. Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

“Code” means the U.S. Internal Revenue Code of 1986, as amended.

“Core Benefits” means retirement, separation pay, paid time off, medical (excluding retiree medical), dental, vision, life, short-term and long-term disability plans or coverage.

“Core Benefit Plans” means Benefit Plans offering any of the Core Benefits.

“Core Merck Health and Welfare Plan” means a Health and Welfare Plan sponsored by, maintained by, or contributed to by the Merck Group offering any of the Core Benefits.

“Core Non-U.S. Organon Benefit Plan” means an Organon Benefit Plan established, maintained, or contributed to by the Organon Group that is primarily for the benefit of Employees or Former Employees who work primarily outside of the United States which offers any of the Core Benefits.

“Core Organon Health and Welfare Plans” means a Health and Welfare Plan sponsored by, maintained by, or contributed to by the Organon Group which offers any of the Core Benefits.

“Employee” means an employee of the Merck Group or the Organon Group, as applicable, including any employee absent from work on account of long-term disability or workers’ compensation leave (in each case, unless treated as a separated employee for employment purposes), vacation, jury duty, funeral leave, personal leave, sickness, short-term disability, military leave, family leave, pay continuation leave, or other approved leave of absence or for whom an obligation to recall, rehire or otherwise return to employment exists under a contractual obligation or Law.

“Employee Agreement” means any employment contract, whether written or unwritten, between a member of the Merck Group and an Employee or Former Employee, including any standard form employee agreement customarily signed by certain Employees of the Merck Group and any other form of employment agreement, employment letter or notice with respect to the terms of employment between a member of the Merck Group and an Employee or Former Employee signed or otherwise effective under applicable local Law. The term Employee Agreement also includes any cash retention agreement.

“Employee Recoupment Asset” means an employer’s right to repayment from an employee in respect of a tax equalization payment, sign-on bonus payment, relocation expense payment, tuition payment, reimbursement, loan, or other similar item, including any agreement related thereto.

“Employment Tax” means withholding, payroll, social security, workers compensation, unemployment, disability and any similar tax imposed by any Tax Authority, and any interest, penalties, additions to tax or additional amounts with respect to the foregoing imposed on any taxpayer or consolidated, combined or unitary group of taxpayers.

“ERISA” means the U.S. Employee Retirement Income Security Act of 1974, as amended.

“Former Employee” means any individual whose employment with the Merck Group terminated on or prior to the Distribution Date, excluding any employee absent from work immediately prior to the Distribution Date on account of long-term disability or workers’ compensation leave (in each case, to the extent not treated as a separated employee for employment purposes), vacation, jury duty, funeral leave, personal leave, sickness, short-term disability, military leave, family leave, pay continuation leave, or other approved leave of absence or for whom an obligation to recall, rehire or otherwise return to employment exists under a contractual obligation or Law.

“Health and Welfare Plan” means any Benefit Plan established or maintained to provide, through the purchase of insurance or otherwise, medical, dental, prescription, vision, short-term disability, long-term disability, death benefits, life insurance, accidental death and dismemberment insurance, business travel accident insurance, employee assistance program, group legal services, wellness, cafeteria (including premium payment, health care flexible spending account, and dependent care flexible spending account components), travel reimbursement, transportation, vacation benefits, apprenticeship or other training programs, day care centers, or prepaid legal services benefits, including any “employee welfare benefit plan” (as defined in ERISA Section 3(1)) that is not a severance plan.

“Incurred Claim” means a Liability related to services or benefits provided under a Benefit Plan, and shall be deemed to be incurred: (i) with respect to medical, dental, vision, and prescription drug benefits, upon the rendering of services giving rise to such Liability; (ii) with respect to death benefits, life insurance, accidental death and dismemberment insurance, and business travel accident insurance, upon the occurrence of the event giving rise to such Liability; (iii) with respect to disability benefits, upon the date of disability, as determined by the disability benefit insurance carrier or claim administrator, giving rise to such Liability; (iv) with respect to a period of continuous hospitalization, upon the date of admission to the hospital; and (v) with respect to tuition reimbursement or adoption assistance, upon completion of the requirements for such reimbursement or assistance, whichever is applicable.

“Local Closing Transaction” means the local closing transaction involving a Deferred Organon Local Business.

“Merck” has the meaning set forth in the Preamble.

“Merck Benefit Plan” means a Benefit Plan sponsored by, maintained by, or contributed to by the Merck Group.

“Merck Board” means the Merck board of directors.

“Merck Change of Control” has the meaning set forth in Section 6.01(b).

“Merck Compensation & Benefits Committee” means the compensation and benefits committee of the Merck Board.

“Merck Conversion Ratio” means the quotient obtained by dividing (i) the Merck Pre-Spin Value by (ii) the Merck Post-Spin Value.

“Merck DCP” means the Merck & Co., Inc. Deferral Program.

“Merck Deferred Stock Unit” means a deferred unit (a.k.a. a phantom share) credited under a non-employee director’s Merck Common Stock account under the Merck Directors’ DCP.

“Merck Directors’ DCP” means the Merck & Co., Inc. Plan for Deferred Payment of Directors’ Compensation.

“Merck Group” means Merck and its Affiliates (excluding, after the Distribution, any member of the Organon Group).

“Merck Health and Welfare Plan” means a Health and Welfare Plan sponsored by, maintained by, or contributed to by the Merck Group.

“Merck Pension Plan” means the Merck U.S. Pension Plan.

“Merck Phantom Share” means a Merck common-stock-denominated investment pursuant to the Merck DCP.

“Merck Pre-Spin Value” means the price per share of Merck Common Stock trading “regular-way” as reported on the NYSE at the close on the Distribution Date.

“Merck Post-Spin Value” means the volume weighted average trading price per share of Merck Common Stock on the NYSE on the trading day immediately following the Distribution Date, as reported by Bloomberg.

“Merck Retained Employee” means any Employee other than an Organon Employee.

“Merck Retiree Health Care Plan” means the Merck Retiree Medical Plan.

“Merck Savings Plan” means the Merck US Savings Plan.

“Merck SERP” means the MSD Supplemental Retirement Plan.

“Merck Separation Plan” means the Merck U.S. Separation Benefits Plan.

“Merck Stock Programs” means, collectively, (i) the Merck 2007 Incentive Stock Plan, (ii) the Merck & Co., Inc. 2010 Incentive Stock Plan, (iii) the Merck & Co., Inc. 2019 Incentive Stock Plan and (iv) any similar prior Merck plans and all sub-plans or equity plans related to any of the foregoing, together with any incentive compensation program or arrangement that governs the terms of equity-based incentive awards assumed by the Merck Group in connection with a corporate transaction and that is maintained by the Merck Group immediately prior to the Distribution Date, and any sub-plans established under those programs.

“Non-U.S. Merck Benefit Plan” means a Merck Benefit Plan established, maintained, or contributed to by the Merck Group that is primarily for the benefit of Employees or Former Employees who work primarily outside of the United States.

“Non-U.S. Organon Benefit Plan” means an Organon Benefit Plan established, maintained, or contributed to by the Organon Group that is primarily for the benefit of Employees or Former Employees who work primarily outside of the United States.

“Non-U.S. Organon Employee” means an Organon Employee who works primarily outside of the United States.

“Non-U.S. Health and Welfare Plan” means a Health and Welfare Plan established, maintained, or contributed to by the Merck Group or the Organon Group, as applicable, that is primarily for the benefit of Employees (including Former Employees, as appropriate) who work primarily outside of the United States.

“Organon” has the meaning set forth in the Preamble.

“Organon Award” means an Organon Option, Organon PSU Award, or Organon RSU Award granted pursuant to Section 6.01.

“Organon Benefit Plan” means each Benefit Plan sponsored by, maintained by, or contributed to by the Organon Group, including, following the consummation of a Local Closing Transaction, each Benefit Plan sponsored by, maintained by, or contributed to by the applicable Deferred Organon Local Business.

“Organon Board” means the Organon board of directors.

“Organon Change of Control” has the meaning set forth in Section 6.01(b).

“Organon Conversion Ratio” means the quotient obtained by dividing (i) the Merck Pre-Spin Value by (ii) the Adjusted Organon Stock Value.

“Organon DCP” means the Organon & Co. U.S. Non-Qualified Savings Plan.

“Organon Employee” means any Employee who is (i) employed by the Organon Group as of the Distribution Date, or (ii) a Post-Distribution Organon Employee.

“Organon Equity Plan” means the Organon & Co. 2021 Incentive Stock Plan.

“Organon Group” means Organon and its Affiliates.

“Organon Health and Welfare Plan” means a Health and Welfare Plan sponsored by, maintained by, or contributed to by the Organon Group.

“Organon Price” means the volume weighted average trading price per share of Organon Common Stock on the NYSE on the trading day immediately following the Distribution Date, as reported by Bloomberg.

“Organon Retiree Liability” means that portion of the aggregate incremental cost of providing early retirement subsidies, service crediting bridges, and retiree healthcare benefits to Transferred Employees under the Merck Pension Plan, the Merck SERP and the Merck Retiree Health Care Plan, as described in Sections 3.01, 3.03 and 5.01(d) hereof, that is attributable to future service, with such aggregate incremental cost as determined based on reasonable estimates in the discretion of the actuaries designated by Merck to calculate such amounts.

“Organon Savings Plan” means the Organon U.S. Savings Plan. “Option” means (i) when immediately preceded by “Merck,” an option to purchase one or more Merck Common Shares granted under a Merck Stock Program and outstanding immediately prior to the Distribution Date (whether or not then vested or exercisable); (ii) when immediately preceded by “Adjusted Merck,” an option to purchase one or more Merck Common Shares adjusted in accordance with Section 6.01; and (iii) when immediately preceded by “Organon,” an option to purchase one or more shares of Organon Common Stock granted by Organon in accordance with Section 6.01.

“Parties” has the meaning set forth in the Preamble.

“Post-Distribution Organon Employee” means each Employee named as a Post-Distribution Organon Employee on a record maintained by Merck, which includes designated secondees from the Merck Group to the Organon Group and those Employees transferring only upon a Local Closing Transaction if employed in connection with a Deferred Organon Local Business, including any Employee hired on or after the Distribution Date to the extent such Employee is primarily related to a Deferred Organon Local Business or is hired to replace any terminated or departing Employee who would have otherwise been a Post-Distribution Organon Employee.

“PSU Award” means (i) when immediately preceded by “Merck,” a performance share unit award granted pursuant to a Merck Stock Program and outstanding immediately prior to the Distribution Date; (ii) when immediately preceded by “Adjusted Merck,” a performance share unit award granted pursuant to a Merck Stock Program adjusted in accordance with Section 6.01; and (iii) when immediately preceded by “Organon,” a performance share unit award granted by Organon in accordance with Section 6.01.

“Regular Trading Hours” means the period beginning at 9:30 A.M. New York City time and ending 4:00 P.M. New York City time.

“RSU Award” means (i) when immediately preceded by “Merck,” a restricted stock unit award granted pursuant to a Merck Stock Program and outstanding immediately prior to the Distribution Date; (ii) when immediately preceded by “Adjusted Merck,” a restricted stock unit award granted pursuant to a Merck Stock Program adjusted in accordance with Section 6.01 or Section 6.03; and (iii) when immediately preceded by “Organon,” a restricted stock unit award granted by Organon in accordance with Section 6.01 or Section 6.03.

“Securities Act” means the U.S. Securities Act of 1933, as amended.

“Separation and Distribution Agreement” has the meaning set forth in the recitals.

“Trading Day” means the period of time during any given calendar day, commencing with the determination of the opening price on the NYSE and ending with the determination of the closing price on the NYSE, in which trading and settlement in Merck Common Shares or Organon Common Stock, as applicable, is permitted on the NYSE.

“Transfer Date” means the date on which such person first becomes employed by the Organon Group (whether prior to, on or following the Distribution Date).

“Transferred Employee” has the meaning set forth in Section 2.02(a)(i).

“Transferred Flexible Spending Account Balances” has the meaning set forth in Section 5.01(c)(iii).

“Transferred Non-U.S. Employee” means a Transferred Employee who works primarily outside of the United States.

“United States” means, when used in a territorial sense, the fifty states of the United States of America and the District of Columbia, but does not, unless otherwise specifically provided, include Puerto Rico or any other territory of the United States.

“USERRA” means the Uniformed Services Employment and Reemployment Rights Act of 1994, as amended.

ARTICLE II

GENERAL PRINCIPLES

Section 2.01 Allocation of Liabilities.

(a) Organon Liabilities. Except as expressly provided in this Agreement, the Separation and Distribution Agreement or any Transaction Document, Organon hereby assumes (or retains) and agrees to pay, perform, fulfill, and discharge all Liabilities to the extent relating to, arising out of, or resulting from or with respect to:

(i) the employment (or termination of employment), including with respect to any statutory or other Liabilities (whether those Liabilities are otherwise the legal responsibility of the Merck Group or the Organon Group) triggered by or in connection with the Spin-Off, of each Transferred Employee by the Merck Group up to the applicable Transfer Date and by the Organon Group on and after the applicable Transfer Date (including, in each case, all Liabilities with respect to any such Organon Employee relating to, arising out of, or resulting from Employment Taxes, Employee Agreements, any Merck Benefit Plan or any Organon Benefit Plan); provided, however, that, Organon shall assume only the Organon Retiree Liability with respect to any Liabilities relating to, arising out of, or resulting from the Merck Retiree Health Care Plan, the Merck Pension Plan, the Merck SERP, the Merck DCP and Merck Directors' DCP, which Liabilities shall otherwise be expressly retained by Merck;

(ii) the employment (or termination of employment) of each Former Employee to the extent such individual was last employed prior to his or her termination of employment with a manufacturing plant or entity located outside of the United States and wholly transferring to the Organon Group in connection with the Spin-Off (including all Liabilities to the extent relating to, arising out of, or resulting from Employment Taxes, Employee Agreements, any Merck Benefit Plan or any Organon Benefit Plan);

(iii) the retention of any individual who is, or was, an independent contractor, temporary employee, temporary service worker, consultant, freelancer, agency employee, leased employee, on-call worker, incidental worker, or non-payroll worker or any other individual in any other similar relationship to the extent the services provided by any such individual were primarily related to the Organon Group or the Organon Business and such individual is identified to be transferred to the Organon Group in connection with the Spin-Off; provided that, for the avoidance of doubt, this Agreement is not intended to, and does not, address any Liabilities in respect of the services provided by consulting firms, investment advisory firms, valuation advisory firms, legal advisors or other third-party entities retained to provide advice with respect to or in connection with the Spin-Off;

(iv) all Liabilities under any Organon Benefit Plan established or adopted by any member of the Organon Group, regardless of whether established prior to, on or following the Distribution Date; and

(v) Liabilities and responsibilities expressly assumed or retained by Organon pursuant to this Agreement.

(b) Merck Liabilities. Except as expressly provided in this Agreement, the Separation and Distribution Agreement or any Transaction Document, Merck hereby retains (or assumes) and agrees to pay, perform, fulfill, and discharge all Liabilities to the extent relating to, arising out of, or resulting from:

(i) the employment (or termination of employment) of each Merck Retained Employee by the Merck Group prior to, on, or after the Distribution Date (including all Liabilities with respect to any such Merck Retained Employee to the extent relating to, arising out of, or resulting from Employment Taxes, Employee Agreements or any Merck Benefit Plan);

(ii) except as provided in Section 2.01(a)(ii) or (iv), the employment (or termination of employment) of each Former Employee and each Organon Employee unless and until such Organon Employee becomes a Transferred Employee (including all Liabilities to the extent relating to, arising out of, or resulting from Employment Taxes, Employee Agreements or any Merck Benefit Plan);

(iii) the retention of any individual who is, or was, an independent contractor, temporary employee, temporary service worker, consultant, freelancer, agency employee, leased employee, on-call worker, incidental worker, non-payroll worker or any other individual in any other similar relationship to the extent the services provided by any such individual were primarily related to the Merck Group or the Merck Business; provided that, for the avoidance of doubt, this Agreement is not intended to, and does not, address any Liabilities in respect of the services provided by consulting firms, investment advisory firms, valuation advisory firms, legal advisors or other third-party entities retained to provide advice with respect to or in connection with the Spin-Off; and

(iv) Liabilities and responsibilities expressly retained or assumed by Merck pursuant to this Agreement.

(c) Other Liabilities. To the extent that this Agreement does not cover particular Liabilities or responsibilities that relate to, arise out of, or result from employment (or termination of employment), Employment Taxes, Employee Agreements or any Benefit Plan and the Parties later determine that they should be allocated in connection with the Spin-Off, such Liabilities and responsibilities shall be handled in a manner similar to the manner in which this Agreement handles comparable Liabilities and responsibilities, subject to the mutual agreement of the Parties, as evidenced by the written consent of an authorized officer of each Party.

(d) Labor Relations. To the extent required by applicable Law or any contract or arrangement with a labor union, works council or similar employee organization, Organon shall provide notice, engage in consultation and take any similar action which may be required after the Distribution Date on its part in connection with the Spin-Off and shall fully indemnify each member of the Merck Group against any Liabilities arising from its failure to comply with such requirements.

Section 2.02 Employment with Organon.

(a) Employment Transfers. The Parties intend for Organon Employees to transfer to the Organon Group and shall use their respective best efforts and cooperate with each other to effectuate this intent.

(i) Except as otherwise mutually agreed upon by the Parties, as of each Organon Employee's Transfer Date, the Organon Group shall: (A) continue to employ (on a basis consistent with Section 2.02(b)) each Organon Employee employed in a jurisdiction where employment continues automatically by operation of Law (and such individual does not object, where such right exists under applicable Law); (B) offer to employ (on a basis consistent with Section 2.02(b)) each Organon Employee employed in a jurisdiction where employment does not continue automatically by operation of Law; and (C) offer to employ (on a basis consistent with Section 2.02(b) or as otherwise required by applicable Law) each former Employee who would have been an Organon Employee had such former Employee been employed on the Distribution Date, and whose right to re-employment is protected by any applicable Law. Each Organon Employee who accepts an offer of employment with the Organon Group, or who continues employment with the Organon Group following his or her Transfer Date automatically by operation of Law (and does not object where such right exists under applicable Law), as the case may be, will be referred to in this Agreement as a "Transferred Employee."

(ii) The Merck Group may terminate the employment of any Organon Employee who does not become a Transferred Employee as of his or her intended Transfer Date, or, if such Organon Employee cannot be terminated in accordance with applicable Law or otherwise, then the Merck Group may terminate any other Employee of the Merck Group whose employment (in the sole judgment of Merck) is made redundant as a result of the continued retention of such Organon Employee. The Merck Group may also terminate the employment of any Organon Employee if retaining such Employee would constitute a violation of applicable Laws or the Merck Code of Conduct. Organon will be responsible for, and will indemnify the Merck Group from and against, any Liabilities incurred or payments made (including any severance payments made) in connection with the termination of an Organon Employee or any other Employee of the Merck Group pursuant to this Section 2.02(a)(ii) to the extent of any payment occurring on or after the Distribution Date.

(b) Compensation and Benefits.

(i) Except as expressly provided in this Agreement or in local Conveyance and Assumption Instruments, no Transferred Employee shall participate in any Merck Benefit Plan following the later of (i) the Distribution Date; and (ii) his or her Transfer Date.

(ii) Except as expressly provided in this Agreement, as otherwise required by applicable Law or with respect to any Transferred Employee who experiences a change in primary country of employment as part of his or her transfer, from the applicable Transfer Date through December 31, 2022, the Organon Group shall provide to each Transferred Employee (A) at least the same rate of base salary as provided to that Transferred Employee immediately prior to the later of the Distribution Date and his or her Transfer Date (or if greater, as provided to that Transferred Employee pursuant to the terms of any Employee Agreement that becomes effective upon the consummation of or immediately following the Spin-Off), (B) at least the same cash incentive compensation opportunities and long-term incentive compensation opportunities as provided to that Transferred Employee immediately prior to the later of the Distribution Date and his or her Transfer Date (or if greater, as provided to that Transferred Employee pursuant to the terms of any Employee Agreement that becomes effective upon the consummation of or immediately following the Spin-Off), (C) Core Benefits under the Organon Benefit Plans that are substantially comparable in the aggregate to benefits provided under the corresponding Merck Benefit Plans immediately prior to the earlier of the Distribution Date or the date as of which the comparable Organon Benefit Plan is established or adopted by any member of the Organon Group (but, for the avoidance of doubt, Organon is not required to establish any particular types of plans (such as defined benefit pension plans) to satisfy this obligation), and (D) at least the same separation pay and comparable post-termination continuation of Health and Welfare Benefits providing Core Benefits (excluding, for the avoidance of doubt, retiree healthcare and retiree life insurance benefits) as were provided to that Transferred Employee immediately prior to the earlier of the Distribution Date or the date as of which the comparable Organon Health and Welfare Benefits is established or adopted by any member of the Organon Group (or if greater, as provided to that Transferred Employee pursuant to the terms of any Employee Agreement that becomes effective upon the consummation of or immediately following the Spin-Off). Nothing in this Section 2.02(b)(ii) shall prevent the Organon Group from terminating the employment of any Transferred Employee or adopting, amending or terminating any Organon Benefit Plan.

(c) Service Credit. Except as otherwise expressly provided in this Agreement or to the extent it would result in a duplication of benefits, Organon and each Organon Benefit Plan shall, to the extent permitted in accordance with applicable Law, give each Transferred Employee credit for vesting, eligibility, and accrual purposes for all service with the Merck Group (except for defined benefit pension plans and post-employment welfare benefits and, solely if a Transferred Employee receives severance benefits in connection with his or her termination of employment with the Merck Group, for purpose of determining severance benefits under any Organon Benefit Plan that provides severance benefits) (other than as required by law)) and shall calculate such service as it would be calculated by Merck or under the corresponding Merck Benefit Plan as of the applicable Transfer Date.

Section 2.03 Establishment of Organon Plans.

(a) Generally.

(i) U.S. On or prior to the Distribution Date, Organon shall adopt Core Benefit Plans (and related trusts, if applicable, as determined by the Parties), with terms substantially comparable in the aggregate to those of the corresponding Merck Benefit Plans in the U.S., but excluding defined benefit pension plans, deferred compensation plans and post-employment welfare benefit plans; provided, however, that Organon may limit participation in any Organon Benefit Plan to Transferred Employees who participated in the corresponding Merck Benefit Plan immediately prior to the applicable Transfer Date.

(ii) Non-U.S. (including Puerto Rico). On or prior to the Distribution Date, the Organon Group shall, except as otherwise mutually agreed upon by the Parties, adopt Core Non-U.S. Organon Benefit Plans, with terms substantially comparable in the aggregate to those of the corresponding Non-U.S. Merck Benefit Plans immediately prior to the Distribution Date; provided, however, that Organon may limit participation in any such Core Non-U.S. Organon Benefit Plan to Non-U.S. Organon Employees who are Transferred Employees and who participated in the corresponding Non-U.S. Merck Benefit Plan. As described in Article IV, or as otherwise mutually agreed upon by the Parties from time to time, the Merck Group shall, or shall cause the applicable Non-U.S. Merck Benefit Plan's related trust to, transfer to the Organon Group or the relevant Core Non-U.S. Organon Benefit Plan's related trust, trust Assets, insurance reserves, and other Assets of each Non-U.S. Merck Benefit Plan. To the extent a Non-U.S. Merck Benefit Plan is not required to be funded by applicable Law or is not voluntarily funded, there shall be no transfer of assets by the Non-U.S. Merck Benefit Plan or by the Merck Group. As described in Article IV, or as otherwise mutually agreed upon by the Parties from time to time, the Organon Group shall, or shall cause the relevant Core Non-U.S. Organon Benefit Plan to, assume the Liabilities of the corresponding Non-U.S. Merck Benefit Plan with respect to all benefits accrued under that Non-U.S. Merck Benefit Plan by Non-U.S. Organon Employees who are Transferred Employees.

(b) Plan Information and Operation. Merck shall provide Organon with information describing each Merck Benefit Plan election made by a Transferred Employee that may have application following the applicable Transfer Date. Organon shall determine, in its sole discretion (and in compliance with Code Section 409A to the extent applicable), whether to administer the Organon Benefit Plans using those elections or to require Transferred Employees to submit new elections with respect to the Organon Benefit Plans. Except as provided in this Agreement, the Distribution and the transfer of any Employee's employment to the Organon Group shall not cause a distribution from or payment of benefits under any Merck Benefit Plan. Each Party shall, upon reasonable request, provide the other Party and the other Party's respective Affiliates, agents, and vendors all information reasonably necessary to the other Party's operation or administration of its Benefit Plans and to accommodate the transfer of benefits.

Section 2.04 Post-Distribution Organon Employees.

(a) The following provisions shall apply to all Post-Distribution Organon Employees. During the period commencing on the Distribution Date and ending on the applicable Transfer Date, Merck or its appropriate Affiliate shall manage the employment of each Post-Distribution Organon Employee consistently with its management of the employment of similar Merck Employees in the ordinary course of business (including with respect to compensation, annual and other bonuses, and other compensation, subject to Sections 2.04(a)(iii)(E) and 6.02 below); provided that Merck and its Affiliates shall have no obligation to make any equity grant or provide any other equity incentive to any Post-Distribution Organon Employee on or after the Distribution Date, and Organon shall have no obligation to Merck or any of its Affiliates in respect of any equity grant or other equity incentive that is provided by Merck or its appropriate Affiliate to any Post-Distribution Organon Employee on or after the Distribution Date unless and except where the Parties have agreed, as evidenced by the written consent of an authorized officer of each Party, otherwise. Organon shall be responsible for all cash compensation and benefits liabilities arising with respect to such Post-Distribution Organon Employee during such period pursuant to the terms of the applicable Transaction Document. Merck shall until the time of the applicable Local Closing Transaction (or such other Transfer Date with respect to any other Post-Distribution Organon Employee):

(i) provide Organon or its appropriate Affiliate with notice of (A) any material amendment to the Merck Code of Conduct to the extent applicable to the employment of a Post-Distribution Organon Employee or (B) the termination of any Post-Distribution Organon Employee due to a violation or potential violation of Law or the Merck Code of Conduct, or otherwise pursuant to Section 2.02(a)(ii);

(ii) provide Organon or its appropriate Affiliate with at least 30 days' advance written notice prior to (A) making any material substantive change to the Employee Agreement of a Post-Distribution Organon Employee unless such change is required by applicable Law; (B) making any material change to the base salary of a Post-Distribution Organon Employee, other than an increase in the ordinary course of business, any change required by Law or any contract existing as of the Distribution Date, or as otherwise approved by Organon; or (C) making any modification to a Merck Benefit Plan in which a Post-Distribution Organon Employee participates if such modification would result in a significant change in the cost of such plan to the employer or the participant unless such change is required by applicable Law; and

(iii) consult with and request a recommendation from Organon or its appropriate Affiliate prior to (A) hiring any individual (other than in the ordinary course to replace any individual whose employment has terminated) who will be classified as an Organon Employee unless such headcount addition was authorized prior to the Distribution Date, (B) terminating any Post-Distribution Organon Employee, except due to a violation of Law or the Merck Code of Conduct, or otherwise pursuant to Section 2.02(a)(ii), (C) promoting any Post-Distribution Organon Employee to a compensation and career band of 700 or higher (other than in the ordinary course to replace any individual whose employment has terminated) unless such promotion was authorized prior to the Distribution Date, (D) demoting any Post-Distribution Organon Employee or otherwise materially changing the role or responsibility of any Post-Distribution Organon Employee, or (E) establishing targets or goals for bonus and other incentive compensation awards granted to Post-Distribution Organon Employees by Merck or any member of the Merck Group. Organon will be responsible for, and will indemnify the Merck Group from and against, any Liabilities incurred or payments made (including any severance payments made) in connection with the termination of a Post-Distribution Organon Employee pursuant to this Section 2.04(a)(iii) to the extent of any amount owed on or after the Distribution Date in accordance with the terms of the applicable Transaction Document.

(b) Except as otherwise mutually agreed upon by the Parties (including in a Conveyance and Assumption Instrument), if an Organon Employee's transfer of employment to the Organon Group upon the consummation of a Local Closing Transaction or otherwise causes, at the time of such transfer, a forfeiture of awards granted under a Merck Stock Program (or successor thereto), Merck shall not have any obligation, Liability or responsibility to such Organon Employee with respect to such forfeited awards, and Organon shall equitably compensate the affected Organon Employee for such forfeited awards in a manner determined by Organon in its sole discretion. Merck shall inform Organon on a regular basis of any such forfeited awards. The foregoing sentence shall not preclude the Parties from making arrangements, if allowed by the Merck Stock Program (or successor thereto) and applicable Law, to permit affected Organon Employees to continue to hold, after the Local Closing Transaction or other Transfer Date, awards granted under a Merck Stock Program (or successor thereto).

Section 2.05 Collective Bargaining. Organon shall cause the appropriate member of the Organon Group to assume all Liabilities arising under any collective bargaining agreement (including but not limited to any national, sector or local collective bargaining agreement), works council agreement, or other similar agreement with respect to any Transferred Employee. To the extent necessary, Organon shall cause the appropriate member of the Organon Group to join any industrial, employer or similar association or federation if membership is required for the relevant collective bargaining, works council, or other similar agreement to continue to apply.

ARTICLE III

U.S. QUALIFIED AND NON-QUALIFIED RETIREMENT PLANS

Section 3.01 Pension Plan. The Merck Pension Plan shall continue to be responsible for Liabilities in respect of all Employees (including Transferred Employees) and Former Employees. No Employees of the Organon Group shall accrue any additional benefits under the Merck Pension Plan following the later of (i) the Distribution Date, and (ii) their applicable Transfer Date. The accrued benefits of Transferred Employees under the Merck Pension Plan shall become fully vested as of the later of (i) the Distribution Date, and (ii) their applicable Transfer Dates. In addition, until distributions commence under the Merck Pension Plan for a Transferred Employee, the Merck Pension Plan shall continue to credit service earned with Organon and its Affiliates for purposes of early retirement eligibility and subsidies under the Merck Pension Plan. Furthermore, Merck shall provide any pension service crediting bridges offered under the Merck Separation Plan to any Transferred Employee who otherwise meets, on or prior to December 31, 2022, the age and service requirements for such pension service crediting bridges in the event that such Transferred Employee experiences a separation of employment from the Organon Group that would have entitled the Transferred Employee to benefits under the Merck Separation Plan prior to the Spin-Off (including satisfying any requirement to execute a release of claims against Merck and its affiliates).

Section 3.02 Savings Plan.

(a) Establishment of Organon Savings Plan. Effective as of or prior to the Distribution Date, Organon shall establish the Organon Savings Plan. As of the Distribution Date, the Organon Savings Plan shall include provisions so that, subject to the applicable nondiscrimination rules under Code Sections 401(a)(4) and 401(m), the aggregate contributions during any plan year through at least December 31, 2022 for Transferred Employees shall be no less than the aggregate sum of such contributions under the Merck Savings Plan and the pay credits under the Merck Pension Plan as in effect immediately prior to the Distribution Date. On or prior to the Distribution Date, Organon shall provide Merck with (i) a copy of the Organon Savings Plan; and (ii) a copy of certified resolutions of the Organon Board (or its authorized committee or other delegate) evidencing adoption of the Organon Savings Plan and the related trust(s) and the acceptance by the Organon Savings Plan of the Liabilities described in Section 3.02(b) as and when rollovers occur.

(b) Elective Rollovers of Account Balances. As soon as practicable after the later of (i) the Distribution Date, and (ii) the Transferred Employee's applicable Transfer Date, Organon shall take all actions necessary to permit Transferred Employees to directly roll over their account balances in the Merck Savings Plan to the Organon Savings Plan. Such rollovers may be made in cash, promissory notes evidencing outstanding loans or any combination thereof, as elected by the Transferred Employee.

(c) Organon Savings Plan Provisions. The Organon Savings Plan shall provide that:

(i) Transferred Employees shall (A) be eligible to participate in the Organon Savings Plan as of the later of (i) the Distribution Date, and (ii) their applicable Transfer Date, to the extent they were eligible to participate in the Merck Savings Plan as of immediately prior to such date, and (B) receive credit for vesting and benefit accrual purposes for all service credited for that purpose under the Merck Savings Plan as of the later of (y) the Distribution Date, and (z) their applicable Transfer Date, as if that service had been rendered to Organon; and

(ii) the Organon Savings Plan shall provide the opportunity to make up elective deferrals, and any employer contributions, required by USERRA for a Former Employee who is employed by the Organon Group following the Distribution Date pursuant to Section 2.02(a)(i)(C), including any amount that relates to the period of military leave that occurred prior to the Distribution Date.

(d) Determination Letter Request. Unless the Organon Savings Plan may rely on a favorable opinion letter from the Internal Revenue Service, Organon shall submit an application to the Internal Revenue Service either prior to, or as soon as practicable following, the Distribution Date for a determination regarding the qualification of the Organon Savings Plan as of the Distribution Date and shall make any amendments reasonably requested by the Internal Revenue Service to receive a favorable determination letter regarding the Organon Savings Plan.

(e) Merck Savings Plan after Distribution Date. From and after the Distribution Date the Merck Savings Plan shall continue to be responsible for Liabilities in respect of all Employees (including Transferred Employees) and Former Employees. From and after the later of (i) the Distribution Date, and (ii) their applicable Transfer Date, no Employees of the Organon Group shall accrue any benefits under the Merck Savings Plan. Without limiting the generality of the foregoing, Transferred Employees shall cease to be active participants in the Merck Savings Plan effective as of their applicable Transfer Date. For the avoidance of doubt, Merck Employees and Transferred Employees, until their respective Transfer Dates, shall accrue benefits under the Merck Savings Plan.

(f) Plan Fiduciaries. For all periods whether before or after the Distribution Date, the Parties agree that the applicable fiduciaries of each of the Merck Savings Plan and the Organon Savings Plan, respectively, shall have the authority with respect to the Merck Savings Plan and the Organon Savings Plan, respectively, to determine the investment alternatives, the terms and conditions with respect to those investment alternatives and such other matters as are within the scope of their duties under ERISA Section 404. Without limiting the generality of the foregoing, Merck or its designate may recommend initial investment funds available under the Organon Savings Plan, which Organon shall be free to accept or reject in accordance with its fiduciary duties.

Section 3.03 Supplemental Pension Plan. The Merck SERP shall continue to be responsible for Liabilities in respect of all Employees (including Transferred Employees) and Former Employees accrued thereunder. No Employees of the Organon Group shall accrue any benefits under the Merck SERP following the later of the Distribution Date and their applicable Transfer Date, but the Merck SERP shall credit such Employee's continuous service with the Organon Group following the Transfer Date for purposes of early retirement eligibility and early retirement subsidies. Except as otherwise provided by Code Section 409A, a Transferred Employee shall not be considered to have undergone a "separation from service" for purposes of Code Section 409A and the Merck SERP solely by reason of the Spin-Off, and, following his or her Transfer Date, the determination of whether a Transferred Employee has incurred a separation from service with respect to his or her benefit in the Merck SERP shall be based solely upon his performance of services for the Organon Group.

Section 3.04 Deferred Compensation Plan.

(a) Establishment of Organon DCP. Effective as of or before the Distribution Date, Organon shall establish the Organon DCP to permit company credits to Organon Savings Plan participant accounts to the extent contributions cannot be made to the Organon Savings Plan by reason of the limits under the Code, such as Code Section 401(a)(17).

(b) Merck DCP after Spin-Off. From and after the later of the Distribution Date and a Transferred Employee's Transfer Date, such individual shall not actively participate in or accrue any benefits under the Merck DCP. The Merck DCP shall continue to be responsible for Liabilities in respect of all Employees (including Transferred Employees) and Former Employees. Except as otherwise provided by Code Section 409A, a Transferred Employee shall not be considered to have undergone a "separation from service" for purposes of Code Section 409A and the Merck DCP solely by reason of the Spin-Off, and, following his Transfer Date, the determination of whether a Transferred Employee has incurred a separation from service with respect to his or her benefit in the Merck DCP shall be based solely upon his or her performance of services for the Organon Group.

(c) Adjustment of Merck Common-Stock-Denominated Investments ("Merck Phantom Shares"). Each Merck Phantom Share that remains outstanding in the Merck DCP as of immediately prior to the Distribution Date, regardless of by whom held shall be converted concurrently with the Distribution on the Distribution Date into an "Adjusted Merck Phantom Share." The number of units represented by an Adjusted Merck Phantom Share shall be equal to (1) the number of Merck Phantom Shares immediately prior to the Distribution Date, divided by (2) the Merck Conversion Ratio, rounded to the nearest unit.

Section 3.05 Failure to Notify of Employment Termination. Organon shall notify Merck of the "separation from service" (as determined pursuant to Section 409A of the Code) of any Transferred Employee by the 15th day of the calendar month following the calendar month of such Transferred Employee's separation from service. At that time, Organon shall also notify Merck whether the Transferred Employee is a "specified employee" as determined pursuant to Code Section 409A. In the event that a distribution of benefits to a Transferred Employee is not made at the proper time pursuant to any Merck plan because Organon did not timely notify Merck of any such separation from service, or specified employee status, Organon shall reimburse Merck for all costs, including incidental and consequential damages incurred by Merck in connection therewith (including but not limited to additional benefit plan payments, legal fees, accounting fees and advisor fees, service provider fees, the costs of preparing and making any governmental filings, any "gross-up" Merck determines to pay to such Transferred Employee in connection with a violation of Code Section 409A) and any other amounts Merck reasonably determines would have been avoided if Organon had timely notified Merck of such separation from service or specified employee status.

ARTICLE IV

NON-U.S. RETIREMENT PLANS

Section 4.01 Establishment of Non-U.S. Retirement Plans and Transfers of Assets and Liabilities. Except as mutually agreed upon by the Parties or required under this Article IV, effective as of or before the Distribution Date, Organon or its appropriate Affiliate will establish pension and retirement plans (whether defined contribution or defined benefit pension plans) with terms that are substantially comparable in the aggregate to those offered to Transferred Non-U.S. Employees immediately prior to the earlier of (i) the Distribution Date or (ii) their applicable Transfer Date.

(a) Transfer of Non-U.S. Retirement Plan Assets and Liabilities. As soon as practicable following the establishment of a Non-U.S. Organon Benefit Plan, except as otherwise provided in this Agreement or as mutually agreed upon by the Parties, the Assets and Liabilities (determined as of the date of the applicable local closing, whether occurring prior to, on or after

the Distribution Date (such date, the “Applicable Closing Date”) under the corresponding Non-U.S. Merck Benefit Plan attributable to Transferred Non-U.S. Employees who are participants in such plan, along with any other Assets and Liabilities that Organon agrees to assume with respect to such plan, shall be transferred to such Non-U.S. Organon Benefit Plan. The Non-U.S. Merck Benefit Plan shall retain all Assets and Liabilities related to Merck Retained Employees, Former Employees and Post-Distribution Organon Employees (subject to Section 4.01(c)). Except as otherwise mutually agreed upon by the Parties, assets will be allocated between the plans based on the proportion of Liabilities borne by each plan. Except as otherwise mutually agreed upon by the Parties, such Liabilities will be valued using the projected benefit obligation based on plan provisions as in effect at the Applicable Closing Date and applying demographic and other assumptions used in the most recently completed valuation of the applicable Non-U.S. Merck Benefit Plan (and taking into account the requirements of ASC 715 as it exists as of the Applicable Closing Date); provided, however, that all economic assumptions will be updated as of the Applicable Closing Date. The transfer amount described above shall be credited or debited, as applicable, with a pro rata share of the actual investment earnings or losses allocable to the transfer amount for the period between the Applicable Closing Date and an assessment date set by Merck that is as close as practicable, taking into account the timing and reporting of valuation of the applicable Non-U.S. Merck Benefit Plan’s Assets, to the date upon which Assets equal in value to the transfer amount are actually transferred from the applicable Non-U.S. Merck Benefit Plan to the applicable Non-U.S. Organon Benefit Plan; provided that, if actual investment earnings or losses are not then determinable, Merck and Organon shall then agree on a reasonable alternative methodology (which may include expected or estimated returns used for other similar purposes by Merck in the ordinary course of business). During this period, benefits payable to Transferred Non-U.S. Employees shall be paid from the Non-U.S. Merck Benefit Plan. Except as otherwise mutually agreed upon by the Parties, the ultimate transfer amount shall be reduced by the amount of these benefits and credited or debited by the actual investment earnings or losses from the payment date to the assessment date set by Merck above. Any third party fees, costs or expenses incurred under the applicable Non-U.S. Merck Benefit Plan during the period from the Applicable Closing Date to the assessment date set by Merck shall be shared by the Parties based on the proportion of Liabilities borne by the applicable Non-U.S. Merck Benefit Plan and the applicable Non-U.S. Organon Benefit Plan. The Parties agree to use commercially reasonable efforts to accomplish each transfer as soon as practicable on or following the Applicable Closing Date and to cooperate with each other to make such filings and disclosures and obtain such approvals as may be deemed necessary or advisable in accordance with applicable Law. Notwithstanding the foregoing, to the extent a Non-U.S. Merck Benefit Plan is not required to be funded by applicable Law or is not voluntarily funded, there shall be no transfer of Assets by the Non-U.S. Merck Benefit Plan or by the Merck Group in respect thereof.

(b) Non-U.S. Organon Retirement Plan Provisions. Each Non-U.S. Organon Benefit Plan shall provide, except as otherwise provided in this Agreement or local Conveyance and Assumption Instruments, that:

(i) Transferred Non-U.S. Employees shall (A) be eligible to participate in the Non-U.S. Organon Benefit Plan to the extent they were eligible to participate in the corresponding Non-U.S. Merck Benefit Plan, and (B) receive credit for vesting, eligibility and benefit service to the same extent recognized by Merck as of immediately prior to their Transfer Date for all service credited for those purposes under the corresponding Non-U.S. Merck Benefit Plan as if that service had been rendered to Organon;

(ii) the compensation paid by the Merck Group to a Transferred Non-U.S. Employee that is recognized under the Non-U.S. Merck Benefit Plan shall be credited and recognized for all applicable purposes under the corresponding Non-U.S. Organon Benefit Plan as though it were compensation from the Organon Group; and

(iii) the accrued benefit of each Transferred Non-U.S. Employee under the Non-U.S. Merck Benefit Plan that is transferred to the corresponding Non-U.S. Organon Benefit Plan pursuant to Section 4.01(a) shall be paid under such Non-U.S. Organon Benefit Plan in accordance with the terms of such Non-U.S. Organon Benefit Plan and applicable Law, with employment by the Merck Group treated as employment by the Organon Group under the Non-U.S. Organon Benefit Plan for purposes of determining eligibility for optional forms of benefit, early retirement benefits, or other benefit forms.

(c) Subsequent Transfers. Periodically, at such times as agreed upon by the Parties after the initial transfer described in Section 4.01(a), Organon shall cause the applicable Non-U.S. Organon Benefit Plan to receive Assets and assume all Liabilities under the applicable Non-U.S. Merck Benefit Plan for Post-Distribution Organon Employees who become Transferred Employees (including Assets and Liabilities in respect of beneficiaries and/or alternate payees) and the applicable Non-U.S. Merck Benefit Plan shall transfer all such Assets and be relieved of such Liabilities. The amount of such Assets to be transferred shall be determined as provided in Section 4.01(a) (and shall include any employee contributions made by such Post-Distribution Organon Employee between the Distribution Date and the applicable Transfer Date) and shall be subject to the applicable provisions of Section 4.01(a).

(d) Notwithstanding the foregoing, if pension benefits are funded by individually linked insurance contracts, such contracts in respect of Transferred Employees shall be assigned to Organon or its applicable Subsidiary in lieu of the transfers of (and calculations of value with respect to) other Assets otherwise contemplated hereby.

ARTICLE V

WELFARE AND FRINGE BENEFIT PLANS

Section 5.01 Health and Welfare Plans.

(a) Establishment of Organon Health and Welfare Plans. Effective as of or before the Distribution Date, Organon shall establish the Core Organon Health and Welfare Plans, with terms substantially comparable in the aggregate to those of the corresponding Core Merck Health and Welfare Plans unless otherwise provided in this Article V. For the avoidance of doubt, Organon shall not be required to provide retiree medical benefits to any employee hired on or after the Distribution Date.

(b) Waiver of Conditions; Benefit Maximums. Organon shall, to the extent commercially reasonable and permitted under applicable Law and, with respect to Non-U.S. Health and Welfare Plans, to the extent applicable, cause the Organon Health and Welfare Plans to:

(i) with respect to initial enrollment (whether passive or active) prior to, as of or following an individual's applicable Transfer Date:

(A) waive all limitations as to preexisting conditions, exclusions, and service conditions with respect to participation and coverage requirements applicable to any Transferred Employee, other than limitations that were in effect with respect to the Transferred Employee under the applicable Merck Health and Welfare Plan as of immediately prior to such individual's Transfer Date;

(B) waive any waiting period limitation or evidence of insurability requirement applicable to a Transferred Employee other than limitations or requirements that were in effect with respect to such Transferred Employee under the applicable Merck Health and Welfare Plan as of immediately prior to such individual's Transfer Date;

(C) with respect to aggregate annual, lifetime, or similar maximum benefits available under the Organon Health and Welfare Plans, recognize a Transferred Employee's prior claim experience under the Merck Health and Welfare Plans and any Benefit Plan that provides leave benefits; and

(D) cause any eligible expenses incurred by a Transferred Employee and his or her covered dependents during the portion of the plan year of the applicable Merck Health and Welfare Plan ending on the date that the Transferred Employee's coverage commences under the Organon Health and Welfare Plan to be taken into account under such Organon Health and Welfare Plan for purposes of satisfying all deductible, coinsurance, and maximum out-of-pocket requirements applicable to such Transferred Employee and his or her covered dependents for the applicable plan year as if such amounts had been paid in accordance with such Organon Health and Welfare Plan.

(c) Allocation of Health and Welfare Assets and Liabilities.

(i) General Principles. Notwithstanding any other provision hereof and except as otherwise agreed between the Parties, (A) Merck shall retain all Liabilities relating to Incurred Claims of Merck Retained Employees and Former Employees under the Merck Health and Welfare Plans, and shall also retain Assets (including, without limitation, Medicare reimbursements, pharmaceutical rebates, and similar items) associated with such Incurred Claims and (B) Organon shall be responsible for Incurred Claims of Organon Employees from and after the applicable Transfer Date. Organon shall be responsible for all Liabilities relating to Incurred Claims under any Organon Health and Welfare Plan and shall also retain Assets (including, without limitation, Medicare reimbursements, pharmaceutical rebates, and similar items) associated with such Incurred Claims. Merck shall retain any Assets (including, without limitation, Medicare reimbursements, pharmaceutical rebates, and similar items) that are not associated with any specific Incurred Claim.

(ii) Disability Benefits. Notwithstanding any other provision hereof and except as otherwise agreed between the Parties, (A) Merck shall be responsible for Incurred Claims (including ongoing benefit payments) of Merck Retained Employees and Former Employees for short- and long-term disability benefits, regardless of when the applicable Incurred Claim was incurred and (B) subject to the immediately following sentence, Organon shall be responsible for Incurred Claims (including ongoing benefit payments) of Organon Employees from and after the applicable Transfer Date for short-term disability benefits and long-term disability benefits. Notwithstanding the foregoing, an Organon Employee who is on short-term disability leave on the Transfer Date under a U.S. Health and Welfare Plan and who subsequently qualifies for long-term disability without an intervening new Incurred Claim shall receive long-term disability benefits from the Merck long-term disability plan, but all other benefits attributable to his or her disability (including continued pension accrual, if applicable, and participation in any medical or life insurance plan for disabled persons, if applicable) shall be provided by the applicable Organon Benefit Plan, if any, or otherwise be the responsibility of Organon, and if Organon does not sponsor a plan providing any such benefits, such Organon Employee shall not be entitled to such benefits from any Merck Benefit Plan.

(iii) U.S. Flexible Spending Accounts. The Parties shall take all actions necessary to ensure that, effective as of the later of the Distribution Date and the applicable Employee's Transfer Date, (A) the health care and dependent care flexible spending accounts of the applicable Transferred Employees (whether positive or negative) (the "Transferred Flexible Spending Account Balances") under the applicable Merck Health and Welfare Plan shall be transferred to the corresponding Organon Health and Welfare Plan; (B) the elections, contribution levels and coverage of the Transferred Employees shall apply under the Organon Health and Welfare Plan in the same manner as under the corresponding Merck Health and Welfare Plan; and (C) the Transferred Employees shall be eligible for reimbursement from the Organon Health and Welfare Plan on the same basis and the same terms and conditions as under the corresponding Merck Health and Welfare Plan. As soon as practicable after the Distribution Date (and any later Transferred Employee's Transfer Date), and in any event within 30 business days after the amount of the Transferred Flexible Spending Account Balances is determined, Merck shall pay Organon the net aggregate amount of the Transferred Flexible Spending Account Balances, if such amount is positive, and Organon shall pay Merck the net aggregate amount of the Transferred Flexible Spending Account Balances, if such amount is negative.

(d) Retiree Health Care Plan and Retiree Life Insurance. Notwithstanding any other provision hereof (or any other action taken by Merck and Organon on or prior to the Distribution Date, including any assignment and assumption of Assets or Liabilities related thereto), Merck shall retain the Liabilities and responsibility for all obligations under the Merck Retiree Health Care Plan for benefits due to Merck Retained Employees, Transferred Employees and Former Employees, and shall also retain Assets, including, without limitation, Medicare reimbursements, pharmaceutical rebates, and similar items, associated with such benefits. For

each Transferred Employee, Merck shall (i) cause the Merck Retiree Health Care Plan to credit service with Organon and its Affiliates after a Transferred Employee's Transfer Date for purposes of benefit eligibility under the Merck Retiree Health Care Plan, and (ii) in the event of a separation of employment that occurs on or prior to December 31, 2022, that would have entitled the Transferred Employee to benefits under the Merck Separation Plan prior to the Spin-Off (including any requirement to execute a release of claims against Merck and its affiliates), provide any retiree medical bridges that would have been offered under the Merck Separation Plan. For the avoidance of doubt, nothing herein shall be deemed to restrict the right of Merck to amend or terminate the Merck Retiree Health Care Plan at any time; provided, however, that Merck may not amend the Merck Retiree Health Care Plan in any manner that disproportionately, materially and adversely effects the rights of Organon Employees vis-à-vis the Merck Employees.

(e) Merck Health and Welfare Plans after Distribution Date. Except as otherwise provided in Section 5.01, Transferred Employees shall cease to participate in the Merck Health and Welfare Plans effective as of their respective Transfer Dates.

Section 5.02 COBRA. Merck shall continue to be responsible for compliance with the health care continuation requirements of COBRA, and the corresponding provisions of the Merck Health and Welfare Plans with respect to any (a) Merck Retained Employees and any Former Employees (and their covered dependents) who incur a qualifying event under COBRA on, prior to, or following the Distribution Date, (b) Organon Employees who do not at any time become Transferred Employees (and their covered dependents) who incur a qualifying event under COBRA on, prior to, or following the Distribution Date, and (c) subject to Section 2.04, other Organon Employees (and their covered dependents), with respect to qualifying events under COBRA incurred prior to the applicable Transfer Date. Organon shall assume responsibility for compliance with the health care continuation requirements of COBRA and the corresponding provisions of the Organon Health and Welfare Plans with respect to any Transferred Employees (and their covered dependents) who incur a qualifying event or loss of coverage under the Organon Health and Welfare Plans on or after their respective Transfer Dates. The Parties agree that the consummation of the transactions contemplated by the Separation and Distribution Agreement shall not constitute a COBRA qualifying event for any purpose of COBRA.

Section 5.03 Vacation, Holidays and Leaves of Absence. Effective as of the applicable Transfer Date in accordance with Section 2.01(a)(i), Organon shall be responsible for any and all Liabilities to, or relating to, Transferred Employees in respect of vacation, holiday, personal days, sick days, annual leave or other leave of absence, and required payments related thereto (whether accruing prior to, on or after the applicable Transfer Date), including any such Liabilities, and any such required payments related thereto, reasonably determined by Merck in its sole discretion. Merck shall retain all Liabilities with respect to vacation, holiday, annual leave or other leave of absence, and required payments related thereto, for each Merck Retained Employee and Former Employee, as well as Organon Employees until the applicable Transfer Date of such Organon Employees.

Section 5.04 Severance and Unemployment Compensation. Effective as of the applicable Transfer Date, Organon shall be responsible for any and all Liabilities to, or relating to, Transferred Employees in respect of severance and unemployment compensation. Transferred Employees shall receive credit for service with Merck as of the applicable Transfer Date as if that service had been rendered to Organon for determining severance entitlements subject to the limitations on service crediting in Section 2.02(c). Subject to any specific agreement to the contrary in the Separation and Distribution Agreement or any Transaction Document and subject to Sections 2.02(a)(ii) and 2.04 hereof, Merck shall be responsible for any and all Liabilities to, or relating to, Merck Retained Employees and Former Employees, as well as Organon Employees until an applicable Transfer Date occurs with respect to such Organon Employees, in respect of severance and unemployment compensation, regardless of whether the event giving rise to the Liability occurred prior to, on, or following the Distribution Date.

Section 5.05 Workers' Compensation. Except as required by applicable Law or as otherwise determined jointly by the Parties as a result of the requirements of any Governmental Authority, all United States workers' compensation Liabilities relating to, arising out of, or resulting from any claim shall be assumed, or retained as the case may be, by the Party (or its applicable Subsidiary) that employed such Employee as of the time of such claim. The Merck Group shall be responsible for all Liabilities relating to, arising out of, or resulting from any United States workers' compensation claims incurred prior to an applicable Transferred Employee's Transfer Date unless expressly specified otherwise in the immediately preceding sentence or as required by applicable Law. Each member of the Organon Group and the Merck Group shall cooperate with respect to any notification to appropriate governmental agencies of the disposition and the issuance of new, or the transfer of existing, workers' compensation insurance policies and claims handling contracts.

ARTICLE VI

EQUITY, INCENTIVE, AND DIRECTOR AND EXECUTIVE COMPENSATION PROGRAMS

Section 6.01 Equity Incentive Programs.

(a) Options, PSUs and RSUs. The Parties shall use commercially reasonable efforts to take all actions necessary or appropriate so that each outstanding Merck Option, Merck PSU Award, and Merck RSU Award granted under a Merck Stock Program shall be adjusted or converted as set forth in this Section 6.01. This Section 6.01(a) shall not apply to grants made under the Merck Directors' DCP (or any successor or predecessor plan), and the sole provisions with respect to the adjustment and conversion of those grants are set forth in Section 6.03.

(i) Merck Options. Each Merck Option outstanding as of immediately prior to the Distribution Date, whether vested or unvested and regardless of by whom held shall be converted concurrently with the Distribution on the Distribution Date into (x) an Adjusted Merck Option in the case of Merck Employees, Post-Distribution Organon Employees and Former Employees or (y) an Organon Option in the case of Organon Employees (excluding any Post-Distribution Organon Employee). Each such adjusted or converted Option shall, except as otherwise provided in this Section 6.01, be subject to the same terms and conditions (including with respect to vesting) after the Distribution Date as applicable to such Merck Option immediately prior to the Distribution Date; provided, however, that upon such adjustment or conversion:

(A) the number of Merck Common Shares subject to such Adjusted Merck Option (if any) shall be equal to (1) the number of Merck Common Shares subject to the Merck Option immediately prior to the Distribution Date, multiplied by (2) the Merck Conversion Ratio, rounded down to the nearest whole share;

(B) the number of shares of Organon Common Stock subject to the Organon Option into which such Merck Option is converted (if any) shall be equal to (1) (xx) the number of Merck Common Shares subject to the Merck Option immediately prior to the Distribution Date multiplied by (yy) the Distribution Ratio, multiplied by (2) the Organon Conversion Ratio, rounded down to the nearest whole share;

(C) the per share exercise price of each Adjusted Merck Option, shall be equal to (1) the per share exercise price of the Merck Option immediately prior to the Distribution Date divided by (2) the Merck Conversion Ratio, rounded up to the nearest cent; and

(D) the per share exercise price of each Organon Option, shall be equal to (1) the per share exercise price of the Merck Option immediately prior to the Distribution Date divided by (2) the Organon Conversion Ratio divided by (3) the Distribution Ratio, rounded up to the nearest cent;

provided, however, that the exercise price, the number of Merck Common Shares and the number of shares of Organon Common Stock subject to such options, and the terms and conditions of exercise of such options shall be determined in a manner consistent with the requirements of Code Section 409A.

(ii) Merck PSU Awards.

(A) Merck Employees, Post-Distribution Organon Employees and Former Employees. Merck shall, concurrently with the Distribution on the Distribution Date and notwithstanding the existing terms of such awards, cause the performance goals under each outstanding Merck PSU Award held by a Merck Employee, a Post-Distribution Organon Employee or a Former Employee to be equitably adjusted, as determined in its sole discretion. Each such Merck PSU Award held by a Merck Employee, a Post-Distribution Organon Employee or a Former Employee shall be converted concurrently with the Distribution on the Distribution Date into an Adjusted Merck PSU Award. Such converted award shall be (in all other respects) subject to substantially the same terms and conditions immediately following the Distribution Date as applicable immediately prior to the Distribution Date; provided, however, that the number of units represented by the Adjusted Merck PSU Award shall be equal to (1) the number of units subject to the Merck PSU Award immediately prior to the Distribution Date, multiplied by (2) the Merck Conversion Ratio, rounded to the nearest whole unit.

(B) Organon Employees' (other than Post-Distribution Organon Employees') 2019 Merck PSU Awards. Effective as of immediately prior to the Distribution on the Distribution Date, the Merck Compensation and Benefits Committee, pursuant to its authority under the applicable Merck Stock Program and notwithstanding the existing terms of such awards, shall determine and certify the level of attainment of all applicable performance goals under each outstanding Merck PSU Award with a 2019 to 2021 performance period that is held by an Organon Employee (other than a Post-Distribution Organon Employee), whether vested or unvested, as of immediately prior to the Distribution (with December 31, 2020 treated as the last day of the applicable performance period and such level of attained performance applied to 100% of the shares subject to the Merck PSU Award). Any such earned Merck PSU Award shall be converted, concurrently with the Distribution on the Distribution Date, into an Organon RSU Award with respect to a number of shares of Organon Common Stock equal to (1) (xx) the number of units subject to the earned Merck PSU Award immediately prior to the Distribution Date (as determined pursuant to the foregoing sentence) multiplied by (yy) the Distribution Ratio, multiplied by (2) the Organon Conversion Ratio, rounded to the nearest unit. Such Organon RSU Award shall be (in all other respects, including time-based vesting) subject to substantially the same terms and conditions immediately following the Distribution Date as applicable to the Merck PSU Award from which it was converted. Any portion of such Merck PSU Award that is not earned shall be immediately forfeited as of the Distribution Date without the payment of any consideration therefore.

(C) Organon Employees (other than Post-Distribution Organon Employees), 2020 and 2021 Merck PSU Awards. Effective as of immediately prior to the Distribution on the Distribution Date, a number of shares equal to the target number of shares subject to each outstanding Merck PSU Award with a 2020 to 2022 performance period and each outstanding Merck PSU Award with a 2021 to 2023 performance period that is held by an Organon Employee (other than a Post-Distribution Organon Employee), whether vested or unvested, as of immediately prior to the Distribution shall be deemed earned. Any such earned Merck PSU Award shall be converted, concurrently with the Distribution on the Distribution Date, into an Organon RSU Award with respect to a number of shares of Organon Common Stock equal to (1) (xx) the number of units subject to the earned Merck PSU Award immediately prior to the Distribution Date (as determined pursuant to the foregoing sentence) multiplied by (yy) the Distribution Ratio, multiplied by (2) the Organon Conversion Ratio, rounded to the nearest unit. Such Organon RSU Award shall be (in all other respects, including time-based vesting) subject to substantially the same terms and conditions immediately following the Distribution Date as applicable to the Merck PSU Award from which it was converted. Any portion of such Merck PSU Award that is not earned shall be immediately forfeited as of the Distribution Date without the payment of any consideration therefore.

(iii) Merck RSU Awards. Each Merck RSU Award that remains outstanding as of immediately prior to the Distribution Date, regardless of by whom held, whether vested or unvested, shall be converted concurrently with the Distribution on the Distribution Date into (A) an Adjusted Merck RSU Award in the case of Merck Employees, Post-Distribution Organon Employees and Former Employees or (B) an Organon RSU Award in the case of Organon Employees (other than Post-Distribution Organon Employees). Except as set forth in this Section 6.01(a)(iii), all Adjusted Merck RSU Awards and Organon RSU Awards issued in accordance with this Section 6.01(a)(iii) shall be subject to substantially the same terms and conditions (including with respect to vesting) immediately following the Distribution Date as applicable immediately prior to the Distribution Date for those Merck RSU Awards from which such Adjusted Merck RSU Awards and Organon RSU Awards were converted; provided, however, that upon such adjustment or conversion:

(A) the number of units represented by an Adjusted Merck RSU Award shall be equal to (1) the number of units subject to the Merck RSU Award immediately prior to the Distribution Date, multiplied by (2) the Merck Conversion Ratio, rounded to the nearest unit; and

(B) the number of units represented by an Organon RSU Award shall be equal to (1) (xx) the number of units subject to the Merck RSU Award immediately prior to the Distribution Date multiplied by (yy) the Distribution Ratio, multiplied by (2) the Organon Conversion Ratio, rounded to the nearest unit.

(iv) Notwithstanding the foregoing, the Parties may mutually agree not to adjust (or to otherwise adjust as they deem appropriate) certain outstanding Merck equity-based awards pursuant to the foregoing provisions of this Section 6.01 to the extent such actions would create or trigger adverse legal, accounting, administrative, tax consequences or in order to comply with any Employee Agreement or similar agreement with any affected Employee.

(b) Miscellaneous Award Terms. After the Distribution Date, Adjusted Merck Awards, regardless of by whom held, shall be settled by Merck, and Organon Awards, regardless of by whom held, shall be settled by Organon. Except as otherwise provided in this Agreement, with respect to grants described in this Section 6.01, no Transferred Employee (other than a Post-Distribution Organon Employee) shall be treated as having incurred a termination of employment or separation from service with respect to any Merck Award solely by reason of his or her transfer of employment. Following the Distribution Date, for any award adjusted or otherwise received in accordance with this Section 6.01, any reference to a “change in control,” “change of control” or similar definition in an award agreement, employment agreement or Merck Stock Program applicable to such award (A) with respect to Adjusted Merck Awards, shall be deemed to refer to a “change in control,” “change of control” or similar defined term as set forth in the applicable award agreement, employment agreement or Merck Stock Program (a “Merck Change of Control”) and (B) with respect to Organon Awards, shall be deemed to refer to a “change in control,” “change of control” or similar defined term as set forth in the Organon Equity Plan (a “Organon Change of Control”). The Distribution shall not, in and of itself, be treated as either a Merck Change of Control or an Organon Change of Control.

(c) Registration and Other Regulatory Requirements. As soon as possible following (or prior to) the Distribution Date, but in any case before the date of issuance of any shares of Organon Common Stock pursuant to the Organon Equity Plan, Organon agrees to file a Form S-8 Registration Statement (or such other registration statement as may be permitted in lieu thereof if a Form S-8 Registration Statement is not then available for any such awards to be granted in accordance with the terms of this Agreement) with respect to, and to cause to be registered pursuant to the Securities Act, the shares of Organon Common Stock authorized for issuance under the Organon Equity Plan as required pursuant to the Securities Act. The Parties shall take such additional actions as are deemed necessary or advisable to effectuate the foregoing provisions of this Section 6.01, including compliance with securities Laws and other legal requirements associated with equity compensation awards in affected non-U.S. jurisdictions.

(d) Merck Equity-Based Awards in Certain Non-U.S. Jurisdictions. Notwithstanding the foregoing provisions of this Section 6.01, the Parties may mutually agree, in their sole discretion (including as set forth in Schedule 6.01(d)), not to adjust certain outstanding Merck equity-based awards pursuant to the foregoing provisions of this Section 6.01, where those actions would create or trigger adverse legal, accounting or tax consequences for Merck, Organon, and/or the affected non-U.S. award holders. In such circumstances, Merck and/or Organon may take any action necessary or advisable to prevent any such adverse legal, accounting or tax consequences, including, but not limited to, agreeing that the outstanding Merck equity-based awards of the affected non-U.S. award holders shall terminate in accordance with the terms of the Merck Stock Programs and the underlying award agreements, in which case Organon or Merck, as applicable, shall equitably compensate the affected non-U.S. award holders in an alternate manner determined by Organon or Merck, as applicable, in its sole discretion, or apply an alternate adjustment method. Where and to the extent required by applicable Law or tax considerations outside the United States, the adjustments described in this Section 6.01 shall be deemed to have been effectuated immediately prior to the Distribution Date.

Section 6.02 Annual Bonus. The Organon Group shall be responsible for all annual bonus payments or other forms of cash incentive compensation (including commissions) payable to Transferred Employees (including Post-Distribution Organon Employees) the performance period for which ends after the applicable Transferred Employee's Transfer Date. For the avoidance of doubt, the Merck Group shall have no obligation or responsibility to pay such amounts to such Transferred Employees (including Post-Distribution Employees) in respect of any portion of such performance period and annual bonus payments or other forms of cash incentive compensation (including commissions) for such full performance period shall be the sole obligation and responsibility of the Organon Group pursuant to the final applicable program terms and conditions established and administered by the Organon Group. The Merck Group shall be responsible for any annual bonus payments or other forms of cash incentive compensation payable to Transferred Employees (including Post-Distribution Organon Employees) the performance period for which ends on or prior to the applicable Transferred Employee's Transfer Date.

Section 6.03 Merck Deferred Stock Units. Each outstanding Merck Deferred Stock Unit shall be adjusted or converted as set forth in this Section 6.03. For the avoidance of doubt, the remainder of this Section 6.03 applies only to grants made under the Merck Directors' DCP (or any successor or predecessor plan), while Section 6.01 is intended to apply to other programs included within the Merck Stock Programs. Each holder of a Merck Deferred Stock Unit that remains outstanding as of immediately prior to the Distribution Date (regardless of by whom held, whether vested or unvested), shall be converted concurrently with the Distribution on the Distribution Date into an Adjusted Merck Deferred Stock Unit Award. Except as set forth in this Section 6.03(a), all Adjusted Merck Deferred Stock Unit Awards issued in accordance with this Section 6.03(a) shall be subject to substantially the same terms and conditions (including with respect to vesting) immediately following the Distribution Date as applicable immediately prior to the Distribution Date for those Merck Deferred Stock Units from which such Adjusted Merck Deferred Stock Unit Awards were converted; provided, however, that with respect to each Merck Deferred Stock Unit converted in accordance with the immediately preceding sentence the number of units represented by an Adjusted Merck RSU Award (if any) shall be equal to (1) the number of units subject to the Merck Deferred Stock Unit immediately prior to the Distribution Date, multiplied by (2) the Merck Conversion Ratio, rounded to the nearest unit. To the maximum extent permitted by Treasury Regulations Section 1.409A-1(h)(4), a member of the Merck Board who no longer serves on the Merck Board immediately following the Distribution Date shall be considered to have undergone a "separation from service" for purposes of Code Section 409A and the Merck Directors' DCP.

Section 6.04 Directors' Deferred Compensation Plan.

(a) Retention of Directors' DCP Liabilities. Merck shall retain all of the Liabilities under the Merck Directors' DCP following the Distribution Date. To the maximum extent permitted by Treasury Regulations Section 1.409A-1(h)(4), a member of the Merck Board who no longer serves on the Merck Board immediately following the Distribution Date shall be considered to have undergone a "separation from service" for purposes of Code Section 409A and the Merck Directors' DCP.

(b) Merck Directors' DCP after Transfer Date. From and after the Distribution Date, each person who no longer serves on the Merck Board, as of immediately following the Distribution Date, shall not accrue any additional benefits under the Merck Directors' DCP.

ARTICLE VII

POST-DISTRIBUTION COVENANTS

Section 7.01 Non-Hire; Non-Solicit.

(a) To the fullest extent permitted by applicable Law, from the Distribution Date through the first anniversary of the Distribution Date, Organon shall not, and shall cause the Organon Group not to, recruit, solicit or hire (whether as an employee, consultant, contractor or

otherwise) any individual who was an Employee of the Merck Group as of or within six months prior to the Distribution Date and who both (i) rejected any offer of employment made by the Organon Group in connection with the Separation and Distribution and (ii) received severance payments in connection with the termination of their employment with the Merck Group, for a position that is the same as or similar to such previously rejected position.

(b) Organon specifically acknowledges and agrees that this provision does not impede the Organon Group from competing in the marketplace or obtaining sufficient talent to effectively innovate, develop, grow, or sustain its business.

(c) The Parties further specifically acknowledge and agree that any remedy at law for any breach of this Section 7.01 shall be inadequate and that in the event of any actual or threatened breach of this Section 7.01, the non-breaching party, in addition to any other relief available to it, shall be entitled to temporary and permanent injunctive relief without the necessity of proving actual damage.

(d) The Parties specifically acknowledge and agree that an exception may be made to this provision at the sole discretion and with the written consent of Organon's Chief Human Resources Officer. Any exception made shall not be used as precedent to compel or allow any further exceptions.

ARTICLE VIII

TAXES

Section 8.01 Reporting, Withholding and Deductions. Unless otherwise provided under this Agreement, the Party that has been allocated a Liability under this Agreement shall take responsibility for tax reporting and withholding (including paying any corresponding employer tax obligation and remitting both the employer taxes and the withheld taxes) with respect to that Liability, and shall be entitled to claim the benefit of any corresponding tax deductions on an applicable income tax return. The Party with responsibility for reporting and withholding shall prepare all associated Tax Returns (as defined in the Tax Matters Agreement) and shall be Liable and shall indemnify and hold harmless the other Party for any Taxes (as defined in the Tax Matters Agreement), including interest, penalties, additions to Tax, or additional amounts in respect of Taxes. The Party responsible for preparing and filing the required Tax Returns shall be determined as set forth in Sections 3.1 and 3.3 of the Tax Matters Agreement, and each Party shall provide to the other Party all information and assistance requested to fulfill the obligations set forth herein applying the standards set forth in Section 3.2 of the Tax Matters Agreement.

For the avoidance of doubt, the allocation of Tax deductions in this Section 8.01 shall be taken into account for purposes of the allocation of Tax Attributes under Section 2.10 of the Tax Matters Agreement and for purposes of all other provisions of the Tax Matters Agreement relating to Income Taxes, including Section 2.2 (Allocation of Income Taxes), Section 2.6 (Determination of Tax Attributable to Merck Business and Organon Business), Section 2.9 (Carrybacks and Claims for Refund), and Article III (Tax Returns, Tax Contests, and Other Administrative Matters) of the Tax Matters Agreement.

(a) Qualified Retirement Plans. Unless otherwise required by non-U.S. law, where applicable, Merck will report and withhold, as necessary, on distributions with respect to Liabilities it retains with respect to Merck Employees, Former Employees, and Organon Employees under the Merck Pension Plan under Section 3.01 of this Agreement. Merck shall be entitled to claim the benefit of any tax deductions for amounts it contributes to the Merck Pension Plan.

(b) Nonqualified Retirement Plans. Unless otherwise required by non-U.S. law, where applicable, Merck will report and withhold, as necessary, on Merck SERP and Merck DCP distributions with respect to Liabilities it retains under Sections 3.03 and 3.04(b) with respect to Merck Employees, Former Employees, and Organon Employees. Merck shall be entitled to claim the benefit of any tax deductions with respect to the amounts paid under such plans.

(c) Health and Welfare Plans. Unless otherwise required by non-U.S. law, where applicable, Merck shall be entitled to claim the benefit of any tax deductions with respect to amounts contributed to fund obligations to Transferred Employees and Former Employees under Section 5.01(d) under the Merck Retiree Health Care Plan on the applicable income tax return.

(d) Equity Compensation. Unless otherwise required by non-U.S. law, where applicable, Merck shall report and withhold on any Adjusted Merck Options, Adjusted Merck PSU Awards, and Adjusted Merck RSU Awards and Organon shall report and withhold on any Organon Options and Organon RSU Awards. The entity that transfers its stock shall be entitled to claim the benefit of any tax deduction on any applicable income tax returns.

(e) Annual Bonus. Unless otherwise required by non-U.S. law, where applicable, the 2021 annual bonuses paid to Transferred Employees by the Organon Group shall be reported and withheld upon by Organon. Organon shall be entitled to claim the benefit of any tax deduction of such payments on any applicable income tax returns.

ARTICLE IX

MISCELLANEOUS

Section 9.01 Transfer of Records and Information. Merck shall transfer to Organon originals or copies of employment records and information with respect to Transferred Employees that are reasonably required by Organon to enable Organon properly to carry out its obligations under this Agreement. Such transfer of records and information generally shall occur as soon as administratively practicable on or after the Distribution Date (or, if later, the applicable Transfer Date) and shall in each case be required and shall occur only to the extent permitted by applicable local Law; provided that it is understood and agreed that certain records required to effect the contemplated transfer of employment may be provided prior to the Transfer Date to the extent required by applicable local Law. Each Party will permit the other Party reasonable access to Employee records and information, to the extent reasonably necessary for such accessing Party to carry out its obligations hereunder.

Section 9.02 Cooperation. Each Party shall upon reasonable request provide the other Party and the other Party's respective Affiliates, agents, and vendors all information reasonably necessary to the other Party's performance of its obligations hereunder. The Parties agree to use their respective best efforts and to cooperate with each other in order to carry out their obligations hereunder and to effectuate the terms of this Agreement.

Section 9.03 Employee Agreements. Effective as of the applicable Transfer Date of each Transferred Employee, or such earlier date as may be required by applicable Law, Merck and the applicable members of the Merck Group hereby assign to Organon or another member of the Organon Group, to the extent a Transferred Employee did not otherwise sign an Employee Agreement to affect his or her transfer to and hiring by the Organon Group, each Employee Agreement entered into between a member of the Merck Group and any Organon Employee, and all rights and obligations thereunder; provided, however, that Merck and the Merck Group shall retain all rights under each Employee Agreement to the extent that such rights are related to any continuing Liability of the Merck Group not assumed by Organon in connection with the Separation and Distribution.

Section 9.04 Recoupment Assets. Effective as of the Distribution Date, the Merck Group shall be entitled to all Employee Recoupment Assets in respect of Merck Retained Employees and all Former Employees. The Organon Group shall be entitled to all Employee Recoupment Assets in respect of Organon Employees, effective as of the applicable Transfer Date.

Section 9.05 Compliance. The agreements and covenants of the Parties hereunder shall at all times be subject to the requirements and limitations of applicable Law (including, for purposes of Article IV, local rules and customs relating to the treatment of pension plans) and collective bargaining, works council, or other similar agreements. Where an agreement or covenant of a Party hereunder cannot be effected in compliance with applicable Law or an applicable collective bargaining, works council, or other similar agreement, the Parties agree to negotiate in good faith to modify such agreement or covenant to the least extent possible in keeping with the original agreement or covenant in order to comply with applicable Law or such applicable collective bargaining agreement. Each provision of this Agreement is subject to and qualified by this Section 9.05, whether or not such provision expressly states that it is subject to or limited by applicable Law or by applicable collective bargaining, works council, or other similar agreements. Each reference to the Code, ERISA, or the Securities Act or any other Law shall be deemed to include the rules, regulations, and guidance issued thereunder.

Section 9.06 Preservation of Rights. Unless expressly provided otherwise in this Agreement, nothing herein shall be construed as a limitation on the right of the Merck Group or the Organon Group to (a) amend, modify or terminate any Benefit Plan or (b) terminate the employment of any Employee.

Section 9.07 Reimbursement. The Parties acknowledge that the Merck Group, on the one hand, and the Organon Group, on the other hand, may incur costs and expenses (including, without limitation, contributions to Benefit Plans and the payment of insurance premiums) which are, as set forth in this Agreement, the responsibility of the other Party. Accordingly, the Parties agree to reimburse each other for Liabilities and obligations for which such Party is responsible, and shall provide such reimbursement reasonably promptly and in accordance with the terms of any agreement between the Parties or their Affiliates expressly addressing such matters.

Section 9.08 Not a Change in Control. The Parties acknowledge and agree that the transactions contemplated by the Separation and Distribution Agreement and this Agreement do not constitute a “change in control” or a “change of control” for purposes of any U.S. Benefit Plan.

Section 9.09 Incorporation by Reference. The following sections of the Separation and Distribution Agreement are hereby incorporated into this Agreement by reference: Section 10.01. Counterparts, Entire Agreement, Corporate Power, Facsimile or Electronic Signatures; Section 10.02. Governing Law; Section 10.03. Assignability; Section 10.04. Third Party Beneficiaries; Section 10.05. Notices; Section 10.06. Severability; Section 10.07. Force Majeure; Section 10.08. No Set Off; Section 10.09. Responsibility for Expenses; Section 10.10. Headings; Section 10.11. Survival of Covenants; Section 10.12. Subsidiaries and Employees; Section 10.13. Waivers; Section 10.14. Amendments; Section 10.15. Interpretation; Section 10.16. Public Announcements; Section 10.17. Specific Performance; and Section 10.18. Mutual Drafting.

Section 9.10 Limitation on Enforcement. This Agreement is an agreement solely between the Parties. Nothing in this Agreement, whether express or implied, shall be construed to: (a) confer upon any current or former Employee of the Merck Group or the Organon Group, or any other person any rights or remedies, including, but not limited to any right to (i) employment or recall; (ii) continued employment or continued service for any specified period; or (iii) claim any particular compensation, benefit or aggregation of benefits, of any kind or nature; or (b) create, modify, or amend any Benefit Plan.

Section 9.11 Further Assurances and Consents. In addition to the actions specifically provided for elsewhere in this Agreement, each of the Parties hereto shall use commercially reasonable efforts to (a) execute and deliver such further instruments and documents and take such other actions as the other party may reasonably request to effectuate the purposes of this Agreement and carry out the terms hereof; (b) take, or cause to be taken, all actions, and do, or cause to be done, all things, reasonably necessary, proper or advisable under applicable Laws and agreements or otherwise to consummate and make effective the transactions contemplated by this Agreement, including, without limitation, using commercially reasonable efforts to obtain any consents and approvals and to make any filings and applications necessary or desirable to consummate the transactions contemplated by this Agreement; provided that no Party shall be obligated to pay any consideration therefor (except for filing fees and other similar charges) to any third party from whom those consents, approvals and amendments are required or to take any action or omit to take any action if the taking of action or the omission to take action would be unreasonably burdensome to the Party or the business thereof.

Section 9.12 Third Party Consent. If the obligation of any Party under this Agreement depends on the consent of a third party, such as a vendor or insurance company, and that consent is withheld, the Parties shall use commercially reasonable efforts to implement the applicable provisions of this Agreement to the fullest extent practicable. If any provision of this Agreement cannot be implemented due to the failure of a third party to consent, the Parties shall negotiate in good faith to implement the provision in a mutually satisfactory manner, taking into account the original purposes of the provision in light of the Spin-Off and communications to affected individuals.

Section 9.13 Effect if Distribution Does Not Occur. If the Spin-Off does not occur, then all actions and events that are to be taken under this Agreement, or otherwise in connection with the Distribution, shall not be taken or occur, except to the extent specifically provided by Merck.

Section 9.14 Disputes. The Parties agree to use commercially reasonable efforts to resolve in an amicable manner any and all controversies, disputes and claims between them arising out of or related in any way to this Agreement. The Parties agree that any controversy, dispute or claim (whether arising in contract, tort or otherwise) arising out of or related in any way to this Agreement that cannot be amicably resolved informally will be resolved pursuant to the dispute resolution procedures set forth in Article VIII of the Separation and Distribution Agreement.

[SIGNATURE PAGE FOLLOWS]

The Parties have caused this Agreement to be signed by their authorized representatives as of the date of this Agreement.

Merck & Co., Inc.

By: _____

Title:

Organon & Co.

By: _____

Title:

[Signature Page to Employee Matters Agreement]

ORGANON & CO.
2021 INCENTIVE STOCK PLAN
(Effective May 24, 2021)

1. PURPOSE

The Plan is established to encourage employees of the Company, its subsidiaries, its affiliates and its joint ventures to acquire common stock in the Company. The Plan shall be available to provide Incentives, including cash incentives, to Eligible Employees of the Company, its subsidiaries, its affiliates and its joint ventures, as provided under the terms of the Plan. It is believed that the Plan will serve the interests of the Company and its stockholders because it allows service providers to have a greater personal financial interest in the Company through ownership of, or the right to acquire the Company's Common Stock and to earn cash incentives based on the achievement of performance goals, which in turn will stimulate such individuals' efforts on the Company's behalf and maintain and strengthen their desire to remain with the Company. It is believed that the Plan also will assist in the recruitment and retention of service providers of the Company, its subsidiaries, its affiliates and its joint ventures.

2. DEFINITIONS

"Award Period" has the meaning set forth in Section 10(a).

"Board of Directors" means the Board of Directors of the Company.

"Change in Control" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

- (a) any Person becomes the owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities or (C) solely because the level of ownership held by any Person (the "**Subject Person**") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

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- (b) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not own, directly or indirectly, either (A) outstanding voting securities representing 50% or more of the combined outstanding voting power of the surviving entity in such merger, consolidation or similar transaction or (B) 50% or more of the combined outstanding voting power of the parent of the surviving entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their ownership of the outstanding voting securities of the Company immediately prior to such transaction;
 - (c) there is consummated a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than 50% of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or
 - (d) individuals who, on the Effective Date, are members of the Board of Directors (the “**Incumbent Board**”) cease for any reason to constitute at least a majority of the members of the Board of Directors; provided, however, that if the appointment or election (or nomination for election) of any new Board of Directors member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing definition or any other provision of this Plan, (A) the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, and (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any affiliate and the Eligible Employee will supersede the foregoing definition with respect to Incentives subject to such agreement; provided, however, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply.

If required for compliance with Section 409A of the Code, in no event will a Change in Control be deemed to have occurred if such transaction is not also a “change in the ownership or effective control of” the Company or “a change in the ownership of a substantial portion of the assets of” the Company as determined under U.S. Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder). The Board of Directors may, in its sole discretion and without an Eligible Employee’s consent, amend the definition of “Change in Control” to conform to the definition of “Change in Control” under Section 409A of the Code, and the regulations thereunder.

“Code” means the Internal Revenue Code of 1986, as amended.

“Committee” means the Talent Committee of the Board of Directors of the Company or subcommittee thereof, or such other successor committee of the Board of Directors.

“Common Stock” means the common stock, \$0.01 par value per share, of the Company and any other securities into which such shares are changed or for which such shares are exchanged.

“Company” means Organon & Co., a Delaware corporation.

“Eligible Employees” shall have the meaning set forth in Section 4(a).

“Employee” means a person employed on a regular full-time or part-time basis by the Company, or its subsidiaries, its affiliates or its joint ventures, including officers, whether or not directors of the Company, and employees of a joint venture partner or affiliate of the Company who provide services to the joint venture with such partner or affiliate. The term “Employee” shall not include any of the following: a person who is an independent contractor, or agrees or has agreed that he/she is an independent contractor of the Company; a person who has any agreement or understanding with the Company, or any of its affiliates or joint venture partners that he/she is not an employee or an Eligible Employee, even if he/she previously had been an employee or Eligible Employee; or a person who is employed by a temporary or other employment agency, regardless of the amount of control, supervision or training provided by the Company or its affiliates; a “leased employee” as defined under Section 414(n) of the Code, in each case, even if a court, agency or other authority rules that he/she is a common-law employee of the Company or its affiliates.

“Exchange Act” means the Securities Exchange Act of 1934, as amended.

“Fair Market Value” means as of any date, unless otherwise determined by the Committee the value of the Common Stock determined as follows: (i) if the Common Stock is listed on any established stock exchange, system or market, its Fair Market Value shall be the closing price for the Common Stock as quoted on such exchange, system or market as reported in the Wall Street Journal or such other source as the Committee deems reliable (or, if no sale of Common Stock is reported for such date, on the next preceding date on which any sale shall have been reported); and (ii) in the absence of an established market for the Common Stock, the Fair Market Value thereof shall be determined in good faith by the Committee by the reasonable application of a reasonable valuation method, taking into account factors consistent with Treas. Reg. § 409A-1(b)(5)(iv)(B) as the Committee deems appropriate.

“Incentive Stock Option” or **“ISO”** means a stock option satisfying the requirements of Section 422 of the Code and designated by the Committee as an Incentive Stock Option.

“Incentive” means a grant of Stock Options, Stock Appreciation rights, Restricted Stock Grants, Performance Awards, Share Awards, Phantom Stock Awards, and cash or any or all of them.

“Nonqualified Option” means a stock option that is not an Incentive Stock Option.

“Performance Shares” means an award denominated in shares granted to an Eligible Employee under Section 10.

“Performance Awards” means Performance Units or Performance Shares or either or both of them.

“Performance Goals” has the meaning set forth in Section 10(a).

“Performance Units” means an award denominated in shares of Common Stock or cash granted to an Eligible Employee under Section 10.

“Person” means any individual, corporation, partnership, association, limited liability company, joint-stock company, trust or unincorporated organization.

“Phantom Stock Award” means an award of phantom shares of Common Stock granted to an Eligible Employee under Section 12.

“Plan” means this Organon & Co. 2021 Incentive Stock Plan, as amended from time to time.

“Restricted Period” has the meaning set forth in Section 11.

“Restricted Stock” means shares of Common Stock issued or transferred to an Eligible Employee under Section 11.

“Restricted Stock Grants” has the meaning set forth in Section 11.

“Restricted Stock Units” means a right granted to an Eligible Employee under Section 11 representing a number of phantom shares of Common Stock.

“Section 16 Officer” means an individual who serves as an “officer” of the Company as such term is defined in Rule 16(a)-1(f) of the Exchange Act.

“Securities Act” means the Securities Act of 1933, as amended.

“Share Award” means an award of actual shares of Common Stock granted to an Eligible Employee under Section 12.

“Spread” shall have the meaning set forth in Section 9(b).

“Stand Alone SAR” means a Stock Appreciation Right granted without an underlying Stock Option as provided in Section 9.

“Stock Appreciation Right” means a right to receive the appreciation in the Fair Market Value of shares of Common Stock, as provided in Section 9.

“Stock Option” means a Nonqualified Option or an Incentive Stock Option, or either or both of them.

“Substitute Incentive” means an Incentive granted in assumption of, or in substitution or exchange for, awards previously granted, or the right or obligation to make future awards, in each case by a company acquired by the Company or any subsidiary or affiliate with which the Company or any subsidiary or affiliate combines.

“Successor Incentive” shall have the meaning set forth in Section 25(a).

“Tandem SAR” means a Stock Appreciation Right granted with respect to an underlying Stock Option as provided in Section 9.

“Ten Percent Stockholder” means a person who owns (or is deemed to own pursuant to Section 424(d) of the Code) stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or any “parent” or “subsidiary of the Company, as such terms are defined in Rule 405 of the Securities Act.

3. ADMINISTRATION

The Plan shall be administered by the Committee or any designated subcommittee thereof (and references in this Plan to the Committee shall be to such subcommittee, acting in accordance with their governing documents). A Director may serve on the Committee only if he or she is a “Non-Employee Director” of the Company for purposes of Rule 16b-3 under the Exchange Act. The Committee shall be responsible for the administration of the Plan including, without limitation, determining which Eligible Employees receive Incentives, the types of Incentives they receive under the Plan, the number of shares covered by Incentives granted under the Plan, and the other terms and conditions of such Incentives. Determinations by the Committee under the Plan 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.

The Committee shall have the responsibility of construing and interpreting the Plan and any instrument or agreement relating to the Plan, including but not limited to, the right to correct any defect or supply any omission, construe disputed or doubtful provisions, reconcile any inconsistency in the Plan or in any related instrument or agreement, and of establishing, amending, rescinding and construing such rules and regulations as it may deem necessary or desirable for the proper administration of the Plan, related instrument or agreement. 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 the Plan, related instrument or agreement, and the Plan’s rules and regulations, 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.

The Committee, as permitted by applicable state law, may delegate to one or more officers of the Company any or all of its power and authority hereunder, including the authority to do one or both of the following: (i) designate Eligible Employees who are not Section 16 Officers or Directors to receive Incentives and the terms of such Incentives; and (ii) determine the number of shares of Common Stock, if any, subject to such Incentives; *provided, however*, that the Committee resolutions regarding such delegation will specify the total number of shares of Common Stock that may be subject to the Incentives granted by such delegate and such delegate may not grant any Incentive to himself or herself; *and provided further*, that such officer of the Company may further delegate such authority in accordance with the Company's policy on delegation of authority.

For the purpose of this section and all subsequent sections, the Plan shall be deemed to include this Plan and any comparable sub-plans established by subsidiaries which, in the aggregate, shall constitute one Plan governed by the terms set forth herein.

4. ELIGIBILITY

- (a) **Employees.** Employees shall be eligible to participate in the Plan if designated by the Committee ("**Eligible Employees**").
- (b) **No Right To Continued Employment.** Nothing in the Plan shall interfere with or limit in any way the right of the Company, its subsidiaries, its affiliates or its joint ventures to terminate the employment of any person at any time, nor confer upon any person the right to continue in the employ of the Company, its subsidiaries, its affiliates or its joint ventures. No Eligible Employee shall have a right to receive an Incentive or any other benefit under this Plan or having been granted an Incentive or other benefit, to receive any additional Incentive or other benefit. Neither the award of an Incentive nor any benefits arising under such Incentives shall constitute an employment contract with the Company, its subsidiaries, its affiliates or its joint ventures, and accordingly, this Plan and the benefits hereunder may be terminated at any time in the sole and exclusive discretion of the Company without giving rise to liability on the part of the Company, its subsidiaries, its affiliates or its joint ventures for severance. Except as may be otherwise specifically stated in any other employee benefit plan, policy or program, neither any Incentive under this Plan nor any amount realized from any such Incentive shall be treated as compensation for any purposes of calculating an employee's benefit under any such plan, policy or program.

5. TERM OF THE PLAN

This Plan was approved by the Board of Directors and the sole stockholder of the Company on May 24, 2021, and is effective as of that same day (the "**Effective Date**"). No Incentive that is an Incentive Stock Option shall be granted under the Plan following the tenth anniversary of the Effective Date (or such earlier date that the Plan may be terminated by the Board of Directors), but the term and exercise of Incentives granted theretofore may extend beyond such expiration date.

6. INCENTIVES

Incentives under the Plan may be granted in any one or a combination of (a) Incentive Stock Options, (b) Nonqualified Options, (c) Stock Appreciation Rights, (d) Restricted Stock Grants, (e) Performance Awards, (f) Share Awards, (g) Phantom Stock Awards, and (h) cash. All Incentives shall be subject to the terms and conditions set forth herein and to such other terms and conditions as may be established by the Committee. Notwithstanding anything to the contrary, any Incentives granted to an individual who is not an Eligible Employee or otherwise in error shall be void *ab initio*.

7. SHARES AVAILABLE FOR INCENTIVES

- (a) **Shares Available.** Subject to adjustment as described in subsection (b), the maximum number of shares of Common Stock that may be issued under the Plan is 35,000,000 (the “Share Reserve”). No more than an aggregate of 35,000,000 shares may be issued as Incentive Stock Options during the term of the Plan. For the avoidance of doubt, any stock options, performance share units or restricted share units of Merck & Co., Inc. (“Merck”) converted into Company Incentives in connection with the separation of the Company’s business from Merck in accordance with the terms and conditions of that certain Employee Matters Agreement dated as of June 2, 2021 by and between Merck and the Company shall count against the Share Reserve.
- (i) The following shares of Common Stock shall be added to the maximum share limitation described in the first sentence of paragraph (a): (1) shares tendered or withheld by the Company in payment of all or part of the exercise price of a Stock Option; (2) shares tendered or withheld by the Company to satisfy all or part of the tax withholding obligation of an Incentive on the vesting or exercise thereof; and (3) shares not issued upon exercise of all or a portion of a Stock Appreciation Right that is settled in shares. Shares under this Plan may be delivered by the Company from its authorized but unissued shares of Common Stock or from issued and reacquired Common Stock held as treasury stock, or both. In no event shall fractional shares of Common Stock be issued under the Plan. For purposes of determining the number of shares of Common Stock remaining available for issuance under the Plan, only Incentives payable in shares of Common Stock shall be counted.
- (ii) In the event that a company acquired by the Company or any subsidiary or affiliate or with which the Company or any subsidiary or affiliate combines has shares available under a pre-existing plan approved by stockholders and not adopted in contemplation of such acquisition or combination, the shares available for issuance pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Incentives and shall not be counted as issued for purposes of determining the number of shares remaining available for issuance under the first sentence of this paragraph (a); provided that such Incentives shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not employees or directors of the Company or any subsidiary or affiliate prior to such acquisition or combination.

(iii) The following shares of Common Stock relating to Incentives are not counted as issued for purposes of determining the number of shares remaining available for issuance under the Plan:

- (1) Shares of Common Stock subject to an Incentive that is settled in cash in lieu of shares;
- (2) Shares of Common Stock subject to an Incentive that expires, is forfeited, cancelled or terminates for any reason without issuance of shares;
- (3) Shares of Common Stock subject to a Substitute Incentive; and
- (4) Shares of Restricted Stock that are forfeited and returned to the Company upon a participant's termination of employment.

(b) **Adjustment of Shares.** In the event of a reorganization, recapitalization, reclassification, stock split or reverse stock split, stock dividend, extraordinary cash dividend, combination or exchange of shares, repurchase of shares, merger, consolidation, rights offering, spin off, split off, split up, change in corporate structure, or other event identified by the Committee, the Committee shall make such equitable adjustments, in a manner it may deem appropriate, in (i) the number and kind of shares authorized for issuance under the Plan, (ii) the number and kind of shares subject to outstanding Incentives, (iii) the option price of Stock Options, (iv) the grant price of Stock Appreciation Rights; and (v) the terms and conditions of any outstanding Incentives (including, without limitation, any applicable performance targets or criteria with respect thereto). Any such determination shall be final, binding and conclusive on all parties.

8. STOCK OPTIONS

The Committee may grant options qualifying as ISOs and Nonqualified Options. Such Stock Options shall be subject to the following terms and conditions and such other terms and conditions as the Committee may prescribe:

(a) **Stock Option Price.** The option price per share with respect to each Stock Option shall be determined by the Committee, but shall not be less than 100 percent of the Fair Market Value of the Common Stock on the date the Stock Option is granted other than Stock Options that are Substitute Incentives, as determined by the Committee. Notwithstanding the foregoing, a Ten Percent Stockholder will not be granted an ISO unless the exercise price of the ISO is at least 110 percent of the Fair Market Value of the Common Stock on the date the ISO is granted.

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- (b) **Period of Stock Option.** The period of each Stock Option shall be fixed by the Committee, provided that the period for all Stock Options shall not exceed ten years from the grant, provided further, however, that, (i) in the event of the death of an Optionee prior to the expiration of a Nonqualified Option, such Nonqualified Option may, if the Committee so determines, be exercisable for up to 11 years from the date of the grant, (ii) the Committee may provide in a grant agreement that the term of any Stock Option shall be extended during any period that such Stock Option may not be exercised under any applicable law or during an applicable blackout period, and (iii) an ISO granted to a Ten Percent Stockholder will not be exercisable after the expiration of five years from the date of grant. The Committee may, subsequent to the granting of any Stock Option, extend the term thereof, but in no event shall the extended term exceed ten years from the original grant date (11 in case of a grantee's death).
- (c) **Exercise of Stock Option and Payment Thereof.** No shares shall be issued until full payment of the option price has been made. The option price may be paid in cash or, if the Committee determines, in shares of Common Stock (by tendering previously acquired Shares, either actually or by attestation, or by the Company withholding shares otherwise issuable in connection with the exercise of the Option), a combination of cash and shares of Common Stock, or through a cashless exercise procedure that allows grantees to sell immediately some or all of the shares underlying the exercised portion of the Option in order to generate sufficient cash to pay the option price. If the Committee approves the use of shares of Common Stock as a payment method, the Committee shall establish such conditions as it deems appropriate for the use of Common Stock to exercise a Stock Option. Stock Options awarded under the Plan shall be exercised through such procedure or program as the Committee may establish or define from time to time, which may include a designated broker that must be used in exercising such Stock Options.
- (d) **First Exercisable Date.** The Committee shall determine how and when shares covered by a Stock Option may be purchased. The Committee may establish waiting periods, the dates on which Stock Options become exercisable or non-forfeitable and, subject to paragraph (b) of this section, exercise periods. The Committee may accelerate the exercisability of any Stock Option or portion thereof.
- (e) **Termination of Employment.** Unless determined otherwise by the Committee, upon the termination of a Stock Option grantee's employment (for any reason other than gross misconduct), Stock Option privileges shall be limited to the shares that were immediately exercisable at the date of such termination. The Committee, however, in its discretion, may provide that any Stock Options outstanding but not yet exercisable upon the termination of a Stock Option grantee's employment may become exercisable in accordance with a schedule determined by the Committee. Such Stock Option privileges shall expire unless exercised within such period of time after the date of termination of employment as may be established by the Committee, but in no event later than the expiration date of the Stock Option.

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- (f) **Termination Due to Misconduct.** If a Stock Option grantee's employment is terminated for gross misconduct, as determined by the Company, all rights under the Stock Option shall expire upon the date of such termination.
 - (g) **Limits on ISOs.** Except as may otherwise be permitted by the Code, an Eligible Employee may not receive a grant of ISOs for stock that would have an aggregate Fair Market Value in excess of \$100,000 (or such other amount as the Internal Revenue Service may decide from time to time), determined as of the time that the ISO is granted, that would be exercisable for the first time by such person during any calendar year. If any grant is made in excess of the limits provided in the Code, such grant shall automatically become a Nonqualified Option. In addition, ISOs may only be granted to Employees of the Company and its subsidiaries.
 - (h) **Dividends.** Anything in the Plan to the contrary notwithstanding, no dividends or dividend equivalents may be paid on Stock Options.

9. STOCK APPRECIATION RIGHTS

The Committee may, in its discretion, grant a Stock Appreciation Right either singly or in combination with an underlying Stock Option granted hereunder. Such Stock Appreciation Right shall be subject to the following terms and conditions and such other terms and conditions as the Committee may prescribe:

- (a) **Time and Period of Grant.** If a Stock Appreciation Right is granted as a Tandem SAR, it may be granted at the time of the Stock Option grant or at any time thereafter but prior to the expiration of the Stock Option grant. At the time the Tandem SAR is granted the Committee may limit the exercise period for such Stock Appreciation Right, before and after which period no Stock Appreciation Right shall attach to the underlying Stock Option. In no event shall the exercise period for a Tandem SAR exceed the exercise period for such Stock Option. If a Stock Appreciation Right is granted as a Stand Alone SAR the period for exercise of the Stock Appreciation Right shall be set by the Committee. The maximum term of a Stand Alone SAR shall not exceed ten years from the grant, provided further, however, that, in the event of the death of the grantee prior to the expiration of such Stand Alone SAR, such Stand Alone SAR may, if the Committee so determines, be exercisable for up to eleven years from the date of the grant and the Committee may provide in a grant agreement that the term of any Stock Option shall be extended during any period that such Stock Option may not be exercised under any applicable law or during an applicable blackout period.
- (b) **Value of Stock Appreciation Right.** The grantee of a Tandem SAR will be entitled to surrender the Stock Option which is then exercisable and receive in exchange therefore an amount equal to the excess of the Fair Market Value of the Common Stock on the date the election to surrender is received by the Company in accordance with exercise procedures established by the Company over the Stock Option price (the "Spread") multiplied by the number of shares covered by the Stock Option which is surrendered. The grantee of a Stand Alone SAR will receive upon exercise of the Stock Appreciation Right an amount equal to the excess of the

Fair Market Value of the Common Stock on the date the election to surrender such Stand Alone SAR is received by the Company in accordance with exercise procedures established by the Company over the Fair Market Value of the Common Stock on the date of grant multiplied by the portion being exercised of the number of shares covered by the grant of the Stand Alone SAR. Notwithstanding the foregoing, in its sole discretion the Committee at the time it grants a Stock Appreciation Right may provide that the Spread covered by such Stock Appreciation Right may not exceed a specified amount.

- (c) **Payment of Stock Appreciation Right.** Payment of a Stock Appreciation Right shall be in the form of shares of Common Stock, cash or any combination of shares and cash. The form of payment upon exercise of such a right shall be determined by the Committee either at the time of grant of the Stock Appreciation Right or at the time of exercise of the Stock Appreciation Right.
- (d) **Dividends.** Anything in the Plan to the contrary notwithstanding, no dividends or dividend equivalents may be paid on Stock Appreciation Rights.
- (e) **Termination of Employment.** Unless determined otherwise by the Committee, upon the termination of a Stock Appreciation Right grantee's employment (for any reason other than gross misconduct), Stock Appreciation Right privileges shall be limited to the shares that were immediately exercisable at the date of such termination. The Committee, however, in its discretion, may provide that any Stand Alone Stock Appreciation Right outstanding but not yet exercisable upon the termination of a Stock Appreciation Right grantee's employment may become exercisable in accordance with a schedule determined by the Committee. Such privileges shall expire unless exercised within such period of time after the date of termination of employment as may be established by the Committee, but in no event later than the expiration date of the Stock Appreciation Right.
- (f) **Termination Due to Misconduct.** If a Stock Appreciation Right grantee's employment is terminated for gross misconduct, as determined by the Company, all rights under the Stock Appreciation Right shall expire upon the date of such termination.

10. PERFORMANCE AWARDS

The Committee may grant Performance Awards, including Performance Shares or Performance Units, if the performance of the Company or its parent or any subsidiary, division, business unit, affiliate or joint venture of the Company selected by the Committee during the Award Period meets certain goals established by the Committee. Performance Awards shall be subject to the following terms and conditions and such other terms and conditions as the Committee may prescribe:

- (a) **Award Period and Performance Goals.** The Committee shall determine and include in the terms and conditions of a Performance Award the period of time for which a Performance Award is made ("**Award Period**"). The Committee also shall establish performance objectives ("**Performance Goals**") to be met by the Company, its subsidiary, division, business unit, affiliate or joint venture of the Company during the Award Period as a condition to payment of the Performance Award. The Performance Goals may include minimum and optimum objectives or a single set of objectives, may be applied to either the Company as a whole or to a subsidiary, division, business unit, affiliate or joint venture, either individually, alternatively or in any combination, and measured either annually or cumulatively over a period of years, on an absolute basis or relative to a pre-established target, to previous years' results or to a designated comparison group, in each case as specified by the Committee.
- (b) **Payment of Performance Awards.** The Committee shall establish the method of calculating the amount of payment to be made under a Performance Award if the Performance Goals are met, including the fixing of a maximum payment. After the completion of an Award Period, the performance of the Company, its subsidiary, division, business unit, affiliate or joint venture of the Company shall be measured against the Performance Goals, and the Committee shall determine,

in accordance with the terms of such Performance Award, whether all, none or any portion of a Performance Award shall be paid. The Committee, in its discretion, may elect to make payment in shares of Common Stock, cash or a combination of shares and cash. Any cash payment of an award measured relative to Common Stock shall be based on the Fair Market Value of shares of Common Stock on, or as soon as practicable prior to, the date of payment. The Committee may establish rules and procedures to permit a grantee to defer recognition of income upon the attainment of a Performance Award.

- (c) **Revision of Performance Goals.** The Committee may revise the Performance Goals and the computation of payment if one or more events occur which have a substantial effect on the performance of the Company, subsidiary, division, affiliate or joint venture of the Company and which, in the judgment of the Committee, make the application of the Performance Goals unfair unless a revision is made, including without limitation, to reflect losses from discontinued operations, extraordinary, unusual or nonrecurring gains and losses, the cumulative effect of accounting changes, acquisitions or divestitures, structural changes/outsourcing, foreign exchange impacts, the impact of specified corporate transactions, accounting or tax law changes and other extraordinary or nonrecurring events.
- (d) **Requirement of Employment.** Except as otherwise provided in the grant agreement evidencing the Incentive, a grantee of a Performance Award must remain in the employ of the Company, its subsidiary, affiliate or joint venture until the completion of the Award Period in order to be entitled to payment under the Performance Award; provided that the Committee may, in its discretion, provide for a full or partial payment where such an exception is deemed equitable.
- (e) **Dividends.** The Committee may, in its discretion, at the time of the Performance Award grant, determine if any dividends declared on the Common Stock during the Award Period which would have been paid with respect to Performance Shares had they been owned by a grantee or dividend equivalents be either (i) accumulated for the benefit of the grantee and used to increase the number of Performance Shares of the grantee, or paid as cash, at the end of the Award Period or (ii) not paid or accumulated. Notwithstanding anything to the contrary, such dividends or dividend equivalents shall only be payable following the end of the Performance Period to the extent that the Performance Shares have been earned.

11. RESTRICTED STOCK GRANTS

The Committee may grant Restricted Stock or Restricted Stock Units to an Eligible Employee, which shall be subject to the following terms and conditions and such other terms and conditions as the Committee may prescribe (“**Restricted Stock Grants**”). Such grants shall not be free from restriction during the period designated by the Committee (the “**Restricted Period**”).

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- (a) **Requirement of Employment.** A grantee of a Restricted Stock Grant must remain in the employment of the Company during the Restricted Period in order to receive the shares, cash or combination thereof under the Restricted Stock Grant. Except as otherwise provided in the grant agreement evidencing the Incentive, if the grantee leaves the employment of the Company prior to the end of the Restricted Period, the Restricted Stock Grant shall terminate and any shares of Common Stock shall be returned immediately to the Company, provided that the Committee may provide for the employment restriction to lapse with respect to a portion or portions of the Restricted Stock Grant at different times during the Restricted Period. The Committee may, in its discretion, also provide for such complete or partial exceptions to the employment restriction as it deems equitable.
 - (b) **Restrictions on Transfer and Legend on Stock Certificates.** During the Restricted Period, the grantee may not sell, assign, transfer, pledge or otherwise dispose of the Restricted Stock Grant, including but not limited to any shares of Common Stock. Any certificate for shares of Common Stock issued hereunder shall contain a legend giving appropriate notice of the restrictions in the grant.
 - (c) **Escrow Agreement.** The Committee may require the grantee to enter into an escrow agreement providing that any certificates representing the Restricted Stock Grant will remain in the physical custody of an escrow holder until all restrictions are removed or expire.
 - (d) **Lapse of Restrictions.** All restrictions imposed under the Restricted Stock Grant shall lapse upon the expiration of the Restricted Period if the conditions as to employment set forth above have been met. The grantee shall then be entitled to have the legend removed from any certificates for Restricted Stock. Restricted Stock Units may be paid in the form of shares of Common Stock, cash or any combination of shares and cash as determined by the Committee. The Committee may establish rules and procedures to permit a grantee to defer recognition of income upon the expiration of the Restricted Period.
 - (e) **Dividends.** The Committee may, in its discretion, at the time of the Restricted Stock Grant, provide that any dividends declared on Common Stock during the Restricted Period or dividend equivalents be (i) accumulated for the benefit of the grantee and used to increase the number of shares of Common Stock subject to the Restricted Stock Grant, or paid as cash, to the grantee at the expiration of the Restricted Period or (ii) not accumulated. Notwithstanding anything to the contrary, such dividends or dividend equivalents shall only be payable following the expiration of the Restricted Period to the extent that the Restricted Stock Grant has been earned.

12. OTHER SHARE-BASED AWARDS

The Committee may grant a Share Award or Phantom Stock Award to any Eligible Employee on such terms and conditions as the Committee may determine in its sole discretion. Share Awards may be made as additional compensation for services rendered by the Eligible Employee or may be in lieu of cash or other compensation to which the Eligible Employee is entitled from the Company. The Committee may, in its discretion, at the time a Share Award or Phantom Award is granted, provide that any dividends declared on Common Stock during the applicable Restricted Period or dividend equivalents be (i) accumulated for the benefit of the grantee and

used to increase the number of shares of Common Stock subject to the applicable Share Award or Phantom Award, or paid as cash, to the grantee at the expiration of the Restricted Period or (ii) not accumulated. Notwithstanding anything to the contrary, such dividends or dividend equivalents shall only be payable to the extent that the applicable Share Award or Phantom Award has been earned.

13. CASH AWARDS

The Committee may grant a Cash Award to any Eligible Employee on such terms and conditions as the Committee may determine in its sole discretion. Cash Awards may be made as additional compensation for services rendered by the Eligible Employee or may be in lieu of other compensation to which the Eligible Employee is entitled from the Company. A Cash Award may or may not be subject to vesting conditions, including performance-based vesting conditions consistent with other forms of Performance Awards.

14. TRANSFERABILITY

Each Stock Option and Stock Appreciation Right granted under the Plan shall not be transferable other than by will or the laws of descent and distribution; each other Incentive granted under the Plan will not be transferable or assignable by the recipient, and may not be made subject to execution, attachment or similar procedures, other than by will or the laws of descent and distribution or as determined by the Committee in accordance with the Exchange Act or any other applicable law or regulation. Notwithstanding the foregoing, the Committee, in its discretion, may adopt rules permitting the transfer, solely as gifts during the grantee's lifetime, of Stock Options (other than ISOs) and Stock Appreciation Right to members of a grantee's immediate family or to trusts, family partnerships or similar entities for the benefit of such immediate family members. For this purpose, immediate family member means the grantee's spouse, parent, child, stepchild, grandchild and the spouses of such family members. The terms of a Stock Option and Stock Appreciation Right shall be final, binding and conclusive upon the beneficiaries, executors, administrators, heirs and successors of the grantee.

15. DISCONTINUANCE OR AMENDMENT OF THE PLAN

The Board of Directors may discontinue the Plan at any time and may from time to time amend or revise the terms of the Plan as permitted by applicable statutes, except that it may not, without the consent of the grantees affected, revoke or alter, in a manner that is materially unfavorable to the grantees of any Incentives hereunder, any Incentives then outstanding, nor may the Board of Directors amend the Plan without stockholder approval where the absence of such approval would cause the Plan to fail to comply with any requirement of applicable law or regulation or the listing requirements of any national securities exchange or association on which the Common Stock is then listed. Notwithstanding the foregoing, without consent of affected grantees, Incentives may be amended, revised or revoked when necessary to avoid penalties under Section 409A of the Code, to ensure compliance with the listing requirements any national securities exchange or association on which the Common Stock is then listed, or as may be required or appropriate to comply with changes in applicable laws and regulations. Unless approved by the Company's stockholders or as otherwise specifically provided under this Plan, no adjustments or reduction of the exercise price of any outstanding Stock Appreciation Rights or Stock Options

shall be made in the event of a decline in stock price, either by reducing the exercise price of outstanding Incentives or through cancellation of outstanding Incentives in connection with regranting of Incentives at a lower price to the same individual, nor may Stock Appreciation Rights or Stock Options be cancelled in exchange for a cash payment to account for a decline in stock price.

16. NO LIMITATION ON COMPENSATION

Nothing in the Plan shall be construed to limit the right of the Company to establish other plans or to pay compensation to its service providers, in cash or property, in a manner which is not expressly authorized under the Plan.

17. NO CONSTRAINT ON CORPORATE ACTION

Nothing in the Plan shall be construed (i) to limit, impair or otherwise affect the Company's right or power to make adjustments, reclassifications, reorganizations or changes of its capital or business structure, or to merge or consolidate, or dissolve, liquidate, sell or transfer all or any part of its business or assets, or (ii) except as provided in Section 15, to limit the right or power of the Company, or any subsidiary, affiliate or joint venture to take any action which such entity deems to be necessary or appropriate.

18. WITHHOLDING TAXES

The Company shall be entitled to deduct from any payment under the Plan, regardless of the form of such payment, the amount of all applicable income, excise and employment taxes required or permitted by law to be withheld with respect to such payment or may require the Eligible Employee to pay to it such tax prior to and as a condition of the making of such payment. In accordance with any applicable administrative guidelines it establishes, the Committee may allow an Eligible Employee to pay the amount of taxes required by law to be withheld from an Incentive by withholding from any payment of Common Stock due as a result of such Incentive, or by permitting the Eligible Employee to deliver to the Company, shares of Common Stock having a Fair Market Value, as determined by the Committee, equal to the amount of such required or permitted withholding taxes.

19. COMPLIANCE WITH SECTION 16 OF THE EXCHANGE ACT

With respect to Eligible Employees who are Section 16 Officers, transactions under the Plan are intended to comply with all applicable conditions of Rule 16b-3 or its successor under the Exchange Act. To the extent that compliance with any Plan provision applicable solely to the Section 16 Officers is not required in order to bring a transaction by such Section 16 Officer into compliance with Rule 16b-3, it shall be deemed null and void as to such transaction, to the extent permitted by law and deemed advisable by the Committee and its delegates. To the extent any provision of the Plan or action by the Plan administrators involving such Section 16 Officers is deemed not to comply with an applicable condition of Rule 16b-3, it shall be deemed null and void as to such Section 16 Officers, to the extent permitted by law and deemed advisable by the Plan administrators.

20. COMPLIANCE WITH SECTION 409A OF THE CODE

To the extent applicable, to the extent an Incentive is granted to an Eligible Employee subject to the Code, it is intended that such Incentive be exempt from Section 409A of the Code or be structured in a manner that would not cause the Eligible Employee to be subject to taxes and interest pursuant to Section 409A of the Code. Notwithstanding anything to the contrary in the Plan (and unless the award document specifically provides otherwise), if an Eligible Employee holding an Incentive that constitutes “deferred compensation” under Section 409A of the Code is a “specified employee” for purposes of Section 409A of the Code and the Eligible Employee is otherwise subject to Section 409A of the Code, no distribution or payment of any amount that is due because of a “separation from service” (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six months following the date of such Eligible Employee’s “separation from service” or, if earlier, the date of the Eligible Employee’s death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

21. USE OF PROCEEDS

Any proceeds received by the Company under the Plan shall be added to the general funds of the Company and shall be used for such corporate purposes as the Board of Directors shall direct.

22. GOVERNING LAW

The Plan, and all agreements hereunder, shall be construed in accordance with and governed by the laws of the State of Delaware without giving effect to the principles of conflicts of laws. Unless otherwise set forth in the applicable grant agreement, the State and Federal courts located in the State of Delaware shall have exclusive jurisdiction for any action brought under the Plan or pursuant to any Incentive.

23. REGISTRATION AND APPROVALS

The obligation of the Company to sell or deliver shares of Common Stock with respect to Incentives granted under the Plan shall be subject to all applicable laws, rules and regulations, including all applicable federal and state securities laws, and the obtaining of all such approvals by governmental agencies as may be deemed necessary or appropriate by the Committee. Each Incentive is subject to the requirement that, if at any time the Committee determines, in its discretion, that the listing, registration or qualification of shares of Common Stock issuable pursuant to the Plan is required by any securities exchange or under any state or federal law, or the consent or approval of any governmental regulatory body is necessary or desirable as a condition of, or in connection with, the grant of an Incentive or the issuance of shares of Common Stock, no Incentives shall be granted or payment made or shares of Common Stock issued, in whole or in part, unless listing, registration, qualification, consent or approval has been effected or obtained free of any conditions as acceptable to the Committee. Notwithstanding anything contained in the Plan, the terms and conditions related to the Incentive, or any other agreement to the contrary, in the event that the disposition of shares of Common Stock acquired pursuant to the Plan is not covered by a then current registration statement under the Securities Act, and is not otherwise exempt from such registration, such shares of Common Stock shall be restricted against transfer to the extent required by the Securities Act and Rule 144 or other

regulations thereunder. The Committee may require any individual receiving shares of Common Stock pursuant to an Incentive granted under the Plan, as a condition precedent to receipt of such shares of Common Stock, to represent and warrant to the Company in writing that the shares of Common Stock acquired by such individual are acquired without a view to any distribution thereof and will not be sold or transferred other than pursuant to an effective registration thereof under said Act or pursuant to an exemption applicable under the Securities Act or the rules and regulations promulgated thereunder. The certificates evidencing any of such shares of Common Stock shall be appropriately amended or have an appropriate legend placed thereon to reflect their status as restricted securities as aforesaid.

24. OFFSET AND SUSPENSION OF EXERCISE

Anything to the contrary in the Plan notwithstanding, the Plan administrators may (i) offset any Incentive by amounts reasonably believed to be owed to the Company by the grantee and (ii) disallow an Incentive to be exercised or otherwise payable during a time when the Company is investigating reasonably reliable allegations of gross misconduct by the grantee.

25. EFFECT OF A CHANGE IN CONTROL

The following provisions will apply to Incentives in the event of a Change in Control unless otherwise provided in the grant agreement evidencing the Incentive or any other written agreement between the Company or any affiliate and the Eligible Employee or unless otherwise expressly provided by the Committee at the time of grant of an Incentive. In the event of a Change in Control, then, notwithstanding any other provision of this Plan, the Committee will take one or more of the following actions with respect to each outstanding Incentive, contingent upon the closing or completion of the Change in Control:

- (a) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Incentive or to substitute a similar award for the Incentive (including, but not limited to, an award to acquire the same consideration per share paid to the stockholders of the Company pursuant to the Change in Control);
- (b) accelerate the vesting, in whole or in part, of the Incentive (and, if applicable, the time at which the Incentive may be exercised) to a date prior to the effective time of such Change in Control as the Committee determines, with such Incentive terminating if not exercised (if applicable) at or prior to the effective time of the Change in Control, and with such exercise reversed if the Change in Control does not become effective;
- (c) cancel or arrange for the cancellation of the Incentive, to the extent not vested or not exercised prior to the effective time of the Change in Control, in exchange for such cash consideration, if any, as the Committee, in its reasonable determination, may consider appropriate as an approximation of the value of the canceled Incentive, taking into account the value of the Common Stock subject to the canceled Incentive, the possibility that the Incentive might not otherwise vest in full, and such other factors as the Committee deems relevant; and

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- (d) cancel or arrange for the cancellation of the Incentive, to the extent not vested or not exercised prior to the effective time of the Change in Control, in exchange for a payment, in such form as may be determined by the Committee equal to the excess, if any, of (A) the value in the Change in Control of the property the Eligible Employee would have received upon the exercise of the Incentive immediately prior to the effective time of the Change in Control, over (B) any exercise price payable by such holder in connection with such exercise

The Committee need not take the same action or actions with respect to all Incentives or portions thereof or with respect to all Participants. The Committee may take different actions with respect to the vested and unvested portions of an Incentive.

In the absence of any affirmative determination by the Committee at the time of a Change in Control, each outstanding Incentive will be assumed or an equivalent award will be substituted by such successor corporation or a parent or subsidiary of such successor corporation (the “**Successor Corporation**”), unless the Successor Corporation does not agree to assume the Incentive or to substitute an equivalent award, in which case the vesting of such Incentive will accelerate in its entirety (along with, if applicable, the time at which the Incentive may be exercised) to a date prior to the effective time of such Change in Control as the Committee determines, with such Incentive terminating if not exercised (if applicable) at or prior to the effective time of the Change in Control, and with such exercise reversed if the Change in Control does not become effective.

An Incentive may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the grant agreement evidencing the Incentive or as may be provided in any other written agreement between the Company or any affiliate and the Eligible Employee, but in the absence of such provision, no such acceleration will occur.

26. CLAWBACK, RECOUPMENT

The Committee may specify in a grant agreement evidencing an Incentive that the Eligible Employee’s right, payment and benefits with respect to an Incentive shall be subject to reduction, cancellation, forfeiture, clawback or recoupment upon the occurrence of certain specified events or as required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law, in addition to any otherwise applicable forfeiture provisions that apply to the Incentive. Without limiting the generality of the foregoing, any Incentive under the Plan shall be subject to the terms of any clawback policy maintained by the Company or as required by law, as it may be amended from time to time.

October 14, 2020

MERCK

INVENTING FOR LIFE

Kevin Ali

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Kenilworth, NJ 07033 U.S.A.
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merck.com

October 14, 2020

Dear Kevin,

It is my pleasure to offer you the position of Chief Executive Officer of Organon & Co. (“Organon”) (the “Position”), an independent publicly traded company which will aspire to become the world’s leading Women’s Health company with a global portfolio that will include biosimilars and a broad array of medicines spanning important therapeutic categories. We currently expect that the legal separation of Organon from Merck & Co., Inc. (“Merck”) will occur in the first half of 2021 (the “Separation Date”).

Upon the first wave of legal entity separation from Merck, (hereinafter referred to as “LES Wave 1”), you will be placed in your new Position and continue to report to me and will be accountable for performing the transitional activities necessary for the successful separation of Organon from Merck. At such time as Merck directs (currently contemplated to be when Organon is officially established as a separate company within Merck (also known internally as “Company in Company”), you will continue to report to me and exclusively perform the functions of your Organon Position. After the Separation Date, you will report to the Organon Board of Directors and will become a member of the Organon Executive Committee and an Officer of Organon (as defined in Section 16 of the Securities Exchange Act of 1934).

Until the Separation Date, the Position will be based at your current work location. On and after the Separation Date, the Position will be based at Organon’s corporate headquarters.

Unless otherwise provided herein or by law, our offer is subject to the following terms and conditions: Your compensation (base salary, target bonus and target long-term incentive), severance and relocation benefits will be effective upon the first payroll cycle following the LES Wave 1 Date. All other benefits listed below will be effective upon the Separation Date.

Base Salary	\$1,100,000 less applicable payroll deductions
Target Bonus ¹	125%
Target Long-Term Incentive ²	\$8,000,000
Relocation (if applicable)	Localization to the U.S. in accordance with the terms of the global assignment policies.
Severance (payable if Merck announces that it will not consummate the transaction in separating Organon from Merck and as a result your employment with Merck is terminated)	1x base + bonus at proposed Organon compensation <i>or</i> severance pay calculated per the applicable Separation Plan for your Position (the “Plan”) at the time of separation, whichever is greater. You would be eligible for all other applicable benefits provided under the Plan.

¹ Effective on the Separation Date, your AIP target bonus will remain the same and be subject to the terms and conditions of the Organon annual cash incentive bonus plan.

² Effective on the Separation Date, your target LTI will remain the same and be subject to the terms and conditions of Organon’s LTI Program.

Change in Control

We expect the Organon Board of Directors to establish a Change in Control Plan for Organon commensurate with other similarly situated senior executives and/or employees at Organon

Benefits

We expect Organon to provide core health and welfare benefits, a retirement plan, paid time off and separation benefits of an overall similar value as those provided by Merck.

Your employment will remain at-will (meaning that you and your employer remain free to end the employment relationship at any time, for any lawful reason, either with or without prior notice) and additionally will be subject to the terms and conditions of your current employer. Following the legal separation of Organon from Merck, you will remain an at-will employee and be subject to Organon's terms and conditions of employment.

Congratulations on your decision to lead Organon. I believe this position offers an outstanding career opportunity and look forward to your acceptance.

To accept this offer, please sign and return to me as soon as possible. In the meantime, should you have any questions, please do not hesitate to call me or Steve.

Sincerely,

/s/ Ken Frazier

Ken Frazier
Chairman and Chief Executive Officer

I accept the employment offer and its terms contained in this letter.

/s/ Kevin Ali
Kevin Ali

10-15-2020
Date

cc: Steve Mizell
Carl Segerstrom
Ryan VanAlphen

March 24, 2020

MERCK

INVENTING FOR LIFE

Matthew M. Walsh

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E: steven.mizell@merck.com

merck.com

Dear Matt:

It is my pleasure to offer you a position with Merck Sharp & Dohme Corp., (“Merck” or the “Company”) a wholly-owned subsidiary of Merck & Co., Inc. At Merck, we see ourselves as a company inspired to invent. We are determined to discover, develop and deliver medicines and vaccines that will improve the lives of more people in more places around the world.

As we discussed, our offer to you is in conjunction with and anticipation of our announced intention to separate into two independent companies: (a) Merck — which will remain a premier research-intensive, biopharmaceutical company focused on innovative solutions for unmet medical needs; and (b) Organon & Co., (“Organon”) Organon — which will aspire to become the world’s leading Women’s Health company with a global portfolio that will also include biosimilars and a broad array of medicines that span important therapeutic categories.

Your offer of employment with Merck will be for the position of Executive Vice President and Chief Financial Officer of Organon the (“Position”) with duties and responsibilities following the Separation Date (as defined below) consistent with those generally applicable to the chief financial officer of a publicly traded company. Until the Separation Date, you will have the title of Executive Vice President of the Company. We currently expect that the legal separation of Organon from Merck will occur in the first half of 2021 (the “Separation Date”). Until the Separation Date, you will report to Rob Davis and will be responsible to take such actions as necessary to prepare for the legal separation of Organon, including taking direction from Kevin Ali, Organon CEO. At such time as Merck directs (currently contemplated to be on or around October 1, 2020), you will report to Kevin Ali, Organon CEO, and after the Separation Date, you will report to the Organon CEO and become a member of the Organon Executive Committee and be an Officer of Organon (as defined in Section 16 of the Securities Exchange Act of 1934).

Until the Separation Date, the Position will be based at the Kenilworth, NJ site. On and after the Separation Date, the Position will be based at Organon’s corporate headquarters.

Our offer is subject to the following terms and conditions:

Total Compensation

Base Salary: You will be paid a gross annual salary of **\$800,000**. This will be paid (bi-weekly) at a rate of **\$30,769.25** per pay period.

We expect Organon will maintain your base salary after the Separation Date and establish an annual review of your base salary thereafter.

Annual Incentive Plan: You will be eligible to participate in the Company’s Annual Incentive Plan (MP) as it applies to similarly situated employees. The target bonus for the Position is 80% of your annual base salary. The bonus is discretionary and the amount of the bonus, if any, will be determined based on

Company and/or individual performance. To be eligible for an award, you must have at least 90 days of active service in the plan year and remain actively employed through December 31 of the plan year. Your award, if any, will be pro-rated based on the number of eligible months you have worked during that plan year. Bonuses, if any, for the current performance year will be paid in March of the following year. Eligibility for and payment of a bonus for any calendar year that includes service at the Company and Organon will be governed by transitional rules between Merck and Organon as such rules apply to similarly situated employees.

We expect Organon will establish an annual cash incentive bonus plan and will maintain your same bonus target level after the Separation Date.

Long-Term Incentive (LTI) Program:

You will be eligible for consideration for annual grants of stock-based incentives. The annual grant target value for the Position is \$3,000,000. For 2020, your annual LTI grant value will be \$2,600,000 ("2020 Annual Grant"). The 2020 Annual Grant will be governed by the terms and conditions of the Merck & Co., Inc. 2019 Incentive Stock Plan. The 2020 Annual Grant will be issued in the form of Restricted Stock Units which will vest one-third on each anniversary of the grant date, which is expected to occur three business days after the next Company quarterly earnings release following your date of hire. The exact number of shares will be determined based on the value of Merck stock on the date of grant. The associated terms and conditions for this grant will be provided under separate cover following the issuance of your grant.

As of the Separation Date, any unvested RSUs will either be converted to Organon equity or remain as Merck equity in the same manner as determined for all other similarly situated employees.

We expect Organon will establish its own LTI program and maintain the same LTI target value for grants to be made under the NEWCO LTI program after the Separation Date.

In all events, the terms of all LTI awards will be governed by the terms of the applicable stock plan and the relevant award agreements.

As an intended Officer of Organon, it is likely that you will be subject to Organon stock ownership guidelines and retention requirements. We expect Organon to establish these guidelines in closer proximity to the Separation Date.

Sign-On Incentives

Sign-On Bonus: You will be paid a one-time sign-on bonus of **\$200,000** (less applicable payroll deductions and withholdings), which you will receive in your first regularly scheduled paycheck following your start date. Your right to retain the sign-on bonus is conditioned upon your continued employment with the Company prior to the Separation Date and Organon immediately on and after the Separation Date (the "Employer") for a total of two years from the date of this letter. By your signature below, you agree that, if prior to completing two years of continuous employment, you voluntarily terminate your employment or are terminated for Cause, as defined below, you will reimburse your Employer the full net (after-tax) amount if your termination occurs within this calendar year 2020 and the full gross amount of the sign-on bonus of your termination occurs in subsequent years. ("Repayment Obligation"). You further authorize your Employer to withhold any and all monies otherwise owed to you, to the extent permitted by law, as payment against such Repayment Obligation. In such case, such monies will be credited towards the Repayment Obligation, but will not relieve you of your obligation to pay the balance of any Repayment Obligation.

“Cause” as used in this offer letter means an act or omission by you, which constitutes: an unauthorized and deliberate or reckless disclosure of proprietary or other confidential information relating to your employer or any parent, subsidiary or affiliate company of your Employer, any of their personnel, research or business; embezzlement, theft or other misappropriation of the assets of your Employer; deliberate or reckless falsification of records or reports; deliberate bad faith action or reckless action that causes actual or potential injury or loss to your Employer or any of their employees; insubordination (meaning the repeated refusal to carry out work assignments and/or direction); failure to demonstrate a reasonable effort to perform assigned job duties; an illegal act that is in bad faith or reckless on the property of your Employer or in representing your Employer; other conduct by you that is in violation of a policy of your Employer that causes actual or potential financial or reputational damage to your Employer, including but not limited to ethical breaches; or a breach by you of your representations as set forth in this letter.

Merck Benefits

Health and Insurance Benefits Program: Prior to the Separation Date you will be eligible to participate in Merck’s Health and Insurance Benefits Program, which allows you to choose from various options for medical, dental, vision, employee term life insurance, accidental death and dismemberment insurance (**AD&D**), dependent life insurance, long-term disability, and health care and dependent care flexible spending accounts. For most benefits, participation begins on your date of hire. A Merck Benefits New Hire Package will be mailed within 2 weeks of your hire date to your address of record from the Merck Benefits Service Center at Fidelity. This package provides important information and instructions for enrolling in your Merck benefits. You will have 30 days from the date Fidelity mails your benefits information to enroll. If you do not enroll by the date indicated in the package, you automatically will be enrolled in medical coverage for you only in the Horizon BlueCross BlueShield PPO plan option (including prescription drug coverage), dental coverage for you only, company-provided basic life insurance and short-term and long term disability coverage. If you enroll dependents, you will receive a letter or e-mail from HMS Employer Solutions (an independent third-party vendor designated by Merck to conduct dependent eligibility verifications) requesting documentation to verify your dependent’s(s’) eligibility. Failure to respond or provide required documentation within the required timeframe will result in the removal of your dependent(s) from benefits coverage.

Pension Plan: Prior to the Separation Date you will be eligible to participate in the Merck U.S. Pension Plan, which is a defined benefit pension plan that uses a cash balance formula to calculate your benefit. Your benefit is expressed as a notional account balance that grows with annual Pay Credits from Merck ranging from 4.5% to 10.0% of your total pay (based on age and service) and Interest Credits of CPI plus 3% (not less than 3.3%). You will also participate in Merck’s Supplemental Retirement Plan, which is an unfunded non-qualified Plan that restores retirement plan benefits that are capped by IRS limits.

401(k)/Savings Plan and Deferral Program: Prior to the Separation Date you will be eligible to participate in the Merck U.S. Savings Plan. You will be mailed a separate enrollment package for the Merck Savings Plan from the Merck Benefits Service Center at Fidelity within 2 weeks following your date of hire. The Savings Plan includes before-tax, after-tax and Roth savings options and Company matching contributions of \$0.75 for every \$1.00 you contribute, up to 6% of total pay per pay period (maximum match is 4.5% of total pay, subject to plan limits and IRS limits). If you do not make an active election within 60 days of your hire date, you automatically will be enrolled for before-tax base pay contributions of 6%, with an annual increase of **1%** until you reach a contribution rate of 10%. Contributions vest immediately. To maximize the Company Match, you must contribute at least 6% of your base salary and 6% of your ALP. Merck will also make an automatic contribution of 4.5% of your eligible pay above the IRS pay limit to the Merck Deferral Program.

Vacation and Paid Holiday Policy: Prior to the Separation Date you will be eligible for 30 vacation days per year as well as 10 fixed holidays and 4 year-end shutdown days between Christmas and New Year's holidays. The number of vacation days for which you are eligible in your first year of employment is dependent upon your date of hire.

Workplace Accommodations: Merck seeks to support employees of all abilities. Merck's Workplace EnABLEment program offers employees the resources they need to contribute to Merck at the highest level and to advance the business goals of the Company. If you need an accommodation while at Merck, contact the Workplace Accommodation Team via email at workacc@merck.com or by phone at 1-866-675-4748.

Severance: Prior to the Separation Date you will be a Merck employee at-will. This means that either you or Merck may terminate the employment relationship at any time for any lawful reason or for no reason. In order to accommodate any concerns you may have in joining Merck, Merck will agree to the following special arrangement.

1. In the event that Merck announces that it will not consummate the transaction in separating Organon from Merck and as a result your employment is terminated:
 - (i) Merck will (a) offer you severance benefits in accordance with the Merck & Co., Inc. US Separation Benefits Plan (the "Plan"), except that your lump sum severance payment will be no less than 52 week's pay (at your then current base rate) and your pay in lieu of Annual Incentive Plan bonus will be no less than 100% of your target ATP bonus (each subject to applicable tax withholding); and (b) relieve you from any Repayment Obligation (as defined above).
 - (ii) In addition, if any such termination occurs prior to the first-year anniversary of the 2020 Annual Grant, the severance offer will also include an additional amount equal to the product obtained by multiplying the sum of the value of the 2020 Annual Grant times a fraction, the numerator for which is the number of full months of your employment between the grant date and the date of your termination and the denominator of which is 36, subject to applicable tax withholding.
2. In the event that (i) Merck terminates your employment other than for Cause prior to the Separation Date and such termination is not for the reason set forth in 1 above; or (ii) the transaction is not consummated before January 1, 2022, and you provide written notice of your decision to terminate your employment received by me (or my successor) and do in fact terminate your employment on or before January 31, 2022:
 - (i) Merck will offer you (a) a lump sum in an amount of your then current annual base salary plus your target AIP bonus for your then current performance year subject to appropriate tax withholding (less any amount you would otherwise be eligible to receive under any Company plan or policy); and (b) relieve you from any Repayment Obligation (as defined above).
 - (ii) In addition, if any such termination occurs prior to the first-year anniversary of the 2020 Annual Grant, the severance offer will also include an additional amount equal to the

product obtained by multiplying the sum of the value of the 2020 Annual Grant times a fraction, the numerator for which is the number of full months of your employment between the grant date and the date of your termination and the denominator of which is 36, subject to applicable tax withholding.

(iii) This offer will be in lieu of any severance pay provided under the Plan and you will not be eligible for benefits under the such Plan

The benefits set forth above are collectively referred to as the "Severance Benefits." Your right to receive Severance Benefits is conditioned upon your signing and refraining from revoking a Severance Agreement in a format prescribed by Merck, which Agreement will contain a full release, non-solicitation, nondisclosure, mutual non-disparagement and cooperation in litigation covenants and such other reasonable and customary terms as Merck provides.

If at the time your employment terminates you are a "Specified Employee" as defined in Treas. Reg. Sec. 1.409A-1(i) or any successor thereto (which in general includes the top 50 employees of a company ranked by compensation) of the Employer, to the extent required by Section 409A of the Internal Revenue Code of 1986, as amended (the "Code") and to avoid incurring any potential associated tax penalties, the severance payment described above will be made in a lump sum, without interest, as soon as administratively feasible on the first day of the sixth month after the termination of your employment. The severance payment described above will be paid within 30 days after you sign the release agreement and the revocation period has expired but in no event (if at all) later than March 15th following the year after your termination and you and Merck intend that the severance payment above will be exempt from Section 409A of the Code and, based on the current Code, this letter shall be interpreted consistent with such intent.

Organon Benefits:

Upon the Separation Date, we expect Organon to provide: Core health and welfare benefits, a retirement plan, paid time off and separation benefits of an overall similar value as those provided by Merck.

Change of Control: We expect the Organon Board of Directors to establish a Change in Control Plan for Organon.

Right to Amend or Terminate Plans, Programs and Policies: To the extent that the compensation and benefits described in this letter are provided under and subject to the terms and conditions of the applicable Merck or Merck & Co., Inc. plans, programs and policies or will be provided and subject to applicable Organon plans, programs and policies, nothing in this letter in any way limits Merck's, Merck & Co., Inc.'s or Organon's right to amend or terminate those plans, programs or policies.

Representations: This offer is made to you based upon your representations that (i) your employment at Merck will not conflict with, or result in the breach of or violation of, any other agreement, instrument, order, judgment or decree to which you are a party or by which you are bound, and (ii) you are not a party to or bound by any employment agreement, restrictive covenant, non-compete agreement or confidentiality agreement with any other person or entity that would restrict your employment at Merck or Organon.

By your signature below, you affirm that these representations are true.

This offer is contingent upon your successful completion of a pre-placement drug screen, satisfactory verification of your employment, education, criminal check, satisfactory references and background check results and proof of your eligibility to work in the United States. *(A List of Acceptable Documents that establishes your eligibility to work in the U.S., which you are required to bring with you on your first day of work, will be forwarded to you upon your acceptance of the offer).* As explained above, your employment at the Company and later at Organon will be that of an at-will employee (meaning that you and the Employer remain free to end the employment relationship at any time, for any lawful reason, either with or without prior notice) and additionally will be subject to Merck's terms and conditions of employment, which will be provided to you when this offer is confirmed and, after transition, to those terms and conditions established by Organon, if any. We advise you not to alter your current employment status until all of the contingencies have been satisfied. Nothing herein shall be construed as creating a contractual relationship between you and the Company.

Please call Kevin Ali, Organon CEO at +41 79 377 0648 upon receipt of this letter to acknowledge your acceptance of this offer. Further to your acceptance, Renae Morris will be your point of contact to begin your "on boarding" process for employment and will confirm your start date upon successful completion of the above contingencies. Renae can be reached at 215-652-3718. In addition, please print, sign, scan and return this offer letter via email to renae_morris@mcrcck.com.

With your abilities and experience, I know you will be able to help build and sustain Organon as its own sector-leading healthcare company. I believe this position offers an outstanding career opportunity and look forward to your acceptance.

Sincerely,

/s/ Steven C. Mizell

Steven C. Mizell
Executive Vice President, Chief Human Resources Officer

I accept the employment offer and its terms contained in this letter.

/s/ Matthew M. Walsh

Matthew M. Walsh

3/25/2020

Date

cc: Kevin Ali
Rob Davis
Michael Bataglio
Renae Morris

May 7, 2021

Dear Merck Shareholder:

On May 7, 2021, the board of directors of Merck & Co., Inc. approved the spin-off of its women's health, biosimilars and established brands businesses into a new, publicly traded company, Organon & Co. After the spin-off, Merck will continue to aspire to be the premier research-intensive global biopharmaceutical company focused on bringing to market innovations for unmet medical need as the source of long-term value creation for patients and shareholders.

Merck is taking advantage of its position of strength to reshape its portfolio, streamline its business, further increase its focus on innovation and drive even higher sustained growth and profitability. We believe Merck will benefit from an even more intense focus on high-science and innovation as the source of long-term value creation. The spin-off of Organon will also enable Merck to evolve its operating model and achieve operating efficiencies.

As a result of the spin-off, each Merck shareholder will receive one-tenth of a share of Organon common stock for every Merck share of common stock held on May 17, 2021, the record date for the distribution. You do not need to take any action to receive the common stock of Organon to which you are entitled as a Merck shareholder. The distribution will not affect the number of outstanding shares of Merck common stock or any of your rights as a Merck shareholder.

Please read the attached information statement, which is being provided to all Merck shareholders who hold common stock on May 17, 2021. It describes the separation in detail and contains important information about Organon and the upcoming stock transaction.

Sincerely,

Kenneth C. Frazier

Chairman of the Board and Chief Executive Officer
Merck & Co., Inc.

May 7, 2021

Dear Future Organon Shareholder:

I'm pleased to welcome you as a future shareholder of Organon & Co., which will be an independent company after its spin-off in 2021 from Merck.

Organon will be founded with our long-term vision in mind: to create a better and healthier every day for every woman around the world. We plan to build on our foundational strengths in reproductive health and assemble an array of health solutions to serve women across their lives. Through our journey, we aim to achieve a differentiated leadership position by delivering what society needs—improving the health of women.

Organon will be a global pharmaceutical company with a portfolio of more than 60 trusted medicines. Our portfolio is comprised of our growing contraception and fertility business including patent-protected Nexplanon (etonogestrel implant), an expanding biosimilars business and is led by a stable franchise of trusted established medicines. Organon's portfolio of products generate strong cash flows that will support investments in future growth opportunities in women's health. We will pursue opportunities to partner with innovators looking to commercialize their products by leveraging our scale around the world, with presence in more than 140 markets. Organon will focus on revenue growth using an efficient operating model to improve margins and generate strong cash flow to fund our long-term vision.

Organon will be a new company, but one born out of Merck with its incredible legacy and commitment to integrity and excellence. We are positioned to make a real difference, both in terms of unleashing the full potential of our current portfolio as well as advancing other important health solutions to improve the health of women.

I encourage you to learn more about Organon by reading the attached information statement. We have applied to be listed on the New York Stock Exchange under the symbol "OGN."

This is a unique opportunity and the time is right to establish a company like Organon. I, on behalf of all our people around the world, am looking forward to building a strong company that benefits you and our other stakeholders.

Sincerely,

Kevin Ali

Chief Executive Officer
Organon & Co.

Information contained herein is subject to completion or amendment. A Registration Statement on Form 10 relating to these securities has been filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

PRELIMINARY AND SUBJECT TO COMPLETION, DATED MAY 7, 2021

INFORMATION STATEMENT

Organon & Co.

This information statement is being furnished in connection with the distribution by Merck to its shareholders of all of the outstanding shares of common stock of Organon & Co., a wholly owned subsidiary of Merck that will hold directly or indirectly the assets and liabilities associated with Merck's women's health, biosimilars and established brands businesses. To implement the distribution, Merck will distribute all of the shares of Organon common stock on a pro rata basis to the Merck shareholders in a manner that is intended to be tax-free for U.S. federal income tax purposes.

For each share of Merck common stock held by you as of the close of business on May 7, 2021, the record date for the distribution, you will receive one-tenth of a share of Organon common stock. You will receive cash in lieu of any fractional shares of Organon common stock that you would have received after application of the above ratio. As discussed under "The Separation and Distribution—Trading Between the Record Date and Distribution Date," if you sell your shares of Merck common stock in the "regular-way" market after the record date and before the distribution, you also will be selling your right to receive shares of Organon common stock in connection with the separation. Shares of Organon common stock are expected to be distributed by Merck to you on June 2, 2021. The date of distribution of the Organon common stock is referred to in this information statement as the "distribution date."

No vote of Merck shareholders is required for the distribution. Therefore, you are not being asked for a proxy, and you are requested not to send Merck a proxy, in connection with the distribution. You do not need to pay any consideration, exchange or surrender your existing shares of Merck common stock or take any other action to receive the shares of Organon common stock to which you are entitled as a Merck shareholder.

There is no current trading market for Organon common stock, although Organon expects that a limited market, commonly known as a "when-issued" trading market, will develop on or shortly before the record date for the distribution, and that "regular-way" trading of Organon common stock will begin on the first trading day following the completion of the distribution. Organon intends to apply to have its common stock authorized for listing on the New York Stock Exchange ("NYSE") under the symbol "OGN."

In reviewing this information statement, you should carefully consider the matters described under the caption "[Risk Factors](#)" beginning on page 22.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this information statement is truthful or complete. Any representation to the contrary is a criminal offense.

This information statement does not constitute an offer to sell or the solicitation of an offer to buy any securities.

The date of this information statement is May 7, 2021.

A Notice of Internet Availability of Information Statement Materials containing instructions for how to access this information statement was first mailed to Merck's shareholders on or about May 7, 2021. This information statement will be mailed to Merck's shareholders who previously elected to receive a paper copy of Merck's materials.

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Except as otherwise indicated or unless the context otherwise requires, the information included in this information statement about Organon assumes the completion of all of the transactions referred to in this information statement in connection with the separation and distribution. Unless the context otherwise requires, references in this information statement to “Organon” and “the company” refer to Organon & Co., a Delaware corporation, and its consolidated subsidiaries as they will exist assuming the completion of all of the transactions referred to in this information statement in connection with the separation and distribution. References to Organon’s historical business and operations refer to the business and operations of Merck’s women’s health, biosimilars and established brands businesses that will be transferred to Organon in connection with the separation and distribution. References in this information statement to “Merck” or “Parent” refer to Merck & Co., Inc., a New Jersey corporation, and its consolidated subsidiaries, giving effect to the distribution, unless the context otherwise requires.

“Distribution” or “distribution” refers to the distribution of all of the shares of Organon common stock owned by Merck to shareholders of Merck as of the record date.

“Separation” or “separation” refers to the separation of the women’s health, biosimilars and established brands businesses from Merck through a distribution of shares of Organon common stock to the Merck shareholders as of the record date.

“Spin-off” or “spin-off” refers to the contribution of property by Merck in one or more transfers to Organon in exchange for Organon stock, cash and the assumption of certain liabilities, together with the distribution.

Trademarks, Trade Names and Service Marks

Organon owns or has rights to use the trademarks, service marks and trade names that it uses in conjunction with the operation of its business. Logos and trademarks referred to in this information statement belong to Organon or are licensed for our use. Solely for convenience, we refer to our trademarks in this information statement without the TM and ® symbols, but such references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights to our trademarks. Other service marks, trademarks and trade names referred to in this information statement are the property of their respective owners.

Industry, Ranking and Market Data

This information statement contains various historical and projected information concerning our industry, the markets in which we participate and our positions in these markets. Some of this information is from industry publications and other third-party sources, and other information is from our own analysis of data received from these third-party sources, our own internal data, market research that we commission and our public filings. All of this information involves a variety of assumptions, limitations and methodologies and is inherently subject to uncertainties, and therefore you are cautioned not to give undue weight to it.

Questions and Answers about the Separation and Distribution

What is Organon and why is Merck separating Organon’s business and distributing Organon’s common stock?

Organon, which is currently a wholly owned subsidiary of Merck, was formed to hold Merck’s women’s health, biosimilars and established brands businesses. The separation of Organon from Merck and the distribution of Organon common stock are intended to provide you with equity investments in two separate, independent public companies that will be able to focus on each of their respective business strategies. Merck and Organon expect that the separation will result in enhanced long-term performance of each business for the reasons discussed in the sections entitled “The Separation and Distribution—Background” and “The Separation and Distribution—Reasons for the Separation.”

Why am I receiving this document?

Merck is delivering this document to you because you are a holder of shares of Merck common stock. If you are a holder of shares of Merck common stock as of the close of business on May 17, 2021, each share of Merck common stock that you held at the close of business on such date will entitle you to receive one-tenth of a share of Organon common stock. This document will help you understand how the separation and distribution will affect your investment in Merck and your investment in Organon after the separation.

How will the separation of Organon from Merck work?

To accomplish the separation, Merck will distribute all of the outstanding shares of Organon common stock to Merck shareholders on a pro rata basis.

Why is the separation of Organon structured as a distribution?

Merck believes that a tax-free distribution for U.S. federal income tax purposes of shares of Organon stock to Merck shareholders is an efficient way to separate its women’s health, biosimilars and established brands businesses in a manner that will create long-term value for Merck, Organon and their respective shareholders.

What is the record date for the distribution?

The record date for the distribution will be May 17, 2021.

When will the distribution occur?

It is expected that all of the shares of Organon common stock will be distributed by Merck on June 2, 2021 to holders of shares of Merck common stock at the close of business on May 17, 2021, the record date.

What do shareholders need to do to participate in the distribution?

Shareholders of Merck as of the record date will not be required to take any action to receive Organon common stock in the distribution, but you are urged to read this entire information statement carefully. No shareholder approval of the distribution is required. You are not being asked for a proxy. You do not need to pay any consideration, exchange or surrender your existing shares of Merck common stock or take any other action to receive the shares of Organon common stock to which you are entitled as a Merck shareholder. Please do not send in your Merck stock certificates. The distribution will not affect the number of outstanding shares of Merck common stock or any rights of Merck shareholders, although it will affect the market value of each outstanding share of Merck common stock.

How will shares of Organon common stock be issued? You will receive shares of Organon common stock through the same or substantially similar channels that you currently use to hold or trade shares of Merck common stock, whether through a brokerage account or other channel. Receipt of shares of Organon common stock will be documented for you in substantially the same manner that you typically receive shareholder updates, such as monthly broker statements or other plan statements.

If you own shares of Merck common stock as of the close of business on the record date, including shares owned in certificated form, Merck, with the assistance of Equiniti Trust Company (Organon's transfer agent and registrar), the settlement and distribution agent, will electronically distribute shares of Organon common stock to you or to your brokerage firm on your behalf by way of direct registration in book-entry form. Your bank or brokerage firm will credit your account for the shares. Organon will not issue any physical stock certificates to any shareholders, even if requested.

How many shares of Organon common stock will I receive in the distribution? You will receive one-tenth of a share of Organon common stock for each share of Merck common stock held as of the close of business on May 17, 2021, the record date. Based on approximately 2,531,303,747 shares of Merck common stock outstanding as of March 31, 2021, and assuming a distribution of all of Organon's common stock and applying the distribution ratio (without accounting for cash to be issued in lieu of fractional shares), Organon expects that a total of approximately 253,130,375 shares of Organon common stock will be distributed to Merck's shareholders. For additional information on the distribution, see "The Separation and Distribution."

Will Organon issue fractional shares in the distribution? No. Organon will not issue fractional shares of its common stock in the distribution. Fractional shares that Merck shareholders would otherwise have been entitled to receive will be aggregated and sold in the public market by the distribution agent. The aggregate net cash proceeds of these sales will be distributed pro rata (based on the fractional share such holder would otherwise be entitled to receive) to those shareholders who would otherwise have been entitled to receive fractional shares. Recipients of cash in lieu of fractional shares will not be entitled to any interest on the amounts of payment made in lieu of fractional shares and may be subject to tax.

What are the conditions to the distribution?

The distribution is subject to several conditions, including, among others:

- the receipt of opinions from Merck’s tax advisors to the effect that the distribution and certain related transactions will qualify as tax-free to Merck and its shareholders under Sections 355 and 368 of the Internal Revenue Code of 1986, as amended (the “Code”);
- the making of a distribution of approximately \$9.0 billion from Organon to Merck, and the determination by Merck in its sole discretion that following the separation Merck will have no further liability or obligation whatsoever with respect to any of the financing arrangements that Organon will be entering into in connection with the separation;
- the receipt of an opinion from an independent appraisal firm to the Merck Board of Directors confirming the solvency of Merck giving effect to the distribution of Organon and confirming the solvency of Organon giving effect to the cash dividend that is in form and substance acceptable to Merck in its sole discretion;
- the U.S. Securities and Exchange Commission (the “SEC”) declaring effective Organon’s registration statement on Form 10 of which this information statement forms a part, and the making available of the information statement to all holders of shares of Merck common stock as of the close of business on May 17, 2021, the record date;
- no order, injunction, or decree issued by any court of competent jurisdiction or other legal restraint or prohibition preventing the consummation of the separation, distribution or any of the related transactions shall be in effect;
- the shares of Organon common stock to be distributed shall have been accepted for listing on the NYSE, subject to official notice of distribution; and
- no other event or development existing or having occurred that, in the judgment of Merck’s Board of Directors, in its sole discretion, makes it inadvisable to effect the separation, distribution and other related transactions.

Merck and Organon cannot assure you that any or all of these conditions will be met. In addition, Merck will have the sole and absolute discretion to determine (and change) the terms of, and whether to proceed with, the distribution and, to the extent it determines to so proceed, to determine the record date and the distribution date and the distribution ratio. Merck does not intend to notify its shareholders of any modifications to the terms of the separation that, in the judgment of its Board of Directors, are not material. For a complete discussion of all of the conditions to the distribution, see “The Separation and Distribution—Conditions to the Distribution.”

What is the expected date of completion of the distribution?

The completion and timing of the distribution are dependent upon a number of conditions. It is expected that the shares of Organon

common stock will be distributed by Merck on June 2, 2021 to the holders of shares of Merck common stock at the close of business on the record date. However, we cannot assure you as to the timing of the distribution or that all conditions to the distribution will be met.

Can Merck decide to cancel the distribution of Organon common stock even if all the conditions have been met? Yes. The distribution is subject to the satisfaction or waiver of certain conditions. See the section entitled “The Separation and Distribution—Conditions to the Distribution.” Until the distribution has occurred, Merck has the right to terminate the distribution, even if all of the conditions are satisfied.

What if I want to sell my Merck common stock or my Organon common stock? You should consult with your financial advisors, such as your stockbroker, bank or tax advisor.

What is “regular-way” and “ex-dividend” trading of Merck stock? Beginning on or shortly before the record date and continuing until the time of the distribution, it is expected that there will be two markets in shares of Merck common stock: a “regular-way” market and an “ex-dividend” market. Shares of Merck common stock that trade in the “regular-way” market will trade with an entitlement by the purchaser of such shares to shares of Organon common stock distributed pursuant to the distribution. Shares that trade in the “ex-dividend” market will trade without an entitlement by the purchaser of such shares to shares of Organon common stock distributed pursuant to the distribution.

If you decide to sell any shares of Merck common stock before the distribution date, you should make sure your stockbroker, bank or other nominee understands whether you want to sell your shares of Merck common stock with or without your right to receive Organon common stock pursuant to the distribution.

Where will I be able to trade shares of Organon common stock? Organon intends to apply to list its common stock on the NYSE under the symbol “OGN.” Organon anticipates that trading in shares of its common stock will begin on a “when-issued” basis on or shortly before the record date and will continue until the time of the distribution and that “regular-way” trading in Organon common stock will begin on the first trading day following the completion of the distribution. If trading begins on a “when-issued” basis, you may purchase or sell shares of Organon common stock until the time of the distribution, but your transaction will not settle until after the distribution. Organon cannot predict the trading prices for its common stock before, on or after the distribution date.

What will happen to the listing of shares of Merck common stock? Shares of Merck common stock will continue to trade on the NYSE after the distribution.

Will the number of shares of Merck common stock that I own change as a result of the distribution? No. The number of shares of Merck common stock that you own will not change as a result of the distribution.

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Will the distribution affect the market price of my Merck common stock? Yes. As a result of the distribution, Merck expects the trading price of shares of Merck common stock immediately following the distribution to be different than the “regular-way” trading price of such shares immediately prior to the distribution because the trading price will no longer reflect the value of Organon. The combined trading prices of one share of Merck common stock and one share of Organon common stock after the distribution may be equal to, greater than or less than the trading price of one share of Merck common stock before the distribution.

What are the material U.S. federal income tax consequences of the contribution and the distribution? Assuming that the spin-off qualifies as a tax-free transaction under Sections 355 and 368 of the Code, Merck shareholders are not expected to recognize any gain or loss for U.S. federal income tax purposes solely as a result of the spin-off, except to the extent of any cash received in lieu of fractional shares. With respect to such cash received in lieu of a fractional share, however, you will recognize gain or loss for U.S. federal income tax purposes. For more information regarding the potential U.S. federal income tax consequences to Merck and to you of the separation and the distribution, see the section entitled “Material U.S. Federal Income Tax Consequences.”

How will I determine my tax basis in the shares of Organon common stock I receive in the distribution? For U.S. federal income tax purposes, your aggregate basis in the common stock that you hold in Merck and the new Organon common stock received in the distribution (including any fractional share interest in Organon common stock for which cash is received) will equal the aggregate basis in the shares of Merck common stock held by you immediately before the distribution, allocated between your shares of Merck common stock and the Organon common stock (including any fractional share interest in Organon common stock for which cash is received) you receive in the distribution in proportion to the relative fair market value of each on the distribution date.

You should consult your tax advisor about the particular consequences of the distribution to you, including the application of the tax basis allocation rules and the application of state, local and foreign tax laws.

What will Organon’s relationship be with Merck following the distribution? Organon will enter into a separation and distribution agreement with Merck to effect the separation and provide a framework for Organon’s relationship with Merck after the distribution. Organon and Merck will also enter into certain other agreements, including one or more transition services agreements, manufacturing and supply agreements, trademark license agreements, intellectual property license agreements, an employee matters agreement, a tax matters agreement and certain other commercial agreements. These agreements will provide for the separation between Merck and Organon of the assets, employees, liabilities and obligations (including investments, property, employee benefits and tax-related assets and liabilities) of Merck attributable to periods prior to, at and after the distribution. These agreements will also govern the relationship between Merck and Organon subsequent to the

completion of the distribution. For additional information regarding the separation and distribution agreement and other transaction agreements, see the sections entitled “Risk Factors—Risks Related to the Separation and Distribution” and “Certain Relationships and Related Party Transactions.”

Who will manage Organon after the distribution?

Organon benefits from having in place a management team with an extensive background in the women’s health, biosimilars and established brands businesses. Led by Kevin Ali, who will be Organon’s Chief Executive Officer after the distribution, Organon’s management team possesses deep knowledge of, and extensive experience in, its industry. For more information regarding Organon’s management team and leadership structure, see “Management.”

Are there risks associated with owning Organon common stock?

Yes. Ownership of Organon common stock is subject to both general and specific risks related to Organon’s business, the industry in which it operates, its ongoing relationships with Merck and its status as a separate, publicly traded company. Ownership of Organon common stock is also subject to risks related to the separation and distribution. These risks are described in the “Risk Factors” section of this information statement. You are encouraged to read that section carefully.

Does Organon plan to pay dividends?

Prior to completion of the distribution, the Board of Directors of Organon will adopt a policy with respect to the payment of dividends on Organon common stock following the distribution. Organon currently expects that it will initially pay regular cash dividends, however, the declaration and payment of any dividends in the future by Organon will be subject to the sole discretion of its board of directors and will depend upon many factors. See “Dividend Policy.”

Who will be the distribution agent, transfer agent and registrar for the Organon common stock?

The distribution agent, transfer agent and registrar for the Organon common stock will be Equiniti Trust Company. For questions relating to the transfer or mechanics of the stock distribution, you should contact:

Equiniti Trust Company
1110 Centre Pointe Curve
Suite 101
Mendota Heights, MN 55120 USA
800-522-9114

How can I contact Merck or Organon with any questions?

Before the distribution, if you have any questions relating to Merck’s business performance, you should contact:

Merck Investor Relations
investor_relations@merck.com
908-740-1468

After the distribution, Organon shareholders who have any questions relating to Organon’s business performance should contact:

Organon Investor Relations
investor_relations@organon.com
551-430-6900

Information Statement Summary

The following is a summary of information discussed in this information statement. This summary may not contain all the details concerning the separation or other information that may be important to you. To better understand the separation and distribution and Organon's business and financial condition, you should carefully review this entire information statement. Except as otherwise indicated or unless the context otherwise requires, the information included in this information statement assumes the completion of all the transactions referred to in this information statement in connection with the separation and distribution. Unless the context otherwise requires, references in this information statement to "Organon," "the company," "we," "us" and "our" refer to Organon & Co. and its consolidated subsidiaries as they will exist assuming the completion of all of the transactions referred to in this information statement in connection with the separation and distribution. References in this information statement to "Merck" refer to Merck & Co., Inc., a New Jersey corporation, and its consolidated subsidiaries, giving effect to the distribution, unless the context otherwise requires.

This information statement describes the businesses to be transferred to Organon by Merck in the separation as if the transferred businesses were Organon's businesses for all historical periods described. References in this information statement to Organon's historical assets, liabilities, products, businesses or activities of Organon's business are generally intended to refer to the historical assets, liabilities, products, businesses or activities of the transferred businesses as the businesses were conducted as part of Merck and its subsidiaries prior to the separation.

Company Overview

Organon is a science-based global pharmaceutical company that develops and delivers innovative health solutions through a portfolio of prescription therapies within women's health, biosimilars and established brands. No other large global pharmaceutical company has women's health as its primary therapeutic area of focus. Our women's health portfolio has historically delivered strong revenues, underpinned by our contraceptives products, which include Nexplanon / Implanon NXT, our patented long-acting reversible contraceptive, with its sales growing at an 11% CAGR between 2010 and 2020. Our biosimilars portfolio has delivered more than \$650 million in sales since 2017, and we expect growth will be fueled by planned launches in the United States and Europe. Finally, our established brands portfolio continues to generate strong operating profit across many markets, including the United States, China, Japan, Korea and countries in Europe, despite loss of market exclusivity across a majority of brands. For many of our products, the impacts of loss of patent exclusivity events in the United States and Europe have passed, and, as a result, combined with enhanced management focus, an established supply chain and targeted resourcing, we believe that our portfolio will continue to deliver strong, reliable operating profit at low promotional and development expense requirements. See "Business—Products" for more information on loss of patent exclusivity for our key products.














Our mission is to be the world's leading women's health company and deliver a better and healthier every day for every woman. We plan to build on our strengths in reproductive health to assemble an array of health solutions to serve women from adolescence to menopause and beyond. We are focused on generating strong and growing cash flow by selectively investing in development and inorganic opportunities to drive innovation and future growth across our core areas. Our portfolio of diverse and branded products is supported by commercialization and market access, regulatory affairs, manufacturing and clinical development expertise globally. Our global footprint lends scale to our business by enabling management to identify and focus on unique market opportunities across our broad portfolio.

Our women's health, biosimilars and established brands portfolios, together with the expertise and experience of our employees, enable us to pursue an exciting innovation agenda, carving out a unique position in the health care sector. Our product portfolio is unified by a central focus on patient needs addressed by our

therapies, a commitment to driving organic and inorganic growth, a heritage of successful commercialization and clinical development, and a disciplined approach to cost and operational efficiency. We believe our women's health portfolio, in combination with our biosimilars and established brands portfolios, will enable us to deliver value to patients and the health care system while creating value for our shareholders. We also believe our geographic scale, long heritage and sustained successes within women's health will enable us to become the commercialization and distribution partner of choice for smaller women's health companies. Our global commercial capabilities and market access, established relationships with health care providers, patients and payors and clinical expertise support our long-term strategy to launch therapies and recognize development opportunities within and beyond our existing portfolios.

Our business strategy is focused on advancing our mission to be the world's leading women's health company, pursuing growth in biosimilars and maximizing opportunities from our established brands portfolio. In particular:

- We believe there is significant growth potential in women's health broadly. In addition to our ten marketed products, we intend to focus our growth efforts in two areas, on needs and conditions that uniquely impact women, generally referred to as the core women's health market, and on needs and conditions that disproportionately impact women. We estimate that the combined global market for pharmaceuticals in the core women's health market, which includes therapeutic areas such as contraception and fertility, endometriosis and uterine fibroids, was \$33 billion in 2020. We project that the core women's health market will grow to \$40 billion by 2026. In addition, we estimate that the segment of therapeutic areas that disproportionately impact women, such as osteoporosis, lupus, urinary tract infections, migraines and celiac disease, will grow annually at an approximately 10% CAGR from 2020 to 2026, adding a further \$21 billion to the core women's health market size estimates.
- Our existing biosimilars portfolio positions us for success in this attractive and fast growing area of health care. We estimate the total size of the global market for biosimilars was approximately \$17.3 billion as of September 2020, reflecting 60 biosimilars approved in the European Union ("EU") and 29 approved in the United States. Industry publications estimate that 54 major biologics, with an aggregate market value of approximately \$220 billion, will lose patent protection in the next decade, which has potential to expand the biosimilars global market to over \$30 billion in the next decade or so. We do not have biosimilars corresponding to all biologics that will lose patent protection in the next decade. All five biosimilars in our portfolio have launched in certain countries globally, including two biosimilars in the United States. We intend to expand our biosimilars portfolio through commercialization of additional products and expanded marketing of existing products. We believe our size, capabilities and experience position us competitively in this area.
- Our established brands portfolio consists of 49 products covering cardiovascular, respiratory, dermatology and non-opioid pain management. A number of our established brands that face generic competition still contribute meaningful profitability. We intend to stimulate the performance of our established brands products through renewed focus and attention on strategic marketing to create a significant source of capital to fuel the company's growth aspirations. We believe our established brands products will, over time, continue to deliver meaningful revenue and operating profit that can be redirected into organic and inorganic growth opportunities in key product areas and geographies. Our established brands portfolio is supported by our large commercial and manufacturing capabilities, including a global network that enables us to distribute products to patients in more than 140 countries and territories.

Women's Health	Key Products Biosimilars	Established Brands
		
		
		
		
		

In 2020, the Organon Products segment recorded revenue of \$6.5 billion and generated \$2.3 billion of net income. We expect to be well positioned for low to mid-single digit annual revenue growth off of a 2021 base year. We operate on a global scale and our global network enables us to distribute products to patients in more than 140 countries and territories around the world, with approximately 80% of 2020 Organon Products segment revenue, or \$5.1 billion, generated outside the United States. Upon the separation, we will have approximately 9,950 employees worldwide, with approximately 4,030 employees focusing on sales, marketing and key commercialization activities and approximately 730 employees focusing on clinical development, safety, and medical affairs and product registration. Additionally, we expect to operate six manufacturing sites globally and have approximately 3,020 manufacturing employees.

Our operations are principally managed on a products basis and include two operating segments, the Organon Products segment and the Merck Retained Products segment. We consider the Organon Products segment to be our only business going forward, and, as such, all discussion and financial information presented in this section relates only to the Organon Products segment.

Upon separation, Merck will retain operations of the Merck Retained Products segment, and we will no longer present financial information related to this segment in our financial statements. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Organon is a Delaware corporation incorporated on March 11, 2020. Our corporate offices are located at 30 Hudson Street, 33rd Floor, Jersey City, New Jersey 07302.

Strengths

We have a number of advantages that distinguish us from our competitors and support our strategy:

- **Leading portfolio of health solutions for women.** We intend to be the world's leading women's health company, with a long history of innovative, first-to-market contraceptive products. We have a broad offering of contraception and fertility brands that we believe have long-term growth potential, and we are one of only two global contraception manufacturers operating in the highly fragmented contraception market. Our portfolio of ten products includes Nexplanon / Implanon NXT, globally one of the highest revenue-generating long-acting reversible contraceptives, or LARC, a class of contraceptives recognized as the most effective method of hormonal contraception available to patients with a lower long-term average cost. Our management team has the development and commercial expertise to drive innovation in therapeutics and drug-device combinations across the women's health landscape through opportunities related to our existing portfolio and by externally sourcing therapies through in-licensing, acquisition and other business development transactions with innovators seeking to benefit from our global commercial presence in women's health.
- **Growing position in biosimilars.** We have a growing position in biosimilars. We have strong, global commercialization capabilities, with a portfolio spanning oncology and immunology treatments, two areas primed for significant growth in biosimilars. We plan to continue evaluating opportunities in other potential therapeutic areas, including ophthalmology, diabetes and neuroscience. Our oncology biosimilars have been launched in 20 countries and our immunology biosimilars have been launched in five countries. All five biosimilars in our portfolio have launched in certain countries globally, including two biosimilars in the United States. We expect that our biosimilars business will continue to generate growth in the near term.
- **Market Leading Established Brands.** In established brands, we have a broad and robust portfolio of mature brands generally beyond market exclusivity, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management. Our established brands portfolio generates strong operating profit, which we anticipate will continue to fund our future growth. We have proven development, regulatory, manufacturing and commercial capabilities, which we believe will support growth in targeted existing geographies, new geographies, and through new indications and line extensions.
- **Broad and fit-for-purpose capabilities.** We have enterprise capabilities delivered by seasoned leaders in global commercialization and market access, regulatory affairs, manufacturing and clinical development. In particular, our capabilities include:
 - **Global commercialization expertise:** Our experienced team will execute targeted investment in, and successful commercialization of, organic growth opportunities across our global portfolio. These efforts will be supported by data-driven, science-based decision-making and execution at scale, enabled by data and analytics and by digital engagement of health care providers and patients.
 - **Development capabilities:** We have approximately 730 employees focused on clinical development, safety, medical affairs and product registration. Our employees have deep expertise in these areas that we believe will facilitate generation of robust clinical data capable of enabling rapid global product registration, as well as valuable insights to expand the commercial reach of our portfolio.
 - **Digital and omni-channel marketing capabilities:** We market our products using a digital and omni-channel approach, reaching a broad base of market participants, including health care providers, patients and policy makers and payors in a cost-efficient manner. Our health care

provider, patient and payor-focused relationship management is facilitated by an integrated digital ecosystem that coordinates health care provider and patient engagement across many channels, including face-to-face, email, social media, mobile and websites.

- **Strategic alliances:** We have an extensive track record of managing strategic alliances and creating value through global partnerships to guide investment and growth in inorganic pipeline opportunities. For example, our collaboration with Samsung Bioepis Co., Ltd. (“Samsung Bioepis”) allows us to work together with a biopharmaceutical company that complements our capabilities and strengths.
- **Established manufacturing and supply chain:** Beyond our commercial capabilities, we expect to have approximately 440 employees operating in supply chain management, which we believe, together with our manufacturing capabilities, will enable us to maintain a high-quality, reliable global supply chain. See “Business—Manufacturing Capabilities and Global Supply Chain.”
- **Geographic scale and platform.** In 2020, we generated \$5.1 billion in sales outside the United States, representing approximately 80% of our total Organon Products segment sales. Our footprint spans the globe with a direct presence in 58 countries and the ability to deliver therapies to patients in more than 140 countries and territories. We plan to initially focus on 14 key markets, which currently generate approximately 75% of our global sales, and we expect our broader geographic reach and manufacturing capabilities to drive long-term growth and expansion opportunities. Specifically, in women’s health and biosimilars, we believe our global footprint will enable us to expand the market for our current products in order to meet the increasing demand for these products. We also believe our geographic scale, long heritage and sustained successes within women’s health will enable us to become the commercialization and distribution partner of choice for smaller women’s health companies. In established brands, where opportunities vary significantly depending on the exact dynamics and characteristics of each country, we believe our geographic scale enables us to capitalize on global opportunities and increase brand share by responding to these dynamics.
- **Strong financial profile with significant free cash flow generation and improving operating leverage.** In 2020, the Organon Products segment generated approximately \$2.3 billion in operating cash flow and spent \$255 million on capital expenditures. The Organon Products segment also generated Adjusted EBITDA of \$3.1 billion on \$6.5 billion of sales, representing an EBITDA margin of approximately 47%. We expect that 2021 operating cash flow from the Organon Products Segment will be comparable to, though slightly down from, 2020 before the impact of estimated interest expense. We anticipate we will continue to generate significant cash flow and expect our operating leverage to improve in the future.
- **Scientific heritage, expertise and culture of excellence inherited from Merck.** Merck’s rich, over-125-year scientific heritage is imbued in our strong scientific principles, innovative development strategies and quality-focused culture. Building on our heritage of regulatory and scientific expertise, we expect to have the capabilities to continue to optimize pathways for clinical development and regulatory approvals. We also expect to have the data generation capabilities required to support patient access, formulary placement and reimbursement.
- **Strong, leading and established brand in the area of women’s health.** The Organon brand has a long history in the area of women’s health, both with patients and health care providers, and with employees who initially came to Merck through the acquisition of Organon. Our proud heritage in women’s health began with Organon’s launch of one of the first-ever combined hormonal oral contraceptives, Lyndiol, in 1962. This was followed by an impressive series of innovative firsts, including:
 - the launch of Marvelon in 1981, the first lower dose (30mcg) estrogen combined oral contraceptive with a selective progestin,
 - the launch of Livial in 1987, the first non-estrogen gonadomimetic hormonal replacement treatment,

- the launch of Follistim / Puregon (“Follistim”), the first recombinant follicle-stimulating hormone available in the United States for infertility,
 - the launch of NuvaRing in 2001, the first once-a-month contraceptive ring, and
 - the launch of Nexplanon / Implanon NXT in 2011, the first and only single-rod radiopaque contraceptive implant with preloaded applicator.
- ***Experienced management team and Board with track record of successful performance.*** Our executive management team has a strong track record of leadership, performance and execution in the pharmaceutical industry. Together, they bring a diverse set of leadership experience at respected companies both within and beyond the biopharmaceutical industry. Our CEO and a majority of our executive leadership team have been appointed from within Merck where they each established reputations as global leaders. Our management team is supported by a seasoned Board of Directors providing guidance and strategic vision based on a diverse set of backgrounds and experiences. The extensive company and industry experience of our management team as well as our Board of Directors will serve as a source of strength and innovation to guide us into the future.

Strategies

Our strategy is to be the world’s leading women’s health company by leveraging our historical strength in this area and investing in therapies and innovations that support the medical needs of women, to pursue growth in biosimilars and to maximize opportunities from our established brands, all while reinvesting our strong operating cash flow to fund growth initiatives across our portfolio. We believe our portfolio will benefit from the increased investment and attention we can provide as an independent company. Our focus will be to:

- ***Leverage our existing position in women’s health to become the global leader in this space.*** No other large global pharmaceutical company has women’s health as its primary therapeutic area of focus. We intend to be the world’s leading women’s health company to address the needs and conditions that uniquely and disproportionately impact women. We plan to achieve this by leveraging our scale, deep experience, geographic reach, strong relationships with payors, health care providers, large clinics and important stakeholder groups such as societies, patients and scientific leaders to grow revenue for our contraception and fertility brands and expand into additional women’s health therapeutic areas, and through strategic acquisitions and collaborations. In 2020, approximately one quarter of our revenue was derived from women’s health products and, over time, we expect to grow this share by:
 - expanding the marketing and distribution of our key brands, including Nexplanon / Implanon NXT, Follistim and Elonva,
 - investing in manufacturing to expand the supply capacity for Nexplanon / Implanon NXT and our fertility product portfolio,
 - focusing our contraception commercial strategy on expanding global access to Nexplanon / Implanon NXT and increasing communication and education about LARC, which we believe will expand the market opportunity for Nexplanon / Implanon NXT,
 - focusing our fertility commercial strategy on increasing communication and education about antagonist protocols, which we believe will expand the market opportunity for both Follistim and Elonva,
 - applying our long history of women’s health scientific development experience to invest in late lifecycle activities that will broaden the geographic footprint of our women’s health portfolio and further enhance the value of the portfolio, and

- tracking scientific innovation globally to source commercialized and development-stage inorganic opportunities across women’s health broadly in order to develop products that target specific unmet medical need in conditions that impact women both uniquely and disproportionately.
- **Maximize value from our biosimilars portfolio through increased focus and strategic investment.** We believe that the biosimilars market offers potential for value creation for a company with our strengths. In the short term, we are focused on commercializing the five biosimilars sourced from our collaboration with Samsung Bioepis, including the recent EU launch of Aybintio in oncology. In the longer term, we expect to focus on expanding our portfolio through ongoing identification and evaluation of new opportunities in therapeutic areas such as oncology, immunology, ophthalmology, diabetes and neuroscience, both through our Samsung Bioepis collaboration and through other potential collaborations. We believe that our focused approach enables us to further capitalize on the momentum in the biosimilars industry to drive growth through commercialization of additional biosimilars and expansion of our existing products into additional countries. In addition, we believe the biosimilars market will continue to favorably mature through continued policy efforts, both in the United States and globally, that recognize the important role biosimilars can play in alleviating cost pressures for health care systems. In addition, we believe our commercial experience, particularly in the areas of tendering and policy, obtained from our prior biosimilars launches (Renflexis in the United States and Ontruzant in the United States and the EU) provides us a competitive advantage in the market.
- **Drive near-term growth through investment in our existing portfolio.** We believe that our broad portfolio affords us a range of options to drive future growth by developing products that target specific unmet medical need, including in-licenses, commercial collaborations, partnerships and acquisitions consistent with our focused strategy. For example, our established brands portfolio has a particularly strong foothold in emerging markets where we have a broad base of products enabling us to build targeted additional product offerings and developments. We expect that greater managerial focus to capture local market opportunities, along with targeted investments in expanding our geographic footprint, digital promotion and commercial trade channels, will provide new revenue opportunities for select brands in our established brands portfolio. We also believe there are meaningful opportunities to be realized through further investment in, and lifecycle management of, our current products across our portfolios.
- **Drive long-term growth through investment in inorganic opportunities.** To drive longer-term growth, we intend to expand our scientific capabilities in targeted therapeutic areas through investment in inorganic opportunities and acquisitions in order to further augment our existing product businesses. We believe these investments will help us build a development pipeline that will drive our future revenues.
- **Enhance our digital and omni-channel marketing capabilities to drive growth.** Our commercial strategy focuses on growing our product portfolio by increasing productivity across our sales force and leveraging digital channels, data and analytics to improve the return on investment in health care provider and patient engagement. We plan to continually expand our digital and omni-channel capabilities to optimize sales opportunities for our products and to further invest in digital engagement models that allow us to reach our customers and patients effectively. We also plan to further strengthen the design and execution of personalized omni-channel campaigns, engaging health care providers and patients through the most cost-effective channels and building upon existing strengths, such as our sophisticated capabilities to successfully target women and maximize our promotional response, which we achieved through nearly 10 years of executing and analyzing women’s health consumer campaigns in the United States.
- **Drive efficiency to improve operating leverage and cash flow.** As an independent company, we intend to focus on delivering operating efficiencies. We have identified a number of key areas in which we plan to generate cost efficiencies by simplifying our operating model, standardizing and centralizing

service activities and designing and enhancing our commercial model and supply chain functions. We also plan to leverage external providers where there is a cost and service advantage. In addition, we are in the process of implementing systems and process improvements to reduce general and administrative costs, and simplify our infrastructure following the termination of our transition services agreement with Merck. We believe the combination of these efficiencies will allow us to drive growth in free cash flow.

- ***Deploy our free cash flow to invest in our existing product portfolio, fund inorganic opportunities and return capital to our shareholders.*** We are committed to the success of our existing product portfolio and plan to make commercial decisions that will allow us to maximize its value. In addition, we plan to invest in inorganic growth opportunities such as in-licenses, commercial collaborations and acquisitions of development-stage or in-market products. We also plan to acquire products that fit within our existing commercial infrastructure, which we believe will generate attractive risk-adjusted returns on investment. There are inorganic growth opportunities, particularly in women’s health and biosimilars, that we plan to target. We believe that our global commercial and market access capabilities, regulatory affairs, specialized manufacturing and clinical development expertise, will enable us to evaluate and integrate external opportunities. In addition, we plan to pay a dividend to our shareholders, pay down debt consistent with our financial policy and, to the extent that we generate excess free cash flow, we will consider returning additional free cash flow to our shareholders via share repurchases. We expect our targeted dividend payout to be in the low 20s as a percentage of post-separation Adjusted Net Income.
- ***Capitalize on our status as a newly independent company to align our talented employee base with our performance expectations and drive a culture of high performance.*** Our strong heritage of excellence and scientific foundation enables us to approach complex problems with innovative science-based solutions. As a new, independent company, we have a rare opportunity to forge a distinct identity and align hiring, training, development and incentive activities around a clear set of performance expectations related to our core strategy. To establish this culture, we plan to draw upon key aspects of our shared history with Merck while charting a new course. We expect to be a performance-focused and entrepreneurial company with simplified organizational layers and governance, and a focus on alignment and leadership empowerment that enables our leaders to understand and address the evolving and unmet medical need of patients and health care providers around the world.

Summary of Risks Related to Organon’s Business and the Separation

An investment in Organon common stock is subject to a number of risks, including risks related to the separation and distribution. The following list of risk factors is not exhaustive. Please read the information in the section entitled “Risk Factors” for a more thorough description of these and other risks.

Risks Related to Organon’s Business

- **We have no history operating as an independent company, and we expect to incur increased administrative and other costs following the separation by virtue of our status as an independent public company. Our historical and pro forma financial information is not necessarily representative of the results that we would have achieved as a separate, publicly traded company and may not be a reliable indicator of our future results.** Our historical and pro forma financial information included in this information statement is derived from the consolidated financial statements and accounting records of Merck. Accordingly, the historical and pro forma financial information included in this information statement does not necessarily reflect the financial condition, results of operations or cash flows that we would have achieved as a separate, publicly traded company during the periods presented or those that we will achieve in the future, primarily as a result of the following factors: developing an independent ability to operate without access to Merck’s existing

operational and administrative infrastructure, loss of ability to utilize Merck's size and purchasing power in procuring various goods and services on favorable terms, potential need to obtain additional financing, increased cost of capital for our business and issuance of any debt we expect to incur as part of the separation. Other significant changes may occur in our cost structure, management, financing and business operations as a result of operating as a company separate from Merck.

- **Key products generate a significant amount of our profits and cash flows, and any events that adversely affect the markets for our leading products could adversely affect our results of operations and financial condition.** Our ability to generate profits and operating cash flow depends largely upon the continued profitability of our key products, such as Nexplanon / Implanon NXT, Cozaar/Hyzaar, Zetia, Singulair and Atozet. As a result of our dependence on key products, any event that adversely affects any of these products or the markets for any of these products could adversely affect our sales, results of operations and cash flows. These adverse events could include increased costs associated with manufacturing, product shortages, increased generic or over-the-counter availability of our products or competitive products, 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 these products for any reason. We also expect that competition will continue to adversely affect the sales of these products.
- **We face continued pricing pressure with respect to our products.** In the United States, we experience and expect to continue experiencing significant pricing pressure from: managed care groups, institutional and governmental purchasers, U.S. federal laws and regulations related to Medicare and Medicaid (including the Medicare Prescription Drug Improvement and Modernization Act of 2003), the Affordable Care Act (the "ACA") and state activities aimed at regulating prices and increasing price transparency. Outside the United States, numerous major markets have pervasive government involvement in health care funding and, in that regard, extensive pricing and reimbursement mechanisms and processes for pharmaceutical products, which in turn means that we are subject to government decision-making and budgetary actions with respect to our products.
- **We face intense competition from competitors' products.** Our products face intense competition from competitors' products, including lower cost generic versions of our products that have lost market exclusivity, which may be equally safe and as effective as our products but sold at a substantially lower price than our products. Alternatively, our 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 our products. Our efforts to compete with other companies or our failure to maintain our competitive position could adversely affect our business, cash flow, results of operations, financial condition and prospects.
- **We expect to have limited in-house research and development capabilities and will rely on future acquisitions, partnerships and collaborations to expand our research and development capabilities, which means we may not be able to develop new products or expand our existing products into new markets to replace the sales of products that lose patent protection, and therefore we may not be able to maintain our current levels of profitability.** Upon our separation from Merck, we will have limited in-house research and development staff and facilities, and we do not currently intend to hire or acquire such staff or facilities immediately after the separation and instead, we intend to rely on future acquisitions, partnerships and collaborations with third parties to expand our existing portfolio and research capabilities. In addition, we rely on our collaboration with Samsung Bioepis for the successful development and manufacture of our biosimilars products and expect to do so for the foreseeable future. We also intend to grow our product portfolio of prescription therapies by acquiring products developed by third parties. If our expansion into new products, new indications or formulations of our existing products or expansion of existing products into new markets or new geographies does not offset the sales lost through loss of patent exclusivity, then we may not be able to

maintain our current levels of profitability, and this could adversely affect our business, cash flow, results of operations, financial condition and prospects.

- **We may experience difficulties identifying and effecting acquisition opportunities.** We may pursue acquisitions of complementary businesses, licensing arrangements and strategic partnerships to expand our product offerings and geographic presence as part of our business strategy. We may not complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the expected benefits of any acquisition, license arrangement or strategic partnerships. In identifying, evaluating and selecting acquisition targets, we may encounter intense competition from other companies that have similar business objectives, extensive experience, and greater resources. In addition, certain provisions of the tax matters agreement may discourage, delay or prevent acquisition proposals or otherwise limit our ability to pursue certain strategic transactions or engage in other specified transactions for a period of time.
- **After the distribution, we expect to have significant indebtedness.** We expect to have total indebtedness of approximately \$9.5 billion, consisting of term loans and 144A senior notes with such aggregate principal amount. Approximately \$9.0 billion of such amount will be incurred to pay a distribution to Merck, with the remaining net proceeds intended to be used for general corporate purposes. Such indebtedness and any future indebtedness we may incur could restrict our ability to pay dividends and adversely affect our financing options and liquidity position.
- **We may be unable to market our products if we do not obtain and maintain required regulatory approvals.** Our activities, including the manufacturing and marketing of our products, are subject to extensive regulation by numerous federal and state governmental authorities in the United States and by foreign regulatory authorities, including in the EU, China and Japan. Our failure to obtain approval, significant delays in the approval process or our failure to maintain approval in any jurisdiction will prevent us from marketing and selling the products in that jurisdiction. We would not be able to realize revenues for our products in any jurisdiction where we do not have approval.
- **Developments following regulatory approval may adversely affect sales of our products.** Even after a product reaches the market, certain developments may decrease demand for our products, including 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. Further, we are at risk for product liability and consumer protection claims and civil and criminal governmental actions related to our products, research and marketing activities. In addition, dissemination of promotional materials through evolving digital channels serves to increase visibility and scrutiny in the marketplace.
- **The health care industry in the United States has been, and will continue to be, subject to increasing regulation and political action.** We believe that the health care industry will continue to be subject to increasing regulation and political and legal action at both the Federal and state levels. Recent health care reform legislation, such as the ACA, have resulted in requirements such as a point of service discount and an annual non-tax deductible health care reform fee. In addition, there are currently several proposed draft rules or legislation that may have a material adverse effect on our business, results of operations and financial condition.

Current Developments

In March 2021, Merck and Alydia Health announced a definitive agreement pursuant to which, after the spin-off, Organon will acquire Alydia Health for up to \$240 million in total consideration, subject to customary purchase price adjustments. Total consideration includes a \$215 million upfront payment plus a \$25 million sales-based contingent milestone payment. Alydia Health is a commercial-stage medical device company

focused on preventing maternal morbidity and mortality caused by postpartum hemorrhage or abnormal postpartum uterine bleeding. Of the \$215 million upfront payment, \$50 million was paid by Merck and the remaining \$165 million will be paid by Organon upon the closing of the acquisition, which remains subject to customary closing conditions and completion of the spin-off of Organon from Merck. The \$25 million contingent milestone payment will be paid by Organon upon achievement of the milestone.

The Separation and Distribution

On February 5, 2020, Merck announced that it intended to spin-off its women's health, biosimilars and established brands businesses and create a standalone pharmaceutical company. Merck announced that it intended to effect the spin-off through a pro rata distribution of all of the common stock of a new entity, which has since been named Organon and holds the assets and liabilities associated with the women's health, biosimilars and established brands businesses.

On May 7, 2021, the Merck Board of Directors approved the distribution of all of Organon's issued and outstanding shares of common stock to holders of shares of Merck common stock as of the close of business on May 17, 2021, the record date.

On June 2, 2021, the distribution date, each Merck shareholder will receive one-tenth of a share of Organon's common stock for each share of Merck common stock held at the close of business on the record date. Merck shareholders will receive cash in lieu of any fractional shares of Organon common stock that they would have received after application of this ratio. Shareholders will not be required to make any payment, or surrender or exchange their shares of Merck common stock or take any other action to receive their shares of Organon's common stock in the distribution. The distribution of Organon's common stock as described in this information statement is subject to the satisfaction or waiver of certain conditions. For a more detailed description of these conditions, see the section entitled "—Conditions to the Distribution."

Organon's Post-Distribution Relationship with Merck

Organon will enter into a separation and distribution agreement with Merck, which is referred to in this information statement as the "separation and distribution agreement." In connection with the separation, Organon will enter into various other agreements to effect the separation and provide a framework for its relationship with Merck after the distribution, including one or more transition services agreements, manufacturing and supply agreements, trademark license agreements, intellectual property license agreements, an employee matters agreement, a tax matters agreement and certain other commercial agreements. These agreements will provide for the allocation between Merck and Organon of Merck's assets, employees, liabilities and obligations (including investments, property, employee benefits and tax-related assets and liabilities) attributable to periods prior to, at and after Organon's separation from Merck. These agreements will also govern certain relationships between Merck and Organon after the separation. For additional information regarding the separation and distribution agreement and other transaction agreements, see the sections entitled "Risk Factors—Risks Related to the Separation and Distribution" and "Certain Relationships and Related Party Transactions."

Reasons for the Separation

The Merck Board of Directors believes that separating the women's health, biosimilars and established brands businesses from the remainder of Merck is in the best interests of Merck and its shareholders for a number of reasons, including that the spin-off will:

- give each of Organon and Merck its own dedicated management team, focused on its unique business opportunities and capital needs, thereby allowing each business to pursue more effectively its own distinct operating priorities and strategies;

- give each of Organon and Merck its own source of capital dedicated to its own investment priorities, and allow each of Organon and Merck to implement a capital structure appropriate for its respective cash flow and growth profile;
- give each of Organon and Merck its own equity currency for use in connection with acquisitions; and
- enhance the ability of Organon and Merck to attract and retain qualified management and to better align incentive-based compensation with the performance of each of Organon and Merck's separate businesses.

The Merck Board of Directors considered a number of potentially negative factors in evaluating the separation, including risks relating to the creation of a new public company and possible increased overall costs, as well as one-time separation costs, but concluded that the potential benefits of the separation outweighed these factors. For more information, see the sections entitled "The Separation and Distribution—Reasons for the Separation" and "Risk Factors" included elsewhere in this information statement.

Conditions to the Distribution

The distribution is subject to a number of conditions, including, among others:

- the receipt of opinions (the "Tax Opinions") from Baker & McKenzie LLP and Ernst & Young LLP (the "Tax Advisors") to the effect that the distribution and certain related transactions will qualify as tax-free to Merck and its shareholders under Sections 355 and 368 of the Code;
- the making of a distribution of approximately \$9.0 billion from Organon to Merck, and the determination by Merck in its sole discretion that following the separation Merck will have no further liability or obligation whatsoever with respect to any of the financing arrangements that Organon will be entering into in connection with the separation;
- the receipt of an opinion from an independent appraisal firm to the Merck Board of Directors confirming the solvency of Merck giving effect to the distribution of Organon and confirming the solvency of Organon giving effect to the cash dividend that is in form and substance acceptable to Merck in its sole discretion;
- the SEC declaring effective Organon's registration statement on Form 10 of which this information statement forms a part, and the making available of the information statement to all holders of shares of Merck common stock as of the close of business on May 17, 2021, the record date;
- no order, injunction, or decree issued by any court of competent jurisdiction or other legal restraint or prohibition preventing the consummation of the separation, distribution or any of the related transactions shall be in effect;
- the shares of Organon common stock to be distributed shall have been accepted for listing on the NYSE, subject to official notice of distribution; and
- no other event or development existing or having occurred that, in the judgment of Merck's Board of Directors, in its sole discretion, makes it inadvisable to effect the separation, distribution and other related transactions.

Merck and Organon cannot assure you that any or all of these conditions will be met. In addition, Merck will have the sole and absolute discretion to determine (and change) the terms of, and whether to proceed with, the distribution and, to the extent it determines to so proceed, to determine the record date and the distribution date and the distribution ratio. Merck does not intend to notify its shareholders of any modifications to the terms of the separation that, in the judgment of its Board of Directors, are not material. For a complete discussion of all of the conditions to the distribution, see "The Separation and Distribution—Conditions to the Distribution."

Corporate Information

Organon & Co. was incorporated in Delaware on March 11, 2020. The address of Organon's principal executive offices is 30 Hudson Street, 33rd Floor, Jersey City, New Jersey 07302. Organon's telephone number is 551-430-6900.

After the separation, Organon will maintain an Internet website at www.organon.com. Organon's website and the information contained therein or connected thereto shall not be deemed to be incorporated herein, and you should not rely on any such information in making an investment decision.

Reason for Furnishing this Information Statement

This information statement is being furnished solely to provide information to shareholders of Merck who will receive shares of Organon common stock in the distribution. It is not and is not to be construed as an inducement or encouragement to buy or sell any of Organon's securities. The information contained in this information statement is believed by Organon to be accurate as of the date set forth on its cover. Changes may occur after that date and neither Merck nor Organon will update the information except in the normal course of their respective disclosure obligations and practices.

Summary Historical and Unaudited Pro Forma Financial Information

The following tables set forth summary historical combined and unaudited pro forma financial information. You should read this information in conjunction with the information under "Selected Historical Financial Data," "Unaudited Pro Forma Financial Information," "Management's Discussion and Analysis of Financial Condition and Results of Operations," our audited annual combined financial statements and the related notes included elsewhere in this information statement.

We derived the selected historical combined financial information for each of the fiscal years in the three-year period ended December 31, 2020 from our audited annual combined financial statements included elsewhere in this information statement.

The selected unaudited pro forma financial information at and for the year ended December 31, 2020 is unaudited and has been derived from our unaudited pro forma financial information included elsewhere in this information statement.

Combined Balance Sheet

(\$ in millions)	Pro Forma	As of December 31,	
	as of December 31, 2020	2020	2019
Assets			
Current Assets			
Cash and cash equivalents	\$ 500	\$ 70	\$ 319
Accounts receivable (net of allowance for doubtful accounts of \$18 in 2020 and \$20 in 2019)	1,092	1,360	1,474
Inventories (excludes inventories of \$127 in 2020 and \$93 in 2019 classified in Other Assets)	913	971	1,071
Due from related party	—	—	13
Other current assets	929	977	1,078
Total current assets	<u>3,434</u>	<u>3,378</u>	<u>3,955</u>
Property, Plant and Equipment (at cost)			
Land	14	15	7
Buildings	647	653	382
Machinery, equipment and office furnishings	787	803	824
Construction in progress	356	362	143
	<u>1,804</u>	<u>1,833</u>	<u>1,356</u>
Less: accumulated depreciation	<u>820</u>	<u>835</u>	<u>676</u>
	<u>984</u>	<u>998</u>	<u>680</u>
Goodwill	<u>4,603</u>	<u>4,603</u>	<u>4,603</u>
Other Intangibles, Net	<u>503</u>	<u>503</u>	<u>569</u>
Other Assets	<u>910</u>	<u>438</u>	<u>741</u>
	<u>\$ 10,434</u>	<u>\$ 9,920</u>	<u>\$10,548</u>
Liabilities and Equity			
Current Liabilities			
Trade accounts payable	\$ 259	\$ 294	\$ 258
Accrued and other current liabilities	833	752	807
Due to related party	—	1,150	34
Income taxes payable	109	288	242
Total current liabilities	<u>1,201</u>	<u>2,484</u>	<u>1,341</u>
Deferred Income Taxes	<u>121</u>	<u>128</u>	<u>139</u>
Related Party Loans Payable	<u>—</u>	<u>—</u>	<u>70</u>
Other Noncurrent Liabilities	<u>9,932</u>	<u>1,822</u>	<u>1,963</u>
Organon & Co. Equity			
Common stock	3	—	—
Accumulated deficit	(219)	—	—
Net investment from Parent	—	6,108	7,949
Accumulated other comprehensive loss	(604)	(622)	(914)
Total equity	<u>(820)</u>	<u>5,486</u>	<u>7,035</u>
	<u>\$ 10,434</u>	<u>\$ 9,920</u>	<u>\$10,548</u>

Combined Statements of Income

(\$ in millions)	Pro Forma Year Ended December 31, 2020	For the Year Ended December 31,		
		2020	2019	2018
Sales ⁽¹⁾	\$ 6,607	\$ 8,096	\$ 9,530	\$ 9,777
Costs, expenses and other				
Cost of sales ⁽²⁾	2,316	3,347	3,621	4,693
Selling, general and administrative	1,722	1,666	1,922	2,013
Research and development	315	304	332	365
Restructuring costs	3	70	101	119
Other (income) expense, net	436	29	(1)	(142)
Income before taxes	1,815	2,680	3,555	2,729
Taxes on income	315	520	337	576
Net income	\$ 1,500	\$ 2,160	\$ 3,218	\$ 2,153

⁽¹⁾ Actual results include related party sales of \$599 million in 2020, \$501 million in 2019 and \$432 million in 2018.

⁽²⁾ Actual results include costs for inventory purchases from related parties of \$1.0 billion in 2020, \$1.1 billion in 2019 and \$923 million in 2018.

Risk Factors

You should carefully consider the following risks and other information in this information statement in evaluating Organon and Organon's common stock. Any of the following risks could materially and adversely affect Organon's results of operations or financial condition. The risk factors generally have been separated into three groups: risks related to Organon's business, risks related to the separation and distribution, and risks related to Organon's common stock.

Risks Related to Our Business

We have no history operating as an independent company, and we expect to incur increased administrative and other costs following the separation by virtue of our status as an independent public company. Our historical and pro forma financial information is not necessarily representative of the results that we would have achieved as a separate, publicly traded company and may not be a reliable indicator of our future results.

The historical information about Organon in this information statement refers to Organon's business as operated by and integrated with Merck. Our historical and pro forma financial information included in this information statement is derived from the consolidated financial statements and accounting records of Merck. Accordingly, the historical and pro forma financial information included in this information statement does not necessarily reflect the financial condition, results of operations or cash flows that we would have achieved as a separate, publicly traded company during the periods presented or those that we will achieve in the future, primarily as a result of the following factors:

- Prior to the distribution, our business was operated by Merck as part of its broader corporate organization, rather than as an independent company. Merck or one of its affiliates performed various corporate functions for us, such as tax, treasury, finance, internal audit, risk management, legal, information technology, human resources, shareholder relations, compliance, insurance, employee benefits and compensation. Following the distribution, Merck will continue to provide some of these functions to us after we transition to an independent, publicly traded company, as described in "Certain Relationships and Related Party Transactions." Our historical and pro forma financial results reflect allocations of corporate expenses from Merck for such functions. These allocations will not be indicative of the actual expenses we would have incurred had we operated as an independent, publicly traded company in the periods presented. We will need to make significant investments to replicate or outsource from other providers certain facilities, systems, infrastructure and personnel to which we will no longer have access once the terms of our arrangements with Merck expire. These initiatives to develop our independent ability to operate without access to Merck's existing operational and administrative infrastructure will be costly to implement, and we will incur additive costs in implementing such initiatives currently provided to us by Merck. In addition, we may be unable to obtain replacement services on similar terms as those provided by Merck. We may not be able to operate our business as efficiently or at comparable costs, and our results of operations may be adversely affected.
- Currently, our business is integrated with the other businesses of Merck. We are able to utilize Merck's size and purchasing power in procuring various goods and services and have shared economies of scope and scale in costs, employees, vendor relationships and customer relationships. Although we will enter into transition agreements with Merck, these arrangements may not fully capture the benefits we have enjoyed as a result of being integrated with Merck and may result in us paying higher charges than in the past for these services. As a separate, independent company, we may be unable to obtain goods and services at the prices and terms obtained prior to the separation, which could adversely affect our results of operations. As a separate, independent company, we also may not be as successful in negotiating favorable tax treatment with governmental entities. This could adversely affect our results of operations and financial condition.
- Our working capital requirements and capital for our general corporate purposes, including acquisitions, research and development and capital expenditures, have historically been satisfied as part

of the corporate-wide cash management policies of Merck. Following the completion of the distribution, we may need to obtain additional financing from banks, through public offerings or private placements of debt or equity securities, strategic relationships or other arrangements.

- After the completion of the distribution, the cost of capital for our business is likely to be higher than Merck's cost of capital prior to the distribution.
- Our historical financial information does not reflect the issuance of any debt we expect to incur as part of the separation and distribution or our obligations to purchase from Merck certain operations and assets, and assume the corresponding liabilities, of our business after the distribution date.

Other significant changes may occur in our cost structure, management, financing and business operations as a result of operating as a company separate from Merck. For additional information about the past financial performance of our business and the basis of presentation of the historical combined financial statements and the unaudited pro forma financial information of our business, see "Unaudited Pro Forma Financial Information," "Selected Historical Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the historical financial statements and accompanying notes included elsewhere in this information statement.

Key products generate a significant amount of our profits and cash flows, and any events that adversely affect the markets for our leading products could adversely affect our results of operations and financial condition.

Our ability to generate profits and operating cash flow depends largely upon the continued profitability of our key products, such as Nexplanon / Implanon NXT, Cozaar/Hyzaar, Zetia, Singulair and Atozet. As a result of our dependence on key products, any event that adversely affects any of these products or the markets for any of these products could adversely affect our sales, results of operations and cash flows. These adverse events could include increased costs associated with manufacturing, product shortages, increased generic or over-the-counter availability of our products or competitive products, 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 these products for any reason. We also expect that competition will continue to adversely affect the sales of these products.

We face continued pricing pressure with respect to our products.

We face continued pricing pressure globally and, particularly, in mature markets from managed care organizations, government agencies and programs that could adversely affect our sales and profit margins. We expect pricing pressure to continue in the future. For example, in the United States, we experience significant pricing pressure from: managed care groups, institutional and governmental purchasers, 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 state activities aimed at regulating prices and increasing price transparency. 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. We 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. Outside the United States, numerous major markets, including the EU, China and Japan have pervasive government involvement in health care funding and, in that regard, extensive pricing and reimbursement mechanisms and processes for pharmaceutical products. Consequently, in those markets, we are subject to government decision-making and budgetary actions with respect to our products. In China, pricing pressure from the Chinese government has increased, including through a series of health care reforms to accelerate generic substitution. While pricing pressure has always existed in China, health care reforms have increased this pressure in part due to the acceleration of generic substitution through the government's volume-based procurement ("VBP") and generic quality consistency evaluation ("GQCE") programs. In Japan, the

pharmaceutical industry is subject to government-mandated biennial price reductions of pharmaceutical products. 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 pricing reduction will occur in April 2021 and is expected to impact many Organon products.

We face intense competition from competitors' products.

Our products face intense competition from competitors' products, including lower cost generic versions of our products that have lost market exclusivity. Competitors' products may be equally safe and as effective as our products but sold at a substantially lower price than our products. Alternatively, our 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 our products. Our efforts to compete with other companies or our failure to maintain our competitive position could adversely affect our business, cash flow, results of operations, financial condition and prospects.

We expect to have limited in-house research and development capabilities and will rely on future acquisitions, partnerships and collaborations to expand our research and development capabilities, which means we may not be able to develop new products or expand our existing products into new markets to replace the sales of products that lose patent protection, and therefore we may not be able to maintain our current levels of profitability.

Upon our separation from Merck, we will have limited in-house research and development staff and facilities, and do not currently intend to hire or acquire such staff or facilities immediately after the separation. Instead, we intend to rely on future acquisitions, partnerships and collaborations with third parties to expand our existing portfolio and research capabilities. We also intend to grow our business through new indications or formulations of our existing products or expansion of existing products into new markets or new geographies. However, we expect that our ability to do so will be limited by the scope of our limited intellectual property licenses for certain women's health products. For example, our license for Nexplanon / Implanon NXT permits use of the underlying technology solely as a contraceptive implant containing only the active pharmaceutical ingredient currently used in the product. We may not be able to offset any sales losses for products that lose or do not have exclusivity by growing sales in other markets. If we cannot produce sufficient revenues from expansion into new products, new indications or formulations of our existing products or expansion of existing products into new markets or new geographies, then we may not be able to maintain our current levels of profitability, and this could adversely affect our business, cash flow, results of operations, financial condition and prospects.

We may experience difficulties identifying and effecting acquisition opportunities.

We may pursue acquisitions of complementary businesses, licensing arrangements and strategic partnerships to expand our product offerings and geographic presence as part of our business strategy. We may not complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the expected benefits of any acquisition, license arrangement or strategic partnerships. Such opportunities may relate to products, technologies or operations with which we have limited or no historical experience. For example, in March 2021, Merck announced the signing of a definitive agreement for us to acquire Alydia Health, which is a commercial-stage medical device company. In identifying, evaluating and selecting acquisition targets, we may encounter intense competition from other companies having a business objective similar to ours. Many of these companies are well established and have extensive experience identifying and effecting these types of strategic acquisitions. Moreover, some of these competitors may possess greater financial, technical, human and other resources than we do. In addition, certain provisions of the tax matters agreement, which are intended to preserve the intended tax treatment of the separation and certain related transactions, may discourage, delay or prevent acquisition proposals or otherwise limit our ability to pursue certain strategic transactions or engage in other transactions, including mergers or consolidations for a period of time following the spin-off. Even if we are successful in making acquisitions, the products and technologies we acquire may not be successful or may require significantly greater resources and investments than we originally anticipated. We could experience

negative effects on our results of operations and financial condition from acquisition-related charges, amortization of intangible assets and asset impairment charges. We could experience difficulties in integrating geographically separated organizations, systems and facilities, and personnel with diverse backgrounds. If an acquired business fails to operate as anticipated or cannot be successfully integrated with our existing business, our business, financial condition, results of operations and cash flows could be materially and adversely affected.

We may be unable to market our products if we do not obtain and maintain required regulatory approvals.

Our activities, including the manufacturing and marketing of our products, are subject to extensive regulation by numerous federal and state governmental authorities in the United States, including the Food and Drug Administration (“FDA”), and by foreign regulatory authorities, including in the EU, China and Japan. In the United States, the FDA administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals. Regulation outside the United States also is primarily focused on drug safety and effectiveness and, in many cases, reduction in the cost of drugs. In addition, regulatory authorities such as the FDA, the European Medicines Agency (“EMA”), China’s National Medical Products Administration (“NMPA”) and Japan’s Ministry of Health, Labour and Welfare have increased their focus on safety when assessing the benefit/risk balance of drugs. These regulatory authorities, including in China and Japan, also 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.

Our applications for regulatory approval may be rejected or otherwise delayed by the FDA or other foreign regulatory authorities. For example, the FDA may issue complete response letters indicating that our applications are not ready for approval. We cannot market our products or new indications or formulations of our existing products unless and until we have obtained all required regulatory approvals in each relevant jurisdiction. Once obtained, we must maintain approval as long as we plan to market products in each jurisdiction where approval is required. Our failure to obtain approval, significant delays in the approval process or our failure to maintain approval in any jurisdiction will prevent us from selling the products in that jurisdiction. We would not be able to realize revenues for our products in any jurisdiction where we do not have approval.

Developments following regulatory approval may adversely affect sales of our products.

Even after a product reaches the market, certain developments may decrease demand for our 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 several years, clinical trials and post-marketing surveillance of certain marketed drugs of our 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 health care providers 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, may consume considerable resources.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of our products, it could significantly reduce demand for the product or require us to

take actions that could negatively affect sales, including removing the product from the market, restricting our distribution or applying for labeling changes. Further, we are at risk for product liability and consumer protection claims and civil and criminal governmental actions related to our products, research and marketing activities. In addition, dissemination of promotional materials through evolving digital channels serves to increase visibility and scrutiny in the marketplace.

Certain of our products currently benefit from patent protection and market exclusivity. When the patent protection and market exclusivity periods for such products expire, we generally experience a significant and rapid loss of sales from those products. Expiry of patent protection and market exclusivity for products that contribute significantly to our sales will adversely affect our business.

We depend upon patents to provide us with exclusive marketing rights for certain of our products for some period of time. Loss of patent protection 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 current or future products that contribute significantly to our sales, a loss of market exclusivity could materially adversely affect our business, cash flow, results of operations, financial condition and prospects. For example, the patent that provided United States market exclusivity for NuvaRing expired in April 2018 and generic competition began in December 2019. We experienced a rapid and substantial decline in NuvaRing sales in the United States in 2020 as a result of this generic competition. In addition, we expect to have market exclusivity for Nexplanon / Implanon NXT in the United States until 2027 and the majority of countries where Nexplanon / Implanon NXT is commercialized outside the United States until 2025. See “Business—Products” for details, including the patent protection for certain of our marketed products.

We are dependent on our patent rights for the marketing of certain of our products, and invalidation or circumvention of our patent rights would adversely affect our business.

Patent protections are important to the marketing of certain of our products, particularly certain of our women’s health products in the United States and in most major foreign markets. Patents covering products that we have introduced normally provide market exclusivity, which is important for the successful marketing and sale of certain of our products.

Even if we succeed in obtaining patents covering our products, third parties or government authorities may challenge or seek to invalidate or circumvent our patents and patent applications. It is important for our business to defend successfully the patent rights that provide market exclusivity for our products. We are often involved in patent disputes relating to challenges to our patents or claims by third parties of infringement against us. We defend our patents both within and outside the United States, including by filing claims of infringement against other parties. In particular, manufacturers of generic pharmaceutical products from time to time file abbreviated new drug applications (“ANDAs”) with the FDA seeking to market generic forms of our products prior to the expiration of relevant patents owned or licensed by us. We normally respond by defending our patent, including by filing lawsuits alleging patent infringement. Patent litigation and other challenges to our patents are costly and unpredictable and may deprive us of market exclusivity for a patented product or, in some cases, third-party patents may prevent us from marketing and selling a product in a particular geographic area, negatively affecting our business and results of operations.

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 our business and 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 of our 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. Our results

of operations may be adversely affected by the lost sales unless and until we have launched commercially successful products that replace the lost sales. In addition, if products with intangible assets that were measured at fair value and capitalized in connection with acquisitions experience difficulties in the market that negatively affect product cash flows, we may recognize material non-cash impairment charges with respect to the value of those products.

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

We believe that the health care industry will continue to be subject to increasing regulation and political and legal action at both the Federal and state levels.

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 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. Also, pharmaceutical manufacturers are required to pay an annual non-tax deductible health care reform fee. 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.

As discussed in “Business—Competition and Health Care Environment,” there is significant uncertainty about the future of the ACA and, in particular, health care laws generally in the United States. There are various court cases and other regulatory actions ongoing that may result in the invalidation of all or portions of the ACA. If the individual mandate is held to be unconstitutional and not severable from the remainder of the ACA, we expect this would result in invalidation of the Biologics Price Competition and Innovation Act (“BPCIA”), which provides for an abbreviated pathway for obtaining FDA approval of biologic drugs that satisfy certain criteria and which is incorporated into the ACA.

In 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 provided comprehensive guidance on the calculation of Average Manufacturer Price and Best Price, which are two metrics that determine the rebates drug manufacturers are required to pay to state Medicaid programs. On December 31, 2020, CMS published a Final Rule on the Medicaid Program, which, among other things, introduced new definitions of “line extension” and “new formulation.” CMS defined “line extension” as a new formulation of the drug, not including an abuse-deterrent formulation of the drug, and adopted an expansive definition of “new formulation” to include “an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients.” This expanded definition will result in a number of drugs being subject to a higher Medicaid rebate. The new definitions of “line extension” and “new formulation” will take effect on January 1, 2022. The Final Rule also revised regulations regarding authorized generic sales when manufacturers calculate the average manufacturer price (AMP), manufacturer reporting requirements under the Medicaid Drug Rebate Program (MDRP), and payments for prescription drugs under the Medicaid program. The implementation date of these revised regulations is January 1, 2023. We will evaluate the financial effects of these elements once there is more certainty.

In addition, as discussed in “Business—Competition and the Health Care Environment,” a Final Rule was issued that allows importation of certain lower-cost prescription drugs from Canada. As a result of this Final Rule, effective November 30, 2020, states or certain other non-federal governmental entities will be able to submit importation program proposals to the FDA for review and authorization of two-year programs (with the opportunity to extend for two more years). This rule is currently facing a legal challenge and is currently pending

in federal district court, but if upheld, or if additional future legislative action is taken on drug importation, it would be expected to adversely affect our revenues.

Various executive and legislative actions in the United States have been proposed, or may in the future be proposed, to mandate reduced drug prices. For example, in November 2020, CMS issued a Final 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.” The rule was immediately challenged in at least four federal courts and has been temporarily enjoined from going into effect. The Department of Health and Human Services has indicated that the most favored nation, or MFN, model will not be implemented without further rulemaking.

Additionally in November 2020, the Department of Health and Human Services Office of Inspector General (“OIG”) issued a Final Rule that would, effective January 1, 2022, 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. In response to litigation brought by a trade association on behalf of PBMs, the rule’s effective date has been delayed until January 1, 2023. It remains to be seen whether, and to what extent, these measures will take effect. These executive measures, if upheld, or future legislative action on drug prices may adversely affect our revenues.

We cannot predict the likelihood of additional future changes in the health care industry in general, or the pharmaceutical industry in particular, or what impact they may have on our business, cash flow, results of operations, financial condition and prospects.

We are subject to a variety of United States and international laws and regulations.

We are 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 our business, cash flow, results of operations, financial condition and prospects. The costs of compliance and non-compliance may be particularly significant with respect to health care reform initiatives in the United States or in other countries, including additional mandatory discounts or fees; the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 or other anti-bribery and corruption laws; new laws, regulations and judicial or other governmental decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; new and increasing data privacy regulations and enforcement, particularly in the EU and the United States; legislative mandates or preferences for local manufacturing of pharmaceutical products; emerging and new global regulatory requirements for reporting payments and other value transfers to health care professionals; environmental regulations; and importation restrictions, embargoes, trade sanctions and legislative or other regulatory changes.

We have significant global operations, which expose us to additional risks, and any adverse event could adversely affect our results of operations and financial condition.

The extent of our 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 our ability to manufacture and sell our products in key markets;

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- 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 our business and strategic position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, health epidemics (including the outbreak of the novel Coronavirus Disease 2019 (“COVID-19”)), riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease.

We are increasingly dependent on sophisticated software applications and computing infrastructure. Cyber-attacks against our IT systems could result in exposure of confidential information, the modification of critical data or the disruption of our worldwide operations, including manufacturing and sales operations.

We are 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, including Merck, to assist in conducting our business. Disruption, degradation or manipulation of these IT systems through intentional or accidental means by our employees, third parties with authorized access or unauthorized third parties could adversely affect key business processes. Cyber-attacks against our 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. We continue to leverage new and innovative technologies across the enterprise to improve the efficacy and efficiency of our business processes; the use of which can create new risks.

In 2017, Merck experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations, and resulting losses. We could experience similar adverse effects from cyber-attacks.

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

Merck has in the past, and we in the future may be, a target of events of this nature. We monitor our data, information technology and personnel usage of IT systems to reduce these risks and continue to do so on an ongoing basis for any current or potential threats. There can be no assurance that our efforts to protect our data and IT systems or the efforts of third-party providers to protect their IT systems will be successful in preventing disruptions to our operations, including our manufacturing and sales operations. Such disruptions could result in loss of revenue, or the loss of critical or sensitive information from our or our third-party providers’ databases or IT systems, or result in financial, legal, business or reputational harm to us and substantial remediation costs.

We carry insurance against certain losses resulting from cyber-attacks, but such insurance may not cover a particular event that arises or the amount of such coverage may not be sufficient to fully compensate us for losses we experience.

We may experience difficulties and delays in manufacturing certain of our products.

We may experience difficulties and delays inherent in manufacturing our products, such as: failure of us or our suppliers to comply with applicable regulations and quality assurance guidelines, which failures may lead to manufacturing shutdowns, product shortages or manufacturing delays; delays related to the construction of new facilities or the expansion of existing facilities; and other manufacturing or distribution problems, including changes in manufacturing production sites and limits to manufacturing capacity resulting from regulatory requirements, changes in types of products produced and physical limitations that could impact supply. In addition, we could experience difficulties or delays in manufacturing our products caused by natural disasters, such as hurricanes. Manufacturing difficulties can result in product shortages, leading to lost sales and reputational harm to us.

The global COVID-19 pandemic is having an adverse impact on our business, operations and financial performance. We are unable to predict the full extent to which the pandemic and related impacts will continue to adversely impact our business, operations, financial performance, results of operations, and financial condition.

Our 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 negatively impacts our results in 2021 will depend on future developments, beyond our 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 and thus far in 2021, the COVID-19 pandemic has impacted our business and we continue to expect that it will impact our business in numerous ways, including but not limited to those outlined below. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments.”

In 2020, the negative impact of COVID-19 to Organon Products segment sales was estimated to be approximately \$400 million. A significant amount of our revenue is comprised of physician-administered products, which, despite underlying demand, have been affected by social distancing measures, fewer medical visits and delays in elective procedures. These impacts, as well as the prioritization of COVID-19 patients at health care providers, have resulted in reduced administration of many products within established brands and women’s health, in particular Nexplanon / Implanon NXT, throughout 2020. We expect that the COVID-19 pandemic will negatively affect our sales in 2021.

Despite our efforts to manage these impacts, their ultimate impact will also depend on factors beyond our knowledge or control, including the duration of the COVID-19 pandemic 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.

We may be unable to obtain sufficient components or raw materials on a timely basis or for a cost-effective price or we may experience other supply difficulties that could adversely affect our ability to deliver our products and our results of operations and financial condition.

We acquire our components, materials and other requirements for manufacturing from many suppliers and vendors in various countries, including sometimes from ourselves for self-supplied requirements. We endeavor to achieve, either alone or working closely with our suppliers, continuity of our inputs and supplies but we cannot guarantee these efforts will always be successful. For instance, Follistim has been challenged by intermittent supply disruptions over the past several years. Further, while efforts are made to diversify certain of our sources of components and materials, in certain instances there is only a sole source or supplier with no alternatives yet identified. For many of our components and materials for which a single source or supplier is used, alternative

sources or suppliers may exist, but we have made a strategic determination to use the single source or supplier. Although we do carry strategic inventory and maintain insurance to help mitigate the potential risk related to any related supply disruption, we cannot assure you that such measures will always be sufficient or effective. Our ability to achieve continuity of our supply may also be affected by public health crises and epidemics/pandemics. A reduction or interruption in supply and an inability to quickly develop acceptable alternative sources for such supply, could adversely affect our ability to manufacture and distribute our products in a timely or cost-effective manner, and our ability to sell our products.

We may not be able to realize benefits from our investments in emerging markets.

We have been taking steps to increase our sales in emerging markets. However, there is no guarantee that our 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 us to successfully implement our emerging markets strategy, we must attract and retain qualified personnel. We may also be required to increase our 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 we cannot offset the devaluations, our financial performance within such countries could be adversely affected.

For example, our business in China has grown rapidly in the past few years, and China is now our second largest market, thereby increasing the importance of China to our overall pharmaceutical business. Continued growth of our business in China is dependent upon ongoing development of a favorable regulatory environment, sustained access for our currently marketed products and the absence of trade impediments or adverse pricing controls. Pricing pressure in China has increased as the Chinese government has been taking steps to reduce costs, including implementing healthcare reform that has led to the acceleration of generic substitution, where available. 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 and GQCE programs. In 2019, the government implemented the VBP program through a tendering process for products that have generic substitutes with a GQCE approval. Mature products that have entered into the first three rounds of VBP had, on average, a price reduction of 50%. We expect VBP to be a semi-annual process that will have a significant impact on mature products moving forward. In addition, we anticipate 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 U.S., leading to significant increased headcount spending in the countries and access to innovative medicines for patients. In addition, we plan to pivot in China from a primary focus on the public tender market to growth opportunities in the private retail segment. A failure to make such pivot effectively, or a failure to develop and maintain a presence in emerging markets could adversely affect our business, cash flow, results of operations, financial condition and prospects.

We are exposed to market risk from fluctuations in currency exchange rates and interest rates.

We operate in multiple jurisdictions and virtually all our sales outside the United States are denominated in currencies other than the United States dollar. Additionally, we, as part of Merck, have historically entered into, and will in the future enter into, business development transactions, borrowings or other financial transactions that may give rise to currency and interest rate exposure.

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

In order to mitigate against the adverse impact of these market fluctuations, we, as part of Merck, may 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.

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

We are subject to evolving and complex tax laws in multiple jurisdictions. We must apply significant judgment to determine our tax liabilities, and our tax returns are periodically examined by various tax authorities. The ultimate resolution of tax matters may result in payments greater or less than the amounts we have accrued for such tax liabilities. In addition, we may be adversely affected by changes in tax laws and regulations or changes in interpretations of such laws and regulations.

Pharmaceutical products can develop unexpected safety or efficacy concerns.

Unexpected safety or efficacy concerns can arise with respect to marketed pharmaceutical products such as our products, whether or not scientifically justified, which concerns may lead to product recalls, withdrawals or declining sales, as well as product liability, consumer fraud or other claims, including potential civil or criminal governmental actions. Such incidents could have a material impact on our results of operations, cash flows and financial condition.

Reliance on third-party relationships and outsourcing arrangements could materially adversely affect our business.

We depend on third parties, including Merck and other suppliers, alliances with other pharmaceutical and biotechnology companies, and third-party service providers, for key aspects of our business including development, manufacture and commercialization of our products and support for our IT systems. In addition, in connection with the interim operating arrangements we intend to put in place following the separation, we may enter into agreements with third-parties in certain jurisdictions, including China, to continue our business operations in compliance with local regulatory requirements. Failure of these third parties to meet their contractual, regulatory and other obligations to us or the development of factors that materially disrupt the relationships between us and these third parties could adversely affect our business.

The markets for our products, including the women's health market, may not develop successfully as expected.

Our focus on women's health is a key component of our strategy. Our ability to successfully execute our growth strategy in this area is subject to numerous risks, both known and unknown, including:

- uncertainty of the development of a market for such products;
- trends relating to, or the introduction or existence of, competing products, technologies or alternative treatments or therapies that may be more effective, safer or easier to use than our products, technologies, treatments or therapies;
- the perception of our products as compared to other products;
- recommendation and support for the use of our products or fertility treatments by influential customers, such as obstetricians, gynecologists, reproductive endocrinologists and treatment centers;
- changes in government policy or regulations could impair or repeal contraception coverage mandates under the ACA or state laws, which may affect payments to us or impose additional coverage limitations or cost-sharing obligations on our patients;
- the availability and extent of data demonstrating the clinical efficacy of our products or treatments;

- competition, including the presence of competing products sold by companies with longer operating histories, more recognizable names and more established distribution networks; and
- other technological developments.

If we are unable to successfully commercialize and create a significant market for our women's health products, our business and prospects could be harmed.

Biosimilars carry unique risks and uncertainties, which could adversely affect our results of operations and financial condition.

There are unique risks and uncertainties related to biosimilars. The regulation of the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of biosimilars are subject to regulation by the FDA, the EMA and other regulatory bodies. These laws and regulations differ from, and are not as well-established as, those governing pharmaceutical products or the approval of generic pharmaceutical products. In addition, manufacturing biosimilars, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells and micro-organisms. Any changes to the regulatory framework governing biosimilars or in the ability of our partners to manufacture an adequate supply of biosimilars may adversely affect our ability to commercialize the biosimilars in our portfolio.

We rely on our collaboration with Samsung Bioepis for the successful development and manufacture of our biosimilars products and expect to do so for the foreseeable future.

Our current biosimilars portfolio consists entirely of products developed and manufactured by Samsung Bioepis for which we have worldwide commercialization rights, with certain geographic exceptions specified on a product-by-product basis. Our access rights to each product under our agreement with Samsung Bioepis last for 10 years from each such product's launch date on a market-by-market basis. See "Business—Third-Party Agreements—Samsung Bioepis Development and Commercialization Agreement." Our ability to successfully commercialize products in our biosimilars portfolio may depend upon maintaining a successful relationship with Samsung Bioepis. The success of our commercialization activities may also depend, in part, on the performance, operations and regulatory compliance of Samsung Bioepis and its suppliers, over which we do not have control. We cannot assure you that our collaboration will be successful or that we will achieve the benefits of our collaboration.

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

We will be responsible for a number of ongoing product liability claims. We also may become subject to significant product liability claims in the future. Product liability insurance has become less available in recent years while the cost of such insurance has increased significantly. As a result, we intend to self-insure substantially all of our risk. We have evaluated our risks and have determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, we have no external insurance with respect to most product liabilities. We will continually assess the most efficient means to address our risk; however, there can be no guarantee that, if deemed necessary or desirable, outside insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise.

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 us or our products on any social networking platforms could damage our reputation, brand image and goodwill. Further, the disclosure of non-public sensitive information by our workforce or others through external media channels could lead to information loss. Although we have an internal Social Media Policy that guides employees on appropriate personal and professional use of social media about us, 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 Separation and Distribution

As we build our information technology infrastructure and transition our data to our own systems, we could incur substantial additional costs and experience temporary business interruptions.

In connection with the separation, we have begun to install and implement information technology infrastructure to support our critical business functions, including accounting and reporting, manufacturing process control, quality and compliance systems, customer service, inventory control and distribution. We may incur temporary interruptions in business operations if we cannot transition effectively from Merck's existing transactional and operational systems, data centers and the transition services that support these functions as we replace these systems. We may not be successful in implementing our new systems and transitioning our data, and we may incur substantially higher costs for implementation than currently anticipated. Our failure to avoid operational interruptions as we implement the new systems and replace Merck's information technology services, or our failure to implement the new systems and replace Merck's services successfully, could disrupt our business or adversely affect our results of operations. In addition, if we are unable to replicate or transition certain systems, our ability to comply with regulatory requirements could be impaired.

The separation may adversely affect our ability to attract and retain key personnel, which could materially harm our business.

Operating as an independent public company will result in new and increased demands on our management team and other employees coming from Merck, which may give rise to increased employee turnover. Our success depends in large part upon continuing leadership and performance of our management team and other key employees. If we lose the services of members of our management team or other key employees, we may not be able to successfully manage our business or achieve our business objectives.

Following the separation, we will need to continue to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in governmental regulation and commercialization. Our ability to attract, recruit and retain such talent will depend on a number of factors, including the hiring practices of our competitors, our compensation and benefits, work location and work environment and economic conditions affecting our industry generally. We cannot be sure that we will be able to attract and retain quality personnel or that the costs of doing so will not materially increase. If we cannot effectively hire and retain qualified employees, our business, results of operations and prospects could suffer.

Merck may not satisfy its obligations under various transaction agreements that have been or will be executed as part of the separation or we may not have necessary systems and services in place when certain of the transition agreements expire.

In connection with the separation, Organon and Merck will enter into a separation and distribution agreement and will enter into various other agreements, including one or more transition services agreements, manufacturing and supply agreements, trademark license agreements, intellectual property license agreements, an employee matters agreement, a tax matters agreement and certain other commercial or operating agreements. These agreements are discussed in greater detail in the section entitled "Certain Relationships and Related Party Transactions." Certain of these agreements will provide for the performance of services by each company for the benefit of the other for a period of time after the distribution. We will rely on Merck to satisfy its performance and payment obligations under these agreements. If Merck is unable to satisfy its obligations under these agreements, including its indemnification obligations, we could experience operational difficulties or losses.

If we do not have our own systems and services in place, or if we do not have agreements with other providers of these services when these agreements terminate, we may not be able to operate our business effectively and our profitability may decline. We are in the process of creating our own, or engaging third parties to provide, systems and services to replace many of the systems and services Merck currently provides to us. We may not be successful in effectively or efficiently implementing these systems and services or in transitioning data from Merck's systems to ours. These systems and services may also be more expensive or less efficient than the systems and services Merck is expected to provide during the transition period.

Potential indemnification liabilities to Merck pursuant to the separation and distribution agreement could adversely affect us.

The separation and distribution agreement with Merck covers, among other things, the principal corporate transactions required to effect the separation, certain conditions to the distribution, and provisions governing the relationship between Merck and us with respect to and resulting from the separation. For a description of the separation and distribution agreement, see “Certain Relationships and Related Party Transactions—Agreements with Merck—The Separation and Distribution Agreement,” which includes additional details regarding the scope of our indemnification obligations. Among other things, the separation and distribution agreement provides for indemnification obligations designed to make us financially responsible for many liabilities that may exist relating to our business activities, whether incurred prior to or after the distribution pursuant to the separation and distribution agreement, including any pending or future litigation. These liabilities, which could be material to us, include a general obligation to indemnify Merck for litigation relating to our products, including currently pending litigation relating to Fosamax, Nexplanon / Implanon NXT and Propecia / Proscar. However, we will not be liable for the results of the antitrust litigation related to Zetia or the product liability litigation in Brazil related to Vioxx. For a description of the related legal proceedings, see Note 10 to our audited annual combined financial statements. These indemnification liabilities are intended to ensure that, as between Merck and us, we are responsible for all liabilities we assume in connection with the separation and that we pay for any liability incurred by Merck (including directors, officers, employees and agents) related to our failure to satisfy such obligations or otherwise in respect of the operation of our business, or any breach by us of the separation and distribution agreement or any ancillary agreement. Our indemnity obligations to Merck under the circumstances set forth in the separation and distribution agreement may be substantial.

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.

Merck expects that, prior to completion of the Spin-off, it will receive the Tax Opinions from the Tax Advisors that are expected to conclude, among other things, that the distribution 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. The Tax Opinions are not binding on the Internal Revenue Service (“IRS”). Accordingly, while Merck 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 Tax Opinions. The Tax Opinions 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 Tax Opinion.

If the proposed Spin-off is ultimately determined to be taxable, 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. Each of Merck and Organon generally will be responsible for any tax-related losses imposed on Merck or Organon as a result of the failure of a transaction to qualify for tax-free treatment, to the extent that the failure to so qualify is attributable to actions, events or transactions relating to Merck’s or Organon’s respective stock, assets or business, or a breach of the relevant covenants made by Merck or Organon in the tax matters agreement. For a further description of the sharing of such liabilities between Merck and Organon, see “Certain Relationships and Related Party Transactions—Agreements with Merck—Tax Matters Agreement.”

We will not be able to engage in certain corporate transactions after the separation.

To preserve the tax-free treatment to Merck of the separation and the distribution, under the tax matters agreement that we will enter into with Merck, we will be restricted from taking any action that prevents the distribution and related transactions from being tax-free for U.S. federal income tax purposes. In particular, under

the tax matters agreement, for the two-year period following the distribution, it is expected that we will be prohibited, except in certain circumstances, from, among other things:

- entering into any transaction resulting in the acquisition of above a certain percentage of our stock or substantially all of our assets, whether by merger or otherwise;
- merging, consolidating, or liquidating;
- sales or transfers of our assets beyond certain thresholds;
- issuing equity securities beyond certain thresholds;
- repurchasing our capital stock;
- amending our organizational documents in certain respects;
- ceasing to actively conduct certain businesses or causing our applicable affiliates to cease to actively conduct certain of their businesses; and
- taking or failing to take any action that prevents the distribution and related transactions from being tax-free.

These restrictions may limit our ability to pursue certain strategic transactions or other transactions that we may believe to be in the best interests of our shareholders or that might increase the value of our business. In addition, under the tax matters agreement, we will be required to indemnify Merck against any tax liabilities as a result of such actions, even if we did not participate in or otherwise facilitate such actions. In the event the spin-off failed to be tax-free as a result of such actions, our indemnity obligation for Merck's tax liability under the tax matters agreement would be substantial and could materially affect our cash flow.

After the distribution, certain of our executive officers and directors may have actual or potential conflicts of interest because of their previous positions at Merck.

Because of their current or former positions with Merck, certain of our initial post-distribution executive officers and directors are expected to own shares of Merck common stock and may continue to participate in certain Merck benefit programs. Following the distribution, even though our Board of Directors will consist of a majority of directors who are independent, and our expected executive officers who are currently employees of Merck will cease to be employees of Merck, some Organon executive officers and directors will continue to have financial interests in Merck. Continuing ownership of Merck common stock and continued participation in Merck benefit programs could create, or appear to create, potential conflicts of interest if Organon and Merck pursue the same corporate opportunities or face decisions that could have different implications for us and Merck.

We may not achieve some or all of the expected benefits of the separation, and the separation may adversely affect our business.

The separation and distribution is expected to provide strategic and financial benefits to Organon, but such benefits may be delayed or not be realized at all or to the extent expected for a variety of reasons, including:

- the separation will require significant amounts of management's time and effort, which may divert management's attention from operating and growing our business;
- the separation will require us to implement interim operational arrangements in certain key markets, including China, to comply with existing regulatory and local manufacturing policies, which may introduce additional complexity to our business than if we were still part of Merck;
- following the separation, we may be more susceptible to market fluctuations and other adverse events than if we were still a part of Merck;
- following the separation, our business will be less diversified than Merck's business prior to the separation; and

- the other actions required to separate Merck's and our respective businesses could disrupt our operations.

If we fail to achieve some or all of the benefits expected to result from the separation, or if such benefits are delayed, our business, financial condition, and results of operations could be adversely affected.

We may have been able to receive better terms from unaffiliated third parties than the terms we will receive in our agreements with Merck.

The agreements we will enter into with Merck in connection with the separation, including one or more transition services agreements, manufacturing and supply agreements, trademark license agreements, intellectual property license agreements, an employee matters agreement, a tax matters agreement and certain other commercial agreements, were prepared in the context of the separation while we were still a wholly owned subsidiary of Merck. Accordingly, during the period in which the terms of those agreements were prepared, we did not have an independent board of directors or a management team that was independent of Merck.

After the distribution, we will have indebtedness, which could restrict our ability to pay dividends and adversely affect our financing options and liquidity position.

Prior to completion of the distribution, the Board of Directors of Organon will adopt a policy with respect to the payment of dividends on Organon common stock following the distribution. Organon currently expects that it will pay regular cash dividends. However, we expect to have a total indebtedness of approximately \$9.5 billion, consisting of term loans and 144A senior notes with such aggregate principal amount that we intend to enter into prior to the distribution. Approximately \$9.0 billion of such amount will be incurred to pay a distribution to Merck, with the remaining net proceeds intended to be used for general corporate purposes. We may also incur additional indebtedness in the future, including to fund future acquisitions. Our current or future indebtedness may in the future impose restrictions on us that could have material adverse consequences by:

- limiting our ability to obtain additional financing in the future for working capital, capital expenditures and acquisitions;
- limiting our ability to refinance our indebtedness on terms acceptable to us or at all;
- imposing restrictive covenants on our operations;
- requiring us to dedicate a significant portion of our cash flows from operations to paying the principal of and interest on our indebtedness, thereby reducing funds available for other corporate purposes; and
- making us more vulnerable to economic downturns and limiting our ability to withstand competitive pressures. See "Description of Material Indebtedness."

Challenges in the commercial and credit environment may adversely affect our ability to complete the separation and our future access to capital.

Our ability to issue debt or enter into other financing arrangements on acceptable terms could be adversely affected if there is a material decline in the demand for our products or in the solvency of our customers or suppliers or other significantly unfavorable changes in economic conditions. Volatility in the world financial markets could increase borrowing costs or affect our ability to access the capital markets. These conditions may adversely affect our ability to obtain and maintain our credit ratings prior to and following the distribution.

Risks Related to Our Common Stock

We cannot be certain that an active trading market for our common stock will develop or be sustained after the distribution, and following the distribution, our stock price may fluctuate significantly.

A public market for our common stock does not currently exist. We anticipate that on or prior to the record date for the distribution, trading of shares of our common stock will begin on a "when-issued" basis and will

continue until the time of the distribution. We cannot predict the prices at which shares of our common stock may trade after the distribution, the liquidity of the market for our common stock after the distribution, the effect of the separation and distribution on the trading prices of our common stock or whether the combined market value of the shares of our common stock and the shares of Merck common stock will be less than, equal to or greater than the market value of Merck's common stock prior to the distribution.

The market price of our common stock may fluctuate significantly due to a number of factors, some of which may be beyond our control, including:

- actual or anticipated fluctuations in our operating results;
- changes in earnings estimated by securities analysts or our ability to meet those estimates;
- the operating and stock price performance of comparable companies;
- changes to the regulatory and legal environment under which we operate; and
- domestic and worldwide economic conditions.

Shareholders often institute securities class action lawsuits when the market price of a public company's common stock drops significantly, which lawsuits could result in substantial costs to us and could divert the time and attention of our management and other resources.

Shares of our common stock are or will be eligible for future sale, and substantial sales of such shares may cause the price of our common stock to decline.

Any sales of substantial amounts of our common stock in the public market or the perception that such sales might occur, in connection with the distribution or otherwise, may cause the market price of our common stock to decline. We are unable to predict whether large amounts of our common stock will be sold in the open market following the distribution. Dispositions of significant amounts of our common stock or the perception in the market that this will occur may result in the lowering of the market price of our common stock.

We cannot guarantee the timing, amount or payment of any dividends on our common stock.

Prior to completion of the distribution, our Board of Directors will adopt a dividend policy with respect to the payment of dividends on our common stock following the distribution. We currently expect that we will pay regular cash dividends following the distribution. The timing, declaration, amount and payment of any future dividends to shareholders will fall within the discretion of our Board of Directors. The Board of Directors' initial and future decisions regarding the payment of dividends will depend on many factors, such as our financial condition, earnings, corporate strategy, capital requirements, debt service obligations, industry practice, legal requirements, regulatory constraints, and other factors that the Board deems relevant. For more information, see "Dividend Policy." Our ability to pay any dividends will depend on our ongoing ability to generate cash from operations and access capital markets. We cannot guarantee that we will pay any dividends in the future or continue to pay any dividend if we commence paying dividends.

Certain provisions in our amended and restated certificate of incorporation and bylaws, and of Delaware law, may prevent or delay an acquisition of us, which could decrease the trading price of our common stock.

We are a Delaware corporation and our amended and restated certificate of incorporation and bylaws will contain, and Delaware law contains, provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the bidder and to encourage prospective acquirors to negotiate with our Board of Directors rather than to attempt a hostile takeover.

Specifically, because we have not chosen to be exempt from Section 203 of the Delaware General Corporation Law, this provision could also delay or prevent a change of control that shareholders may favor.

Section 203 provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15% of the outstanding voting stock of a Delaware corporation shall not engage in any business combination with that corporation, including by merger, consolidation or acquisitions of additional shares, for a three-year period following the date on which that person or their affiliates becomes the holder of more than 15% of the corporation's outstanding voting stock.

In addition, our amended and restated certificate of incorporation and bylaws will include additional provisions that may have anti-takeover effects and may delay, deter or prevent a takeover attempt that our shareholders might consider in their best interests. For example, our amended and restated certificate of incorporation and bylaws will:

- permit our Board of Directors to issue one or more series of preferred stock with such powers, rights and preferences as the Board of Directors shall determine;
- subject to a three-year sunset starting with our first annual meeting of shareholders, provide for a classified Board of Directors, with each class serving a staggered three-year term, which could have the effect of making the replacement of incumbent directors more time consuming and difficult;
- provide that, as long as our Board of Directors is classified, our directors can be removed for cause only;
- prohibit shareholder action by written consent;
- provide that special meetings of shareholders can be called only by the Board of Directors;
- provide that vacancies on the Board of Directors could be filled only by a majority vote of directors then in office, even if less than a quorum, or by a sole remaining director;
- establish advance notice requirements for shareholder proposals and nominations of candidates for election as directors.

For additional details, see “Description of Capital Stock—Anti-Takeover Effects of Various Provisions of DGCL and our Amended and Restated Certificate of Incorporation and Bylaws” for a further description of certain of these provisions.

We believe these provisions will protect our shareholders from coercive or otherwise unfair takeover tactics by requiring potential acquirors to negotiate with our Board of Directors and by providing our Board of Directors with more time to assess any acquisition proposal. These provisions are not intended to make us immune from takeovers. However, these provisions will apply even if the offer may be considered beneficial by some shareholders and could delay or prevent an acquisition that our Board of Directors determines is not in the best interests of us and our shareholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors. In addition, these limitations may adversely affect the prevailing market price and market for our common stock if they are viewed as limiting the liquidity of our stock or discouraging takeover attempts in the future.

Certain of the agreements that we will enter into with Merck will require Merck's consent to any assignment by us of our rights and obligations under the agreements. The consent and termination rights set forth in these agreements might discourage, delay or prevent a change of control that shareholders may consider favorable. See “—We may not be able to engage in certain corporate transactions after the separation,” “Certain Relationships and Related Party Transactions” and “Description of Capital Stock—Anti-Takeover Effects of Various Provisions of DGCL and our Amended and Restated Certificate of Incorporation and Bylaws” for a more detailed description of these agreements and provisions.

In addition, an acquisition or further issuance of our stock could trigger the application of Section 355(e) of the Code. See “Risks Related to the Separation and Distribution—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”

and “Material U.S. Federal Income Tax Consequences.” Under the tax matters agreement, we would be required to indemnify Merck for the resulting taxes, and this indemnity obligation might discourage, delay or prevent a change of control that shareholders may consider favorable.

Our amended and restated bylaws will designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, and the United States federal district courts as the exclusive forum for claims under the Securities Act, which could limit our shareholders’ ability to obtain what such shareholders believe to be a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws will provide that, unless we select or consent to the selection, in writing, of an alternative forum, all internal corporate claims, which include claims in the right of our company (i) that are based upon a violation of a duty by a current or former director, officer, employee or shareholder in such capacity or (ii) as to which the DGCL confers jurisdiction upon the Court of Chancery, shall, to the fullest extent permitted by law, be exclusively brought in the Court of Chancery of the State of Delaware or, if such court does not have jurisdiction, another state court or a federal court located within the State of Delaware. Furthermore, unless we select or consent to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. These exclusive provisions may limit a shareholder’s ability to bring a claim in a judicial forum that he, she or it believes to be favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. It is possible that a court could find these exclusive forum provisions inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, and we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially adversely affect our business, financial condition and results of operations and result in a diversion of the time and resources of our management and board of directors.

Cautionary Statement Concerning Forward-Looking Statements

This information statement contains “forward-looking statements.” Forward-looking statements may be identified by words such as “expects,” “intends,” “anticipates,” “plans,” “believes,” “seeks,” “estimates,” “will” or words of similar meaning. Examples of forward-looking statements include, but are not limited to, statements regarding the outlook for our future business and financial performance, such as those contained in “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Trends Affecting our Results of Operations.” Forward-looking statements are based on management’s current expectations and assumptions, and are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. As a result, actual results could differ materially from those indicated in these forward-looking statements. Factors that could cause actual results to differ materially include global political, economic, business, competitive, market, regulatory and other factors and risks, such as:

- difficulties in operating as an independent company;
- costs and temporary business interruptions related to the separation;
- competition from generic and/or biosimilar products as our products lose patent protection;
- expanded competition in the women’s health market;
- difficulties with performance of third parties we will rely on for our business growth;
- difficulties developing and sustaining relationships with commercial counterparties;
- increased “brand” competition in therapeutic areas important to our long-term business performance;
- expiration of current patents or loss of patent protection for our products;
- difficulties and uncertainties inherent in the implementation of our acquisition strategy;
- 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 our business, operations and financial performance;
- changes in government laws and regulations, including laws governing intellectual property, and the enforcement thereof affecting our business;
- efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales;
- future actions of third-parties including 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 forgoing health care insurance coverage;
- loss of key employees or inability to identify and recruit new employees;
- 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 our or third-party providers’ information technology systems, which could disrupt our operations;
- lost market opportunity resulting from delays and uncertainties in the approval process of the FDA and foreign regulatory authorities;

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- increased focus on privacy issues in countries around the world, including the United States and the EU and a more difficult legislative and regulatory landscape for privacy and data protection that continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect directly our 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 us; and
- economic factors over which we have no control, including changes in inflation, interest rates and foreign currency exchange rates.

This list should not be considered an exhaustive statement of all potential risks and uncertainties. See “Risk Factors” for a further description of these and other factors. For the reasons described above, we caution you against relying on any forward-looking statements, which should also be read in conjunction with the other cautionary statements that are included elsewhere in this information statement, including in “Risk Factors.” Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update or revise any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as otherwise may be required by law.

Dividend Policy

We currently expect that we will pay regular cash dividends following the distribution. We expect our targeted dividend payout to be in the low 20s as a percentage of post-separation Adjusted Net Income. The timing, declaration, amount of, and payment of any dividends following the separation by Organon is within the discretion of its Board of Directors and will depend upon many factors, including Organon's financial condition, earnings, corporate strategy, capital requirements of its operating subsidiaries, covenants associated with certain of Organon's debt service obligations, legal requirements, regulatory constraints, industry practice, ability to access capital markets, and other factors deemed relevant by Organon's Board of Directors.

Capitalization

Set forth below is our capitalization at December 31, 2020, on a historical and a pro forma basis, which reflects the adjustments described in the notes to the unaudited pro forma financial information included elsewhere in this information statement. You should read this information in conjunction with those notes, as well as "Unaudited Pro Forma Financial Information," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited annual combined financial statements and the related notes, each included elsewhere in this information statement.

<u>(\$ in millions)</u>	<u>Historical</u>	<u>Pro Forma</u>
Assets:		
Cash and cash equivalents	<u>\$ 70</u>	<u>\$ 500</u>
Liabilities:		
144A Senior Notes	\$ —	\$ 5,588
Term Loans	—	3,892
Shareholders' Equity:		
Net investment from Parent	6,108	—
Common stock	—	3
Accumulated deficit	—	(219)
Accumulated other comprehensive loss	(622)	(604)
Total Capitalization	<u>\$ 5,486</u>	<u>\$ 8,660</u>

Unaudited Pro Forma Financial Information

On May 7, 2021, the board of directors of Merck & Co., Inc. approved the spin-off of its women's health, biosimilars and established brands businesses into a new, publicly traded company, Organon & Co. The spin-off will be effected through a distribution of shares of Organon common stock to the Merck shareholders.

The following unaudited pro forma condensed combined financial statements of Organon give effect to the Separation and related adjustments in accordance with Article 11 of the Securities and Exchange Commission's Regulation S-X. In May 2020, the SEC adopted Release No.33-10786 "Amendments to Financial Disclosures about Acquired and Disposed Businesses," or the Final Rule. The Final Rule is effective on January 1, 2021 and the unaudited pro forma condensed combined financial information herein is presented in accordance therewith.

The unaudited condensed combined pro forma balance sheet gives effect to the Separation and related transactions described below as if they had occurred on December 31, 2020. The unaudited pro forma adjustments to the condensed combined statement of income for the year ended December 31, 2020 assume that the Separation and related transactions occurred as of January 1, 2020.

The unaudited pro forma condensed combined statement of income for the years ended December 31, 2020, 2019 and 2018 has been derived from the audited historical combined statement of income of Organon for the years ended December 31, 2020, 2019 and 2018. The unaudited pro forma condensed combined balance sheet as of December 31, 2020 has been derived from the audited historical combined balance sheet of Organon as of December 31, 2020.

The unaudited pro forma condensed combined statement of income for fiscal years 2019 and 2018 has been adjusted to give effect to the impact of removing Merck Retained Products. See Note (a) to the unaudited pro forma financial information below.

The unaudited pro forma condensed combined statement of income for the year ended December 31, 2020 and the unaudited pro forma condensed combined balance sheet as of December 31, 2020 have been prepared to reflect adjustments to Organon's historical combined financial information for the following transaction and autonomous entity adjustments:

- the removal of Merck Retained Products (see Note (a)) included in Organon's historical financial statements but retained by Merck;
- the issuance of \$9.5 billion of debt at an interest rate of 3.8%;
- the adjustment for differences between Organon's historical combined balance sheet prepared on a carve-out basis and assets and liabilities expected to be contributed by Merck to Organon;
- the issuance of approximately 253,130,375 shares of Organon's common stock as part of the spin-off;
- the incremental costs Organon expects to incur as an autonomous entity;
- the one-time expenses associated with separation of Organon; and
- the impact of the separation and distribution agreement, the tax matters agreement, transition services agreements, interim operating agreements, the employee matters agreement, manufacturing and supply agreements and other commercial agreements between Organon and Merck and the provisions contained therein.

The unaudited pro forma financial information is for informational purposes only and does not purport to represent what Organon's financial position and results of operations actually would have been had the Separation and Distribution occurred on the dates indicated, or to project Organon's financial performance for any future period. The audited annual combined financial statements of Organon have been derived from

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Merck's historical accounting records and reflect certain allocation of expenses. All of the allocations and estimates in such financial statements are based on assumptions that Merck's management believes are reasonable. The historical combined financial statements of Organon do not necessarily represent the financial position or results of operations of Organon had it been operated as a standalone company during the periods or at the dates presented. As a result, autonomous entity adjustments have been reflected in the pro forma condensed combined financial information.

The unaudited pro forma condensed combined financial information reported below should be read in conjunction with Organon's "Management's Discussion and Analysis of Financial Condition and Results of Operations," the audited annual combined financial statements and the corresponding notes included elsewhere in this information statement.

Unaudited Pro Forma Condensed Combined Statement of Income

(\$ in millions except per share data)	Year ended December 31, 2020					
	Historical	Transaction Accounting Adjustments		Autonomous Entity Adjustments		Pro Forma
		Business Retained by Merck^(a)	Other Adjustments			
Sales	\$ 8,096	\$ (1,564)	\$ —	\$ 75	(c)	\$ 6,607
Costs, Expenses and Other						
Cost of sales	3,347	(1,228)	—	197	(c),(l)	2,316
Selling, general and administrative	1,666	(310)	5	361	(l)	1,722
Research and development	304	(94)	—	105	(l)	315
Restructuring costs	70	(10)	—	(57)	(l)	3
Other (income) expense, net	29	6	379	22	(l)	436
	<u>5,416</u>	<u>(1,636)</u>	<u>384</u>	<u>628</u>		<u>4,792</u>
Income from Continuing Operations Before Taxes	2,680	72	(384)	(553)		1,815
Taxes on Income	520	(24)	(81)	(100)	(e)	315
Net Income from Continuing Operations	<u>\$ 2,160</u>	<u>\$ 96</u>	<u>\$ (303)</u>	<u>\$ (453)</u>		<u>\$ 1,500</u>
Basic Earnings per Common Share from Continuing Operations					(f)	\$ 5.93
Diluted Earnings per Common Share from Continuing Operations					(g)	\$ 5.90
Weighted-average common shares outstanding						
Basic					(f)	253,130,375
Diluted					(g)	254,195,902

See accompanying notes to unaudited pro forma financial information.

Unaudited Pro Forma Condensed Combined Statement of Income

(\$ in millions)	Year ended December 31, 2019		
	Historical	Business Retained by Merck ^(a)	Pro Forma
Sales	\$ 9,530	\$ (1,753)	\$ 7,777
Costs, Expenses and Other			
Cost of sales	3,621	(1,347)	2,274
Selling, general and administrative	1,922	(479)	1,443
Research and development	332	(112)	220
Restructuring costs	101	(23)	78
Other (income) expense, net	(1)	67	66
	5,975	(1,894)	4,081
Income from Continuing Operations Before Taxes	3,555	141	3,696
Taxes on Income	337	53	390
Net Income from Continuing Operations	\$ 3,218	\$ 88	\$ 3,306

See accompanying notes to unaudited pro forma financial information.

Unaudited Pro Forma Condensed Combined Statement of Income

(\$ in millions)	Year ended December 31, 2018		
	Historical	Business Retained by Merck ^(a)	Pro Forma
Sales	\$ 9,777	\$ (1,485)	\$ 8,292
Costs, Expenses and Other			
Cost of sales	4,693	(1,152)	3,541
Selling, general and administrative	2,013	(446)	1,567
Research and development	365	(103)	262
Restructuring costs	119	(11)	108
Other (income) expense, net	(142)	91	(51)
	7,048	(1,621)	5,427
Income from Continuing Operations Before Taxes	2,729	136	2,865
Taxes on Income	576	4	580
Net Income from Continuing Operations	\$ 2,153	\$ 132	\$ 2,285

See accompanying notes to unaudited pro forma financial information.

Unaudited Pro Forma Condensed Combined Balance Sheet

(\$ in millions)	As of December 31, 2020					
	Historical	Transaction Accounting Adjustments			Autonomous Entity Adjustments	Pro Forma
		Business Retained by Merck ^(a)	Other Adjustments			
Assets						
Current Assets						
Cash and cash equivalents	\$ 70	\$ (58)	\$ 488	(h)	\$ —	\$ 500
Accounts receivable (net of allowance for doubtful accounts of \$18)	1,360	(322)	54	(j)	—	1,092
Inventories (excludes inventories of \$127 classified in Other assets)	971	(58)	—		—	913
Other current assets	977	(47)	—		(1)	(k) 929
Total current assets	3,378	(485)	542		(1)	3,434
Property, Plant and Equipment (at cost)						
Land	15	(1)	—		—	14
Buildings	653	(6)	—		—	647
Machinery, equipment and office furnishings	803	(16)	—		—	787
Construction in progress	362	(6)	—		—	356
	1,833	(29)	—		—	1,804
Less: accumulated depreciation	835	(15)	—		—	820
	998	(14)	—		—	984
Goodwill	4,603	—	—		—	4,603
Other Intangibles, Net	503	—	—		—	503
Other Assets	438	(77)	300	(b),(e),(i),(o)	249	(k),(n) 910
	<u>\$ 9,920</u>	<u>\$ (576)</u>	<u>\$ 842</u>		<u>\$ 248</u>	<u>\$ 10,434</u>
Liabilities and Equity						
Current Liabilities						
Trade accounts payable	\$ 294	\$ (35)	\$ —		\$ —	\$ 259
Accrued and other current liabilities	752	(93)	138	(d),(m)	36	(n) 833
Due to related party	1,150	189	(1,339)	(j)	—	—
Income taxes payable	288	—	—		(179)	(k) 109
Total current liabilities	2,484	61	(1,201)		(143)	1,201
Deferred Income Taxes	128	—	(7)	(e)	—	121
Other Noncurrent Liabilities	1,822	(83)	9,536	(b),(i)	(1,343)	(k),(n) 9,932
Organon Equity						
Net investment from Parent	6,108	(572)	(5,536)	(j)	—	—
Common stock, \$0.01 par value, 500,000,000 shares authorized; 253,130,375 shares issued and outstanding on a pro forma basis	—	—	3	(j)	—	3
Accumulated deficit	—	—	(1,953)	(j)	1,734	(k) (219)
Accumulated other comprehensive loss	(622)	18	—		—	(604)
Total equity	5,486	(554)	(7,486)		1,734	(820)
	<u>\$ 9,920</u>	<u>\$ (576)</u>	<u>\$ 842</u>		<u>\$ 248</u>	<u>\$ 10,434</u>

See accompanying notes to unaudited pro forma financial information.

Organon
Notes to the Unaudited Pro Forma Financial Information

(a) The historical Organon financial statements include operations related to other Merck products that will be retained by the Parent (Merck Retained Products) in certain legal entities that will be contributed to Organon in connection with the spin-off. Pro forma adjustments, including income tax, represent the impact of removing the historical results of Merck Retained Products from Organon's historical financial statements.

(b) The pro forma condensed combined balance sheet reflects indebtedness of approximately \$9.5 billion, consisting of term loans and senior notes, which are expected to be issued in connection with the Separation, and related debt issuance costs of \$139 million. Organon plans to distribute approximately \$9.0 billion of the proceeds received from the issuance of debt to Merck in connection with the Separation. Details of the term loans and senior notes are as follows:

<i>(\$ in millions)</i>	
LIBOR plus 300 bps term loan due 2028	\$3,000
LIBOR plus 300 bps euro-denominated term loan due 2028	892
4.125% secured notes due 2028	2,100
2.875% euro-denominated secured notes due 2028	1,488
5.125% notes due 2031	2,000
Total principal long-term debt issued	<u>\$9,480</u>

In addition, on or about the distribution date, an unsecured, unsubordinated 5-year revolving credit facility that provides for the availability of \$1.0 billion of borrowings is expected to become available to Organon. No adjustment has been made to the unaudited pro forma financial information to reflect the potential draw down on the revolving credit facility.

The interest rate on the issued debt is expected to be approximately 3.8%. The pro forma condensed combined statement of income reflects estimated interest expense of \$386 million related to the debt and amortization of deferred issuance costs. Interest expense was calculated assuming constant debt levels throughout the periods. A 1/8% change to the annual interest rate would change interest expense by \$12 million for the year ended December 31, 2020.

(c) Reflects the effect of manufacturing and supply agreements (MSAs) that Organon and Merck have entered into or will enter into prior to the Separation. The historical combined statement of income reflects certain Sales and Cost of sales relating to the inventory transfers pursuant to newly entered or pre-existing intercompany arrangements between Organon and Merck during the year ended December 31, 2020. The net adjustment to Sales of \$75 million reflects sales price adjustments relating to such historical inventory transfers to reflect the pricing terms set forth in the MSAs, as well as incremental sales from inventory transfers from Organon to Merck expected in the first year after the Separation that also reflect the pricing terms set forth in the MSAs. The Cost of sales adjustment includes \$76 million of costs expected to be incurred to manufacture the products relating to the incremental inventory transfers for Merck. The Cost of sales adjustment also includes an adjustment of \$17 million to reflect the approximate cost of products sold by Merck to Organon at the supply price set forth in the MSAs. Historically, inventory transfers from Merck to Organon were recorded at cost.

(d) Reflects removal of \$20 million from Accrued and other current liabilities related to certain litigation matters included in the historical combined balance sheet that will be retained by Merck.

(e) Reflects the tax effects of the pro forma adjustments at the applicable statutory income tax rates.

(f) The number of Organon shares used to compute basic earnings per share for the year ended December 31, 2020 is based on the number of shares of Organon common stock assumed to be outstanding on December 31, 2020, assuming the anticipated distribution ratio of one-tenth share of Organon common stock for each share of

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Merck common stock outstanding. The assumed number of outstanding shares of common stock is based on the number of Merck common shares of 2,531,303,747 outstanding as of March 31, 2021.

(g) The number of shares used to compute diluted earnings per share is based on the number of basic shares of Organon common stock as described in Note (f) above, plus incremental shares assuming exercise of dilutive outstanding options and vesting of other outstanding stock awards expected to be issued by Organon as replacement awards to Merck employees transferring to Organon.

(h) Reflects an adjustment to represent \$500 million of cash at the balance sheet date, which is the approximate amount of cash Organon will have following the completion of the Separation. This reflects the \$9.5 billion of borrowings expected to be incurred in connection with the Separation, net of approximately \$9.0 billion expected to be distributed to Merck.

(i) Reflects the addition of net benefit plan liabilities of \$56 million and deferred benefit plan costs of \$43 million that will be transferred to Organon by Merck prior to completion of the Separation and related transactions. The net benefit plan liabilities are excluded from the historical combined balance sheet as Organon is not the plan sponsor for the related benefit plans. The benefit plan expenses associated with these liabilities are included in Organon's historical combined statement of income. The deferred benefit plan costs relate to service crediting Merck will provide to employees transferred to Organon in connection with the Separation for purposes of early retirement eligibility and subsidies under certain U.S.-defined benefit plan retained by Merck. The pro forma condensed combined statement of income reflects \$5 million of amortization related to the deferred benefit plan costs.

(j) Represents the reclassification of Merck's net investment in Organon, including the additional net assets expected to be contributed by Merck and other pro forma adjustments, into Accumulated deficit and Common stock, par value \$0.01, to reflect the number of shares of Organon common stock expected to be outstanding at the distribution date. The assumed number of outstanding shares of common stock is based on the number of Merck common shares of 2,531,303,747 outstanding as of March 31, 2021 and an assumed pro-rata distribution ratio of one-tenth share of Organon common stock for each share of Merck common stock.

(k) For purposes of the unaudited pro forma condensed combined financial information, Organon's income tax liabilities attributable to its one-time transition tax assessed on previously undistributed earnings of its international subsidiaries pursuant to the Tax Cuts and Jobs Act of 2017 (the "TCJA") were removed. These income tax liabilities were computed using a separate return methodology yielding approximately \$161 million that was recorded within Income Taxes Payable and \$1.3 billion that was recorded within Other Noncurrent Liabilities.

Organon is responsible for unrecognized tax benefits, net of indirect deferred tax benefits, to the extent a reserve relates exclusively to separate tax returns filed by Organon. Accordingly, to remove unrecognized tax benefits included in the historical combined balance sheet that were calculated on a separate return basis but will not be settled or paid by Organon, the pro forma condensed combined financial information reflects a decrease to Other current assets in the amount of \$1 million, a decrease to Other Assets in the amount of \$18 million, a decrease to Income taxes payable in the amount of \$18 million, and a decrease to Other Noncurrent Liabilities in the amount of \$193 million.

(l) As a standalone public company, Organon expects to incur certain additional costs including costs resulting from:

- separation and establishment of Organon as a standalone company including incremental costs related to commercial, manufacturing, research and business support functions that were previously shared with Merck;
- costs to perform financial reporting and regulatory compliance, and costs associated with accounting, auditing, tax, legal, information technology, human resources, investor relations, risk management, treasury and other general and administrative related functions;

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- higher costs for the services to be provided by Merck to Organon under the transition services agreement with respect to information technology services, research and development, distribution, support for operations, legal, payroll, finance, tax and accounting, general administrative services and other support services;
- one-time expenses associated with the separation of Organon's information systems and facilities;
- compensation including new equity-based awards in connection with the Separation;
- insurance premiums; and
- depreciation and amortization related to information technology infrastructure investments.

As a result, Organon expects to incur approximately \$535 million of expenses (including one-time expenses of approximately \$165 million expected to be incurred within 12 months following the completion of the Separation), in addition to Merck's corporate and shared costs allocated in the historical combined financial statements. Accordingly, the pro forma condensed combined financial statements have been adjusted to depict the Company as an autonomous entity. The additional expenses have been estimated based on assumptions that management believes are reasonable. However, actual additional costs that will be incurred could be different from the estimates and would depend on several factors, including the economic environment and strategic decisions made in areas such as separation, manufacturing, selling and marketing, research and development, information technology and infrastructure.

(m) The pro forma condensed combined balance sheet reflects \$158 million in Accrued and other current liabilities with respect to additional employee related obligations of employees expected to be transferred from Merck to Organon prior to separation. These liabilities were excluded from the historical combined balance sheet as the related employees were not fully dedicated to Organon.

(n) The pro forma condensed combined balance sheet reflects \$267 million in Other assets, \$36 million in Accrued and other current liabilities and \$231 million in Other Noncurrent liabilities, with respect to additional right-of-use assets and related lease liability for Organon's real estate leases executed at December 31, 2020 that had not yet commenced.

(o) The pro forma condensed combined balance sheet reflects \$110 million in Other assets with respect to a note receivable from a third party contract manufacturer expected to be contributed by Merck to Organon upon completion of negotiations currently ongoing with the third party. The pro forma condensed combined statement of income reflects \$7 million of related interest income.

Unaudited Pro Forma Non-GAAP Financial Measures

Earnings before interest, income taxes, depreciation and amortization (EBITDA), Adjusted EBITDA and Adjusted Net Income (non-GAAP financial measures) are alternative views of our performance that we provide because management believes this information enhances investors' understanding of our results as it permits investors to understand how management assesses performance. Further discussion on non-GAAP financial measures is provided in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this information statement.

The unaudited pro forma non-GAAP financial measures presented below have been prepared to provide certain non-GAAP information for Organon, giving effect to the pro forma adjustments to Organon's historical results of operations to arrive at Organon's pro forma results of operations, more fully described above. The unaudited pro forma non-GAAP measures assume that the Separation and related transactions occurred as of January 1, 2020.

A reconciliation between pro forma Net Income from Continuing Operations, Pro Forma EBITDA and Pro Forma Adjusted EBITDA is as follows:

<i>(\$ in millions)</i>	2020
Pro Forma Net Income from Continuing Operations	\$1,500
Interest expense, net	379
Taxes on income	315
Depreciation	116
Amortization	85
Pro Forma EBITDA	<u>\$2,395</u>
Restructuring costs	3
Organon formation costs	238
Pro Forma Adjusted EBITDA	<u><u>\$2,636</u></u>

A reconciliation between pro forma financial measures and pro forma adjusted financial measures is as follows:

<i>(\$ in millions)</i>	2020
Pro Forma Income from Continuing Operations before taxes	\$1,815
Amortization	85
Restructuring costs	3
Organon formation costs	238
Pro Forma Adjusted income before taxes	<u>2,141</u>
Pro Forma Taxes on income	315
Estimated tax benefit on above items	55
Pro Forma Adjusted taxes on income	<u>370</u>
Pro Forma Adjusted Net Income	<u><u>\$1,771</u></u>

Selected Historical Financial Data

The following table presents our selected historical combined financial data as of and for each of the fiscal years in the three-year period ended December 31, 2020 and certain unaudited pro forma financial information. We derived the selected historical combined financial data as of December 31, 2020 and 2019, and for each of the fiscal years in the three-year period ended December 31, 2020, from our audited annual combined financial statements. The selected unaudited pro forma financial information at and for the year ended December 31, 2020 is unaudited and has been derived from our unaudited pro forma financial information included elsewhere in this information statement. You should read this information in conjunction with the information under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited annual combined financial statements and the related notes thereto, which are included elsewhere in this information statement. Organon & Co. was incorporated in Delaware on March 11, 2020 and will hold Merck’s women’s health, biosimilars and established brands businesses after the separation and distribution described herein. The contribution of these businesses to Organon will begin to occur over a period of several months prior to the distribution, and Organon will have no operations prior to any such contribution. We have prepared our historical combined financial statements as if Organon had conducted Merck’s women’s health, biosimilars and established brands businesses through all relevant periods. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Basis of Presentation of Our Financial Information.”

Selected Combined Financial Data

(\$ in millions)	Pro Forma Year Ended December 31, 2020	2020	2019	2018
Results for Year:				
Sales ⁽¹⁾	\$ 6,607	\$8,096	\$ 9,530	\$ 9,777
Cost of sales ⁽²⁾	2,316	3,347	3,621	4,693
Selling, general and administrative	1,722	1,666	1,922	2,013
Research and development	315	304	332	365
Restructuring costs	3	70	101	119
Other (income) expense, net	436	29	(1)	(142)
Income before taxes	1,815	2,680	3,555	2,729
Taxes on income	315	520	337	576
Net income	1,500	2,160	3,218	2,153
Capital expenditures	255	278	109	101
Depreciation	116	72	69	68
Other Data:				
EBITDA ⁽³⁾	\$ 2,395	\$2,827	\$ 3,896	\$ 4,387
Adjusted EBITDA ⁽³⁾	2,636	3,026	3,997	4,393
Adjusted Net Income ⁽³⁾	1,771	2,396	3,286	3,550
Year-End Position:				
Working capital	\$ 2,233	\$ 894	\$ 2,614	\$ 2,169
Property, plant and equipment, net	984	998	680	651
Total assets	10,434	9,920	10,548	10,494
Total equity	(820)	5,486	7,035	6,348

⁽¹⁾ Actual results include related party sales of \$599 million in 2020, \$501 million in 2019 and \$432 million in 2018.

⁽²⁾ Actual results include costs for inventory purchases from related parties of \$1.0 billion in 2020, \$1.1 billion in 2019 and \$923 million in 2018.

⁽³⁾ Earnings before interest, income taxes, depreciation and amortization (EBITDA), Adjusted EBITDA and Adjusted Net Income (non-GAAP financial measures) are alternative views of our performance that we provide because management believes this information enhances investors’ understanding of our results as it permits investors to understand how management assesses performance. Further

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discussion and a reconciliation of U.S. GAAP financial measures to EBITDA, Adjusted EBITDA and Adjusted Net Income are provided in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this information statement. The information on EBITDA, Adjusted EBITDA and Adjusted Net Income should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with generally accepted accounting principles in the United States (“GAAP”).

Management’s Discussion and Analysis of Financial Condition and Results of Operations

Company Overview

Our operations are principally managed on a products basis and include two operating segments, the Organon Products segment and the Merck Retained Products segment.

The Organon Products segment is engaged in developing and delivering innovative health solutions through our portfolio of prescription therapies within women’s health, biosimilars, and established brands (the “Organon Products”). We sell these 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. We expect to operate six manufacturing facilities in Belgium, Brazil, Indonesia, Mexico, the Netherlands and the UK.

The Organon Products segment portfolio includes:

- *Women’s Health:* We have innovative contraception and fertility brands that we believe have long-term growth potential, such as Nexplanon/Implanon NXT, globally one of the highest revenue generating LARCs, a class of contraceptives which are recognized as the most effective type of hormonal contraception available to patients with a lower long-term average cost.
- *Biosimilars:* Our current portfolio spans immunology and oncology treatments. We expect that our biosimilars business will continue to generate growth in the near term as we continue to expand our existing products into new markets. All five of the biosimilars in our portfolio have launched in certain countries globally, including two biosimilars in the United States.
- *Established Brands:* We have a broad portfolio of established brands, which generally are beyond market exclusivity, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management. Our established brands portfolio generates strong operating profit which we anticipate will continue to fund our future growth.

The Merck Retained Products segment reflects the results of certain Merck non-United States legal entities that will be contributed to Organon in connection with the spin-off (the “Transferring Entities” and each, a “Transferring Entity”). The Transferring Entities include operations related to other Merck products that will be retained by Merck (the “Merck Retained Products”). See “Basis of Presentation of Our Financial Information.”

Separation from Merck

On May 7, 2021, the board of directors of Merck approved the spin-off of its women’s health, biosimilars and established brands businesses into a new, independent publicly traded company, Organon & Co., through a distribution of our publicly traded stock to Merck shareholders.

Completion of the spin-off is subject to certain conditions which are described more fully under “The Separation and Distribution—Conditions to the Distribution,” including receipt of the Tax Opinions from the Tax Advisors to the effect that the distribution and certain related transactions will qualify as tax-free to Merck and its shareholders under Sections 355 and 368 of the Code.

Basis of Presentation of Our Financial Information

Our audited historical combined financial statements have been prepared on a standalone basis and are derived from Merck’s consolidated financial statements and accounting records. The combined financial statements reflect our financial position, results of operations and cash flows as we were operated as part of Merck prior to the spin-off, in conformity with U.S. GAAP. The assets, liabilities, revenue and expenses of the Company have been reflected in our combined financial statements on a historical cost basis, as included in the

consolidated financial statements of Merck, using the historical accounting policies applied by Merck. These combined financial statements do not purport to reflect what our results of operations, comprehensive income, financial position, equity or cash flows would have been had we operated as a standalone public company during the periods presented.

Our combined financial statements were prepared following a legal entity approach, which resulted in the inclusion of the following:

- Certain assets and liabilities, results of operations and cash flows attributable to the sales of products in the Organon Products segment that will be contributed to us prior to the consummation of the spin-off, and
- The Transferring Entities, which have historically included the results from the sales of products included both in the Organon Products segment and the Merck Retained Products segment. Each Transferring Entity's historical operations, including its results of operations, assets and liabilities, and cash flows have been fully reflected in these combined financial statements; however, prior to the consummation of the spin-off, the products in the Merck Retained Products segment will be contributed to newly formed Merck entities that will be retained by Merck. Upon full contribution of the Merck Retained Products by us to Merck and its affiliates, the historical results of operations of such products in the Merck Retained Products segment will be reflected as discontinued operations in the Organon financial statements.

During the fourth quarter of 2020, in contemplation of the spin-off:

- The Merck Retained Products business in certain Transferring Entities was distributed to Merck affiliates (the "MRP Distribution") and the Merck Retained Products segment's results of operations, assets and liabilities, and cash flows for such Transferring Entities are included in these combined financial statements through the date of distribution to Merck affiliates.
- The Organon Products business in certain jurisdictions has been transferred by Merck affiliates to legal entities established to operate the Organon Products business and, as noted above, such entities will be contributed to Organon (the "Organon Entities").

Our businesses have historically functioned together with the other businesses controlled by Merck. Accordingly, we relied on Merck's corporate and other support functions for our business. Therefore, certain corporate and shared costs have been allocated to us (see Note 2 to our audited annual combined financial statements).

Management believes these cost allocations are a reasonable reflection of the utilization of services provided to, or the benefit derived by, us during the periods presented, though the allocations may not be indicative of the actual costs that would have been incurred had we operated as a standalone public company. Actual costs that may have been incurred had we been a standalone company would depend on a number of factors, including the chosen organizational structure, whether functions were outsourced or performed by our employees, and strategic decisions made in areas such as manufacturing, selling and marketing, research and development, information technology and infrastructure.

The combined balance sheet reflects all of the assets and liabilities that are either specifically identifiable or are directly attributable to us and our operations, as well as the assets and liabilities attributable to Merck Retained Products in the Transferring Entities. However, the balance sheet at December 31, 2020 excludes the assets and liabilities of the Merck Retained Products in certain Transferring Entities that were distributed to the Parent in the fourth quarter of 2020 as part of the MRP Distribution. The assets and liabilities in the remaining Transferring Entities attributable to Merck Retained Products will be distributed to the Parent prior to the spin-off. Property, plant and equipment reflected in the combined balance sheet is primarily attributable to the six manufacturing facilities we expect to operate. No assets or liabilities are reflected in the combined balance sheet for amounts related to derivatives and hedging activities.

Merck maintains various employee benefit plans which our employees participate in, and a portion of the costs associated with these plans has been included in our combined financial statements. The combined balance sheet only includes assets and liabilities relating to plans for which the entity being transferred is the plan sponsor; most of these plans are on the Transferring Entities and substantially all of the related assets and liabilities were transferred to Merck as part of the MRP Distribution in the fourth quarter of 2020 or will be prior to the spin-off.

Income tax expense and deferred tax balances in the combined financial statements have been calculated on a separate tax return basis. Our operations are included in the tax returns of certain Organon Entities, Transferring Entities or the respective Merck entities of which our business is a part. In the future, as a standalone company, we will file tax returns on our own behalf, and our deferred taxes and effective income tax rate may differ from those in the historical periods.

Merck utilizes a centralized approach to cash management and the financing of its operations. Cash generated by us is routinely transferred into accounts managed by Merck's centralized treasury function and cash disbursements for our operations are funded as needed by Merck. Cash and cash equivalents of the Organon Entities and the Transferring Entities are reflected in our combined balance sheet. Balances held by the Organon Entities and the Transferring Entities with Merck for cash transfers and loans are reflected as *Due from related party*, *Due to related party* or *Related Party Loans Payable*. All other cash, cash equivalents, short-term investments and related transfers between Merck and us are generally held centrally through accounts controlled and maintained by Merck and are not specifically identifiable to us. Accordingly, such balances have been accounted for through *Net investment from Parent*. Merck's third-party debt and related interest expense have not been attributed to us because we are not the legal obligor of the debt and the borrowings are not specifically identifiable to us. However, in connection with the spin-off, we expect to incur indebtedness as set forth under "Description of Certain Indebtedness." Such indebtedness would cause us to record additional interest expense in future periods.

Relationship with Merck

Following the spin-off, certain functions that Merck provided to us prior to the spin-off will either continue to be provided to us by Merck under a transition services agreement or will be performed using our own resources or third-party service providers. Additionally, under manufacturing and supply agreements, we will manufacture certain products for Merck or its applicable affiliate and Merck will manufacture certain products for us or our applicable affiliate. We expect to incur certain costs in establishing ourselves as a standalone public company, as well as ongoing additional costs associated with operating as an independent, publicly traded company.

Concurrent with the spin-off, we will enter into certain agreements with Merck. See "Certain Relationships and Related Party Transactions—Agreements with Merck."

Key Trends Affecting Our Results of Operations

- *Generic Competition*: The majority of our established brands products are beyond market exclusivity. However, these products continue to represent a significant value opportunity arising from long-term sustainable revenue streams and well-established supply chains that together generate significant operating profit relative to low promotional and development expenses.
- *Sustained Shift Towards Long-Acting Reversible Contraceptives*: Although daily contraceptive pills remain the largest market segment, the LARC market segment, which includes Nexplanon/Implanon NXT, has experienced significant growth in the years leading up to 2019 due to a sustained shift from daily oral contraception to LARC. This was driven by payors, providers and patients looking for options beyond commonly used daily contraceptive pills. The COVID-19 pandemic negatively affected

the LARC segment during 2020 due to clinic closures and the postponement of non-essential medical procedures during country lockdowns. However, LARC segment growth quickly rebounded during months when clinic restrictions were removed and the sustained shift to LARC is expected to continue with fundamental drivers unchanged.

- *Increased Access to Fertility Solutions:* We believe governments and payors are implementing favorable policies across major markets that, in turn, drive growth in the market for women's health therapies. For example, in the United States, there has been an increase in fertility insurance mandates and employer coverage, albeit subject to certain exemptions.
- *Emergence of Biosimilars:* Biologics continue to experience strong growth trends. However, given the high cost of many of these treatments, biosimilars, as a more affordable alternative, represent a significant opportunity for patients, providers, and payors once a biologics product loses patent protection. Moreover, a significant number of biologics are expected to lose exclusivity over the next decade, representing a large opportunity for more biosimilar approvals.
- *Increased Competitive Pressures:* The markets in which we conduct our business and the pharmaceutical industry in general are highly competitive and highly regulated. Our competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus and generic drug manufacturers.

COVID-19

In March 2020, the World Health Organization ("WHO") declared the outbreak of COVID-19 a global pandemic and recommended containment and mitigation measures worldwide. Although COVID-19-related disruptions, including patients' inability to access health care providers, prioritization of COVID-19 patients, as well as social distancing measures have negatively affected our results, we remain confident in the underlying demand for our products.

In 2020, the negative impact of the COVID-19 pandemic to Organon Products segment sales was estimated to be approximately \$400 million. A significant portion of our revenue is comprised of physician-administered products, which, despite underlying demand, have been affected by social distancing measures, as well as fewer medical visits and elective procedures. These impacts, as well as the prioritization of COVID-19 patients at health care providers, resulted in reduced administration of many products within established brands and women's health, in particular Nexplanon/Implanon NXT, throughout 2020. The COVID-19 pandemic also had a negative effect on sales within the Merck Retained Products segment as discussed below.

We believe that global health systems and patients have largely adapted to the impacts of the COVID-19 pandemic, but our assumption is that ongoing residual negative impacts will persist, particularly during the first half of 2021. We expect that the negative impact to Organon Products segment revenues in 2021 will be less than the negative impact in 2020, principally affecting products within established brands and women's health, primarily Nexplanon/Implanon NXT. The COVID-19 pandemic will also continue to negatively affect sales within the Merck Retained Products segment in 2021.

Operating expenses in 2020 were positively affected by the COVID-19 pandemic, primarily driven by lower promotional and selling costs as discussed below.

Operating Results

(\$ in millions)	2020	2019	2018
Sales	\$8,096	\$9,530	\$9,777
Costs, Expenses and Other			
Cost of sales	3,347	3,621	4,693
Selling, general and administrative	1,666	1,922	2,013
Research and development	304	332	365
Restructuring costs	70	101	119
Other (income) expense, net	29	(1)	(142)
	5,416	5,975	7,048
Income Before Taxes	2,680	3,555	2,729
Taxes on Income	520	337	576
Net Income	\$2,160	\$3,218	\$2,153

Sales Overview

(\$ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
United States	\$1,402	(30)%	(30)%	\$1,997	— %	— %	\$1,995
International	6,694	(11)%	(9)%	7,533	(3)%	— %	7,782
Total	\$8,096	(15)%	(14)%	\$9,530	(3)%	— %	\$9,777

Worldwide sales were \$8.1 billion in 2020, a decline of 15% compared with 2019. Sales for the Organon Products segment were \$6.5 billion in 2020, a decline of 16% compared with 2019, primarily due to recent generic competition for women’s health product NuvaRing, and ongoing generic competition for products within the established brands business, particularly for respiratory products Singulair and Nasonex, and cardiovascular products Zetia and Vytorin. As described above, the COVID-19 pandemic negatively affected sales in 2020, contributing to declines in established brands, particularly respiratory and cardiovascular products, as well as declines in women’s health products, particularly Nexplanon/Implanon NXT, Follistim AQ and Orgalutran. The Organon Products segment sales decline was partially offset by revenue resulting from an arrangement for the sale of generic etonogestrel/ethinyl estradiol vaginal ring, higher sales of biosimilars resulting from the continued uptake of Renflexis in existing markets and the launch of Ontruzant into new markets, as well as higher sales of cardiovascular product Atozet. We expect Organon Products segment revenues to decline in 2021 relative to 2020, but the 2021 decline is expected to be more modest than the decline experienced in 2020, as a result of growth in Nexplanon/Implanon and biosimilars and ongoing recovery from the COVID-19 pandemic. Sales for the Merck Retained Products segment were \$1.6 billion in 2020, a decline of 11% compared with 2019.

Worldwide sales were \$9.5 billion in 2019, a decline of 3% compared with 2018. Sales for the Organon Products segment were \$7.8 billion in 2019, a decline of 6% compared with 2018, primarily due to ongoing generic competition in the established brands business, particularly for Zetia, Vytorin, Nasonex, antidepressant Remeron, and non-opioid pain product Arcoxia. Higher sales of biosimilars resulting from the ongoing launches of Renflexis, Ontruzant and Brenzys, as well as higher sales of Nexplanon/Implanon NXT, and cardiovascular products Rosuzet and Atozet, partially offset the Organon Products segment revenue decline. Sales for the Merck Retained Products segment were \$1.8 billion in 2019, an increase of 18% compared with 2018.

Sales by Product Details

Sales of our products were as follows:

(\$ in millions)	2020			2019			2018		
	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Organon Products Segment									
Women's Health									
Nexplanon/Implanon	\$ 488	\$ 192	\$ 680	\$ 568	\$ 219	\$ 787	\$ 495	\$ 208	\$ 703
NuvaRing	110	127	236	742	136	879	722	180	902
Follistim AQ	84	109	193	103	138	241	115	153	268
Orgalutran	11	69	81	25	86	112	48	93	141
Cerazette	—	67	67	—	71	71	—	90	90
Biosimilars									
Renflexis	122	13	135	94	3	97	26	1	27
Ontruzant	3	113	115	—	83	83	—	20	20
Brenzys	—	74	74	—	72	72	—	16	16
Established Brands									
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
Rosuzet	—	130	130	—	120	120	—	58	58
Cozaar/Hyzaar	21	365	386	24	418	442	23	431	453
Zocor	2	75	77	6	107	112	5	116	121
Respiratory									
Singulair	18	444	462	29	669	698	20	688	708
Dulera	188	35	222	188	30	217	199	28	227
Nasonex	12	206	218	9	284	293	23	353	376
Clarinet	7	123	130	8	133	142	10	145	155
Asmanex	75	8	83	84	10	94	100	13	113
Non-Opioid Pain, Bone and Dermatology									
Arcoxia	—	258	258	—	288	288	—	335	335
Fosamax	4	176	180	9	188	197	4	205	209
Diprosan	—	118	118	—	102	102	—	102	102
Diprosone	1	82	83	1	83	84	(1)	92	91
Other									
Proscar	2	174	176	2	202	203	2	183	185
Propecia	10	119	129	11	120	131	12	119	131
Sinemet	(1)	78	77	1	78	79	4	98	102
Remeron	2	61	64	3	79	82	2	130	132
Other Organon Products segment ⁽¹⁾	232	807	1,041	60	826	885	131	793	926
Total Organon Products segment sales	1,402	5,130	6,532	1,997	5,780	7,777	1,995	6,297	8,292
Merck Retained Products									
Keytruda	—	529	529	—	493	493	—	309	309
Januvia/Janumet	—	76	76	—	110	110	—	113	113
Gardasil/Gardasil 9	—	52	52	—	70	70	—	63	63
Zostavax	—	50	50	—	65	65	—	76	76
Simponi	—	49	49	—	69	69	—	92	92
Varivax	—	1	1	—	93	93	—	19	19
Supply sales to Merck affiliates	—	542	542	—	501	501	—	432	432
Other Merck Retained Products segment ⁽¹⁾	—	265	265	—	352	352	—	381	381
Total Merck Retained Products segment sales	—	1,564	1,564	—	1,753	1,753	—	1,485	1,485
	\$1,402	\$6,694	\$8,096	\$1,997	\$7,533	\$9,530	\$1,995	\$7,782	\$9,777

United States plus international may not equal total due to rounding.

⁽¹⁾ Includes sales of products not listed separately, revenue resulting from an arrangement for the sale of generic etonogestrel/ethinyl estradiol vaginal ring, allocated amounts from revenue hedging activities, and manufacturing sales to Merck and third parties.

A discussion of performance for select products in the businesses follows.

Organon Products Segment

Women's Health

(\$ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Nexplanon/Implanon	\$680	(14)%	(13)%	\$787	12%	14%	\$703
NuvaRing	236	(73)%	(73)%	879	(3)%	(2)%	902
Follistim AQ	193	(20)%	(20)%	241	(10)%	(7)%	268
Orgalutran	81	(28)%	(27)%	112	(21)%	(18)%	141

Contraception

Worldwide sales of Nexplanon/Implanon NXT, a single-rod subdermal contraceptive implant, declined 14% in 2020 primarily due to lower demand in the United States and in the EU resulting from the COVID-19 pandemic. Global sales of Nexplanon/Implanon NXT grew 12% in 2019 primarily due to higher demand and pricing in the United States.

Worldwide sales of NuvaRing, a vaginal contraceptive product, declined 73% in 2020 due to generic competition in the United States. The patent that provided market exclusivity for NuvaRing in the United States expired in April 2018 and generic competition began in December 2019. Accordingly, we are experiencing a rapid and substantial decline in NuvaRing sales in the United States and we expect the decline to continue. In addition to sales of branded NuvaRing, we have an agreement with a generic manufacturer that authorizes the sale of generic etonogestrel/ethinyl estradiol vaginal ring. Under the terms of the agreement, we are reimbursed on a cost-plus basis by the generic manufacturer for supplying finished goods and receive a share of the net profits recorded by the generic manufacturer. In 2020, we recorded revenue of \$148 million related to this arrangement. We expect revenue under this arrangement to decline significantly in 2021. Global *NuvaRing* sales declined 3% in 2019 primarily due to lower demand in the EU due to ongoing generic competition, largely offset by higher sales in the United States reflecting higher pricing that was partially offset by lower demand.

Fertility

Worldwide sales of Follistim AQ (marketed in most countries outside the United States as Puregon), a fertility treatment, declined 20% in 2020 largely due to lower demand globally resulting from the COVID-19 pandemic. Worldwide sales of Follistim AQ declined 10% in 2019 primarily due to lower demand in the EU and in the United States, partially offset by higher demand in China.

Worldwide sales of Orgalutran, a fertility treatment, declined 28% in 2020 primarily due to lower pricing in the United States, as well as lower demand in international markets attributable both to the COVID-19 pandemic and generic competition. Worldwide sales decreased 21% in 2019 primarily due to lower demand in the United States as a result of generic competition.

Biosimilars

(\$ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Renflexis	\$135	39%	39%	\$97	*	*	\$27
Ontruzant	115	38%	37%	83	*	*	20
Brenzys	74	3%	4%	72	*	*	16

* Calculation not meaningful.

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The following biosimilar products are part of a development and commercialization agreement between Merck and Samsung Bioepis entered into in 2013. See “Business—Third-Party Agreements—Samsung Bioepis Development and Commercialization Agreement” and Note 4 to our annual combined financial statements. Our commercialization territories under the agreement vary by product as noted below.

Renflexis (infliximab-abda) is a biosimilar to Remicade (infliximab) for the treatment of certain inflammatory diseases. Sales growth in 2020 and 2019 was driven primarily by continued uptake in the United States since launch in 2017. Higher demand in Canada also contributed to the sales increase in 2020. We have worldwide commercialization rights to Renflexis in countries outside the EU, Korea, China, Turkey and Russia.

Ontruzant (trastuzumab-dttb) is a biosimilar to Herceptin (trastuzumab) for the treatment of HER2-overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Sales growth in 2020 was driven by the launch in Brazil. Sales growth in 2019 was driven by continued uptake in the EU since launch in early 2018. In December 2019, the WHO announced that Ontruzant is the first biosimilar medicine approved for WHO pre-qualification. With this designation, Ontruzant is eligible for procurement through international agencies, which could give many more women with HER2-positive breast cancer access to this essential medicine in low-income countries. We have worldwide commercialization rights to Ontruzant in countries outside of Korea and China.

Brenzys (etanercept) is a biosimilar to Enbrel (etanercept) for the treatment of certain inflammatory diseases. Sales in 2020 were relatively flat compared to 2019. Sales growth in 2019 was driven by the launch in Brazil. We have worldwide commercialization rights to Brenzys in countries outside of the United States, the EU, Korea, China and Japan.

Aybintio (bevacizumab) is a biosimilar to Avastin (bevacizumab) for the treatment of metastatic carcinoma of the colon or rectum, metastatic non-squamous, non-small cell lung cancer, metastatic renal cell carcinoma, metastatic cervical cancer, epithelial ovarian, fallopian tube, or primary peritoneal cancer and metastatic breast cancer. Aybintio was approved in the EU in August 2020 and was launched in September 2020. We currently have no plan for the timing of any launch of Aybintio in the United States nor do we know when such timing would be determined. We have commercialization rights to Aybintio in the United States, Canada, Germany, Italy, France, the UK and Spain.

Hadlima (adalimumab-bwvd) is a biosimilar to Humira (adalimumab) for the treatment of certain inflammatory diseases. We have worldwide commercialization rights to Hadlima in countries outside of the EU, Korea, China, Turkey and Russia. Samsung Bioepis reached a global settlement with AbbVie permitting us to launch Hadlima in the United States in June 2023 and outside of the United States starting in 2021. Hadlima is currently approved in the United States, Australia, Canada, and Israel. Hadlima was launched in Australia and Canada in February 2021.

Established Brands

Established brands represents a broad portfolio of well-known brands, which generally are beyond market exclusivity, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management, for which generic competition varies by market.

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
Cozaar/Hyzaar	386	(13)%	(11)%	442	(3)%	2%	453
Zocor	77	(31)%	(32)%	112	(7)%	(4)%	121

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Combined global sales of Zetia (marketed in most countries outside of the United States as Ezetrol) and Vytorin (marketed outside of the United States as Inegy), medicines for lowering LDL cholesterol, declined 24% in 2020 primarily driven 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 overall sales decline in 2020 also reflects lower pricing due to loss of exclusivity in Australia. Partially offsetting the sales decline in 2020 were higher sales of Ezetrol in China, reflecting higher demand that was partly offset by lower pricing. Combined global sales of Zetia and Vytorin declined 35% in 2019 primarily due to lower sales in the EU, as well as in Australia due to generic competition.

Sales of Atozet (marketed outside of the United States), a medicine for lowering LDL cholesterol, grew 16% in 2020 primarily due to higher demand in most markets, particularly in the EU, Japan and other countries in the Asia Pacific region. Sales of Atozet grew 13% in 2019 primarily due to higher demand in the EU and Korea.

Sales of Rosuzet (marketed outside of the United States), a medicine for lowering LDL cholesterol, grew 8% in 2020 primarily due to higher demand in Korea and Japan. We expect sales of Rosuzet to decline in 2021 due to the expiration of a distribution agreement in Korea. Sales of Rosuzet more than doubled in 2019, primarily due to the launch in Japan, as well as higher demand in Korea.

Combined global sales of Cozaar, and its companion agent Hyzaar (a combination of Cozaar and hydrochlorothiazide that is marketed in Japan as Preminent), a medicine for the treatment of hypertension, declined 13% in 2020 primarily due to lower demand in China, Japan and the EU. Combined global sales of Cozaar and Hyzaar declined 3% in 2019 primarily due to the unfavorable effect of foreign exchange. Excluding the unfavorable effect of foreign exchange, sales performance reflects higher demand in the Asia Pacific region, particularly in China, partially offset by lower demand and lower pricing in Japan.

Worldwide sales of Zocor, a statin for modifying cholesterol, declined 31% in 2020 primarily due to lower demand in China, and decreased 7% in 2019 primarily due to lower sales in the EU and Japan.

Respiratory

(\$ in millions)	<u>2020</u>	<u>% Change</u>	<u>% Change Excluding Foreign Exchange</u>	<u>2019</u>	<u>% Change</u>	<u>% Change Excluding Foreign Exchange</u>	<u>2018</u>
Singulair	\$462	(34)%	(34)%	\$698	(1)%	1%	\$708
Dulera	222	2%	2%	217	(4)%	(4)%	227
Nasonex	218	(26)%	(24)%	293	(22)%	(19)%	376

Worldwide sales of Singulair, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, declined 34% in 2020 primarily due to lower demand in China and Japan attributable in part to the COVID-19 pandemic. Global sales of Singulair declined 1% in 2019 primarily reflecting the unfavorable effect of foreign exchange. Excluding the unfavorable effect of foreign exchange, sales performance in 2019 reflects higher demand in China and a favorable adjustment to customer discounts in the United States, largely offset by lower demand and lower pricing in Japan and the EU.

Global sales of Dulera Inhalation Aerosol, a combination medicine for the treatment of asthma, increased 2% in 2020 due to higher demand in Canada. We expect sales of Dulera to decline in 2021 due to generic competition in the United States. Sales of Dulera declined 4% in 2019 due to lower demand in the United States.

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Global sales of Nasonex, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, declined 26% in 2020 primarily due to continued generic competition in Japan, as well as lower demand in several other international markets resulting from the COVID-19 pandemic, partially offset by higher demand in China. Global sales decreased 22% in 2019 primarily due to ongoing generic competition in Japan and the United States.

Non-Opioid Pain, Bone and Dermatology

(\$ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Arcoxia	\$258	(11)%	(8)%	\$288	(14)%	(10)%	\$335

Sales of Arcoxia, for the treatment of arthritis and pain, declined 11% in 2020 primarily due to lower demand in the Asia Pacific region related to the COVID-19 pandemic, partially offset by higher demand in the EU. Sales of Arcoxia declined 14% in 2019 primarily due to lower demand in the EU and Latin America.

Other

(\$ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Proscar	\$176	(13)%	(13)%	\$203	10%	15%	\$185
Remeron	64	(22)%	(21)%	82	(38)%	(36)%	132

Worldwide sales of Proscar, for the treatment of symptomatic benign prostate enlargement, declined 13% in 2020 primarily due to lower demand in China. Global sales of Proscar increased 10% in 2019 due to higher volumes in China reflecting a recovery from supply constraints in the prior year.

Worldwide sales of *Remeron*, for the treatment of depression, declined 22% in 2020 and 38% in 2019 primarily due to lower demand in Japan. *Remeron* lost market exclusivity in Japan in December 2018.

Merck Retained Products Segment

(\$ in millions)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
Keytruda	\$529	7%	16%	\$493	60%	67%	\$309
Januvia/Janumet	76	(31)%	(23)%	110	(3)%	3%	113
Gardasil/Gardasil 9	52	(27)%	(23)%	70	11%	16%	63
Zostavax	50	(23)%	(22)%	65	(15)%	(11)%	76
Simponi	49	(30)%	(30)%	69	(25)%	(22)%	92
Varivax	1	(99)%	(98)%	93	*	*	19

* Calculation not meaningful.

As discussed above, prior to the consummation of the spin-off, the products in the Merck Retained Products segment will be contributed to newly formed Merck entities that will be retained by Merck. Upon full contribution of the Merck Retained Products segment by us to Merck and its affiliates, the historical results of operations of such products in the Merck Retained Products segment will be reflected as discontinued operations in the Organon financial statements. As described in “Basis of Presentation of Our Financial Information” above, the MRP Distribution that occurred in the fourth quarter of 2020 contributed to lower sales of the Merck Retained Products in 2020 compared with 2019.

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Keytruda is an anti-PD-1 (programmed death receptor-1) therapy approved for the treatment of many types of cancer. Sales of Keytruda in the Transferring Entities grew 7% in 2020 and 60% in 2019 primarily driven by higher demand reflecting both uptake across approved indications and the launch of new indications in the UK, Brazil and Switzerland entities. However, the COVID-19 pandemic had a dampening effect on growing demand in 2020. Sales growth in 2020 was partially offset by lower sales resulting from the MRP Distribution.

Januvia and Janumet are medicines that help lower blood sugar levels in adults with type 2 diabetes. Combined sales of Januvia and Janumet in the Transferring Entities declined 31% in 2020 largely due to lower volumes in the UK entity attributable in part to the MRP Distribution, as well as lower pricing in the Brazil entity. Combined sales of Januvia and Janumet in the Transferring Entities were relatively flat in 2019 compared with 2018.

Gardasil/Gardasil 9 are vaccines to help prevent certain cancers and other diseases caused by certain types of human papillomavirus (HPV). Sales of Gardasil/Gardasil 9 in the Transferring Entities declined 27% in 2020 due to lower demand in the UK entity attributable both to the COVID-19 pandemic and to the MRP Distribution. Sales of Gardasil/Gardasil 9 in the Transferring Entities grew 11% in 2019 primarily due to higher volumes in the UK entity.

Zostavax is a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older. Sales of Zostavax in the Transferring Entities declined 23% in 2020 and 15% in 2019 primarily due to lower government tenders in the UK. The sales decline in 2020 was also attributable to the MRP Distribution.

Simponi is a once-monthly subcutaneous treatment for certain inflammatory diseases. Sales of Simponi in the Transferring Entities declined 30% in 2020 and 25% in 2019 primarily driven by lower demand in the UK entities due to the launch of biosimilars for a competing product. The sales decline in 2020 was also attributable to the MRP Distribution.

Varivax is a vaccine to help prevent chickenpox (varicella). Sales of Varivax in the Transferring Entities declined 99% in 2020 driven by lower sales in the Brazil entity due to government tenders. Sales growth of Varivax in the Transferring Entities in 2019 was driven by higher sales in the Brazil entity due to government tenders.

Costs, Expenses and Other

(\$ in millions)	2020	% Change	2019	% Change	2018
Cost of sales	\$3,347	(8)%	\$3,621	(23)%	\$4,693
Selling, general and administrative	1,666	(13)%	1,922	(5)%	2,013
Research and development	304	(9)%	332	(9)%	365
Restructuring costs	70	(31)%	101	(15)%	119
Other (income) expense, net	29	*	(1)	*	(142)
	<u>\$5,416</u>	<u>(9)%</u>	<u>\$5,975</u>	<u>(15)%</u>	<u>\$7,048</u>

* Calculation not meaningful.

Cost of Sales

Cost of sales includes expenses for the amortization of intangible assets which totaled \$85 million in 2020, \$285 million in 2019 and \$1.6 billion in 2018. The decline in amortization expenses in 2020 compared with 2019 is primarily due to the intangible assets related to Nasonex, Clarinex and Atozet, which were fully amortized at the end of 2019. The decline in amortization expenses in 2019 as compared with 2018 is primarily due to the intangible assets related to Zetia and Vytorin, which were almost fully amortized at the end of 2018.

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Gross margin was 58.7% in 2020, 62.0% in 2019 and 52.0% in 2018. The gross margin decline in 2020 compared with 2019 reflects pricing pressure and product mix, partially offset by lower amortization of intangible assets as noted above. The gross margin increase in 2019 compared with 2018 was primarily due to lower amortization of intangible assets noted above.

Selling, General and Administrative

Selling, general and administrative expenses declined 13% in 2020 primarily due to lower selling and promotional costs, reflecting lower travel and meeting expenses, due in part to the impact of the COVID-19 pandemic, as well as lower costs due to the MRP Distribution. These declines were partially offset by costs incurred to establish Organon as a standalone entity. Selling, general and administrative expenses declined 5% in 2019 primarily due to lower selling and promotional costs on products within established brands, partially offset by higher spending to support the ongoing launches of biosimilars and higher spending on the Merck Retained Products, particularly Keytruda.

Research and Development

Research and development expenses declined 9% in 2020 primarily due to lower costs from post-marketing research activities, as well as lower costs due to the MRP Distribution, partially offset by higher spending associated with Organon development programs. Research and development expenses declined 9% in 2019, primarily reflecting lower costs from post-marketing research activities, as well as lower spending driven by the conclusion of certain clinical development programs. The decline was partially offset by higher spending for clinical trials and research collaborations associated with the Merck Retained Products.

Restructuring Costs

Certain of our operations have been affected by restructuring plans initiated by Merck. These restructuring plans include a global restructuring program approved in 2019 focused primarily on further optimizing Merck's manufacturing and supply network and reducing its global real estate footprint. Our operations were also affected by previous restructuring plans designed to streamline Merck's cost structure, which included the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites, and the consolidation of office facilities. Separation costs incurred were associated with actual headcount reductions made by Merck, as well as those headcount reductions that were probable and could be reasonably estimated. Also included in restructuring costs are costs associated with facilities to be sold or closed, asset abandonment, shut-down and other related costs (see Note 5 to our audited annual combined financial statements).

Other (Income) Expense, Net

For details on the components of Other (income) expense, net, see Note 13 to our audited annual combined financial statements.

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\$ in millions	Merck			Merck			Merck		
	Organon Products	Retained Products	Total	Organon Products	Retained Products	Total	Organon Products	Retained Products	Total
	2020			2019			2018		
Sales	\$ 6,532	\$ 1,564	\$8,096	\$ 7,777	\$ 1,753	\$9,530	\$ 8,292	\$ 1,485	\$9,777
Costs, Expenses and Other									
Cost of sales	2,119	1,228	3,347	2,274	1,347	3,621	3,541	1,152	4,693
Selling, general and administrative	1,356	310	1,666	1,443	479	1,922	1,567	446	2,013
Research and development	210	94	304	220	112	332	262	103	365
Restructuring costs	60	10	70	78	23	101	108	11	119
Other (income) expense, net	35	(6)	29	66	(67)	(1)	(51)	(91)	(142)
Income (Loss) Before Taxes	<u>\$ 2,752</u>	<u>\$ (72)</u>	<u>\$2,680</u>	<u>\$ 3,696</u>	<u>\$ (141)</u>	<u>\$3,555</u>	<u>\$ 2,865</u>	<u>\$ (136)</u>	<u>\$2,729</u>

Organon Products Segment

Organon Products segment profits declined 26% in 2020 primarily due to lower sales, partially offset by lower amortization of intangible assets, lower selling and promotional spending due in part to the COVID-19 pandemic, and favorability in other (income) expense, net.

Organon Products segment profits grew 29% in 2019 primarily due to lower amortization of intangible assets. Declines in selling and promotional spending related to established brands, lower research and development spending resulting from the conclusion of certain clinical trials, and lower restructuring costs also contributed to the increase in Organon Products segment profits. Partially offsetting Organon Products segment profit growth in 2019 were lower sales, as well as unfavorability in other (income) expense, net, largely due to a gain on the settlement of certain patent litigation recorded in 2018.

Merck Retained Products Segment

Merck Retained Products segment losses declined 49% in 2020 primarily due to lower selling and promotional spending, partially offset by lower sales and unfavorability in other (income) expense, net.

Merck Retained Products segment losses increased 3% in 2019 primarily reflecting higher selling and promotional spending and unfavorability in other (income) expense, net, partially offset by higher sales.

Taxes on Income

The effective income tax rates of 19.4% in 2020, 9.5% in 2019 and 21.1% in 2018 reflect the beneficial impact of foreign earnings and the unfavorable impact of the amortization of intangible assets. The effective income tax rate in 2019 also reflects the favorable impact of a \$258 million net tax benefit related to the settlement of certain federal income tax matters.

Net Income

Net income was \$2.2 billion in 2020, \$3.2 billion in 2019 and \$2.2 billion in 2018.

EBITDA, Adjusted EBITDA and Adjusted Net Income

Earnings before interest, incomes taxes, depreciation and amortization (EBITDA), Adjusted EBITDA, and Adjusted Net Income (non-GAAP financial measures) are alternative views of our performance that we provide below because management believes this information enhances investors' understanding of our results as it permits investors to understand how management assesses performance. EBITDA, Adjusted EBITDA and Adjusted Net Income are expected to be important internal measures for us. Our management intends to use these measures internally for planning and forecasting purposes and to measure our performance along with other metrics. Also, we anticipate that our senior management's annual compensation will be derived in part using these non-GAAP measures. Additionally, EBITDA and Adjusted EBITDA are important metrics for debt investors who utilize debt to EBITDA ratios. Since EBITDA, Adjusted EBITDA and Adjusted Net Income 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 a similar measure of other companies. These metrics should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP. As discussed above, our combined balance sheet and statement of income do not include an allocation of third-party debt or interest expense from Merck because we were not the legal obligor of the debt and because Merck's borrowings were not directly attributable to our business. However, in connection with the spin-off, we expect to incur debt and such indebtedness would cause us to record additional interest expense in future periods. See "Description of Certain Indebtedness."

Organon Products Adjusted EBITDA and Organon Products Adjusted Net Income

Organon Products Adjusted EBITDA and Organon Products Adjusted Net Income exclude Adjusted EBITDA and Adjusted Net Loss attributable to the Merck Retained Products. As noted above, prior to the consummation of the spin-off, the Merck Retained Products will be contributed to newly formed Merck entities that will be retained by Merck and the historical results of operations related to the Merck Retained Products will be reflected as discontinued operations in the Organon financial statements.

A reconciliation between GAAP net income, EBITDA, Adjusted EBITDA and Organon Products Adjusted EBITDA is as follows:

(\$ in millions)	2020	2019	2018
Net income as reported under GAAP	\$2,160	\$3,218	\$2,153
Interest income, net	(10)	(13)	(15)
Taxes on income	520	337	576
Depreciation	72	69	68
Amortization	85	285	1,605
EBITDA	<u>\$2,827</u>	<u>\$3,896</u>	<u>\$4,387</u>
Restructuring costs (excluding depreciation costs above)	73	101	121
Organon formation costs	126	—	—
Gain on settlement of certain patent litigation	—	—	(115)
Adjusted EBITDA	<u>\$3,026</u>	<u>\$3,997</u>	<u>\$4,393</u>
Less: Merck Retained Products Adjusted EBITDA ⁽¹⁾	(54)	(110)	(121)
Organon Products Adjusted EBITDA	<u>\$3,080</u>	<u>\$4,107</u>	<u>\$4,514</u>

⁽¹⁾ Calculated as net loss under GAAP of \$(96) million, \$(88) million and \$(132) million in 2020, 2019 and 2018, respectively, excluding net interest income, income taxes, depreciation and restructuring costs, which aggregated \$(42) million, \$22 million and \$(11) million in 2020, 2019 and 2018, respectively.

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A reconciliation between GAAP financial measures and adjusted financial measures is as follows:

(\$ in millions)	2020	2019	2018
Income before taxes as reported under GAAP	\$2,680	\$3,555	\$2,729
Amortization	85	285	1,605
Restructuring costs	73	108	126
Other items:			
Organon formation costs	126	—	—
Gain on settlement of certain patent litigation	—	—	(115)
Adjusted income before taxes	2,964	3,948	4,345
Taxes on income as reported under GAAP	520	337	576
Estimated tax benefit on above items	48	67	219
Net tax benefit from the settlement of certain federal income tax matters	—	258	—
Adjusted taxes on income	568	662	795
Adjusted Net Income	\$2,396	\$3,286	\$3,550
Less: Merck Retained Products Adjusted Net Loss ⁽¹⁾	(86)	(66)	(120)
Organon Products Adjusted Net Income	<u>\$2,482</u>	<u>\$3,352</u>	<u>\$3,670</u>

⁽¹⁾ Calculated as net loss under GAAP of \$(96) million, \$(88) million and \$(132) million in 2020, 2019, and 2018, respectively, excluding restructuring costs and non-GAAP tax effects, which aggregated \$(10) million, \$(22) million and \$(12) million in 2020, 2019 and 2018, respectively.

Items excluded from Adjusted EBITDA and Adjusted Net Income are as follows:

- The amortization of intangible assets recorded in connection with business acquisitions and licensing activities (see Note 8 to our audited annual combined financial statements).
- Costs related to restructuring actions, including employee separation costs and costs associated with facilities to be sold or closed, asset abandonment, shut-down and other related costs (see Note 5 to our audited annual combined financial statements).
- Other items are adjusted for after they are evaluated 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 Adjusted EBITDA and Adjusted Net Income in 2020 are costs incurred to establish Organon as a standalone entity, primarily employee-related and information technology costs. Excluded from Adjusted EBITDA and Adjusted Net Income in 2018 is a gain on the settlement of certain patent litigation (see Note 10 to our audited annual combined financial statements).
- EBITDA and Adjusted EBITDA by definition exclude all income taxes. Adjusted Net Income excludes the estimated tax benefit on the reconciling items and a net tax benefit related to the settlement of certain federal income tax matters in 2019 (see Note 14 to our audited annual combined financial statements).

Analysis of Liquidity and Capital Resources

Historic Liquidity and Capital Resources

We have historically participated in Merck's centralized treasury management, including its centralized cash pooling and overall financing arrangements. We have historically generated, and expect to continue to generate, positive cash flow from operations. Due to our participation in Merck's centralized treasury management, the only cash and cash equivalents we have reported on our balance sheet are attributable to the Organon Entities and the Transferring Entities.

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Working capital was \$894 million in 2020, \$2.6 billion in 2019 and \$2.2 billion in 2018. The decrease in working capital in 2020 compared with 2019 was primarily due to an increase in related party current liabilities coupled with a decrease in cash and cash equivalents resulting from the establishment of new Organon Entities and subsequent activity between these entities and Merck affiliates. The decline in working capital in 2020 was also attributable to a decrease in accounts receivable due to lower sales and the MRP Distribution, a decline in prepaid taxes and lower inventory also related to the MRP Distribution.

The increase in working capital in 2019 as compared with 2018 was primarily driven by an increase in inventories and a related increase in the income tax consequences deferred for intra-entity inventory transfers reflected in other current assets, a decrease in related party current liabilities due to activity during the period and timing of settlement, a decline in income taxes payable, and an increase in cash and cash equivalents.

Cash provided by operating activities was \$2.2 billion in 2020, \$2.8 billion in 2019 and \$3.7 billion in 2018. Cash provided by operating activities is being unfavorably affected by sales declines. The lower cash provided by operating activities in 2019 compared with 2018 is also attributable in part to higher tax payments related to settlements with the Internal Revenue Service.

Cash used in investing activities was \$258 million in 2020, \$102 million in 2019 and \$69 million in 2018, mostly reflecting capital expenditures.

Cash used in financing activities was \$2.2 billion in 2020, \$2.6 billion in 2019 and \$4.2 billion in 2018, reflecting transactions with Merck (see Note 17 to our audited annual combined financial statements).

Merck has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. Merck factored \$227 million and \$488 million of accounts receivable related to us 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 combined statement of cash flows.

Post Spin-Off Liquidity and Capital Resources

Subsequent to the spin-off, we will no longer participate in cash management and funding arrangements with Merck. Our ability to fund our operations and capital needs depends upon our ability to generate ongoing cash from operations and to access the capital markets. Our principal uses of cash in the future will be primarily to fund our operations, working capital needs, capital expenditures, repayment of borrowings, payment of dividends and strategic business development transactions.

We expect to incur indebtedness in connection with the spin-off, of which a portion will be paid to Merck as a distribution. See “Description of Certain Indebtedness.” Following the debt incurrence, distribution to Merck and cash contributed from Merck in connection with the formation of various Organon entities, we expect to begin operations as an independent company with cash and cash equivalents as set forth under “Capitalization.” We believe that our financing arrangements, future cash from operations and access to capital markets will provide adequate resources to fund our future cash flow needs.

Our contractual obligations as of December 31, 2020 were as follows:

(\$ in millions)	Payments Due by Period				
	Total	2021	2022	2023	2024
Purchase obligations ⁽¹⁾	\$ 954	\$ 170	\$ 308	\$ 260	\$ 216
Leases ⁽²⁾	79	22	35	19	3
	<u>\$ 1,033</u>	<u>\$ 192</u>	<u>\$ 343</u>	<u>\$ 279</u>	<u>\$ 219</u>

⁽¹⁾ Includes inventory purchase commitments.

⁽²⁾ Amounts exclude reasonably certain lease renewals that have not yet been executed (see Note 9 to our audited annual combined financial statements).

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services. Payments of the transition tax related to the TCJA are not reflected in the table above as this liability will be retained by Merck pursuant to the tax matters agreement that Merck and Organon will enter into in connection with the separation. In addition, Organon is expected to be responsible for unrecognized tax benefits pursuant to the tax matters agreement to the extent a reserve relates exclusively to separate tax returns filed by Organon. These reserves amounted to \$50 million at December 31, 2020. 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 and as such, are not reflected in the table above. Contingent milestone payments related to collaborative arrangements are not reflected in the table above because they are not considered contractual obligations until the successful achievement of the related regulatory approval milestones.

Financial Instruments Market Risk Disclosures

Foreign Currency Risk Management

We operate on a global basis and are exposed to the risk that our earnings, cash flows and equity could be adversely affected by fluctuations in foreign exchange rates. We are primarily exposed to foreign exchange risk with respect to forecasted transactions and net assets denominated in the euro, Japanese yen and Chinese renminbi. Merck manages the impact of foreign exchange rate movements on its affiliate's earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments. Merck has established revenue hedging and balance sheet risk management programs to protect against the volatility of future foreign currency cash flows and changes in fair value caused by volatility in exchange rates that we participate in. Accordingly, the combined statement of income includes the impact of Merck's derivative financial instruments that is deemed to be associated with our operations and has been allocated to us utilizing a proportional allocation method. The fair values of outstanding derivative instruments have not been allocated to our combined balance sheet. Following the spin-off, we intend to implement a foreign currency risk management program on our own behalf.

We estimate a hypothetical 10% adverse movement in foreign currency exchange rates would not be material to our financial position, results of operations or cash flows.

Interest Rate Risk Management

Our combined balance sheet and statement of income do not include an allocation of third-party debt or interest expense from Merck because we are not the legal obligor of the debt and the borrowings were not directly attributable to our business. We expect to incur indebtedness in connection with the spin-off, at which time our exposure to interest rate risk is expected to increase.

Critical Accounting Estimates

The audited annual combined 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 in determining the allocation of costs and expenses from Merck, and are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, valuation of goodwill and intangibles, amounts recorded for contingencies, environmental liabilities and other reserves, pension and share-based compensation assumptions, restructuring costs, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

Revenue Recognition

Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. We act as the principal in our customer arrangements

and therefore record revenue on a gross basis. The majority of our contracts 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.

Revenues from sales of products, including sales of Merck Retained Products to affiliates by the Organon Entities and the Transferring Entities, are recognized at a point in time when control of the goods is transferred to the customer, which we have determined is when title and risks and rewards of ownership transfer to the customer and we are entitled to payment.

The nature of our 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 provision for aggregate customer discounts in the United States 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 us 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 our 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. We use 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.

We continually monitor our 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 sales in the United States is as follows:

(\$ in millions)	2020	2019
Balance January 1	\$ 365	\$ 404
Provision	1,770	1,885
Payments	(1,792)	(1,924)
Balance December 31	<u>\$ 343</u>	<u>\$ 365</u>

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 \$41 million and \$302 million, respectively, at December 31, 2020 and were \$52 million and \$313 million, 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 our specific payback obligation. Rebates may also be required based on specific product sales thresholds. We apply an estimated factor against our actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

We maintain a returns policy that allows our customers in the United States 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, we consider 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.

Our payment terms for customers in the United States are typically 36 days from receipt of invoice. Outside of the United States, payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

Contingencies and Environmental Liabilities

We are involved in various claims and legal proceedings of a nature considered normal to our business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters (see Note 10 to our audited annual combined financial statements).

We record 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 us; the development of our legal defense strategy and structure in light of the scope of the litigation; the number of cases being brought against us; 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 \$35 million and \$40 million, respectively, represents our best estimate of the minimum amount of defense costs to be incurred in connection with our outstanding litigation; however, events such as additional trials and other events that could arise in the course of the litigation could affect the ultimate amount of legal defense costs to be incurred by us. We will continue to monitor our 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, we believe it would be appropriate to do so.

We believe that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on us. Expenditures for remediation and environmental liabilities were \$1 million in 2020, and are estimated at \$18 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 \$24 million and \$21 million at December 31, 2020 and 2019,

respectively. 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 \$20 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on our financial condition, results of operations or liquidity for any year.

Impairments of Long-Lived Assets

We assess changes in economic, regulatory and legal conditions and make assumptions regarding estimated future cash flows in evaluating the value of our property, plant and equipment, goodwill and other intangible assets.

We periodically evaluate whether current facts or circumstances indicate that the carrying values of our 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, we 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, attributable only to the Organon Products reporting unit, is 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 fair value is less than carrying value. 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, and overall financial performance. If we conclude it is more likely than not that fair value is less than carrying value, a quantitative fair value test is performed. If carrying value is greater than fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill). As of the most recent goodwill impairment testing date, the reporting unit's fair value exceeded its carrying value by a substantial amount.

Other acquired intangible assets 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, we 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.

The judgments made in evaluating impairment of long-lived intangibles can materially affect our results of operations.

Taxes on Income

Income tax expense and deferred tax balances in the audited annual combined financial statements have been calculated on a separate tax return basis. Our operations are included in the tax returns of certain Organon Entities, Transferring Entities or the respective Merck entities of which our business is a part. We believe the assumptions supporting the allocation and presentation of income taxes on a separate return basis are reasonable. One of these assumptions is that we, on a standalone basis, will not benefit from certain tax incentives that historically benefited Merck.

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. We establish valuation allowances for our deferred tax

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assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. We evaluate 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, we recognize 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, we do not recognize any portion of the benefit in the financial statements. We recognize interest and penalties associated with uncertain tax positions as a component of *Taxes on income* in the combined statement of income.

We do not maintain an income taxes payable to or from account as it is deemed to be settled with the tax paying entities in the respective jurisdictions. These settlements are reflected as changes in *Net investment from Parent* on the combined balance sheet. However, our combined balance sheet reflects balances with taxing authorities for certain Organon Entities and Transferring Entities and the one-time transition tax resulting from the TCJA, as well as for unrecognized income tax benefits along with related interest and penalties. We and Merck will enter into a tax matters agreement prior to the separation. See “Certain Relationships and Related Party Transactions—Agreements with Merck—Tax Matters Agreement.”

Business

Overview

Organon is a science-based global pharmaceutical company that develops and delivers innovative health solutions through a portfolio of prescription therapies within women's health, biosimilars and established brands. No other large global pharmaceutical company has women's health as its primary therapeutic area of focus. Our women's health portfolio has historically delivered strong revenues, underpinned by our contraceptives products, which include Nexplanon / Implanon NXT, our patented long-acting reversible contraceptive, with its sales growing at an 11% CAGR between 2010 and 2020. Our biosimilars portfolio has delivered more than \$650 million in sales since 2017, and we expect growth will be fueled by planned launches in the United States and Europe. Finally, our established brands portfolio continues to generate strong operating profit across many markets, including the United States, China, Japan, Korea and countries in Europe, despite loss of market exclusivity across a majority of brands. For many of our products, the impacts of loss of patent exclusivity events in the United States and Europe have passed, and, as a result, combined with enhanced management focus, an established supply chain and targeted resourcing, we believe that our portfolio will continue to deliver strong, reliable operating profit at low promotional and development expense requirements. See "—Products" for more information on loss of patent exclusivity for our key products.

Our mission is to be the world's leading women's health company and deliver a better and healthier every day for every woman. We plan to build on our strengths in reproductive health to assemble an array of health solutions to serve women from adolescence to menopause and beyond. We are focused on generating strong and growing cash flow by selectively investing in development and inorganic opportunities to drive innovation and future growth across our core areas. Our portfolio of diverse and branded products is supported by commercialization and market access, regulatory affairs, manufacturing and clinical development expertise globally. Our global footprint lends scale to our business by enabling management to identify and focus on unique market opportunities across our broad portfolio.

Our women's health, biosimilars and established brands portfolios, together with the expertise and experience of our employees, enable us to pursue an exciting innovation agenda, carving out a unique position in the health care sector. Our product portfolio is unified by a central focus on patient needs addressed by our therapies, a commitment to driving organic and inorganic growth, a heritage of successful commercialization and clinical development, and a disciplined approach to cost and operational efficiency. We believe our women's health portfolio, in combination with our biosimilars and established brands portfolios, will enable us to deliver value to patients and the health care system while creating value for our shareholders. We also believe our geographic scale, long heritage and sustained successes within women's health will enable us to become the commercialization and distribution partner of choice for smaller women's health companies. Our global commercial capabilities and market access, established relationships with health care providers, patients and payors and clinical expertise support our long-term strategy to launch therapies and recognize development opportunities within and beyond our existing portfolios.

Our business strategy is focused on advancing our mission to be the world's leading women's health company, pursuing growth in biosimilars and maximizing opportunities from our established brands portfolio. In particular:

- We believe there is significant growth potential in women's health broadly. In addition to our ten marketed products, we intend to focus our growth efforts in two areas, on needs and conditions that uniquely impact women, generally referred to as the core women's health market, and on needs and conditions that disproportionately impact women. We estimate that the combined global market for pharmaceuticals in the core women's health market, which includes therapeutic areas such as contraception and fertility, endometriosis and uterine fibroids, was \$33 billion in 2020. We project that the core women's health market will grow to \$40 billion by 2026. In addition, we estimate that the segment of therapeutic areas that disproportionately impact women, such as osteoporosis, lupus, urinary tract infections, migraines and celiac disease, will grow annually at an approximately 10% CAGR from 2020 to 2026, adding a further \$21 billion to the core women's health market size estimates.

- Our existing biosimilars portfolio positions us for success in this attractive and fast growing area of health care. We estimate the total size of the global market for biosimilars was approximately \$17.3 billion as of September 2020, reflecting 60 biosimilars approved in the EU and 29 approved in the United States. Industry publications estimate that 54 major biologics, with an aggregate market value of approximately \$220 billion, will lose patent protection in the next decade, which has potential to expand the biosimilars global market to over \$30 billion in the next decade or so. We do not have biosimilars corresponding to all biologics that will lose patent protection in the next decade. All five biosimilars in our portfolio have launched in certain countries globally, including two biosimilars in the United States. We intend to expand our biosimilars portfolio through commercialization of additional products and expanded marketing of existing products. We believe our size, capabilities and experience position us competitively in this area.
- Our established brands portfolio consists of 49 products covering cardiovascular, respiratory, dermatology and non-opioid pain management. A number of our established brands that face generic competition still contribute meaningful profitability. We intend to stimulate the performance of our established brands products through renewed focus and attention on strategic marketing to create a significant source of capital to fuel the company’s growth aspirations. We believe our established brands products will, over time, continue to deliver meaningful revenue and operating profit that can be redirected into organic and inorganic growth opportunities in key product areas and geographies. Our established brands portfolio is supported by our large commercial and manufacturing capabilities, including a global network that enables us to distribute products to patients in more than 140 countries and territories.

Key Products

Women’s Health	Biosimilars	Established Brands
		
		
		
		
		

In 2020, the Organon Products segment recorded revenue of \$6.5 billion and generated \$2.3 billion of net income. We expect to be well positioned for low to mid-single digit annual revenue growth off of a 2021 base year. We operate on a global scale and our global network enables us to distribute products to patients in more than 140 countries and territories around the world, with approximately 80% of 2020 Organon

Products segment revenue, or \$5.1 billion, generated outside the United States. Upon the separation, we will have approximately 9,950 employees worldwide, with approximately 4,030 employees focusing on sales, marketing and key commercialization activities and approximately 730 employees focusing on clinical development, safety, and medical affairs and product registration. Additionally, we expect to operate six manufacturing sites globally and have approximately 3,020 manufacturing employees.

Our operations are principally managed on a products basis and include two operating segments, the Organon Products segment and the Merck Retained Products segment. We consider the Organon Products segment to be our only business going forward, and, as such, all discussion and financial information presented in this section relates only to the Organon Products segment.

Upon separation, Merck will retain operations of the Merck Retained Products segment and we will no longer present financial information related to this segment in our financial statements. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

Organon is a Delaware corporation incorporated on March 11, 2020. Our corporate offices are located at 30 Hudson Street, 33rd Floor, Jersey City, New Jersey 07302.

Strengths

We have a number of advantages that distinguish us from our competitors and support our strategy:

- **Leading portfolio of health solutions for women.** We intend to be the world’s leading women’s health company, with a long history of innovative, first-to-market contraceptive products. We have a broad offering of contraception and fertility brands that we believe have long-term growth potential, and we are one of only two global contraception manufacturers operating in the highly fragmented contraception market. Our portfolio of ten products includes Nexplanon / Implanon NXT, globally one of the highest revenue generating long-acting reversible contraceptives, or LARC, a class of contraceptives recognized as the most effective method of hormonal contraception available to patients with a lower long-term average cost. Our management team has the development and commercial expertise to drive innovation in therapeutics and drug-device combinations across the women’s health landscape through opportunities related to our existing portfolio and by externally sourcing therapies through in-licensing, acquisition and other business development transactions with innovators seeking to benefit from our global commercial presence in women’s health.
- **Growing position in biosimilars.** We have a growing position in biosimilars. We have strong, global commercialization capabilities, with a portfolio spanning oncology and immunology treatments, two areas primed for significant growth in biosimilars. We plan to continue evaluating opportunities in other potential therapeutic areas, including ophthalmology, diabetes and neuroscience. Our oncology biosimilars have been launched in 20 countries and our immunology biosimilars have been launched in five countries. All five biosimilars in our portfolio have launched in certain countries globally, including two biosimilars in the United States. We expect that our biosimilars business will continue to generate growth in the near term.
- **Market Leading Established Brands.** In established brands, we have a broad and robust portfolio of mature brands generally beyond market exclusivity, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management. Our established brands portfolio generates strong operating profit, which we anticipate will continue to fund our future growth. We have proven development, regulatory, manufacturing and commercial capabilities, which we believe will support growth in targeted existing geographies, new geographies, and through new indications and line extensions.

- **Broad and fit-for-purpose capabilities.** We have enterprise capabilities delivered by seasoned leaders in global commercialization and market access, regulatory affairs, manufacturing and clinical development. In particular, our capabilities include:
 - *Global commercialization expertise:* Our experienced team will execute targeted investment in, and successful commercialization of, organic growth opportunities across our global portfolio. These efforts will be supported by data-driven, science-based decision-making and execution at scale, enabled by data and analytics and by digital engagement of health care providers and patients.
 - *Development capabilities:* We have approximately 730 employees focused on clinical development, safety, medical affairs and product registration. Our employees have deep expertise in these areas that we believe will facilitate generation of robust clinical data capable of enabling rapid global product registration, as well as valuable insights to expand the commercial reach of our portfolio.
 - *Digital and omni-channel marketing capabilities:* We market our products using a digital and omni-channel approach, reaching a broad base of market participants, including health care providers, patients and policy makers and payors in a cost-efficient manner. Our health care provider, patient and payor-focused relationship management is facilitated by an integrated digital ecosystem that coordinates health care provider and patient engagement across many channels, including face-to-face, email, social media, mobile and websites.
 - *Strategic alliances:* We have an extensive track record of managing strategic alliances and creating value through global partnerships to guide investment and growth in inorganic pipeline opportunities. For example, our collaboration with Samsung Bioepis allows us to work together with a biopharmaceutical company that complements our capabilities and strengths.
 - *Established manufacturing and supply chain:* Beyond our commercial capabilities, we expect to have approximately 440 employees operating in supply chain management, which we believe, together with our manufacturing capabilities, will enable us to maintain a high-quality, reliable global supply chain. See “—Manufacturing Capabilities and Global Supply Chain.”
- **Geographic scale and platform.** In 2020, we generated \$5.1 billion in sales outside the United States, representing approximately 80% of our total Organon Products segment sales. Our footprint spans the globe with a direct presence in 58 countries and the ability to deliver therapies to patients in more than 140 countries and territories. We plan to initially focus on 14 key markets, which currently generate approximately 75% of our global sales, and we expect our broader geographic reach and manufacturing capabilities to drive long-term growth and expansion opportunities. Specifically, in women’s health and biosimilars, we believe our global footprint will enable us to expand the market for our current products in order to meet the increasing demand for these products. We also believe our geographic scale, long heritage and sustained successes within women’s health will enable us to become the commercialization and distribution partner of choice for smaller women’s health companies. In established brands, where opportunities vary significantly depending on the exact dynamics and characteristics of each country, we believe our geographic scale enables us to capitalize on global opportunities and increase brand share by responding to these dynamics.
- **Strong financial profile with significant free cash flow generation and improving operating leverage.** In 2020, the Organon Products segment generated approximately \$2.3 billion in operating cash flow and spent \$255 million on capital expenditures. The Organon Products segment also generated Adjusted EBITDA of \$3.1 billion on \$6.5 billion of sales, representing an EBITDA margin of approximately 47%. We expect that 2021 operating cash flow from the Organon Products Segment will be comparable to, though slightly down from, 2020 before the impact of estimated interest expense. We anticipate we will continue to generate significant cash flow and expect our operating leverage to improve in the future.

- **Scientific heritage, expertise and culture of excellence inherited from Merck.** Merck’s rich, over-125-year scientific heritage is imbued in our strong scientific principles, innovative development strategies and quality-focused culture. Building on our heritage of regulatory and scientific expertise, we expect to have the capabilities to continue to optimize pathways for clinical development and regulatory approvals as well as data generation capabilities required to support patient access, formulary placement and reimbursement.
- **Strong, leading and established brand in the area of women’s health.** The Organon brand has a long history in the area of women’s health, both with patients and health care providers, and with employees who initially came to Merck through the acquisition of Organon. Our proud heritage in women’s health began with Organon’s launch of one of the first-ever combined hormonal oral contraceptives, Lyndiol, in 1962. This was followed by an impressive series of innovative firsts, including:
 - the launch of Marvelon in 1981, the first lower dose (30mcg) estrogen combined oral contraceptive with a selective progestin,
 - the launch of Livial in 1987, the first non-estrogen gonadomimetic hormonal replacement treatment,
 - the launch of Follistim, the first recombinant follicle-stimulating hormone available in the United States for infertility,
 - the launch of NuvaRing in 2001, the first once-a-month contraceptive ring, and
 - the launch of Nexplanon / Implanon NXT in 2011, the first and only single-rod radiopaque contraceptive implant with preloaded applicator.
- **Experienced management team and Board with track record of successful performance.** Our executive management team has a strong track record of leadership, performance and execution in the pharmaceutical industry. Together, they bring a diverse set of leadership experience at respected companies both within and beyond the biopharmaceutical industry. Our CEO and a majority of our executive leadership team have been appointed from within Merck where they each established reputations as global leaders. Our management team is supported by a seasoned Board of Directors providing guidance and strategic vision based on a diverse set of backgrounds and experiences. The extensive company and industry experience of our management team as well as our Board of Directors will serve as a source of strength and innovation to guide us into the future.

Strategies

Our strategy is to be the world’s leading women’s health company by leveraging our historical strength in this area and investing in therapies and innovations that support the medical needs of women, to pursue growth in biosimilars and to maximize opportunities from our established brands, all while reinvesting our strong operating cash flow to fund growth initiatives across our portfolio. We believe our portfolio will benefit from the increased investment and attention we can provide as an independent company. Our focus will be to:

- **Leverage our existing position in women’s health to become the global leader in this space.** No other large global pharmaceutical company has women’s health as its primary therapeutic area of focus. We intend to be the world’s leading women’s health company to address the needs and conditions that uniquely and disproportionately impact women. We plan to achieve this by leveraging our scale, deep experience, geographic reach, strong relationships with payors, health care providers, large clinics and important stakeholder groups such as societies, patients and scientific leaders to grow revenue for our contraception and fertility brands and expand into additional women’s health therapeutic areas, and through strategic acquisitions and collaborations. In 2020, approximately one quarter of our revenue was derived from women’s health products and, over time, we expect to grow this share by:
 - expanding the marketing and distribution of our key brands, including Nexplanon / Implanon NXT, Follistim and Elonva,

- investing in manufacturing to expand the supply capacity for Nexplanon / Implanon NXT and our fertility product portfolio,
 - focusing our contraception commercial strategy on expanding global access to Nexplanon / Implanon NXT and increasing communication and education about LARC, which we believe will expand the market opportunity for Nexplanon / Implanon NXT,
 - focusing our fertility commercial strategy on increasing communication and education about antagonist protocols, which we believe will expand the market opportunity for both Follistim and Elonva,
 - applying our long history of women’s health scientific development experience to invest in late lifecycle activities that will broaden the geographic footprint of our women’s health portfolio and further enhance the value of the portfolio, and
 - tracking scientific innovation globally to source commercialized and development-stage inorganic opportunities across women’s health broadly in order to develop products that target specific unmet medical need in conditions that impact women both uniquely and disproportionately.
- **Maximize value from our biosimilars portfolio through increased focus and strategic investment.** We believe that the biosimilars market offers potential for value creation for a company with our strengths. In the short term, we are focused on commercializing the five biosimilars sourced from our collaboration with Samsung Bioepis, including the recent EU launch of Aybintio in oncology. In the longer term, we expect to focus on expanding our portfolio through ongoing identification and evaluation of new opportunities in therapeutic areas such as oncology, immunology, ophthalmology, diabetes and neuroscience, both through our Samsung Bioepis collaboration and through other potential collaborations. We believe that our focused approach enables us to further capitalize on the momentum in the biosimilars industry to drive growth through commercialization of additional biosimilars and expansion of our existing products into additional countries. In addition, we believe the biosimilars market will continue to favorably mature through continued policy efforts, both in the United States, and globally, that recognize the important role biosimilars can play in alleviating cost pressures for health care systems. In addition, we believe our commercial experience, particularly in the areas of tendering and policy, obtained from our prior biosimilars launches (Renflexis in the United States and Ontruzant in the United States and the European Union (“EU”)), provides us a competitive advantage in the market.
 - **Drive near-term growth through investment in our existing portfolio.** We believe that our broad portfolio affords us a range of options to drive future growth by developing products that target specific unmet medical need, including in-licenses, commercial collaborations, partnerships and acquisitions consistent with our focused strategy. For example, our established brands portfolio has a particularly strong foothold in emerging markets where we have a broad base of products enabling us to build targeted additional product offerings and developments. We expect that greater managerial focus to capture local market opportunities, along with targeted investments in expanding our geographic footprint, digital promotion and commercial trade channels, will provide new revenue opportunities for select brands in our established brands portfolio. We also believe there are meaningful opportunities to be realized through further investment in, and lifecycle management of, our current products across our portfolios.
 - **Drive long-term growth through investment in inorganic opportunities.** To drive longer-term growth, we intend to expand our scientific capabilities in targeted therapeutic areas through investment in inorganic opportunities and acquisitions in order to further augment our existing product businesses. We believe these investments will help us build a development pipeline that will drive our future revenues.
 - **Enhance our digital and omni-channel marketing capabilities to drive growth.** Our commercial strategy focuses on growing our product portfolio by increasing productivity across our sales force and

leveraging digital channels, data and analytics to improve the return on investment in health care provider and patient engagement. We plan to continually expand our digital and omni-channel capabilities to optimize sales opportunities for our products and to further invest in digital engagement models that allow us to reach our customers and patients effectively. We also plan to further strengthen the design and execution of personalized omni-channel campaigns, engaging health care providers and patients through the most cost-effective channels and building upon existing strengths, such as our sophisticated capabilities to successfully target women and maximize our promotional response, which we achieved through nearly 10 years of executing and analyzing women's health consumer campaigns in the United States.

- ***Drive efficiency to improve operating leverage and cash flow.*** As an independent company, we intend to focus on delivering operating efficiencies. We have identified a number of key areas in which we plan to generate cost efficiencies by simplifying our operating model, standardizing and centralizing service activities and designing and enhancing our commercial model and supply chain functions. We also plan to leverage external providers where there is a cost and service advantage. In addition, we are in the process of implementing systems and process improvements to reduce general and administrative costs, and simplify our infrastructure following the termination of our transition services agreement with Merck. We believe the combination of these efficiencies will allow us to drive growth in free cash flow.
- ***Deploy our free cash flow to invest in our existing product portfolio, fund inorganic opportunities and return capital to our shareholders.*** We are committed to the success of our existing product portfolio and plan to make commercial decisions that will allow us to maximize its value. In addition, we plan to invest in inorganic growth opportunities such as in-licenses, commercial collaborations and acquisitions of development-stage or in-market products. We also plan to acquire products that fit within our existing commercial infrastructure, which we believe will generate attractive risk-adjusted returns on investment. There are inorganic growth opportunities, particularly in women's health and biosimilars, that we plan to target. We believe that our global commercial and market access capabilities, regulatory affairs, specialized manufacturing and clinical development expertise, will enable us to evaluate and integrate external opportunities. In addition, we plan to pay a dividend to our shareholders, pay down debt consistent with our financial policy and, to the extent that we generate excess free cash flow, we will consider returning additional free cash flow to our shareholders via share repurchases. We expect our targeted dividend payout to be in the low 20s as a percentage of post-separation Adjusted Net Income.
- ***Capitalize on our status as a newly independent company to align our talented employee base with our performance expectations and drive a culture of high performance.*** Our strong heritage of excellence and scientific foundation enables us to approach complex problems with innovative science-based solutions. As a new, independent company, we have a rare opportunity to forge a distinct identity and align hiring, training, development and incentive activities around a clear set of performance expectations related to our core strategy. To establish this culture, we plan to draw upon key aspects of our shared history with Merck while charting a new course. We expect to be a performance-focused and entrepreneurial company with simplified organizational layers and governance, and a focus on alignment and leadership empowerment that enables our leaders to understand and address the evolving and unmet medical need of patients and health care providers around the world.

Products

We are engaged in developing and delivering innovative health solutions through a diverse portfolio of products serving patient needs across multiple therapeutic areas and product categories, consisting of women's health, biosimilars and established brands. These portfolios are further described below, together with select details for products within each group. Our sales for each of our product groups are as follows:

(\$ in millions)	2020	2019	2018
Women's Health	\$ 1,555	\$ 2,264	\$ 2,293
Biosimilars	\$ 330	\$ 253	\$ 64
Established Brands	\$ 4,540	\$ 5,159	\$ 5,887

Approximately 90% of our 2020 sales came from products that no longer have patent exclusivity in the United States or EU. Within this group, Cozaar/Hyzaar, which lost patent protection in the United States and EU in 2010, saw a revenue decline of approximately 41% in that year; Nuvaring experienced a 73% decline in sales in 2020 following loss of patent protection in major markets in April 2018 and generic entry in the United States in 2019; Singulair, which lost patent protection in the United States in 2012 and in the EU in 2013, saw a revenue decline of approximately 78% in 2013 as compared to 2011; and Zetia, which saw generic entry in the United States in December 2016, and lost patent protection in the United States in 2017 and in the EU in 2018, saw a revenue decline of approximately 77% in 2019 as compared to 2016.

Women's Health Portfolio

In 2020, our women's health portfolio accounted for \$1.6 billion, or approximately 24%, of Organon Products segment sales, with approximately 45%, or \$697 million, generated outside the United States. Our women's health products are sold by prescription in two therapeutic areas, contraception, with key brands such as Nexplanon / Implanon NXT and NuvaRing, and fertility, with key brands such as Follistim and Elonva. We are a global leader by revenue in the hormonal contraception market, offering a broad portfolio of products across three core hormonal contraceptive market segments: daily pill, monthly ring and LARC. Our women's health products are sold in over 90 markets worldwide, including the United States, China, Canada, Australia, Brazil, Mexico and many other countries in the EU, South America, Asia and Africa.

Women's Health Market and Opportunity

We intend to pursue opportunities in the broad women's health market as part of our future strategy. Our classification of women's health includes two areas: needs and conditions that uniquely impact women, generally referred to as the core women's health market; and needs and conditions that disproportionately impact women. We estimate that the combined global market for pharmaceuticals in the core women's health market, which includes therapeutic areas such as contraception and fertility, endometriosis and uterine fibroids, was \$33 billion in 2020. We project that the core women's health market will grow to \$40 billion by 2026. In addition, we estimate that the segment of therapeutic areas that disproportionately impact women, such as osteoporosis, lupus, urinary tract infections, migraines and celiac disease, will grow annually at an approximately 10% CAGR from 2020 to 2026, adding a further \$21 billion to the core women's health market size estimates.

We believe governments and payors are implementing favorable policies across major markets that, in turn, drive growth in the market for women's health therapies. For example, in the United States, there has been an increase in fertility insurance mandates and employer coverage, albeit subject to certain exemptions. In Canada, there is strong public and private reimbursement for contraception, accompanied by increased use of LARCs. Across Latin America, there is a significant untapped opportunity for LARCs, particularly given high rates of unintended pregnancy. The women's health market has also been traditionally underserved in terms of science-

based solutions that address unmet medical need. Despite the pipeline of new women's health products in development set to launch across the women's health market later in 2021 and beyond, the unmet need and limited treatment options continue to exist across several therapeutic areas. For example, there is potential to develop non-hormonal long-acting contraceptives, oral therapies for fertility to replace injections, non-narcotic, non-hormonal treatments for endometriosis, non-hormonal treatments for menopause symptoms, and new drug-device combinations such as combining prescription therapies with delivery devices that increase product efficacy and safety. We believe the potential for innovation in the areas outlined above, in addition to areas of unmet need in conditions that disproportionately impact women, represents attractive opportunities to grow our business.

In addition, according to Evaluate Pharma data for 2019, there are more than 140 pipeline assets in women's health in development across phase 1-3. We believe that this level of innovation will translate into an increased flow of licensing and acquisition opportunities for us in the future.

Our Women's Health Strategy

Pharmaceutical companies that participate in the women's health market generally fall into two categories—small specialty players with a concentrated focus but small scale, and large diversified players with a limited, opportunistic attention to their women's health portfolio. There is currently no large player with women's health broadly as their primary therapeutic area of focus. As such, we distinguish ourselves by pairing our portfolio with large-scale size and global distribution capabilities. In order to grow our women's health business in the long-term, we intend to invest in both internal and external innovation. Internally, we intend to pursue clinical development opportunities related to our existing portfolio of therapies that we believe will expand the geographic reach, provide additional benefits for patients and increase the value of our offerings. For example, we are currently developing a next-generation version of Nexplanon / Implanon NXT that will extend the period of contraception provided. Externally, we intend to source innovation and expand our share of the global women's health market through strategic acquisitions, in-licenses and commercial collaborations that leverage our global footprint, strong relationships with health care providers, patients and payors and deep experience within women's health. We intend to focus on commercial assets and development-stage assets that have demonstrated clinical proof of concept where we can leverage our in-house capabilities and experience to accelerate and better maximize these late-stage clinical development and commercialization opportunities. We are initially planning to focus on opportunities that leverage our existing relationships with health care providers in obstetrics and gynecology ("OB/GYN"), and fertility practices and plan to evaluate both therapeutics and drug-device combinations.

Contraception

In 2020, our contraception products accounted for \$1.2 billion, or approximately 19%, of Organon Products segment sales, with approximately 40%, or \$490 million, generated outside the United States.

Contraception Market and Commercial Strategy

We have an estimated global market share of approximately 12.6% in hormonal contraception and approximately 30% in the LARC market segment, each as measured by reported 2020 revenue. Although daily contraceptive pills remain the largest market segment, the LARC market segment, which includes Nexplanon / Implanon NXT, has experienced significant growth in the years leading up to 2019 due to a sustained shift from daily oral contraception to LARC. This was driven by payors, providers and patients looking for options beyond commonly used daily contraceptive pills. For example, in the United States, the share of LARC usage has increased from 5.6% in the period from 2006 to 2010, to 10.3% in the period from 2015 to 2017. In 2020, however, the COVID-19 pandemic resulted in reduced administration of many products within women's health, in particular for Nexplanon / Implanon NXT. The COVID-19 pandemic negatively affected the LARC segment during 2020 due to clinic closures and the postponement of non-essential medical procedures during country lockdowns. However, LARC segment growth quickly rebounded during months when clinic restrictions were

removed and the sustained shift to LARC is expected to continue with fundamental drivers unchanged. We believe a continued shift toward LARC methods represents an opportunity both inside and outside the United States. Scientific research has indicated that the adoption of LARC can reduce rates of unintended pregnancy and we believe that it can also enhance other family planning related outcomes. We expect the body of similar evidence to increase over the next several years, and we plan to actively support ongoing work in this area. Based on revenue and market share, we are favorably positioned to capitalize on this opportunity in the contraception market.

Global growth rates for hormonal contraception vary. Growth rates in emerging markets continue to outpace rates in developed markets as governments prioritize a range of methods to boost economic development, including public funding for the expansion of family planning services to increase rates of female participation in the workforce. We plan to work with payors and other health care stakeholders to improve insurance coverage of our highly effective contraceptive products such as Nexplanon / Implanon NXT.

The traditional sales model for contraceptive products is to market primarily to obstetricians, gynecologists and other health care professionals that prescribe contraceptive products to patients. However, women with knowledge of contraceptive options are the key decision makers regarding the selection of the contraceptive product that meets their individual lifestyle needs. We plan to advance market awareness of contraceptive options primarily through advancing education. We plan to work closely with women's health societies, governments, health care professionals and other key stakeholders to advance education regarding contraceptive options such that women and health care professionals are familiar with our products. To further increase growth opportunities across our contraception portfolio and leverage brand loyalty among patients and health care providers, we intend to increase our investments in both face-to-face and digital methods of medical education.

Contraception Products

Our contraception portfolio currently consists of the following key products:

Nexplanon / Implanon NXT

We expect our core product focus in contraception to be Nexplanon, also known in some markets outside of the United States by the brand name Implanon NXT. In 2020, Nexplanon / Implanon NXT accounted for \$680 million, or approximately 44%, of our total women's health portfolio sales, with approximately 28%, or \$192 million, generated outside the United States. This represents an 11% CAGR growth in sales between 2010 and 2020. Nexplanon / Implanon NXT is a prescription medication for the prevention of pregnancy in women lasting up to three years and is reversible upon removal. Nexplanon / Implanon NXT is a small, thin and flexible arm implant that is placed discreetly under the skin of the inner, upper arm by a health care provider. It is a progestin-only, radiopaque, removable implant, containing 68mg of etonogestrel pre-loaded into an applicator. Nexplanon / Implanon NXT prevents pregnancy in several ways, most importantly by suppressing ovulation, and is typically prescribed in women who are not looking to become pregnant in the near future and do not want the inconvenience of taking a daily contraceptive.

We expect to have market exclusivity for Nexplanon / Implanon NXT in the United States until 2027 and the majority of countries where Nexplanon / Implanon NXT is commercialized outside the United States until 2025. Our Nexplanon / Implanon NXT commercial strategy involves continued and expanded private and public reimbursement for Nexplanon / Implanon NXT within countries where hormonal contraception is well accepted, including in the United States. We intend to focus our commercial efforts on education and training to assist providers to understand Nexplanon / Implanon NXT, become confident with offering Nexplanon / Implanon NXT as one appropriate option for women seeking hormonal contraception, and become skilled with the insertion and removal procedure of Nexplanon / Implanon NXT. We also intend to increase education of contraceptive options to women. In addition, we plan to invest in increasing Nexplanon / Implanon NXT supply capacity to meet expected future demand increases.

NuvaRing

In 2020, NuvaRing accounted for \$236 million, or approximately 15%, of our total women's health portfolio sales, with approximately 53%, or \$126 million, generated outside the United States. NuvaRing

(etonogestrel / ethinyl estradiol vaginal ring) is a monthly vaginal contraceptive ring combination of progestin and estrogen used to prevent pregnancy in women. NuvaRing is prescribed for women that want a monthly contraceptive option, and it prevents pregnancy by suppressing ovulation.

Patent expiration for NuvaRing in the United States, and most countries outside of the United States, occurred in April 2018. Generic versions of NuvaRing were first approved in Europe in December 2018 and in the United States in December 2019. Generic entrants have since entered the United States and select European markets following such approvals. We saw a rapid and substantial decline in United States NuvaRing sales during 2020 due to generic competition. Our focus will be on markets outside of the United States where NuvaRing sales are expected to be relatively stable after initial declines immediately following entry of generic competition.

Cerazette

In 2020, Cerazette accounted for \$67 million, or approximately 4%, of our total women's health portfolio sales. Cerazette (desogestrel) is a progestin-only, daily pill used to prevent pregnancy in women. Progestin-only products like Cerazette, are typically used by women wanting effective hormonal contraception for whom estrogen-containing contraceptives may not be medically appropriate. Cerazette prevents pregnancy by suppressing ovulation. Cerazette is not approved or marketed in the United States but is broadly available globally outside the United States.

Patent expiration for Cerazette occurred in most markets in 2011 and 2012. At the time of patent expiry, Cerazette was the leading progestin-only contraceptive pill globally based on revenue. Generic entrants have entered most markets where Cerazette is commercialized. The progestin-only contraceptive pill market continues to see modest growth globally, creating opportunities for Cerazette.

Marvelon and Mercilon

In 2020, Marvelon and Mercilon accounted for \$95 million, or approximately 6%, of our total women's health portfolio sales. Marvelon and Mercilon (desogestrel and ethinyl estradiol pill) are both combinations of progestin and estrogen used as daily pills to prevent pregnancy. Marvelon contains a higher daily dose of estrogen than Mercilon. Marvelon and Mercilon both prevent pregnancy by suppressing ovulation. We no longer have market exclusivity for these products.

Fertility

We are one of only a few major global manufacturers offering a multi-drug fertility portfolio to fertility clinics and to specialty pharmacies and wholesalers who supply such clinics. In 2020, our fertility products accounted for \$319 million, or approximately 20%, of our total women's health portfolio sales, with approximately 65%, or \$206 million, generated outside the United States.

Fertility products fall broadly into two categories: products used in "long agonist" protocols and products used in "antagonist" protocols. The difference between the protocols principally relates to the type and amount of product used to stimulate the ovaries and the length of use. The antagonist protocol is generally recognized as a safer procedure for patients and has demonstrated similar pregnancy rates for patients when compared to the long agonist protocol. The antagonist protocol is also considered more patient-friendly because it requires fewer days of therapy and fewer injections. In contrast, the long agonist protocol is administered for several weeks along with daily follicle-stimulating hormone ("FSH") products. Our FSH product, Follistim, is used in both long agonist and antagonist protocols, while our Elonva product (a sustained FSH), substitutes for seven daily FSH injections and is indicated for the antagonist protocol. Recognizing the patient benefits from antagonist protocols, we intend to focus our commercial strategy on communication of the advantages of this protocol. We believe this strategy will expand the market opportunity for both Follistim and Elonva because both products are well-

positioned in patient-friendly antagonist protocols. In addition, we intend to build upon Merck's long heritage within the fertility market through focused investment in manufacturing and distribution for continued reliable, high-quality supply to health care providers and patients around the globe.

Global Fertility Market and Strategy

There are three major global fertility drug manufacturers, including our company, as well as several single-product players. We estimate the hormonal fertility market was approximately \$3.7 billion in 2020. The market experienced 7.3% global growth from 2015 to 2020, with even faster growth in the United States and China. Large fertility markets such as the United States and China, with growing rates of in vitro fertilization ("IVF") cycles, are critical to future product performance. In addition, in the United States, there has been an increase in fertility insurance mandates and employer coverage, albeit subject to certain exemptions. In these and other larger fertility markets, we intend to remain highly focused on expanding profitable access to fertility treatments.

Specialist health care providers, many of whom own their own fertility clinics, are the most important decision makers regarding which treatment options are used for each patient in each IVF treatment. Health care providers often tailor treatment protocols to individual patients to increase effectiveness. We intend to build on our long history and strong relationships with fertility clinics to improve services and patient access to our competitive fertility portfolio. In addition, market characteristics have resulted in a concentration in the private practice market, where specialists are embracing new treatment protocols and in particular, the shortened antagonist protocols.

Our Fertility Products

Our portfolio currently consists of three products used primarily for IVF treatment cycles:

Follistim AQ / Puregon

In 2020, Follistim accounted for \$193 million, or approximately 12%, of our total women's health portfolio sales, with approximately 56%, or \$109 million, generated outside the United States. Follistim (follitropin beta injection) is a recombinant FSH used to promote the development of multiple ovarian follicles in assisted reproduction technology procedures, such as IVF, embryo transfer, gamete intrafallopian transfer and intracytoplasmic sperm injection. Follistim belongs to the group of gonadotrophic hormones used by women trying to get pregnant using IVF.

Follistim has been challenged by intermittent supply disruptions over the past several years. We intend to make new investments in our fertility supply chain to bolster supply stabilization and expansion. We also expect to invest in a needle change for our injector pen and new instructions for use meant to enhance patient experience. We no longer have market exclusivity for Follistim and a biosimilar version was launched in the EU in 2014. However, the market share of the biosimilar version remains below 4%.

Elonva

In 2020, Elonva accounted for \$21 million in total sales. We expect that our Elonva revenue will grow, and we plan to continue to invest in expanding Elonva's market reach. Elonva (corifollitropin alfa) is an ovarian follicle stimulant with the same mechanism of action as recombinant FSH, but characterized by a prolonged duration of FSH activity. Due to its ability to initiate and sustain growth of multiple ovarian follicles for an entire week, a single subcutaneous injection of the recommended dose of Elonva may replace the first seven injections of any daily recombinant FSH preparation in an ovarian stimulation treatment cycle. Elonva belongs to the group of gonadotrophic hormones used by women trying to get pregnant using IVF. Elonva's profile offers particular value because women do not need to self-inject daily during IVF cycles. Elonva has not been approved in the United States or in China, but it is approved and widely available in many other global markets where we operate. We are currently reassessing our Elonva worldwide strategy with the opportunity to potentially launch in additional markets.

Orgalutran

In 2020, Orgalutran accounted for \$81 million, or approximately 5%, of our total women's health portfolio sales, with approximately 86%, or \$69 million, generated outside the United States. Orgalutran (ganirelix acetate) is an injectable competitive gonadotropin-releasing hormone ("GnRH") antagonist. Orgalutran is used in fertility treatment in combination with FSH (Follistim) to prevent ovulation. By using Orgalutran, clinicians can continue stimulating follicle growth while preventing ovulation before egg collection. We do not have market exclusivity for Orgalutran.

Biosimilars Portfolio

In 2020, our biosimilars portfolio accounted for \$330 million, or approximately 5%, of Organon Products segment sales, with approximately 62%, or \$206 million, generated outside the United States. Our biosimilars portfolio and experience provide an opportunity to benefit from future growth anticipated in this area.

We believe that through a combination of management focus and strategic investment, we expect that our biosimilars business will continue to generate growth in the near term. Our biosimilars portfolio consists of therapies in oncology and immunology for which we have worldwide commercialization rights with certain geographic exceptions specified on a product-by-product basis pursuant to an agreement between Merck and Samsung Bioepis entered into in February 2013. The biosimilars (with reference products in parenthesis) currently covered by this agreement are Adalimumab (Humira), Bevacizumab (Avastin), Infliximab (Remicade), Trastuzumab (Herceptin) and Etanercept (Enbrel). All five biosimilars products covered by the agreement have launched in certain countries globally, including two biosimilars in the United States. Our oncology biosimilars have so far been launched in 20 countries, while our immunology biosimilars have been launched in five countries, including the United States, Canada, Australia and Ukraine. Once a biosimilar product is launched, our access rights to that product under the agreement last for 10 years on a market-by-market basis from the date of launch. Based on this experience, we believe we are well-positioned to become a commercial partner of choice for future collaborations with Samsung Bioepis or other potential partners to commercialize additional biosimilars products.

Biosimilars Market and Opportunity

Biosimilars are lower-cost alternatives to existing biologic medicines that treat some of life's most serious diseases. Biosimilar therapies have no clinically meaningful differences in the safety profile, potency and purity from their reference biologic medicines. As a result, biosimilars create new choices and competition in the biologics marketplace and have the potential to lower costs for patients and the health care system, potentially expanding the therapeutic options available to fight important diseases, such as cancer, rheumatoid arthritis, psoriasis and inflammatory bowel disease.

As of December 31, 2020, the global biologics market represented an approximately \$300 billion revenue opportunity, with an expected CAGR of approximately 10% until 2024. Given the high cost of many of these biologic treatments, biosimilars, as a more affordable alternative, represent a significant opportunity for patients, providers and payors once a biologics product loses patent protection.

We estimate the total size of the global market for biosimilars was approximately \$17.3 billion as of September 2020, reflecting 60 biosimilars approved in the EU and 29 in the United States. In 2019, the European and United States markets accounted for 70% and 14%, respectively, of global biologics, but 34% and 56%, respectively, of global biosimilars. Industry publications estimate that 54 major biologics, with an aggregate market value of approximately \$220 billion, will lose patent protection in the next decade, which has potential to expand the global biosimilars market to over \$30 billion, based on external estimates. We do not have biosimilars corresponding to all biologics that will lose patent protection in the next decade. This long-term growth is driven in part by an increasingly favorable regulatory framework that has increased the rate of approvals in the United States and the EU, as well as potentially increased demand in new and existing untapped markets, such as China, where only a few biosimilars have so far been approved.

We believe the future outlook for biosimilars is promising, particularly in the United States where broad health care provider, patient and payor acceptance of biosimilars and policy trends continue in a favorable direction, and where initial pricing pressure may not be as significant as in other geographies such as the EU. We believe we are well-positioned to capitalize on the United States market opportunity for biosimilars given our launch experience across our commercial team. We expect that our biosimilars business will continue to generate growth in the near term.

Our Biosimilars Strategy

In the short term, our biosimilars strategy is focused on commercializing the five biosimilars sourced from our collaboration with Samsung Bioepis. We believe the commercial experience obtained from our prior biosimilars launches (Renflexis in the United States and Ontruzant in the United States and the EU) provides us a competitive advantage in the market. All five biosimilars products in our portfolio have launched, two of which are the oncology biosimilars, Ontruzant and Aybintio. We launched Ontruzant in the United States in April 2020 and launched Aybintio in the EU in September 2020. We currently have no plan for the timing of any launch of Aybintio in the United States nor do we know when such timing would be determined. We expect to drive future value through the commercialization of Hadlima, an adalimumab biosimilar, with launches in Australia and in Canada in 2021 and in the United States in 2023. In the long-term, given the favorable outlook for the biosimilars industry, we intend to expand our portfolio through the identification and evaluation of new assets that face biosimilar competition in therapeutic areas such as oncology, immunology, ophthalmology, diabetes and neuroscience, among others, both through our Samsung Bioepis collaboration and through other potential collaborations.

Our Biosimilars Products

The portfolio currently consists of three immunology products, Brenzys, Renflexis and Hadlima, and two oncology products, Ontruzant and Aybintio. Aybintio was recently launched in the EU. For the year ended December 31, 2020, the biologics comparable to our biosimilars products generated sales (unless otherwise noted) in the following amounts, according to public filings:

<u>Our Biosimilar</u>	<u>Biologic Product</u>	<u>Global Sales of Biologic Product⁽¹⁾</u>	<u>Launch of Our Biosimilar</u>
Hadlima	Humira	\$19.8 billion ⁽²⁾	Australia—February 2021; Canada—February 2021; Israel—approved as of February 2021 and expected to be launched third-quarter 2021; and United States—approved as of July 2019 and expected to be launched June 2023.
Brenzys	Enbrel	\$6.4 billion	Canada—September 2016; Brazil—September 2019; Australia—April 2017; and Israel—January 2021.
Renflexis	Remicade	\$4.5 billion	United States—July 2017; Canada—August 2018; and Australia—August 2017.
Aybintio	Avastin	\$5.6 billion	EU—September 2020.
Ontruzant	Herceptin	\$4.2 billion	United States—April 2020; Europe—March 2018; Brazil—August 2020; and Australia—January 2020.

⁽¹⁾ Global sales of commercialized biologic products is presented solely for the purpose of characterizing the addressable market. We expect global sales for each of our biosimilar products to be substantially less than the global sales for the corresponding biologic product.

⁽²⁾ Net revenue.

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Hadlima (SB5)

Hadlima (adalimumab-bwvd) is a tumor necrosis factor (“TNF”) antagonist biosimilar to AbbVie’s Humira (adalimumab) product, approved for treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn’s disease, pediatric Crohn’s disease, ulcerative colitis and plaque psoriasis. Our current Hadlima filing does not include hidradenitis suppurativa and uveitis indications. We have worldwide commercialization rights to Hadlima in countries outside of the EU, Korea, China, Turkey and Russia. Samsung Bioepis reached a global settlement with AbbVie permitting us to launch Hadlima in the United States in June 2023 and outside of the United States starting in 2021. Hadlima is currently approved in the United States, Australia, Canada and Israel and was launched in Australia and Canada in February 2021.

Brenzys (SB4)

Brenzys (etanercept) is a TNF antagonist biosimilar to Amgen / Pfizer’s Enbrel (etanercept) product, approved for treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and plaque psoriasis. We have commercialization rights to Brenzys in countries outside the EU, Korea, China, Japan and the United States, and it is currently approved and commercialized in Australia, Canada, Brazil and Israel.

Renflexis (SB2)

Renflexis (infliximab-abda) is a TNF antagonist biosimilar to Johnson and Johnson’s Remicade (infliximab) product, approved for treatment of Crohn’s disease, pediatric Crohn’s disease, ulcerative colitis, pediatric ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis. We have worldwide commercialization rights to Renflexis in countries outside the EU, Korea, China, Turkey and Russia, and it is currently approved and commercialized in the United States, Australia and Canada.

Aybintio (SB8)

Aybintio (bevacizumab) is a vascular endothelial growth factor inhibitor biosimilar to Roche’s Avastin (bevacizumab) product. Aybintio is currently approved and commercialized in the EU for treatment of metastatic carcinoma of the colon or rectum, metastatic non-squamous, non-small cell lung cancer, metastatic renal cell carcinoma, metastatic cervical cancer, epithelial ovarian, fallopian tube, or primary peritoneal cancer and metastatic breast cancer. We currently have no plan for the timing of any launch of Aybintio in the United States nor do we know when such timing would be determined. We have commercialization rights to Aybintio in the United States, Canada, Germany, Italy, France, the UK and Spain.

Ontruzant (SB3)

Ontruzant (trastuzumab-dttb) is an HER2 / neu receptor antagonist biosimilar to Roche’s Herceptin (trastuzumab) product. Ontruzant was approved by the FDA in January 2019 for the treatment of HER2 overexpressing breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma consistent with Herceptin and by the European Medicines Agency (“EMA”) in November 2017 as the first trastuzumab biosimilar approved in the EU. Samsung Bioepis reached a global settlement with Roche in June 2019 allowing for us to launch Ontruzant worldwide. We have worldwide commercialization rights to Ontruzant in countries outside of Korea and China. Ontruzant launched in Europe in early 2018 and in the United States in April 2020.

Established Brands Portfolio

Established brands represents a broad portfolio of mature brands, developed and launched by Merck or its predecessors, across multiple therapeutic areas and geographies and which are generally beyond market

exclusivity. Our established brands portfolio contributed approximately 70%, or \$4.5 billion of Organon Products segment sales in 2020. These figures reflect the reduced administration of many products within established brands, as a result of the COVID-19 pandemic. Generic competition varies significantly across geographies. Products that have more recently lost market exclusivity, such as Zetia and Vytorin, account for the highest proportion of total established brands portfolio sales declines due to the entrance of new generic competition. Other products are experiencing only minimal sales declines and retaining organic growth opportunities. We believe our established brands portfolio is well-positioned in the market; we have a broad portfolio of brands, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management, we have high-quality manufacturing functions and we maintain competitive pricing across multiple therapeutic areas and geographies. Our established brands portfolio has a particularly strong foothold in emerging markets where we have a broad base of products enabling us to build targeted additional product offerings and developments. We expect that greater managerial focus to capture local market opportunities, along with targeted investments in expanding our geographic footprint, digital promotion and commercial trade channels, will provide new revenue opportunities for select brands.

Established Brands Market and Strategy

The majority of our established brands products are beyond market exclusivity. However, these products continue to represent a significant value opportunity arising from long-term sustainable revenue streams and well-established supply chains that together generate significant operating profit relative to low promotional and development expenses.

We believe that through strategic investment in established brands marketing and distribution, we can continue to deploy our large established brands product portfolio across our broad geographic footprint to identify and manage organic growth opportunities. Our established brands portfolio has been managed through a mix of efficient, digital-only promotion or local and regional promotional collaborations, which we believe enables product promotion while minimizing sales and marketing expenses. We plan to continually assess these collaborations to drive value for both parties.

We believe there is opportunity to deliver growth from this portfolio. We continue to have market exclusivity for Arcoxia in many markets. Our cardiovascular brand Atozet also continues to enjoy market exclusivity in multiple countries where we intend to grow our sales by increasing our share of the global cholesterol-lowering market and expanding our geographic footprint with new country launches. In China, we plan to accelerate our strong progress by pivoting from a sole focus on the public tender market to growth opportunities in the private retail segment. Opportunities to stabilize or grow select products in select countries in this portfolio tend to arise once the largest period of price and unit erosion has occurred immediately after loss of market exclusivity and initial generic entrants. In the United States, there are fewer opportunities for our established brands portfolio to grow after loss of patent exclusivity. However, outside of the United States, product-specific and individual market dynamics create opportunities for sales stabilization and even organic growth. Although the vast majority of our respiratory, dermatology and non-opioid pain management brands have lost market exclusivity for several years, they continue to demonstrate strong resilience with health care providers and patients. We intend to further invest in digital engagement models that allow us to reach our customers and patients effectively.

We intend to make select investments in our manufacturing sites, as well as drive supply chain improvements by our manufacturing partners, to build an efficient, robust and reliable supply chain. We also intend to investigate opportunities to expand our established brands offerings and improve patient access through targeted new market launches and new indications listings. For example, we intend to launch Atozet and Rosuzet in new markets. We believe we have the commercial and market access, regulatory affairs, specialized manufacturing and clinical development expertise that will enable expanded established brands offerings and improved patient access to occur.

Cardiovascular

In 2020, our cardiovascular portfolio accounted for \$1.9 billion, or approximately 29%, of Organon Products segment sales, nearly all of which was generated outside the United States, including approximately 16%, or \$305 million in China. Our cardiovascular portfolio consists of several cholesterol-modifying medicines, including: Zetia (ezetimibe), which is marketed as Ezetrol in most countries outside the United States; Vytorin (ezetimibe / simvastatin), which is marketed as Inegy outside the United States; Atozet (ezetimibe and atorvastatin), which is marketed in certain countries outside of the United States; Rosuzet (ezetimibe and rosuvastatin), which is also marketed in certain countries outside of the United States; and Zocor (simvastatin), which is also available in certain countries outside of the United States, including China. Our portfolio also includes Cozaar and Hyzaar (losartan and losartan / hydrochlorothiazide), which are cardiovascular drugs for the treatment of hypertension.

Respiratory

In 2020, our respiratory portfolio accounted for \$1.2 billion, or approximately 18%, of Organon Products segment sales, with approximately 74%, or \$848 million, generated outside the United States. Our respiratory portfolio includes Singulair (montelukast sodium); Nasonex (mometasone); Clarinex / Aerius (desloratadine); and Dulera (formoterol / mometasone). In markets where Clarinex is classified by regulators as an over-the-counter medicine, the rights for Clarinex were sold to Bayer as part of Merck's divestment of its over-the-counter medicine business in 2014. We currently own prescription rights for Clarinex in the United States and Aerius in markets around the world.

Dermatology, Bone Health and Non-Opioid Pain Management

In 2020, our dermatology, bone health and non-opioid pain management portfolios accounted for \$833 million, or approximately 13%, of Organon Products segment sales, nearly all of which were generated outside the United States. Our dermatology portfolio consists of two core products, including Diprosone (betamethasone cream), a corticosteroid approved for treatment in relief of skin conditions and Elocon (mometasone cream), a topical prescription medicine approved for treatment in relief of inflammation, and other symptoms caused by certain skin conditions. Our bone health portfolio includes Fosamax (alendronate sodium), a bisphosphonate medicine used for the treatment and prevention of osteoporosis in postmenopausal women and to increase bone mass in men with osteoporosis. Our non-opioid pain management portfolio consists of three core products, including Arcoxia (etoricoxib), a selective cyclooxygenase-2 inhibitor used for acute and chronic treatment of conditions such as acute pain, osteoarthritis and rheumatoid arthritis, Diprosan (betamethasone), a glucocorticoids drug approved for treatment of conditions such as bursitis, dermatological disorders and inflammatory conditions and Celestone (betamethasone injectable suspension), a sterile aqueous suspension approved for treatment of pain and inflammation, and conditions such as endocrine disorders and gastrointestinal diseases. We have proven development capabilities that support the potential growth profile of our dermatology, bone health and non-opioid pain management portfolios. These brands have demonstrated strong resilience with health care providers and patients. We expect growth in these portfolios across multiple geographies.

Other Established Brands

This portfolio covers our other mature products, some of which remain significant to our product portfolio, including products such as Proscar (finasteride) and Propecia (finasteride). Proscar, used for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate, accounted for \$176 million of our sales in 2020. In addition, Propecia, used for the treatment of male pattern hair loss, accounted for \$129 million of our sales in 2020. Nearly all of the sales of Proscar and Propecia were generated outside of the United States.

New Product Capabilities

Strategic Acquisition and Business Development and Collaboration Activities

Following our separation from Merck, we expect to actively engage in business development and collaboration activities to supplement our existing portfolio and internal development efforts, with a focus on expanding our leadership position in women's health. Our expertise in women's health will enable us to track innovative science and identify promising products with the potential to address unmet medical need. We believe that our shared history with Merck, our global market access, commercial capabilities, and manufacturing platforms, along with our management team's experience in development and implementation of clinical programs approved by global regulatory agencies, will make us a clear partner of choice to companies seeking to manage global development and commercialization. We plan to further advance our women's health clinical development capabilities through future acquisitions, to drive us toward becoming the leading women's health biopharmaceutical company across needs and conditions that uniquely and disproportionately impact women.

Research and Development

Our research and development initiatives aim to foster an innovative and nimble environment to generate robust clinical data supporting rapid global product registration, as well as value and access insights to expand the commercial reach of our portfolio.

Our development strategy seeks to achieve business continuity with our brands and unlock value from our existing products by utilizing our technical expertise to pursue new line extensions, new indications and in-line value enhancements. As part of our core strategy for growth and improved operating leverage position, we expect to identify scientific collaborations and acquisitions to develop late-stage assets and enhance our pipeline.

Through our internal scientific expertise or close collaborations with partners, we expect to be enabled by a full range of capabilities necessary to achieve the rapid development of product development opportunities and data generation for product registration globally.

Our medical affairs and health economic scientists will utilize data generated by our clinical programs and observational studies, real-world data, and economic models of payor trends in order to demonstrate the value of our products to payors and engage health care providers in scientific dialogue. We intend to use observational and real-world data to drive strategy for future evidence generation, support access strategy development and inform external policy related to product reimbursement. We also intend to use the insights we gain through health, economic and predictive modeling and data analytics to understand and communicate the full value of our products, grow market access and enhance patient care in a dynamic health care environment, as well as inform the design of clinical programs and program investment choices.

Sales, Marketing and Distribution Capabilities

Sales and Marketing

We expect that upon the separation, we will have approximately 4,030 employees worldwide focused on commercialization activities, such as marketing, direct selling, digital and omni-channel and insight generation, covering data stewardship, data analytics and data science. We have experienced marketers and data scientists across geographies that we expect to implement localization and execution of our global brand and business strategies. We believe our commercialization capabilities will allow us to execute customer engagement strategies optimized across preferred channels and aimed at health care providers, patients and payors. We expect that our employees will be focused on building an integrated digital ecosystem that will coordinate engagement across all channels. The engagements will include direct face-to-face engagement, virtual engagement, email, social media and our websites. In addition, we believe we have the knowledge, capabilities and resources to achieve optimal local market access for our portfolio in a changing external environment.

In women's health, we have established relationships with payors, health care providers, large clinics, and important stakeholder groups such as societies, patients and scientific leaders within both contraception and fertility. We have experience and capabilities with two distinctive fit-for-purpose commercialization models that reflect the specific requirements of obstetricians and gynecologists and reproductive endocrinologist specialists in the respective target categories of contraception and fertility. We expect that we will have broad reach where prescribing is done by health care providers.

In biosimilars, we have established capabilities in reimbursement and tendering to maximize global access and medical affairs for payors and health care providers to understand the clinical profile of our biosimilars. We also have experience with commercializing biosimilars within the United States, the fastest growing biosimilars market with the largest market size potential, and in developing value propositions for payors and health care providers in the EU.

In established brands, we have digital omni-channel marketing experience and portfolio-selling capabilities to enable the promotion of multiple and diverse portfolios across multiple diverse geographies. We also have expertise derived from established relationships with our commercial trade partners, including distributors, wholesalers, purchasing groups and pharmacies, that are important in achieving continued product availability and sustained access to our brands in the market. Such expertise and relationships also support our effective inventory management, data insights, product support and relevant pricing and chargeback administration functions.

We have a trade channel strategy that provides a robust capability framework for our activities, including in the selection of channel partners, commercial terms and supportive health care services that promote the efficient, safe and cost-effective delivery of our products. We have significant insight into the use of newer technologies such as blockchain, and the use of valuable patient services such as patient adherence programs that can further drive value in collaboration with our trade partners.

We have no single customer that, if the customer were lost, would have a material adverse effect on our business.

Distribution

Our global network enables us to distribute products directly and indirectly to patients in more than 140 countries and territories, including through our regional distribution centers. We sell our pharmaceutical products primarily to drug wholesalers and retailers, hospitals, clinics, government agencies, pharmacies and managed health care providers, such as health maintenance organizations, pharmacy benefit managers and other institutions. We also sell our pharmaceutical products through third-party distributors and agents for smaller markets. Our professional representatives communicate the effectiveness, safety and value of our pharmaceutical products to health care professionals in private practice, group practices, hospitals and managed care organizations.

Manufacturing Capabilities and Global Supply Chain

We have an established heritage in quality manufacturing, including development and improvement of manufacturing processes. Our principal manufacturing capabilities include formulation, fill-and-finishing of products, packaging of products, and distribution and supply to patients in more than 140 countries and territories.

Internal Manufacturing Capabilities

Following our separation from Merck, we expect to own and operate six manufacturing sites, as shown in the table below, where we will manufacture a range of pharmaceutical products, including hormonal products, sterile formulations, and certain of our medical device combination products.

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Site	Predominant area of Focus	# Markets Served	Workforce ⁽¹⁾
Campinas, Brazil	Women's health, cardiovascular and respiratory	~12 (in Latin America)	~200
Cramlington, United Kingdom	Cardiovascular and respiratory	~140	~400
Heist, Belgium	Respiratory, dermatology, and pain	~140	~720
Oss Pharma, the Netherlands	Women's health	~100	~820
Pandaan, Indonesia	Cardiovascular, respiratory and dermatology	~16 (in Asia Pacific)	~200
Xochimilco, Mexico	Cardiovascular and respiratory	~30 (in Latin America and others) ⁽²⁾	~170

⁽¹⁾ Workforce estimated based on 2021 year-end forecast, represents manufacturing employees and does not include other global support functions or temporary, contingent workers.

⁽²⁾ Including Australia, Canada and the Philippines.

A majority of our internal manufacturing sites have long-standing, deep technical capabilities across the broad base of manufacturing platforms that are required to support our product portfolio. Our specialized manufacturing capabilities include oral solid dosage manufacturing, liquids, ointments and creams manufacturing, aseptic processing of hormonal products, extrusion technology, inhaler and implant medical device combination products, and packaging to facilitate speed to market as well as more direct control of quality and compliance. We also expect to continue to manufacture a range of Merck products at each of our six manufacturing sites. The terms of our arrangement for the manufacture of Merck products will be governed by an agreement with Merck entered into at the time of our separation. See "Certain Relationships and Related Party Transactions."

Contracted Manufacturing

We also intend to contract with Merck or other third-parties for the manufacture of certain of our products. We expect that our manufacturing team will supervise external manufacturing activities conducted by third-parties related to our products.

Global Supply Chain

We manage our global supply chain through planning centers with oversight for the United States, Europe, Canada, the Middle East and Africa, Asia-Pacific, Latin America and in the Caribbean.

We purchase certain raw materials, active pharmaceutical ingredients, components, devices and other supplies necessary for the commercial production of our products from a variety of third-party suppliers. We utilize third-party contract manufacturers for packaging, formulation and fill-and-finish for our products. We also utilize a combination of logistics service providers as part of our global supply chain, primarily for storage and for shipping and delivering raw materials, intermediate goods and finished goods between internal sites and from production sites to customers.

In order to satisfy the manufacturing and regulatory requirements for the products in our portfolio, we rely on a single source for a number of materials and components critical to our products, including, for example, 100% of our active pharmaceutical ingredients and portions of our drug product. The majority of our single-sourced materials and components are from established pharmaceutical suppliers with whom we have significant experience. In addition, we rely heavily on one supplier for formulation and packaging as our gateway to sales in both China and Japan.

To mitigate supply risk, we aim to have a conservative inventory posture and to keep an internal function focused on maintaining an external manufacturing network with operational, quality, technology and procurement capabilities. This function is responsible for identifying, developing and assessing the performance of our suppliers such that they meet quality expectations and satisfy their contractual obligations to us. In addition, this function provides rapid response support for potential supply issues. We also have an established risk management framework, which is intended to assess risk elements across our supply chain to mitigate risks.

Our manufacturing network and supply chains are designed to provide us with a flexible and scalable global platform for continued expansion, including in emerging markets. We believe our extensive manufacturing and supply chain expertise and capabilities position us well to provide critical therapies for distribution in all regions of the world and to meet growing demand over the long-term.

Our global commercial and manufacturing teams collaborate on various operational efficiency initiatives, including yield improvements, procurement savings, site synergies, manufacturing support rationalization and supply chain distribution optimization, each intended to improve our leverage position.

Quality Management

Our facilities and supporting functions, along with our external contractors, suppliers, and partners, make up an integrated, interdependent global network that is dedicated to consistently delivering compliant, reliable product supply to health care providers and patients. We have one quality management system deployed globally that enables the development, manufacturing, packaging, labeling, handling, and distribution of the company's products such that they conform to applicable regulatory requirements in every country we serve. Our quality management system is designed to promote and facilitate regulatory and operational excellence, anticipate risks, and prepare the network to effectively respond and adapt to emerging trends.

Human Capital

Upon the separation, we will have approximately 9,950 employees worldwide with approximately 4,030 employees focusing on sales, marketing and key commercialization activities. Approximately 730 employees will focus on clinical development, safety, and medical affairs and product registration. Our human resources organization is led by an experienced team that monitors our employee base and sets annual targets for managing our human capital, including employee retention, engagement and training targets. Our experienced Talent Committee (as defined herein) develops diversity and inclusion initiatives and regularly reviews our strategies and programs for leadership development. We have established benefit and incentive compensation plans, including comprehensive medical and life insurance coverage, 401K matching programs and other incentive compensation programs that we believe align employee incentives directly with our future performance.

Properties

We expect to own and operate six manufacturing facilities as described above under “—Manufacturing Capabilities and Global Supply Chain—Internal Manufacturing Capabilities.”

Intellectual Property

Patents, Trademarks and Licenses

Patent protection is important to the marketing of certain of our 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.

In particular, we consider the patents that cover the rod technology in Nexplanon / Implanon NXT to be material to our business. Such device patents will expire in 2027 in the United States and in 2025 in other countries around the world. There are currently no contested proceedings or third-party claims that involve these patents. We have been granted licenses to use such patents from Merck. Such licenses permit use of the underlying technology solely as a contraceptive implant containing only the active pharmaceutical ingredient currently used in the product.

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 United States patent law provides additional patent terms 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. Japan provides the additional term for pediatric studies attached to market exclusivity unrelated to patent term.

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 our patents, see the sections entitled "Risk Factors" and Note 10 "Contingencies and Environmental Liabilities" to the Financial Statements included in this information statement.

Worldwide, all of our 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 \$6 million. We also incurred royalty expenses amounting to \$40 million in 2020 under patent and know-how licenses we hold.

Privacy and Data Protection

We are subject to a significant number of privacy and data protection laws and regulations globally, many of which place restrictions on our ability to transfer, access and use personal data across our 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 our business, including both the EU General Data Protection Regulation ("GDPR"), which went into effect in May 2018 and imposes penalties of up to 4% of global revenue, and the California Consumer Privacy Act, which became effective January 1, 2020.

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 we process. 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 European Commission 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 we may face difficulties regarding the transfer of personal data from the European Union 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 us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the interplay between different regulatory frameworks further adds to the complexity that we face 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. We have adopted a comprehensive global privacy program to manage these evolving risks and facilitate the transfer of personal information across international borders, which has been certified as compliant with and approved by the Asia Pacific Economic Cooperation Cross-Border Privacy Rules System.

Competition and the Health Care Environment

Competition

The markets in which we conduct our business and the pharmaceutical industry in general are highly competitive and highly regulated. Our competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus and generic drug manufacturers. Our operations may be adversely affected by generic and biosimilar competition as our 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. Competitive pressures have intensified as pressures in the industry have grown.

To remain competitive, the additional resources required to meet market challenges include quality control, flexibility to meet buyer specifications, an efficient distribution system and a strong technical information service. We plan to acquire and market products through external alliances, such as licensing arrangements and collaborations and have designed our 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 our products in that therapeutic category.

Health Care Environment

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 for which they pay. For example, federal and state laws require us 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. We recorded approximately \$24 million, \$30 million and \$20 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 was \$2.8 billion in both 2019 and 2020. 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. We recorded approximately \$4 million, \$6 million and \$6 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 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. In 2019, CMS took further action on two aspects of the rule that were deferred for later implementation. First, CMS declined to define what constitutes a product “line extension” (beyond the statutory definition) instead advising manufacturers to rely on the statutory definition of the term and permitting manufacturers, where appropriate, to use “reasonable assumptions” in their determination of whether their drug qualifies as a line extension drug, so long as such reasonable assumptions are consistent with the purpose of Section 1927 of the Social Security Act, federal regulations, and the terms of the Medicaid Drug Rebate agreement, and so long as they maintain adequate documentation explaining such assumptions. Second, CMS confirmed a second delay in the participation of the United States Territories in the Medicaid Drug Rebate Program until April 1, 2022.

On December 31, 2020, CMS published a Final Rule on the Medicaid Program, which, among other things, introduced new definitions of “line extension” and “new formulation.” CMS defined “line extension” as a new formulation of the drug, not including an abuse-deterrent formulation of the drug. CMS adopted an expansive definition of “new formulation” to include “an extended release formulation or other change in release mechanism, a change in dosage form, strength, route of administration, or ingredients.” This expanded definition will result in a number of drugs being subject to a higher Medicaid rebate. The new definitions of “line extension” and “new formulation” will take effect on January 1, 2022. The Final Rule also revised definitions of several other terms for purposes of the Medicaid Drug Rebate Program (MDRP), including oral solid dosage form, single source drug, multiple source drug, innovator multiple source drug, and CMS-authorized supplemental rebate agreement. The Final Rule also revised regulations regarding authorized generic sales when manufacturers calculate the average manufacturer price (AMP), manufacturer reporting requirements under the MDRP, and payments for prescription drugs under the Medicaid program. The implementation date of these revised regulations is January 1, 2023.

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 and a decision is expected by the Spring of 2021. If the individual mandate is held to be unconstitutional and not severable from the remainder of the ACA, we expect this would result in invalidation of the BPCIA, which provides for an abbreviated pathway for obtaining FDA approval of biologic drugs that satisfy certain criteria and which is incorporated into the ACA.

We are participating in the healthcare debate and monitoring how any proposed changes could affect our business. We are 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 our 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. These changes include automatic aggregate reductions to Medicare payments to providers of 2% per fiscal year as part of the federal budget sequestration under the Budget Control Act of 2011, which went into effect in April 2013. Section 4408 of the Coronavirus Aid, Relief and Economic Security Act temporarily suspended Medicare sequestration during the period of May 1, 2020 through December 31, 2020, while extending the Medicare sequestration sunset date through 2030. The moratorium on Medicare sequestration was subsequently extended by three months, until March 31, 2021, under the Consolidated Appropriations Act of 2021.

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. We expect that states will continue their focus on pharmaceutical price transparency and that this focus will continue to exert pressure on product pricing.

Drug Pricing

We also face increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect our 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. As discussed above, in

November 2020, the OIG issued a Final Rule that would, effective January 1, 2022, eliminate the Anti-Kickback Statute safe harbor for rebates paid to Medicare Part D plans or to PBMs on behalf of such plans. The Final Rule's effective date has been delayed until January 1, 2023 in response to litigation brought by a trade association on behalf of PBMs. 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. This rule is currently subject to legal challenge. 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, 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 MFN Rule was immediately challenged in federal courts and is prevented from going into effect pending final judgments in the lawsuit. The Department of Health and Human Services has indicated that the MFN model will not be implemented without further rulemaking. 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 Indian tribes, 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 brought suit, which remains pending in federal district court, challenging the commercial importation rule. These changes could have a material adverse effect on our 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. The U.S. House of Representatives approved legislation that would require pharmaceutical companies to directly negotiate the price of 50 drugs with the federal government. Although the U.S. Senate did not approve the bill, similar measures may be reintroduced in the future. It remains very uncertain as to what drug-pricing related proposals, if any, may be included under the current Congress as part of future federal legislative proposals that would directly or indirectly affect us. During his presidential campaign, President Biden expressed support for allowing the federal government to negotiate drug prices for both public and private purchasers.

In addition, additional proposals that allow international reference pricing or, under certain conditions, the importation of medicines from other countries may be considered. For example, in December 2019, the FDA issued guidance describing procedures for drug manufacturers to facilitate the importation of FDA-approved drugs and biologics manufactured abroad and originally intended for sale in a foreign country into the United States. Also, in September 2020, the United States Department of Health and Human Services issued a Final Rule that allows importation of certain lower-cost prescription drugs from Canada. Under the Final Rule, effective November 30, 2020, states or certain other non-federal governmental entities will be able to submit importation program proposals to the FDA for review and authorization of two-year programs (with the opportunity to extend for two more years). This rule is currently facing a legal challenge and is currently pending in federal district court, but if upheld, or if additional future legislative action is taken on drug importation, it would be expected to adversely affect our revenues.

In the United States 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 our 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 United States 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.

European Union

Efforts toward health care cost containment remain intense in the EU. We face 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 ours. 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 our products may mean that the product is not reimbursable or may force us to reduce our reimbursement price or offer discounts or rebates. A negative HTA by a leading and recognized HTA body could also undermine our 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 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, we may be required to conduct studies that compare the cost-effectiveness of our 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 our 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 the European Parliament must consent to it, which we believe will occur. As a result of the TCA, we believe that our 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. Furthermore, the government can order re-pricings for specific products if it determines that use of such products will exceed certain thresholds defined under applicable pricing rules. The next government-mandated pricing reduction will occur in April 2021 and is expected to impact many Organon products.

China

Our business in China has grown rapidly in the past few years, and the importance of China to our overall pharmaceutical business has increased accordingly. Continued growth of our business in China is dependent upon ongoing development of a favorable environment for innovative pharmaceutical products, sustained access for our 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 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%. We expect VBP to be a semi-annual process that will have a significant impact on mature products moving forward.

Other Markets

Our focus on other markets, in addition to China, has continued. Governments in many other markets are also focused on constraining health care costs and have enacted price controls and measures impacting intellectual property, including in exception, 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. We anticipate that pricing pressures and market access challenges will continue in the future to varying degrees in such markets.

Beyond pricing and market access challenges, other conditions in certain countries outside the United States can affect our 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 healthcare partners, such as hospitals, due to COVID-19, and other developments that may adversely impact the business environment for us. Further, we may engage third-party agents to assist in operating in such markets, which may affect our ability to realize continued growth and may also increase our risk exposure.

In addressing cost containment pressures, we engage in public policy advocacy with policymakers and continue to work to demonstrate that our medicines provide value to patients and to those who pay for health care. We advocate 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, we encourage 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 our business, we continually take measures to evaluate, adapt and improve the organization and our business practices to better meet customer needs and believe that we are well-positioned to respond to the evolving health care environment and market forces.

Regulation of Our Products

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 and biosimilar 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. Our policies and procedures are already consistent with the substance of these directives; consequently, we believe that they will not have any material effect on our business.

We believe that we will continue to be able to conduct our operations, including launching new drugs, in this regulatory environment.

The Regulatory Approval Process in the United States

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 suitable for pharmaceutical use through pre-clinical tests and controlled clinical evaluation. Before a new drug 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 biologic submitted to the FDA for the required approval.

Once scientists identify internal technology development opportunities or external technology licensing opportunities to enable improvement of existing products or development of new products, pre-clinical testing with that compound is commenced. Pre-clinical testing includes laboratory testing and safety studies to gather data on chemistry, pharmacology, immunogenicity and toxicology and must be conducted in compliance with Good Laboratory Practice regulations. Pending acceptable pre-clinical data, we will submit an Investigational New Drug (“IND”) application to the FDA through a combination of internal and external resources, which includes the results of pre-clinical testing, information about the drug composition and manufacturing, and our plan for clinical testing on humans. After submission of the IND, we must wait 30 days before initiating clinical testing so that the FDA has the opportunity to review the IND for safety and to determine that clinical testing will not expose human subjects to unreasonable risk. We will then initiate clinical testing under the supervision of qualified investigators in accordance with established regulatory requirements, including Good Clinical Practice regulations. 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 and 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, we commence 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 (such as 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, we submit 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. After a product receives marketing authorization, the FDA may require us to perform post-marketing studies, or Phase 4 studies, which may involve additional clinical trials, nonclinical testing and surveillance programs to monitor the safety of approved products or to provide additional information regarding treatment or a drug’s risks, benefits, or best use.

In the United States, upon completion of clinical testing, a complete NDA or BLA is submitted, received and accepted for review by the FDA. 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, the FDA review period target for NDAs or original BLAs is either six months, for priority review, or 10 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 our 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. 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 we wish to pursue an application after receiving a CRL, we are able to 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 need 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. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform Phase 4 or post-marketing studies to verify and describe the predicted clinical benefit, and the drug may be subject to accelerated withdrawal procedures. The Priority Review designation means that the FDA's goal is to take action on the NDA/BLA within six months, compared to 10 months under standard review.

In addition, the BPCIA provides for an abbreviated pathway for obtaining FDA approval of biologic drugs that satisfy certain criteria. If a manufacturer can show that its proposed biosimilar product is highly similar to and has no clinically meaningful differences from the FDA-approved reference product, it can rely in part on the FDA's previous determination of safety and effectiveness for the reference product for obtaining approval. This can potentially lead to a faster and less costly approval process for these products because it generally means that the biosimilar manufacturer does not need to conduct as many clinical trials.

After the NDA or BLA has been approved, a drug can be marketed in the United States and remains subject to post-marketing drug safety monitoring by the FDA. Any significant changes to an approved drug, such as changes in formulation, labeling, dosage strength, or certain manufacturing changes require prior approval by the FDA through a supplemental application. Additionally, further development of an approved drug for a new use, dosage strength, or a new or different form must be conducted under a new IND. Our activities are subject to the FDA's requirements governing, among other things, drug establishment registration and listing, labeling and advertising, and current Good Manufacturing Practices ("cGMP") regulations, which set forth minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing a drug product. Post-approval reports of product quality defects and adverse events are maintained and submitted to the FDA in accordance with its regulations. The FDA conducts routine inspections of drug manufacturing facilities to monitor compliance with these requirements. Non-compliance with cGMP or other regulatory requirements can lead to regulatory action, including issuance of Warning Letters to the Company or issuance of safety alerts, press releases, or other communications containing warnings about the products; suspension or withdrawal of the marketing authorizations; suspension of any ongoing clinical trials; or other enforcement or regulatory actions, including seeking injunction or imposing civil or criminal penalties or monetary fines.

The FDA regulates the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory approvals, that there are adequate and reasonable data to substantiate the claims, and that our promotional labeling and advertising is neither false nor misleading in any respect.

As a manufacturer and distributor of drug products, our activities are regulated under various federal and state statutes, including the Drug Quality and Security Act of 2013 (the “DQSA”) and Controlled Substances Act (the “CSA”).

Title II of the DQSA, known as the Drug Supply Chain Security Act, calls for the establishment of a nationwide electronic system that tracks certain prescription drugs at each point in the supply chain in order to prevent the introduction of counterfeit, adulterated, or mislabeled drugs into the market. Implementation began in 2015 and is scheduled to be completed by 2023. The FDA has issued regulations and guidance implementing the DQSA, which require manufacturers, distributors, and dispensers to comply with various regulatory requirements related to product identification, product tracing, product verification, detection and response, notification, and wholesaler licensing.

Under the CSA, manufacturers and distributors of controlled substances must maintain registration with the Drug Enforcement Agency (“DEA”) and comply with various regulatory requirements, including with respect to maintaining records and inventory, reporting to the DEA, and meeting certain security and operational safeguards.

The Regulatory Approval Process Outside the United States

Before our pharmaceutical products can be marketed outside of the United States, they may be subject to regulatory approval similar to that required in the United States. The requirements governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with health care professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

The European Union

Drug and Biologic Development Process

Similar to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC (“Clinical Trials Directive”), has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, EU Member States have transposed and applied the provisions of the Clinical Trials Directive in a manner that is not always uniform. This has led to variations in the rules governing the conduct of clinical trials in the individual EU Member States. The EU has, therefore, adopted Regulation (EU) No 536/2014 (“Clinical Trials Regulation”). The Clinical Trials Regulation, which will replace the Clinical Trials Directive, introduces a complete overhaul of the existing regulation of clinical trials for pharmaceutical products in the EU, including a new coordinated procedure for authorization of clinical trials that is reminiscent of the mutual recognition procedure for marketing authorization of pharmaceutical products, and increased obligations on sponsors to publish clinical trial results. The coming into effect of the Clinical Trials Regulation has been postponed several times due to technical difficulties with the underlying IT systems that are still ongoing. Currently, it is not expected to come into force before December 2021.

Under the current regime, before a clinical trial can be initiated, it must be approved in each EU Member State where there is a site at which the trial is to be conducted by two separate entities: the National Competent

Authority (“NCA”), and one or more Ethics Committees. The NCA of the EU Member States in which the clinical trial will be conducted must authorize the conduct of the trial, and the independent Ethics Committee must grant a positive opinion in relation to the conduct of the clinical trial in the relevant EU Member State before the commencement of the trial. Any substantial changes to trial protocol or other information submitted with the clinical trial applications must be submitted to or approved by the relevant NCA and Ethics Committees. Under the current regime, all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the NCA and to the Ethics Committees of the EU Member State where they occur.

However, under the new Clinical Trials Regulation, which will come into force once the underlying IT systems are working, the approval of clinical trials in the EU will be simplified and streamlined. For example, the sponsor will submit a single application for approval of a clinical trial via the clinical trials information system. As part of the application process, the sponsor will propose a reporting Member State, which will coordinate the validation and evaluation of the application. The reporting Member State shall consult and coordinate with the other concerned Member States. If an application is rejected, it can be amended and resubmitted through the EU Portal. If an approval is issued, the sponsor can start the clinical trial in all concerned Member States. However, a concerned Member State can in limited circumstances declare an “opt-out” from an approval. In such a case, the clinical trial cannot be conducted in that Member State. The Clinical Trials Regulation also aims to streamline and simplify the rules on safety reporting, and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database.

National laws, regulations, and the applicable Good Clinical Practice and Good Laboratory Practice standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines on Good Clinical Practice (“GCP”).

During the development of a pharmaceutical product, the EMA and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use (“CHMP”) on the recommendation of the Scientific Advice Working Party. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future Marketing Authorization Application (“MAA”) of the product concerned.

In the EU, pediatric data or an approved Pediatric Investigation Plan (“PIP”), or deferral or waiver, must be approved by the EMA, prior to submission of a MAA to the EMA or to the competent authorities of the EU Member States; an application has to include the results of studies as described in an approved PIP, unless the pharmaceutical product is exempt because of a deferral or waiver. In most EU Member States, companies are also required to have an approved PIP before enrolling pediatric patients in a clinical trial.

Marketing Authorization Procedures

In the EU and in Iceland, Norway and Liechtenstein (together the European Economic Area or “EEA”), pharmaceutical products may only be placed on the market after obtaining a Marketing Authorization (“MA”). Marketing Authorizations can be obtained through the centralized procedure, the mutual recognition procedure, the decentralized procedure, or a national procedure (for pharmaceutical products sold in a single EU Member State only). The primary method we use to obtain a Marketing Authorization of pharmaceutical products in the EU is through the centralized procedure.

The centralized procedure provides for the grant of a single MA by the European Commission (“EC”), that is valid for all 27 EU Member States and, after respective national implementing decisions, in the three additional

EEA Member States (Iceland, Norway and Liechtenstein). The centralized procedure is compulsory for certain pharmaceutical products, including pharmaceutical products derived from biotechnological processes, orphan pharmaceutical products, advanced therapy pharmaceutical products and products with a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. It is optional for pharmaceutical products containing a new active substance not yet authorized in the EEA before May 20, 2004, that constitute significant therapeutic, scientific or technical innovations, or for which the grant of an MA through the centralized procedure would be in the interest of public health at the EU level. Under the centralized procedure, the timeframe for the evaluation of an MA application by the EMA's CHMP is, in principle, 210 days from receipt of a valid application for MA. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more. Applications may be eligible for accelerated assessment if the CHMP decides the product is of major interest for public health and therapeutic innovation. On request, the CHMP can reduce the time frame to 150 days if the applicant provides sufficient justification for an accelerated assessment. The CHMP will provide a positive opinion regarding the application only if it meets certain quality, safety and efficacy requirements. However, the EC has final authority for granting the MA within 67 days after receipt of the CHMP opinion. In light of the UK's decision to leave the EU, the UK Medicines and Healthcare Products Regulatory Agency had proposed that, subject to being approved by the UK Parliament, a centralized MA will automatically convert into a UK MA. However, that proposal has been withdrawn and further changes may be forthcoming in the scope of the centralized approval procedure as the terms of the future relationship are negotiated between the United Kingdom and the European Union.

The decentralized marketing authorization procedure permits companies to file identical applications for an MA to the competent authorities in several EU Member States simultaneously for a pharmaceutical product that has not yet been authorized in any EU Member State. This procedure is available for pharmaceutical products not falling within the mandatory scope of the centralized procedure. The competent authority of a single EU Member State, the reference member state, is appointed to review the application and provide an assessment report. The competent authorities of the other EU Member States, the concerned member states, are subsequently required to grant MA for their territories on the basis of this assessment. The only exception to this is where the competent authority of an EU Member State considers that there are concerns of potential serious risk to public health related to authorization of the product. In these circumstances the matter is submitted to the Heads of Medicines Agencies for review.

Where a pharmaceutical product has already been authorized for marketing in an EEA Member State, this national authorization can be recognized in another Member State through the mutual recognition procedure. The national marketing authorization procedure, which is increasingly rare, permits a company to submit an application to the competent authority of a single EU Member State and, if successful, to obtain a MA that is valid only in this EU Member State. If a pharmaceutical product falls under the optional scope of the centralized procedure, the applicant has the choice of using either the centralized or the national (decentralized / mutual recognition) procedure.

Similar to accelerated approval regulations in the United States, conditional MAs can be granted in the EU by the European Commission in exceptional circumstances. A conditional MA can be granted for pharmaceutical products where, although comprehensive clinical data referring to the safety and efficacy of the pharmaceutical product have not been supplied, a number of criteria are fulfilled; (i) the benefit / risk balance of the product is positive, (ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data, (iii) unmet medical need will be fulfilled by the grant of the marketing authorization and (iv) the benefit to public health of the immediate availability on the market of the pharmaceutical product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional MA must be renewed annually.

All new MAAs must include a Risk Management Plan ("RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. RMPs and

Periodic Safety Update Reports (“PSURs”) are routinely available to third parties requesting access, subject to limited redactions.

Marketing Authorizations have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Applications for renewal must be made to the EMA at least nine (9) months before the five-year period expires.

Data and Market Exclusivity

As in the United States, it may be possible to obtain a period of market and / or data exclusivity in the EU that would have the effect of postponing the entry into the marketplace of a competitor’s generic, hybrid or biosimilar product (even if the pharmaceutical product has already received an MA) and prohibiting another applicant from relying on the MA holder’s pharmacological, toxicological and clinical data in support of another MA for the purposes of submitting an application, obtaining MA or placing the product on the market. New chemical entities (“NCE”) approved in the EU qualify for eight years of data exclusivity and 10 years of marketing exclusivity. An additional noncumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

The data exclusivity period begins on the date of the product’s first MA in the EU. After eight years, a generic product application may be submitted and generic companies may rely on the MA holder’s data. However, a generic product cannot launch until two years later (or a total of 10 years after the first MA in the EU of the innovator product), or three years later (or a total of 11 years after the first MA in the EU of the innovator product) if the MA holder obtains MA for a new indication with significant clinical benefit within the eight-year data exclusivity period. Additionally, another noncumulative one-year period of data exclusivity can be added to the eight years of data exclusivity where an application is made for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication. Another year of data exclusivity may be added to the eight years, where a change of classification of a pharmaceutical product has been authorized on the basis of significant pre-trial tests or clinical trials (when examining an application by another applicant for or holder of market authorization for a change of classification of the same substance the competent authority will not refer to the results of those tests or trials for one year after the initial change was authorized).

However, even if a compound is considered to be a NCE and the MA applicant is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the pharmaceutical product if such company can complete a full MAA with their own complete database of pharmaceutical tests, preclinical studies and clinical trials (without relying on the other initial applicant’s data) and obtain MA of its product.

Post-Approval Regulation

Similar to the United States, both MA holders and manufacturers of pharmaceutical products are subject to comprehensive regulatory oversight by the EMA, the European Commission and / or the competent regulatory authorities of the EU Member States. This oversight applies both before and after grant of manufacturing licenses and marketing authorizations. It includes control of compliance with EU good manufacturing practices rules, manufacturing authorizations, pharmacovigilance rules and requirements governing advertising, promotion, sale, and distribution, recordkeeping, importing and exporting of pharmaceutical products.

Failure by us or by any of our third-party partners, including suppliers, manufacturers and distributors to comply with EU laws and the related national laws of individual EU Member States governing the conduct of

clinical trials, manufacturing approval, marketing authorization of pharmaceutical products and marketing of such products, both before and after grant of marketing authorization, statutory health insurance, bribery and anti-corruption or other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of an EU MA for a pharmaceutical product must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of pharmaceutical products. These pharmacovigilance rules can impose on holders of MAs the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed pharmaceutical products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk-management measures, which may be time consuming and expensive and could impact our profitability. MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of PSURs in relation to pharmaceutical products for which they hold MAs. The EMA reviews PSURs for pharmaceutical products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase IV safety studies. The EMA opinion is submitted to the European Commission for its consideration. If the Commission agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the marketing authorization holder to fulfill the obligations for which the European Commission's decision provides can undermine the on-going validity of the MA.

More generally, noncompliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the MA for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for pharmaceutical products in the EU is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice ("GMP"). We and our third-party manufacturers are also subject to other good manufacturing practices, which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by the EMA, the European Commission, the competent authorities of EU Member States and other regulatory authorities. Companies may be subject to civil, criminal or administrative sanctions, if they fail to comply with these practices. These include suspension of manufacturing authorization in case of non-compliance with the EU or EU Member States' requirements governing the manufacturing of pharmaceutical products.

Compliance with EU GMP standards is required when manufacturing pharmaceutical products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU. Similarly, the distribution of pharmaceutical products into and within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with GMP, before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Sales and Marketing Regulations

The advertising and promotion of our products is also subject to EU laws concerning promotion of pharmaceutical products, interactions with health care providers, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual EU Member States may apply to the advertising and promotion of pharmaceutical products and may differ from one country to another. These laws require that promotional materials and advertising in relation to pharmaceutical products comply with the product's Summary of Product Characteristics ("SmPC") as approved by the competent regulatory authorities. The SmPC is the document that provides information to health care providers concerning the safe and effective use of the pharmaceutical product. It forms an intrinsic and integral part of the marketing authorization granted for the pharmaceutical product. Promotion of a pharmaceutical product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of pharmaceutical products is prohibited in the European Union. The applicable laws at the EU level and in the individual EU Member States also prohibit the direct-to-consumer advertising of prescription-only pharmaceutical products. Violations of the rules governing the promotion of pharmaceutical products in the European Union could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on its promotional activities with health care professionals.

Anti-Corruption Legislation

In the EU, interactions between pharmaceutical companies and health care providers are also governed by strict laws, regulations, industry self-regulation codes of conduct and health care providers' codes of professional conduct both at the EU level and in the individual EU Member States. The provision of benefits or advantages to health care providers to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of pharmaceutical products is prohibited in the European Union. The provision of benefits or advantages to health care providers is also governed by the national anti-bribery laws of the EU Member States. Violation of these laws could result in substantial fines and imprisonment.

Payments made to health care providers in certain EU Member States also must be publicly disclosed. Moreover, agreements with health care providers must often be the subject of prior notification and approval by the physician's employer, his / her regulatory professional organization, and / or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Other Markets

Outside of the United States, the EU, the EEA and other European Jurisdictions, we submit marketing applications to national regulatory authorities. Examples of such are the NMPA in China, the Ministry of Health, Labour and Welfare in Japan, Health Canada, Agência Nacional de Vigilância Sanitária in Brazil, Korea Food and Drug Administration in South Korea and 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.

Environmental Matters

We believe that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on our business. Expenditures for remediation and environmental liabilities were \$1 million in 2020 and are estimated to be \$18 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 \$24 million and \$21 million at December 31, 2020 and

2019, respectively. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, we do not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed \$20 million in the aggregate. We also do not believe that these expenditures should have a material adverse effect on our financial condition, results of operations or liquidity for any year.

We believe that climate change could present risks to our business. Some of the potential effects of climate change to our business include increased operating costs due to additional regulatory requirements, physical risks to our facilities, water limitations and disruptions to our supply chain. These potential risks are integrated into our business planning, including investment in reducing energy, water use and greenhouse gas emissions. We do not believe these risks are material to our business at this time.

Third-Party Agreements

Samsung Bioepis Development and Commercialization Agreement

We are party to a development and commercialization agreement with Samsung Bioepis. The agreement was entered into by Merck and Samsung Bioepis as of February 18, 2013 (as subsequently amended by Amendments No. 1, No. 2, No. 3, No. 4, No. 5, No. 6 and No. 7, the “Samsung Bioepis Agreement”). All of the rights and obligations of Merck under the Samsung Bioepis Agreement were transferred to us in connection with the separation. The Samsung Bioepis Agreement grants us an exclusive license to commercialize the following pre-specified biosimilars products (with reference products in parenthesis) developed by Samsung Bioepis: Adalimumab (Humira), Bevacizumab (Avastin), Infliximab (Remicade), Trastuzumab (Herceptin) and Etanercept (Enbrel). See “—Our Biosimilars Products” for a description of each product and the geographic areas in which we have an exclusive license for regulatory and commercialization activities.

Under the Samsung Bioepis Agreement, Samsung Bioepis is responsible for pre-clinical and clinical development, process development and manufacturing, clinical trials and registration of product candidates. Our access rights to each product under the Samsung Bioepis Agreement last for 10 years from each such product’s launch date on a market-by-market basis. Unless the parties agree to extend the term, the agreement expires upon the expiration of the last such 10 year period. We may terminate the agreement with respect to a particular region or product if a product fails to meet certain milestones in such region. We may terminate the agreement upon 60 days’ written notice to Samsung Bioepis for a particular presentation of a product in a region if Samsung Bioepis’s revenue share for such product presentation in such region exceeds a certain contractual threshold. We may also terminate the agreement upon 60 days’ written notice in the event of a third party infringement claim that Samsung Bioepis decides to litigate despite our opposition to such litigation.

The agreement may be terminated by either party on 30 days’ written notice for a particular product or region if the parties fail to agree upon a strategy regarding third party patents within six months following written notice by either party of the existence of such patents. The agreement may also be terminated by either party upon written notice if the other party commits a material breach of its obligations by specified actions within its reasonable control and has not cured such breach within ninety calendar days after notice requesting cure of the breach.

The Samsung Bioepis Agreement provides that gross profits are shared equally in all markets with the exception of Brazil where gross profits are shared 65% to Samsung Bioepis and 35% to us. The Samsung Bioepis Agreement also provides for payment of certain milestone license fees associated with pre-specified clinical and regulatory milestones to Samsung Bioepis, payment of the supply price for each product to Samsung Bioepis, and an upfront payment to Samsung Bioepis that was completed by Merck at the commencement of the agreement. As of December 31, 2020, there were \$25 million in potential future regulatory milestone payments remaining under the agreement. For further information related to the Samsung Bioepis collaboration, see Note 4 to our audited annual combined financial statements.

Employees

We expect that upon the separation, we will have approximately 9,950 employees worldwide. Approximately 1,530 employees are employed in the United States, including Puerto Rico. Approximately 35% of our worldwide employees are represented by various collective bargaining groups.

Legal Proceedings

We are from time to time subject to claims and litigation arising in the ordinary course of business. These claims and litigation may include, among other things, allegations of violation of United States and foreign competition law, labor laws, consumer protection laws and environmental laws and related regulations, as well as claims or litigation relating to product liability, intellectual property, securities law, breach of contract and tort. We operate in multiple jurisdictions and, as a result, claims in one jurisdiction may lead to claims or regulatory penalties in other jurisdictions. We intend to defend vigorously against any pending or future claims and litigation. For a description of certain legal proceedings, see Note 10 to our audited annual combined financial statements.

While our liability in connection with certain claims cannot be estimated with any certainty, and although the resolution in any reporting period of one or more of these matters could have a significant effect on the company's results of operations and cash flow for that period, the outcome of these legal proceedings is not expected to have a material adverse effect on our combined financial position. Although we believe we have valid defenses in these matters, litigation is inherently uncertain, excessive verdicts do occur, and we may in the future incur material judgments against us or enter into settlements of claims resulting in material financial payments or otherwise having a material and adverse effect on our operations and financial condition.

Subject to certain specified matters, we and Merck generally will assume liability for all pending, threatened and unasserted legal matters related to our respective businesses or assumed or retained liabilities and will indemnify the other party for any liability to the extent arising out of or resulting from such assumed or retained legal matters.

Management

Executive Officers and Directors Following the Distribution

The following table sets forth information as of April 1, 2021, regarding individuals who are expected to serve as our executive officers and/or directors following the distribution.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Kevin Ali	60	Chief Executive Officer and Director Nominee
Matthew Walsh	54	Chief Financial Officer
Kathryn DiMarco	58	Corporate Controller
Aaron Falcione	50	Chief Human Resources Officer
Susanne Fiedler	53	Chief Commercial Officer
Sandra Milligan	57	Head of Research & Development
Joseph T. Morrissey, Jr.	56	Head of Manufacturing
Vittorio Nisita	53	Head of Global Business Services
Geralyn S. Ritter	52	Head of External Affairs and ESG
Rachel Stahler	45	Chief Information Officer
Deborah H. Telman	56	General Counsel
Carrie S. Cox	63	Director Nominee and Chairman of the Board of Directors
Robert Essner	73	Director Nominee
R. Alan Ezekowitz	67	Director Nominee
Ma. Fatima D. Francisco	52	Director Nominee
Helene D. Gayle	65	Director Nominee
Rochelle B. Lazarus	73	Director Nominee
Deborah R. Leone	56	Director Nominee
Martha E. McGarry	69	Director Nominee
Phillip Ozuah	58	Director Nominee
Cynthia M. Patton	59	Director Nominee
Grace Puma	58	Director Nominee
Shalini Sharp	46	Director Nominee

Set forth below is biographical information about each of the executive officers and director nominees named in the table above.

Executive Officers

Kevin Ali will serve as our Chief Executive Officer and one of our directors. In his most recent role at Merck, he has led the Company's global enterprise portfolio strategy initiative, reporting to Chairman and CEO Kenneth Frazier. Prior to this role, between 2017 and 2019, Mr. Ali served as the President of Merck Sharp & Dohme Corp. ("MSD") International with commercial responsibility for all markets outside of the United States. Under his leadership, the MSD International division was a significant driver of Merck's growth. Earlier in his Merck career, Mr. Ali served as the President of the Emerging Markets region where he transformed the performance of many markets into sustained growth and strength and introduced a number of important commercial development partnerships. Mr. Ali has also held several additional leadership roles at Merck, including Senior Vice President and General Manager of the Bone, Respiratory, Immunology and Dermatology franchise; Senior Vice President and Managing Director of MSD in Germany; and Managing Director of MSD in Turkey. Mr. Ali is a graduate of the University of California at Berkeley and holds an MBA from Santa Clara University. Mr. Ali will bring to the Board of Directors three decades of pharmaceutical and commercial experience and extensive knowledge of the industry's customers as well as Organon's core portfolio areas and global operations.

Matthew Walsh will serve as our Chief Financial Officer. Previously, Mr. Walsh served as Executive Vice President and Chief Financial Officer of Allergan plc, a global pharmaceutical company, from 2018 until the sale of the company in 2020. Prior to joining Allergan, Mr. Walsh served as Chief Financial Officer of Catalent, Inc., a global provider of delivery technologies, development, and manufacturing solutions for drugs, biologics, cell and

gene therapies and consumer health products from 2008 to 2018, most recently as Executive Vice President from 2012 to 2018, and prior to that as Senior Vice President from 2008 to 2012. Prior to Catalent, Mr. Walsh progressed through financial roles of increasing responsibility primarily in industrial manufacturing, culminating in chief financial officer roles at several public companies. Since 2020, he has served on the board of directors of Certara, Inc., a provider of software and consulting services to the life sciences industry, where he is also Audit Committee Chair. From 2015 to 2017, he served on the board of directors of Multicolor Corporation, where he also served as Audit Committee Chair. Mr. Walsh is a graduate of Cornell University, College of Engineering and received an M.B.A. from Cornell University, SC Johnson School of Management. Mr. Walsh is a CFA® Charterholder.

Kathryn DiMarco will serve as our Corporate Controller. Previously, Ms. DiMarco served as the Corporate Controller of Allergan plc, a global pharmaceutical company, from 2015 to 2020, where she was responsible for the company's accounting and financial reporting functions. Prior to joining Allergan, Ms. DiMarco held positions of increasing responsibility within finance, controls and compliance at Merck from 1997 to 2015, including, most recently, serving as International Controller from 2014 to 2015 and Finance Transformation Lead from 2010 to 2014. Ms. DiMarco is a graduate of Lehigh University.

Aaron Falcione will serve as our Chief Human Resources Officer. Mr. Falcione has served as Vice President of Human Resources ("HR") at Merck with global HR responsibility for the Human Health commercial organization since 2018. He also previously had HR responsibility for all markets outside the United States between 2017 and 2018 and for the MSD Emerging Markets region between 2014 and 2017. Prior to joining Merck, from 2005 to 2014, Mr. Falcione was at Siemens AG in a mix of HR and mergers & acquisitions ("M&A") roles, working on a number of acquisition and divestiture projects across the Siemens portfolio. He spent the first 10 years of his career with PricewaterhouseCoopers ("PwC") in roles of increasing responsibility within PwC's M&A services practice. Mr. Falcione is a graduate of University of Maryland and received a master's in industrial psychology from Kent State University.

Susanne Fiedler will serve as our Chief Commercial Officer. Since 2019, Ms. Fiedler has served as the President of Europe and Canada for the MSD Human Health commercial organization. Since joining MSD 23 years ago in Germany, she has held various roles with increasing responsibility within marketing and sales. She has had two assignments in the United States: she was a Regional Marketing Leader for pain and osteoporosis from 2005 to 2006, and the Global Brand Leader for the diabetes franchise from 2010 to 2012. In 2012, she moved to Australia to become the Managing Director of MSD in Australia and New Zealand. In 2016, she returned to her home country and became the Managing Director of MSD in Germany. Ms. Fiedler is a graduate of the University of Passau in Germany, where she received a Ph.D. in business administration and marketing.

Sandra Milligan will serve as our Head of Research & Development. Since 2015, Dr. Milligan has served as the Senior Vice President and Head of Global Regulatory Affairs and Clinical Safety, where her responsibilities included leadership of the global clinical and CMC regulatory functions, as well as global clinical safety and pharmacovigilance for Merck Research Laboratories. She served on the Board of Directors of the Drug Information Association (DIA) from 2011 to 2017, including serving as Chair between 2015 and 2016. Prior to joining Merck, from 2012 to 2015, Dr. Milligan was at Genentech, a member of the Roche Group, serving as Vice President, Product Development Regulatory, and from 2002 to 2012, she was at Amgen Inc. in positions of increasing responsibility across legal and regulatory affairs functions. She served in the U.S. Army Medical Corps from 1987 to 1994. Dr. Milligan is a graduate of the University of California, Irvine, and received her M.D. from The George Washington University School of Medicine and a J.D. from the Georgetown University Law Center.

Joseph T. Morrissey, Jr. will serve as our Head of Manufacturing. Since 2017, Mr. Morrissey has served as the Senior Vice President responsible for global manufacturing of animal health products at Merck, and he is responsible for the end-to-end supply operations. Previously, he served as the Senior Vice President responsible for global human health pharmaceutical manufacturing from 2014 to 2016, Europe/Middle East/Africa pharmaceutical manufacturing from 2010 to 2013, and North America manufacturing operations and consumer health care from 2009 to 2010. In addition, over Mr. Morrissey's more than 30-year career at Merck, he has also been the leader of global facilities management, corporate strategy, global supply chain management and has held roles of increasing responsibility in pharmaceutical and vaccine manufacturing, planning, and engineering. Mr. Morrissey is a graduate of Lafayette College and received an M.B.A. from Villanova University.

Vittorio Nisita will serve as our Head of Global Business Services. Since 2017, Mr. Nisita has served as the Vice President of the MSD commercial operations team, which provides support to country teams across several capability areas, including strategy development, digital transformation, sales and marketing excellence, sales and operations planning, and trade channel management. He began his Merck career in 2003, as a member of the corporate strategy office. Prior to joining Merck, Mr. Nisita worked as a consultant in the Italian office of McKinsey & Co., supporting clients in the telecommunications and banking industries. Prior to that, Mr. Nisita led engineering teams and manufacturing operations at Kimberly Clark Corporation and Georgia-Pacific LLC, both of which are global companies in the pulp and paper industry. Mr. Nisita is a graduate of the University of Minnesota and received an M.B.A. from the Kellogg School of Management at Northwestern University.

Geralyn Ritter will serve as our Head of External Affairs and ESG. She has been with Merck for 13 years and served as Senior Vice President, Corporate Secretary and Assistant General Counsel from 2012 to 2020, as well as Senior Vice President, Global Public Policy and Corporate Responsibility from 2012 to 2014, and she was President of the Merck Foundation from 2010 to 2015. Ms. Ritter joined Merck in 2008 as Vice President, Global Public Policy. Prior to joining Merck, Ms. Ritter was Senior Vice President for International Affairs at the Pharmaceutical Research and Manufacturers of America (PhRMA), and Associate General Counsel for Intellectual Property at the Office of the U.S. Trade Representative. She also spent five years in private practice at the law firm of Covington & Burling LLP. She currently serves on the board of trustees of the Duke University Sanford School of Public Policy and as a director of the non-profit organizations Business for Social Responsibility and Power to Decide. Ms. Ritter is a graduate of Duke University, and she received her master's degree from the Johns Hopkins School of Advanced International Studies and her J.D. from Stanford Law School.

Rachel Stahler will serve as our Chief Information Officer. Previously, Ms. Stahler served as Chief Information Officer of Allergan plc, a global pharmaceutical company, from 2019 to 2020. Prior to joining Allergan, from 2017 to 2019, Ms. Stahler served as Chief Information & Digital Officer of Syneos Health, Inc., a global biopharmaceutical solutions company formed in 2017 through the merger of INC Research Holdings Inc. and inVentiv Health Inc. Prior to that, from 2015 to 2017, Ms. Stahler was Chief Information Officer of inVentiv Health, a global provider of outsourced clinical development and commercialization services to biopharmaceutical companies. Ms. Stahler served as Chief Information Officer of inVentiv Health Clinical from 2014 to 2015 and served as Chief Information Officer of Optimer Pharmaceuticals from 2011 to 2014. Ms. Stahler also spent 8 years at Pfizer, Inc., where she held senior level roles in its pharmaceutical and diversified businesses, including technology lead for a Global Center of Excellence for a significant business unit and global technology leadership positions for sales, marketing, market access, strategy and multiple therapeutic areas. Since 2020, Ms. Stahler has served on the board of directors of NeoGenomics, a leading provider of cancer-focused, next generation sequencing and other genetic testing services to physicians, hospitals, and pharmaceutical companies around the world. Ms. Stahler is a graduate of the University of Pennsylvania and received an M.B.A. from Columbia University.

Deborah H. Telman will serve as our General Counsel. Previously, Ms. Telman served as Senior Vice President, General Counsel & Corporate Secretary of Sorrento Therapeutics, Inc., a biopharmaceutical company, from 2018 to 2020. Prior to joining Sorrento, Ms. Telman held several senior executive roles at Johnson Controls International plc, a multinational building technology and solutions company, including Vice President & General Counsel, Building Solutions North America and Global Retail, from 2017 to 2018; Vice President & General Counsel, Corporate Legal Services, from 2016 to 2017; and Vice President & General Counsel, Centers of Excellence—Americas, from 2014 to 2015. Before Johnson Controls, Ms. Telman was at Abbott Laboratories in the position of Divisional Vice President, Associate General Counsel, from 2013 to 2014 and Division Counsel, Corporate Transactions, from 2009 to 2012. She also served as Chief Counsel, Mergers & Acquisitions at The Boeing Company, from 2002 to 2008 and was a Partner at Winston & Strawn LLP between 2000 and 2002. Ms. Telman is a graduate of the University of Pennsylvania and received her J.D. from Boston University School of Law.

Director Nominees

Please see “Executive Officers” above for the biographical information of Kevin Ali.

Carrie Cox will serve as Chairman of the Board of Directors. Ms. Cox served as the Chief Executive Officer of Humacyte, Inc., a privately-held regenerative medical technology company, between 2010 and 2018; in addition, she served as Chairman of the company's board between 2013 and 2019, and she remains a member of the board. Ms. Cox served as Executive Vice President of Schering-Plough and President of Schering-Plough's global pharmaceutical business between 2003 and 2009, when Schering-Plough merged with Merck & Co., Inc. Prior to joining Schering-Plough, Ms. Cox served as President of Pharmacia Corporation's global pharmaceutical business from 1997 until its merger with Pfizer Inc. in 2003. She also currently serves as Chairman of Selecta Biosciences, Inc. and as a director of Texas Instruments Inc. and Cardinal Health Inc. She served on the board of directors of Celgene Corp. from 2009 until its acquisition by Bristol-Myers Squibb Co. in 2019, on the board of directors of electroCore, Inc. between 2018 and 2020, and as Chairman of the board of directors of Array BioPharma, Inc. from 2018 until its acquisition by Pfizer Inc. in 2019. Ms. Cox is a graduate of the Massachusetts College of Pharmacy. Ms. Cox will bring to the Board of Directors extensive executive experience from both large and small pharmaceutical and biopharma companies and deep public company governance expertise.

Robert Essner will serve as one of our directors. He is the former Chairman, Chief Executive Officer and President of Wyeth Pharmaceuticals, Inc., a global pharmaceuticals company, which is now part of Pfizer Inc. Specifically, he served as Wyeth's Chairman between 2003 and his retirement from Wyeth in 2008, as its Chief Executive Officer between 2001 and 2007, its President between 2000 and 2006, its Chief Operating Officer between 2000 and 2001 and its Executive Vice President between 1997 and 2000. Prior to Wyeth, Mr. Essner spent more than a decade in various senior management positions at Sandoz Pharmaceuticals Corporation. Mr. Essner has served as a Senior Advisor of Global Healthcare for The Carlyle Group Inc., a private equity, alternative asset management and financial services corporation between 2009 and 2019. He also serves as an Executive in Residence and Adjunct Professor of Business at Columbia Business School. He also currently serves as a director of Amicus Therapeutics Inc. Mr. Essner is a graduate of Miami University and received his master's degree from the University of Chicago. Mr. Essner will bring to the Board of Directors extensive industry leadership experience in the pharmaceutical industry.

R. Alan Ezekowitz will serve as one of our directors. He has been a Venture Partner at Third Rock Ventures, LLC, a healthcare venture firm, since 2019, and has served as Entrepreneur in Residence at Cardinal Partners, a venture capital firm, since 2011. He also serves as an advisor to Fidelity's Select Biotechnology Portfolio and as a consultant to H. Lundbeck A/S. Dr. Ezekowitz served as the President and Chief Executive Officer of Abide Therapeutics, Inc., a biopharmaceutical company that he co-founded, between 2011 and 2019, when Abide was acquired by H. Lundbeck A/S. Prior to co-founding Abide, he was a Senior Vice President at Merck Research Laboratories responsible for the Bone, Respiratory, Immunology, Inflammation and Dermatology franchises. Prior to joining Merck, Dr. Ezekowitz was the Charles Wilder Professor of Pediatrics at the Harvard Medical School and Head of the Laboratory of Developmental Immunology between 1995 and 2006 and served as the chief of pediatric services at the Massachusetts General Hospital for Children and the Partners Healthcare System between 1999 and 2006. Dr. Ezekowitz served on the board of directors of the Partners Healthcare System and the Massachusetts General Hospital Physicians Organization. He currently serves on the board of directors of Fulcrum Therapeutics, Inc. In 1998, the R. Alan Ezekowitz Professorship in Pediatrics at the Harvard Medical School was established. Dr. Ezekowitz received his medical training at the University of Cape Town in South Africa and received a Doctor of Philosophy degree from Oxford University. Dr. Ezekowitz will bring to the Board of Directors leadership experience in the life sciences industry.

Ma. Fatima D. Francisco will serve as one of our directors. Ms. Francisco is the CEO of Procter & Gamble's Global Baby and Feminine Care sector, serving consumers in nearly 120 countries. Ms. Francisco joined P&G in 1989 in the Philippines and held positions of increasing responsibility in Asia, North America, Europe and globally, including serving as President, Global Feminine Care between 2015 and 2018. She was later appointed as President, Global Baby Care and Baby & Feminine Care Sector in 2018 until she became CEO for that business in 2019. Ms. Francisco is a graduate of the University of the Philippines. Ms. Francisco will bring to the Board of Directors her consumer marketing and operational international experience, especially in the specialized area of women's health.

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Helene D. Gayle will serve as one of our directors. Dr. Gayle has served as the President and Chief Executive Officer of the Chicago Community Trust, an over 100-year-old civic organization currently dedicated to addressing the region's racial and ethnic disparities, since 2017. Dr. Gayle formerly served as the Chief Executive Officer of the McKinsey Social Initiative, a nonprofit founded by McKinsey & Company, between 2015 and 2017, as well as President and Chief Executive Officer of the Cooperative for Assistance and Relief Everywhere (CARE), an international humanitarian and global development organization, between 2006 and 2015. From 2001 to 2006, she was an executive in the Global Health program at the Bill & Melinda Gates Foundation. Dr. Gayle began her career in public health at the U.S. Centers for Disease Control in 1984 and held positions of increasing responsibility over her 20-year tenure there, ultimately becoming the director of the National Center for HIV, STD and TB Prevention and achieving the rank of Assistant Surgeon General and Rear Admiral in the United States Public Health Service. Dr. Gayle also serves as Chair of New America and is on the boards of the Center for Strategic and International Studies and the Brookings Institution. She is a member of the Council on Foreign Relations, the National Academy of Medicine, The American Academy of Arts and Sciences and the American Public Health Association. She currently serves as a director of Colgate Palmolive Company, The Coca-Cola Company, GoHealth, Inc. and Palo Alto Networks. Dr. Gayle is a graduate of the Barnard College and received her M.D. from the University of Pennsylvania and a master's degree from The Johns Hopkins University. Dr. Gayle will bring to the Board of Directors her immense knowledge of the healthcare industry, government and extensive board experience and many years of leadership experience.

Rochelle B. Lazarus will serve as one of our directors. Ms. Lazarus has served as Chairman Emeritus of Ogilvy & Mather, a global advertising and marketing communication company, since 2012. Prior to that, she served as Chairman of Ogilvy & Mather between 2008 and 2012 and as its Chairman and Chief Executive Officer between 1996 and 2008. Prior to becoming its Chief Executive Officer and Chairman, she also served as the President of Ogilvy & Mather Direct North America, Ogilvy & Mather New York, and Ogilvy & Mather North America. She is currently on the board of directors of The Blackstone Group Inc., and she previously served on the board of directors of General Electric Company between 2000 and 2018 and Merck between 2004 and 2020. Ms. Lazarus is a vice chair and trustee of the New York Presbyterian Hospital, a member of the board of overseers of Columbia Business School as well as several other charitable and civic organizations. Ms. Lazarus is a graduate of the Smith College and received her M.B.A. from Columbia University. Ms. Lazarus will bring to the Board of Directors her strong background in reputation management and consumer insight.

Deborah R. Leone will serve as one of our directors. She is a retired partner of the Goldman Sachs Group Inc., a multinational investment bank and financial services company, which she joined in 1989 and where she became partner in 2008. She also served as the Chief Operating Officer for its Investment Management Division (IMD) between 2017 and 2019. Prior to that, she served as the Global Director of Internal Audit between 2011 and 2017 and as the Global Controller for IMD between 2008 and 2011. Ms. Leone currently serves as a director of Goldman Sachs Bank USA, the Goldman Sachs Philanthropy Fund and Ayco Charitable Foundation. She is a graduate of Syracuse University and received her M.B.A. from Syracuse University as well. Ms. Leone will bring to the Board of Directors strategic thinking, regulatory experience, and deep financial and operational expertise.

Martha E. McGarry will serve as one of our directors. Ms. McGarry has been a partner at Skadden, Arps, Slate, Meagher & Flom LLP, an international law firm, since 1985. Her practice focuses on mergers and acquisitions, shareholder activism and corporate governance. Ms. McGarry is a graduate of Middlebury College and received her J.D. from the Fordham University. Ms. McGarry will bring to the Board of Directors extensive experience in mergers and acquisitions and supporting growth companies in their business development efforts.

Philip Ozuah will serve as one of our directors. Since 2019, he has served as the President and Chief Executive Officer of Montefiore Medicine, the umbrella organization for the Montefiore Health System and Albert Einstein College of Medicine, having previously served as the President of Montefiore Health System between 2018 and 2019 and as the Executive Vice President and Chief Operating Officer of Montefiore Health System between 2012 and 2018. Prior to joining Montefiore, Dr. Ozuah was on the faculty of the Albert Einstein College of Medicine and was a professor in the Department of Pediatrics and the Department of Epidemiology &

Population Health. He was named Chairman of the Department of Pediatrics in 2007—a role, in which he served until 2013. Dr. Ozuah received his M.D. from the University of Ibadan, Nigeria, his master’s degree from the University of Southern California, and his Ph.D. from the University of Nebraska. He completed his Pediatric Internship and Residency at Albert Einstein College of Medicine and Montefiore, and his Post-Doctoral Fellowship in Medical Education at the University of Southern California School of Medicine. Dr. Ozuah will bring to the Board of Directors his leadership experience and health system delivery expertise.

Cynthia M. Patton will serve as one of our directors. Since 2020, she has served as the General Counsel and Secretary at Verily Lifesciences, Alphabet Inc.’s research organization devoted to the study of life sciences. Previously, between 2012 and 2020, she served as the Senior Vice President and Chief Compliance Officer at Amgen Inc., a biopharmaceutical company. While at Amgen, she also served as the chair of the Amgen Foundation. Prior to Amgen, she served as the General Counsel of SCAN Health Plan, a California Health Maintenance Organization. Ms. Patton serves on the board of directors of the Martin Luther King, Jr. Community Hospital in Los Angeles, a private, nonprofit, safety-net hospital serving South Los Angeles, the Los Angeles Music Center and the Ethics Research Center of the Ethics and Compliance Initiative. She also serves on the board of trustees of Vassar College, Wildwood School in Los Angeles and the NALP Foundation for Law Career Research and Education. Ms. Patton is a graduate of Vassar College and received her J.D. from the National Law Center at George Washington University. Ms. Patton will bring to the Board of Directors her experience in life sciences and knowledge of data analytics.

Grace Puma will serve as one of our directors. In 2017, she was appointed as the Executive Vice President, Global Operations at PepsiCo, Inc., a multinational food, snack and beverage corporation. Previously, Ms. Puma served as the Senior Vice President and Chief Supply Officer at Pepsico between 2015 and 2017 and as the Senior Vice President and Global Chief Procurement Officer between 2010 and 2015. Prior to Pepsico, Ms. Puma served as the Senior Vice President and Global Chief Procurement Officer at United Airlines Holdings between 2007 and 2010. Before then, Ms. Puma was in positions of increasing responsibility at then-Kraft Foods, Inc. between 1999 and 2007 and then-Motorola, Inc. between 1995 and 1999. Ms. Puma served as a director of Williams-Sonoma, Inc. between 2017 and 2020 and as a director of Marietta Corporation between 2010 and 2015. Ms. Puma is a graduate of Illinois Benedictine University. Ms. Puma will bring to the Board of Directors her operational, global procurement and supply chain knowledge and experiences.

Shalini Sharp will serve as one of our directors. Between 2012 and 2020, Ms. Sharp served as the Chief Financial Officer and Executive Vice President of Ultragenyx Pharmaceutical Inc., a biopharmaceutical company focused on the development and commercialization of therapies for rare genetic diseases. Ms. Sharp retired from Ultragenyx in May 2021 after transitioning her duties to her successor. Prior to joining Ultragenyx, between 2006 and 2012, Ms. Sharp served as the Chief Financial Officer of Agenus Inc., a biotechnology company focused on cancer immunotherapies, where between 2003 and 2006 she served in various finance, corporate development and corporate strategy roles. Ms. Sharp currently serves as a director of Sutro Biopharma, Inc., Precision Biosciences, Inc., Neurocrine Biosciences, Inc., and Mirati Therapeutics Inc. She also serves as a director of TB Alliance, a not-for-profit organization dedicated to the discovery, development and delivery of better, faster-acting and affordable tuberculosis drugs. She previously served as a director of Panacea Acquisition Corporation between 2020 and February 2021, Array Biopharma Inc. between 2017 and 2019 and Agenus Inc. between 2012 and 2018. Ms. Sharp is a graduate of Harvard University and also received her M.B.A. from Harvard University. Ms. Sharp will bring to the Board of Directors her experience in both managing and leading firms in the biopharmaceutical industry and deep financial expertise.

Composition of the Board of Directors after the Distribution

Upon the completion of this distribution, we expect our Board of Directors to consist of at least thirteen members. Our amended and restated certificate of incorporation will provide that, until the annual shareholder meeting in 2025, our Board of Directors will be divided into three classes, with each class consisting, as nearly as may be possible, of one-third of the total number of directors. The directors designated as Class I directors will have

terms expiring at the first annual meeting of shareholders following the distribution, which we expect to hold in 2022, and will be up for re-election at that meeting for a three-year term to expire at the 2025 annual meeting of shareholders; the directors designated as Class II directors will have terms expiring at the following year's annual meeting of shareholders, which we expect to hold in 2023, and will be up for re-election at that meeting for a two-year term to expire at the 2025 annual meeting of shareholders, and the directors designated as Class III directors will have terms expiring at the following year's annual meeting of shareholders which we expect to hold in 2024, and will be up for re-election at that meeting for a one-year term to expire at the 2025 annual meeting of shareholders. Commencing with the 2025 annual meeting of shareholders, directors will be elected annually and for a term of office to expire at the next annual meeting of shareholders, and our Board of Directors will thereafter no longer be divided into classes. Before our Board of Directors is declassified, it would take at least three years after the completion of the distribution for any individual or group to gain control of our Board of Directors.

Committees of the Board of Directors

Effective upon the completion of the distribution, our Board of Directors will have the following committees, each of which will operate under a written charter that will be posted to our website concurrently with, or immediately after, the distribution.

Audit Committee

The Audit Committee will be established in accordance with Rule 10A-3 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the NYSE listing rules. The responsibilities of our Audit Committee will be more fully described in our Audit Committee charter. We anticipate that the primary functions of the Audit Committee, among others, will include:

- assisting our Board of Directors in fulfilling its oversight responsibility relating to: (i) the integrity of our financial statements and financial statement audits; (ii) our and our subsidiaries' accounting and financial reporting processes and system of internal controls over financial reporting and disclosures; (iii) our compliance with legal and regulatory requirements; (iv) the independent public accountants' qualifications and independence; (v) the performance of our internal audit function and our independent public accountants; (vi) our risk management processes and (vii) preparation of the report required by the SEC rules to be included in our annual proxy statement;
- being directly responsible for the appointment (subject to ratification by our shareholders), compensation, retention and oversight of the work of our independent public accountants (including the resolution of disagreements between management and the independent public accountants regarding financial reporting);
- evaluating the independent public accountants' qualifications, performance and independence, including a review and evaluation of the lead partner and partner rotation requirements;
- monitoring our compliance program with respect to legal and regulatory requirements, our code(s) of conduct and our policies on ethical business practices and reporting on these items to the Board of Directors;
- establishing and periodically reviewing policies and procedures for the review, approval and ratification of related person transactions, as defined in applicable SEC rules, and reviewing and approving, disapproving or ratifying related party transactions in accordance with these policies and procedures, and overseeing other related party transactions governed by applicable accounting standards;
- establishing and overseeing procedures for handling (receipt, retention and treatment, on a confidential basis) of complaints of potential misconduct, including: (i) violations of law or our code(s) of conduct; (ii) complaints regarding accounting, internal accounting controls, auditing and federal securities law matters; and (iii) the confidential, anonymous submission of concerns by employees regarding accounting, internal accounting controls, auditing and federal securities law matters; and

- periodically reviewing our enterprise risk assessment policies and processes, including meeting at least annually with our Chief Information Officer regarding our information technology and receiving periodic updates regarding our cybersecurity risk management program, and reporting to the Board of Directors on the principal risks facing us and the steps being taken to manage and mitigate these risks.

The Audit Committee will consist of Dr. Ezekowitz and Mss. Leone, Patton and Sharp, each of whom will meet the independence requirements set forth in the listing standards of the NYSE and Rule 10A-3 under the Exchange Act. Ms. Sharp will chair the Audit Committee. Each of Dr. Ezekowitz and Mss. Leone, Patton and Sharp is financially literate, and each of Mss. Leone and Sharp satisfies the criteria to be an “audit committee financial expert” under the rules and regulations of the SEC.

Talent Committee

The responsibilities of our Talent Committee (the “Talent Committee”) will be more fully described in our Talent Committee charter, and we anticipate that they will include, among others, the following duties:

- annually reviewing and approving corporate goals and objectives relevant to the compensation of the Chief Executive Officer and other executive officers, evaluating their performance against these goals and objectives, and, based on this evaluation, recommending to the independent directors of the Board the CEO’s compensation level and approving compensation of other executive officers;
- overseeing succession planning for positions held by executive officers, and reviewing succession planning and management development at least annually with the Board, including recommendations and evaluations of potential successors to fill these positions;
- regularly reviewing the form and amount of compensation of directors for service on the Board of Directors and its committees and recommending changes in compensation to the Board of Directors as appropriate;
- reviewing and recommending for inclusion executive compensation disclosures made in our annual proxy statement, including the Compensation Discussion and Analysis and the Talent Committee Report;
- reviewing our strategies and programs for leadership development (including considerations of diversity) and for maintaining a talent pipeline for executive roles;
- reviewing and discussing with management our diversity and inclusion initiatives, objectives and progress; and
- reviewing and discussing with management our organizational development activities, including key policies, practices and trends related to: (i) the recruitment, development and retention of our personnel; (ii) employee engagement and effectiveness; and (iii) workplace environment and culture.

The Talent Committee will consist of Mss. Cox, Francisco, McGarry and Puma, each of whom will meet the independence requirements applicable to directors and compensation committee members under the listing standards of the NYSE. The members of our Talent Committee will be “non-employee directors” (within the meaning of Rule 16b-3 under the Exchange Act), unless the Board provides otherwise. Ms. Cox will chair the Talent Committee.

Environmental, Social and Governance Committee

The responsibilities of our Environmental, Social and Governance Committee (the “ESG Committee”) will be more fully described in our ESG Committee charter, and we anticipate that they will include, among others, the following duties:

- engaging in succession planning for the Board of Directors;

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- identifying individuals to become qualified Board of Directors members (consistent with criteria approved by the Board of Directors);
- recommending to the Board of Directors director candidates for election at our annual meeting of shareholders;
- developing and recommending to the Board of Directors a set of corporate governance principles;
- considering and making recommendations to the Board of Directors on other matters pertaining to the effectiveness of the Board of Directors;
- performing a leadership role in shaping our corporate governance;
- periodically reviewing and recommending to the Board of Directors the skills, experience, characteristics and other criteria for identifying and evaluating directors;
- overseeing the annual evaluation of the Board of Directors, its committees and individual directors;
- advising the Board of Directors and management on our policies and practices that pertain to our responsibilities as a global corporate citizen, our special obligations as a health care company whose products and services affect health and quality of life around the world, and our commitment to the highest standards of ethics and integrity in all its dealings; and
- reviewing public policy positions, strategy regarding political engagement, and corporate responsibility initiatives with significant financial or reputational impact, as appropriate, and overseeing and making recommendations to the Board of Directors regarding environmental, social, governance and other sustainability matters relevant to our business.

The ESG Committee will consist of Ms. Cox, Mr. Essner, Dr. Gayle, Ms. Lazarus and Dr. Ozuah, each of whom will meet the independence requirements set forth in the listing standards of the NYSE. Mr. Essner will chair the ESG Committee.

Director Independence

Our Principles of Corporate Governance will provide that a substantial majority of our Board of Directors will consist of independent directors. These standards will be available on our website concurrently with, or immediately after, the distribution date. Our Board of Directors is expected to annually determine the independence of directors based on a review and recommendation of our ESG Committee. We expect that the Board of Directors will determine that each of Mss. Cox, Francisco, Lazarus, Leone, McGarry, Patton, Puma and Sharp, Mr. Essner and Drs. Ezekowitz, Gayle and Ozuah is independent under the applicable NYSE listing standards.

Nomination of Directors

In connection with the completion of our distribution, we intend to establish an ESG Committee which will develop criteria for filling vacant Board of Director positions.

Following the completion of the distribution, the ESG Committee will make recommendations to the full Board of Directors which in turn will make the final determination whether to nominate or appoint the new director after considering the ESG Committee's recommendation.

Compensation Committee Interlocks and Insider Participation

During our fiscal 2019, we were not a standalone, publicly traded company, and did not have a compensation committee or any other committee serving a similar function. Decisions as to the compensation of those who are expected to serve as our executive officers were made by Merck as described in the section of this information statement entitled “—Executive Compensation Discussion and Analysis.”

Director Compensation

Following the Separation, we expect our Board of Directors to approve a compensation program that includes the following components for non-employee directors:

- \$120,000 annual cash retainer, payable quarterly in arrears;
- \$250,000 annual cash retainer for Chairman of the Board, payable quarterly in arrears;
- \$25,000, \$20,000 and \$15,000 committee chair retainers for the chair of the Audit, Talent, and Governance Committees, respectively;
- \$10,000 additional annual cash retainer for service as a non-chair member of the Audit Committee;
- \$200,000 annual equity retainer delivered in the form of fully vested deferred stock units (as described further below); and
- \$200,000 one-time deferred stock unit grant for each non-employee director, other than Ms. Cox, who joins the Board of Directors in connection with the separation and a one-time \$535,500 deferred stock unit grant for Ms. Cox, which deferred stock units will vest in full on the earlier of the one-year anniversary of the Separation or Organon's first annual shareholders meeting after the Separation.

Deferred Stock Units. In connection with the Separation, Organon intends to adopt a Director deferred compensation plan, which will provide for the grants of deferred stock units to directors, including the deferred stock units noted above. Under this plan, each non-employee director will receive a credit in the form of phantom shares denominated in Organon common stock to the director's account under the plan. Directors who join the Board mid-year will be credited with a pro-rata portion of the applicable annual equity retainer amount. All distributions from the directors' deferred account are payable in cash installments or as a lump sum no sooner than one year after service as a Director ceases.

Director Stock Ownership Guidelines. Organon expects to adopt stock ownership guidelines following the Separation, under which non-employee directors will be expected to hold, within five years of joining the Board, shares of Organon common stock with a value equal to five times the annual cash retainer of \$120,000.

Communicating with the Board of Directors

Generally, it is the responsibility of our management to speak for us in communications with outside parties, but we intend to provide information about the processes by which shareholders and other interested third parties may communicate with non-management members of our Board.

Code of Conduct

Prior to or concurrently with the completion of the distribution, our Board of Directors will adopt a code of ethics and a code of conduct as such terms are used in Item 406 of Regulation S-K and NYSE listing rules.

Executive Compensation

Compensation Discussion and Analysis

Introduction

Prior to the distribution, we have and will continue to operate as part of Merck. Until the distribution, our compensation decisions have been and will continue to be made by Merck's senior management and the Compensation and Benefits Committee of Merck's Board of Directors. We expect that our executive compensation program following the distribution will generally include similar elements to Merck's executive compensation program; however, our Talent Committee will review all aspects of compensation and may make adjustments that it believes are appropriate in structuring our executive compensation arrangements. This Compensation Discussion and Analysis describes the historical compensation practices of Merck and outlines certain aspects of Organon & Co.'s anticipated compensation structure for its executive officers following the separation.

For purposes of this Compensation Discussion and Analysis and the disclosure that follows, we do not have any Named Executive Officers for 2020. All of our executive officers joined the Organon business after 2020 fiscal year-end and, therefore, they were not executive officers of the Organon business in 2020. None of the tabular compensation disclosure requirements of the SEC's compensation disclosure rules are applicable in our situation. Detailed information on the compensation arrangements of our Named Executive Officers for 2021 will be provided in our first proxy statement following the spin-off.

As of the date of this filing, we have identified the following individuals who are expected to serve in executive officer positions:

- | | |
|-----------------------------|----------------------------------|
| 1. Kevin Ali | Chief Executive Officer |
| 2. Matthew Walsh | Chief Financial Officer |
| 3. Kathryn DiMarco | Corporate Controller |
| 4. Aaron Falcione | Chief Human Resources Officer |
| 5. Susanne Fiedler | Chief Commercial Officer |
| 6. Sandra Milligan | Head of Research & Development |
| 7. Joseph T. Morrissey, Jr. | Head of Manufacturing |
| 8. Vittorio Nisita | Head of Global Business Services |
| 9. GERALYN S. RITTER | Head of External Affairs and ESG |
| 10. Rachel Stahler | Chief Information Officer |
| 11. Deborah H. Telman | General Counsel |

The terms of Mr. Ali's and Mr. Walsh's offer letters and the general compensation arrangements for our other anticipated executive officers are summarized in the section entitled "*Offer Letters with our Executive Officers.*"

Organon's Anticipated Executive Compensation Programs

Overview

As described above, our Talent Committee will review each of the elements of Merck's compensation programs and may make adjustments that it believes are appropriate in structuring our executive compensation arrangements. At this time, we expect that Organon's executive compensation program will provide for base salaries, annual cash incentive awards, and long-term incentive equity awards. We believe that the spin-off will enable us to offer our key employees compensation directly linked to the performance of our business, which will enhance our ability to attract, retain and motivate qualified personnel to promote the long-term success of our business, in line with the interests of our stockholders.

Offer Letters with Anticipated Executive Officers

Offer Letter with Chief Executive Officer

In October of 2020, Merck entered into an offer letter with Mr. Ali appointing him as Chief Executive Officer of Organon in connection with the legal separation of Organon from Merck. The letter provides Mr. Ali with an annual base salary of \$1,100,000 and an annual cash incentive target opportunity equal to 125% of his annual base salary. Mr. Ali was provided an equity award with a total target grant value of \$8,000,000, \$3,200,000 of which was granted in March of 2021 the form of performance share units (PSUs), which are currently subject to the achievement of operating cash flow and cumulative earnings per share performance criteria over a three-year performance period, and the remainder of which is to be granted 50% in the form of stock options and 50% in the form of time-based RSUs in May of 2021 per Merck's typical grant practices and grant timing. Like all 2021 grants of PSUs to Organon employees, these PSUs are expected to be converted into an award of Organon time-based RSUs in connection with the Separation. Please see the section titled "Certain Relationships and Related Party Transactions" for additional detail on the adjustment of these long-term incentive equity awards in connection with the legal separation of Organon from Merck.

Offer Letter with Chief Financial Officer

In March of 2020, Merck entered into an offer letter with Mr. Walsh appointing him as Executive Vice President and Chief Financial Officer of Organon upon the legal separation of Organon from Merck. The letter provides Mr. Walsh with an annual base salary of \$800,000 and an annual cash incentive target opportunity equal to 80% of his annual base salary. Mr. Walsh is also eligible for an annual long-term incentive award with an initial target annual opportunity of \$3,000,000. In August 2020, Mr. Walsh received a grant valued at approximately \$2,600,000 in the form of Merck time-based RSUs that vest in equal annual installments over three years from the grant date (the "2020 Annual Grant"). The 2020 Annual Grant will convert into an Organon equity award as described in the section titled "*Certain Relationships and Related Party Transactions—Agreements with Merck—Equity Compensation Awards*." In addition, Mr. Walsh received a \$200,000 cash sign-on bonus, which is subject to repayment upon Mr. Walsh's voluntary resignation or termination of employment by Merck or Organon for Cause (as defined in the offer letter) prior to March 24, 2022 (the "Repayment Provision").

The offer letter provides that if Mr. Walsh's employment is (i) terminated by Merck other than for Cause (as defined in the offer letter) prior to the legal separation of Organon from Merck or (ii) the legal separation of Organon from Merck is not consummated prior to January 1, 2022 and Mr. Walsh terminates his employment on or prior to January 31, 2022, Mr. Walsh will be entitled to (1) severance benefits equal to the sum of his current annual base salary and his target annual incentive bonus for the current performance year, (2) the Repayment Provision will be waived and (3) to the extent such termination of employment occurs prior to the one year anniversary of the 2020 Annual Grant, an additional amount equal to the sum of the value of the 2020 Annual Grant multiplied by a fraction, the numerator of which is the number of months Mr. Walsh was employed since the grant date and a denominator of which is 36.

Other Executive Officer Arrangements

The compensation arrangements for our other anticipated executive officers generally provide for the following primary elements of compensation: (i) annual base salary, (ii) an annual cash incentive opportunity, (iii) eligibility for annual long-term incentive awards, and (iv) severance entitlements. Each offer letter provides for general participation in retirement and benefits plans commensurate with those provided to other executives of the Organon business.

Executive Severance Programs

In connection with the Separation, Organon intends to adopt an Executive Severance Program (the "Severance Plan"). The Severance Plan would provide payments and benefits to certain eligible members of Organon's

management team, including each of the executive officers in the event of a termination of employment without cause (as defined in the Severance Plan). Payments and benefits under the Severance Plan would be conditioned upon execution of a release of claims, which may contain restrictive covenants, and would include (i) a lump sum cash payment in an amount equal to 1.0 times (or 2.0 times in the case of the Chief Executive Officer) the sum of the executive officer's annual base salary and target annual cash incentive opportunity; (ii) if such termination occurs between June 30 and December 31 of a year, a pro-rata annual cash incentive payment based on the executive officer's target incentive opportunity for the year of termination, and (iii) subsidized medical and dental coverage for up to 24 months. The Severance Plan would not provide for any payments or benefits upon a termination for cause or any resignation of an eligible employee's employment. Furthermore, severance payments and benefits will be subject to forfeiture in the event and employee breaches any obligations of his or her terms and conditions of employment or makes any false or misleading statements about Organon or any of its affiliates or their products, officers or employees to competitors, customers, potential customers or to current employees or former employees.

In addition to the Severance Plan, Organon also intends to adopt an Executive Change in Control Severance Program (the "CIC Severance Plan"). The CIC Severance Plan will provide "double trigger" severance payments and benefits to eligible employees, including the executive officers, in the event of a termination of employment without cause or a resignation for good reason (each as defined in the CIC Severance Plan) during the six-month period prior to or the two-year period following a change in control (as defined in CIC Severance Plan). Payments and benefits under the CIC Severance Plan would be conditioned upon execution of a release of claims and would include (i) a lump sum cash payment in an amount equal to 2.0 times the sum of the executive officer's annual base salary and target annual cash incentive opportunity; (ii) a pro-rata annual cash incentive payment based on the executive officer's target incentive opportunity for the year of termination, and (iii) a lump sum cash payment intended to offset the costs of continued medical and dental coverage for up to 24 months.

The Severance Plan and the CIC Severance Plan will also provide minimum guaranteed cash benefits should a participant be entitled to greater cash separation pay benefits under Merck's existing severance plans.

Other Employee Benefits

In connection with the Separation, Organon will adopt core employee benefits plans, generally consisting of retirement, separation pay, paid time off, medical (excluding retiree medical), dental, vision, life, short-term and long-term disability plans or coverage, as of or prior to the distribution date and Organon employees generally will be eligible to participate in such benefit plans as of the distribution date. In general, Organon core benefit plans will contain terms substantially comparable in the aggregate to those of the corresponding Merck plans, although Organon is not currently expected to implement any U.S.-defined benefit pension, deferred compensation, or retiree welfare benefit plans.

2021 Incentive Stock Plan

Prior to the Separation, we expect our Board of Directors to adopt, and Merck, as our sole shareholder to approve, the Organon & Co. 2021 Incentive Stock Plan (the "Equity Plan") for the benefit of certain of our current and future employees. The following summary describes the material terms of the Equity Plan. The form of the Equity Plan is filed as an exhibit to the registration statement on Form 10 of which this information statement forms a part, and the following discussion is qualified in its entirety by reference to such text.

Purpose. The purpose of the Equity Plan will be to encourage employees of Organon, its subsidiaries, its affiliates and its joint ventures to acquire common stock in Organon, and to allow such individuals to have a greater personal financial interest in Organon through the ownership of, or the right to acquire, our common stock and to earn cash incentives based on the achievement of performance goals, which in turn will stimulate such individuals' efforts on the company's behalf and maintain and strengthen their desire to remain with the company. The Equity Plan is also expected to assist in the recruitment and retention of service providers.

Shares Available for Awards. It is expected that the maximum aggregate number of shares of our common stock that may be issued under the Equity Plan will not exceed 35,000,000. In addition, it is expected that the

Equity Plan will contain a limit on the number of shares of common stock available for grant in the form of incentive stock options of 35,000,000.

Under the Equity Plan, it is expected that Organon will have the flexibility to grant different types of equity compensation awards, including stock options, stock appreciation rights, restricted stock, performance awards, share awards, phantom stock awards (including restricted stock units), and cash-based awards. The grant, vesting, exercise and settlement of awards granted under the Equity Plan may be subject to the satisfaction of time- or performance-based conditions, as determined at or after the date of grant of an award under the Equity Plan.

In the event of any change in corporate structure that affects our outstanding common stock (e.g., a reorganization, recapitalization, reclassification, stock split or reverse stock split, stock dividend, extraordinary cash dividend, combination or exchange of shares, repurchase of shares, merger, consolidation, rights offering, spin off, split off, split up, change in corporate structure, or other similar event), our Talent Committee will make equitable adjustments including adjustments to the share limits described above, the number and type of shares subject to outstanding awards, and the purchase or exercise price of outstanding awards.

Shares that are subject to awards that are settled in cash, terminate, expire, or are canceled or forfeited, or are tendered or withheld to satisfy the payment of any exercise price or tax withholding obligations would be available again for grant under the Equity Plan and would not be counted for purposes of the limits above.

Eligibility. Employees of Organon or its subsidiaries, affiliates and joint ventures would be eligible to receive awards under the Equity Plan.

Administration. Our Talent Committee or any designated subcommittee thereof would have the authority to administer the Equity Plan, including the authority to select the persons who receive awards, determine the number of shares subject to the awards and establish the terms and conditions of the awards, consistent with the terms of the Equity Plan. Our Talent Committee may specify the circumstances under which the exercisability or vesting of awards may be accelerated or whether awards or amounts payable under awards may be deferred. Our Talent Committee may waive or amend the terms of an award, consistent with the terms of the Equity Plan, but unless approved by our stockholders, may not adjust or reduce the exercise price of any outstanding stock appreciation rights or stock options in the event of a decline in our stock price, either by reducing the exercise price of outstanding awards or through cancellation of outstanding awards in connection with regranting of awards at a lower price to the same individual, nor may stock appreciation rights or stock options be cancelled in exchange for a cash payment to account for a decline in stock price. Our Talent Committee will have the authority to construe and interpret the Equity Plan and establish rules for the administration of the Equity Plan and any agreement or instrument relating to the Equity Plan. Our Talent Committee may delegate its powers and duties under the Equity Plan to one or more officers of the Company or one of its subsidiaries, except that only our Talent Committee would have authority to grant and administer awards to executive officers.

Duration; Amendment; Termination. Unless earlier discontinued by action of our Board of Directors, the Equity Plan will terminate on the tenth anniversary of the date of its approval by our Board, and no further awards may be granted under the Equity Plan after the end of the term; however, awards previously granted thereunder may extend beyond such date. Our Board of Directors may discontinue the Equity Plan at any time and may from time to time amend or revise the terms of the Equity Plan as permitted by applicable statutes, except that it may not, without the consent of the participants affected, revoke or alter outstanding awards in a manner that is materially unfavorable to the award holders, nor may the board of directors amend the Equity Plan without stockholder approval where the absence of such approval would cause the Equity Plan to fail to comply with applicable law or listing standards to which we are subject.

Transfer Restrictions. The rights of a participant to any award granted under the Equity Plan will be exercisable during the participant's lifetime only by the participant and generally will not be transferable other than by will or the laws of descent and distribution. The Talent Committee may, however, permit other transferability, subject to any conditions and limitations that it imposes.

Clawback; Recoupment. Awards under the Equity Plan will be subject to the terms of any clawback policy maintained by Organon or as required by law and any reduction, cancellation, forfeiture, clawback or recoupment provisions specified by the Talent Committee in an applicable grant agreement.

Tax Consequences of Awards. The following is a brief summary of the principal United States federal income tax consequences of awards and transactions under the Equity Plan for the employees selected to participate in the Equity Plan (the “Participants”) and Organon. This summary is not intended to be exhaustive and, among other things, does not describe local, state or foreign tax consequences.

Options and Stock Appreciation Rights. A Participant will not recognize any income at the time a stock option or stock appreciation right is granted, nor will Organon be entitled to a deduction at that time. When a non-qualified stock option is exercised, the Participant will recognize ordinary income in an amount equal to the excess of the fair market value of the shares received as of the date of exercise over the exercise price of the option. When a stock appreciation right is exercised, the Participant will recognize ordinary income in an amount equal to the cash received or, if the stock appreciation right is settled in shares, the shares received as of the date of exercise. Organon generally will be entitled to a corresponding tax deduction in the same time period and amount as the Participant recognizes income. When an incentive stock option is exercised, the Participant will not recognize any income and Organon will not be entitled to any tax deduction; provided, however, that the amount equal to the excess of the fair market value of the shares received as of the date of exercise over the exercise price will be subject to taxation under the alternative minimum tax provisions of the Code. When an incentive stock option is sold, the Participant will recognize ordinary income in an amount equal to the excess of the sales price over the price of the option on the date of grant and Organon will be entitled to a corresponding tax deduction.

Restricted Stock and RSUs. A Participant will not recognize any income at the time of grant of a restricted stock unit or share of restricted stock (whether subject to time-based vesting or performance-based vesting), and Organon will not be entitled to a deduction at that time. The Participant will recognize ordinary income in an amount equal to the fair market value of the shares received or, if the restricted stock unit is paid in cash, the amount payable, upon settlement of a restricted stock unit. In the year in which shares of restricted stock are no longer subject to a substantial risk of forfeiture (i.e., in the year that the shares vest), the Participant will recognize ordinary income in an amount equal to the excess of the fair market value of the shares on the date of vesting over the amount, if any, the Participant paid for the shares. Under certain circumstances and if permitted by an individual award, a Participant may elect (within 30 days after being granted restricted stock) under Code Section 83(b) to recognize ordinary income in the year of receipt instead of the year of vesting of such restricted stock. If such an election is made, the amount of income recognized by the Participant will be equal to the excess of the fair market value of the shares on the date of receipt over the amount, if any, the Participant paid for the shares. Organon generally will be entitled to a corresponding tax deduction in the same time period and amount as the Participant recognizes income.

Other Types of Awards. If other awards are granted under the Equity Plan, the tax consequences may differ from those described above for stock options, stock appreciation rights, restricted stock and RSUs. As a general matter, Organon typically would be entitled to a tax deduction in respect of any such compensatory awards in the same time period and amount as the Participant recognizes income in respect of such awards, provided, however, that any compensation in excess of \$1,000,000 earned by Organon’s listed officers who are subject to Section 162(m) of the Code will not be deductible.

Withholding of Taxes. Organon has the right to deduct from any payment under the Plan, regardless of the form of such payment, the amount of all applicable income, excise and employment taxes required or permitted by law to be withheld with respect to such payment or may require Participants to pay to the company such tax prior to and as a condition of the making of such payment.

Certain Relationships and Related Party Transactions

Agreements with Merck

The Separation and Distribution Agreement

The separation and distribution agreement will set forth the agreements between Merck and Organon regarding the principal transactions required to effect the separation of the Organon business from Merck and contain other agreements governing Organon's relationship with Merck. For purposes of this agreement, the Organon business means developing, manufacturing, commercializing, distributing and selling the products within women's health, biosimilars and established brands to be transferred by Merck to Organon as described herein, and manufacturing activities and all ancillary and related operations occurring at Organon's six manufacturing facilities.

The separation and distribution agreement will identify assets to be transferred, liabilities to be assumed and contracts to be assigned to each of Organon and Merck as part of the separation, and it will provide for when and how these transfers, assumptions and assignments will occur. In particular, the separation and distribution agreement will provide, among other things, that, subject to the terms and conditions contained therein:

- certain assets that relate to the Organon business, and any other assets specified in the separation and distribution agreement, which are collectively referred to as the Organon assets, will be transferred to Organon or one of Organon's subsidiaries;
- certain liabilities that relate to, arise out of or result from the Organon business or an Organon asset, and any other liabilities specified in the separation and distribution agreement, which are collectively referred to as the Organon liabilities, will be transferred to Organon or one of Organon's subsidiaries; and
- all of Merck's assets and liabilities other than the Organon assets and Organon liabilities, as well as certain obligations for certain existing legal proceedings, will be retained by or transferred to Merck or one of its subsidiaries (such assets and liabilities are referred to as the Merck assets and Merck liabilities, respectively).

Except as expressly set forth in the separation and distribution agreement or any ancillary agreement, neither Organon nor Merck will make any representation or warranty as to the assets, business or liabilities transferred, licensed or assumed as part of the separation, as to any approvals or notifications required in connection with the transfers, as to the absence or presence of any defenses to or right of setoff against or freedom from counterclaim with respect to any claim or other asset of either Organon or Merck, or as to the legal sufficiency of any conveyance and assumption instruments or other ancillary agreements to convey title to any asset or thing of value to be transferred in connection with the separation. Except as set forth in the separation and distribution agreement or any ancillary agreement, all assets will be transferred or licensed on an "as is," "where is" basis and the respective transferees or licensees will bear the economic and legal risks that any conveyance will prove to be insufficient to vest in the transferee good and marketable title, free and clear of all security interests, and that any necessary consents are not obtained or that any requirements of laws, agreements, security interests or judgments are not complied with.

Subject to certain specified matters, each of Merck and Organon generally will assume liability for all pending, threatened and unasserted legal matters related to its own business or its assumed or retained liabilities and will indemnify the other party for any liability to the extent arising out of or resulting from such assumed or retained legal matters. In addition, the separation and distribution agreement will provide for cross-indemnities principally designed to place financial responsibility for the obligations and liabilities of the Organon business with Organon and financial responsibility for the obligations and liabilities of Merck's remaining business with Merck. Specifically, each of Organon and Merck will indemnify, defend and hold harmless the other party, its

subsidiaries and their respective directors, officers, employees and agents against any liabilities relating to, arising out of or resulting from, directly or indirectly:

- the liabilities that each such party assumed or retained pursuant to the separation and distribution agreement (which, in the case of Organon, would include the Organon liabilities and, in the case of Merck, would include the Merck liabilities);
- in the case of Organon, the conduct of any business, operation or activity by it or any of its subsidiaries following the distribution;
- in the case of Merck, the conduct of any business, operation or activity by it or any of its subsidiaries following the distribution, other than as conducted on behalf of Organon or any of its subsidiaries;
- any breach by such party of the separation and distribution agreement or any ancillary agreements (subject to the limitations, if any, expressly set forth in such agreements);
- in the case of Organon, any untrue statement or alleged untrue statement of a material fact or omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, with respect to all information contained in this information statement or the registration statement on Form 10 to which this information statement forms a part, except to the extent expressly supplied by Merck; and
- in the case of Merck, any untrue statement or alleged untrue statement of a material fact expressly supplied by Merck for use in this information statement or the registration statement on Form 10 to which this information statement forms a part.

The separation and distribution agreement also will specify procedures with respect to claims subject to indemnification and related matters.

Each of the parties will agree to use commercially reasonable efforts to take or to cause to be taken all actions, and to do, or to cause to be done, all things necessary or advisable under applicable law or contractual obligations to consummate the transactions contemplated by the separation and distribution agreement and the ancillary agreements.

The separation and distribution agreement will also govern the rights and obligations of Merck and Organon regarding the distribution. The separation and distribution agreement will provide that Merck's obligation to complete the distribution is subject to several conditions that must be satisfied (or waived by Merck in its sole discretion), which are described in "The Separation and Distribution—Conditions to the Distribution." Under the separation and distribution agreement, following the distribution, Organon and Merck will be obligated to provide each other access to information in certain circumstances. The separation and distribution agreement also will impose obligations with respect to retention of information and confidentiality.

The separation and distribution agreement will provide for the allocation among the parties of rights and obligations under existing insurance policies with respect to occurrences prior to completion of the distribution. In addition, the separation and distribution agreement will allocate between the parties the right to proceeds and the obligation to incur certain deductibles under certain insurance policies. The separation and distribution agreement will further include procedures governing the parties' obligations and allocate liabilities with respect to ongoing litigation matters that may implicate each of Merck's business and Organon's business.

Transition Services Agreements

Merck and Organon will enter into a transition services agreement pursuant to which Merck and certain of its affiliates will provide Organon and certain of its affiliates, on an interim, transitional basis, various services. The services to be provided by Merck will include, among others, information technology, human resources, finance, quality, regulatory, supply chain management, promotional services, distribution services and certain

other services, and will generally be provided on a cost or, where applicable, a cost-plus basis. The services generally will commence on the separation date and generally will terminate within 25 months following the separation date. Organon will have the right to request the early termination of any or all services generally with advance notice.

Similarly, Organon and Merck will enter into a reverse transition services agreement pursuant to which Organon and certain of its affiliates will provide Merck and certain of its affiliates, on an interim, transitional basis, various services. The services to be provided by Organon will include quality, regulatory, supply chain management, promotional services, distribution services and certain other services and will generally be provided on a cost or, where applicable, a cost-plus basis. The provision of services under the agreement generally will commence on the separation date and terminate within 25 months following the separation. Merck will have the right to request the early termination of any or all services generally with advance notice.

Interim Operating Agreements

Merck and Organon will enter into a series of interim operating agreements pursuant to which Merck and certain of its affiliates that held licenses, permits and other rights in connection with marketing, import and/or distribution of Organon products in various jurisdictions prior to the separation will continue to market, import and distribute such products until such time as the relevant licenses and permits are transferred to Organon or its affiliates, while permitting Organon (or Merck, as applicable) to recognize revenue relating to the sale of its products, to the extent practicable. Under such interim operating agreements and in accordance with the separation and distribution agreement, the relevant Merck entity will continue operations in the affected market on behalf of Organon, with Organon receiving all of the economic benefits and burdens of such activities.

Regulatory Agreements

In connection with the separation, Merck and Organon and/or their applicable affiliates will enter into one or more agreements addressing certain governance and other matters during the transition period in which the relevant Merck or Organon entity, as applicable, continues to hold required marketing authorizations or other regulatory obligations relating to Organon products in certain jurisdictions. These agreements will contain provisions relating to decision rights related to regulatory matters (including regulatory provision of certain commercialization activities), responsibility for post-approval activities needed to achieve or maintain relevant marketing authorizations, recall rights and product inquiries and other related issues that would not be otherwise covered by the transition services agreement.

Manufacturing and Supply Agreements

Merck and Organon and/or their applicable affiliates will enter into a number of manufacturing and supply agreements pursuant to which the relevant Merck entity will (a) manufacture and supply certain active pharmaceutical ingredients for the relevant Organon entity, (b) toll manufacture and supply certain formulated pharmaceutical products for such Organon entity, and (c) package and label certain finished pharmaceutical products for such Organon entity. The term of the manufacturing and supply agreements will generally range in initial duration from four to seven years, with the right to extend the initial term of the agreements upon mutual agreement of the parties. The manufacturing and supply obligations will generally be performed on pricing terms established on an arm's-length basis. The manufacturing and supply agreements will be subject to early termination in certain instances such as an uncured material breach or bankruptcy-related events of the other party, but will not be subject to early unilateral voluntary termination. The parties will also enter into quality agreements with respect to the products to be supplied.

Similarly, Organon and Merck and/or their applicable affiliates will enter into a number of manufacturing and supply agreements pursuant to which the relevant Organon entity will (a) manufacture and supply certain formulated pharmaceutical products for the relevant Merck entity, and (b) package and label certain finished

pharmaceutical products for such Merck entity. The term of the manufacturing and supply agreements will range in initial duration from four to seven years, with the right to extend the initial term of the agreements upon mutual agreement of the parties. The manufacturing and supply obligations will generally be performed on pricing terms established on an arms-length basis. The manufacturing and supply agreements will be subject to early termination in certain instances, such as an uncured material breach or bankruptcy-related events of the other party, but will not be subject to early unilateral voluntary termination. The parties also will enter into quality agreements with respect to the products to be supplied. In addition, Merck and Organon may enter into additional agreements for the supply of clinical or other materials and packaging, with terms generally consistent with the description above.

Liability that could be incurred by either party is capped for each manufacturing and supply agreement on an annual basis at the lesser of (i) four times the amount of total fees the supplying party is contractually forecasted to receive during the calendar year in which the events causing such liability arose; (ii) \$50 million under the particular manufacturing and supply agreement; or (iii) \$100 million in the aggregate across all manufacturing and supply agreements executed by the parties (and/or their affiliates) in connection with the separation. The \$100 million cap is eliminated with respect to a particular manufacturing and supply agreement if a third party becomes a party to that manufacturing and supply agreement.

Trademark License Agreements

Pursuant to individual country asset transfer or demerger agreements, Merck or its applicable affiliate will assign to Organon or its applicable affiliate those trademarks that are exclusively associated with the products that will be owned by Organon. In addition, Merck and Organon and/or their applicable affiliates will enter into trademark license agreements pursuant to which the relevant Merck entity will grant to Organon or its applicable affiliate a royalty-free, exclusive as to field of use, worldwide license under certain product-related trademarks. Such worldwide licenses would allow for Organon to continue to use the related trademarks following the separation to commercialize the applicable Organon products, including, among other things, for use on packaging and labeling as well as for certain promotional materials. This license will be granted on a perpetual basis, but will be subject to certain termination rights such as an uncured material breach or bankruptcy-related events of the other party.

Merck and Organon and/or their applicable affiliates will also enter into licenses to allow Organon to use Merck's corporate name trademarks on a transitional basis. Under these licenses, the relevant Merck entity will grant to Organon or its applicable affiliate a non-exclusive, royalty-free, worldwide license under certain corporate name trademarks in order for Organon to continue to use these corporate name trademarks, as were being used prior to the separation with the Organon products, for a period of time while Organon rebrands or phases out its use of these corporate name trademarks with these Organon products, including, among other things, for use on packaging and labeling, promotional materials and embossing of Organon's products. These licenses will be time-limited, and Organon will generally be required to use efforts to transition away from use of these corporate name trademarks. This license would be subject to certain termination rights, such as an uncured material breach or a bankruptcy-related event of the other party.

Merck and Organon and/or their applicable affiliates will also enter into licenses to allow Merck to use Organon's corporate name trademarks on a transitional basis. Under these licenses, the relevant Organon entity will grant to Merck or its applicable affiliate a non-exclusive, royalty-free, worldwide license under certain corporate name trademarks in order for Merck to continue to use these corporate name trademarks, as were being used prior to the separation with the Merck products, for a period of time while Merck rebrands or phases out its use of these corporate name trademarks with these Merck products, including, among other things, for use on packaging and labeling and promotional materials of Merck's products. These licenses will be time-limited, and Merck will generally be required to use efforts to transition away from use of these corporate name trademarks. This license would be subject to certain termination rights, such as an uncured material breach or a bankruptcy-related event of the other party.

Intellectual Property License Agreements

Merck and Organon and/or their applicable affiliates will enter into a number of intellectual property license agreements pursuant to which the relevant Merck entity will grant to Organon or its applicable affiliate an exclusive as to the specific field of use, license in the applicable territories under certain patents (or, in some cases, certain patents and know-how) for certain development programs or that were otherwise being used with the Organon products prior to the separation in order for Organon or its applicable affiliate to continue to use these patents and know-how following the separation for the applicable development programs or Organon products. These licenses will be royalty-free for products in the Organon portfolio. These licenses would be granted on a perpetual basis or until the expiration of the relevant patent, but would be subject to certain termination rights such as an uncured material breach or bankruptcy-related events of the other party.

In addition, Merck and Organon and/or their applicable affiliates will enter into a number of intellectual property license agreements pursuant to which the relevant Merck entity will grant to Organon or its applicable affiliate licenses with regard to certain development programs that are outside of the Organon product portfolio. These licenses are either (i) royalty-bearing and exclusive as to the specific field of use in the applicable territories under certain know-how or (ii) royalty-free and non-exclusive as to the specific field of use in the applicable territories under certain know-how, in each case in order for Organon or its applicable affiliate to continue to use this know-how following the separation for the applicable development programs. These licenses would be granted on a perpetual basis or until the expiration of the relevant patent, but would be subject to certain termination rights such as an uncured material breach or bankruptcy-related events of the other party.

Merck and Organon and/or their applicable affiliates will enter into a know-how license agreement pursuant to which the relevant Merck entity will grant Organon or its applicable affiliate a royalty-free, non-exclusive and worldwide license under certain know-how that will not transfer in connection with the separation in order for Organon to continue to use this know-how following the separation for certain uses being used by Organon as of the separation date. This license would be granted on a perpetual basis.

Similarly, Organon and Merck and/or their applicable affiliates will enter into a know-how license agreement pursuant to which the relevant Organon entity will grant Merck a royalty-free and worldwide license under certain know-how that will transfer from Merck to Organon in connection with the separation in order for Merck to continue to use this know-how following the separation. This license will be granted on a perpetual basis and will be non-exclusive for human health uses, and exclusive for animal health uses.

Tax Matters Agreement

In connection with the separation, Merck and Organon will enter into a tax matters agreement that will govern the parties' respective rights, responsibilities and obligations with respect to taxes (including responsibility for taxes, entitlement to refunds, allocation of tax attributes, preparation and filing of tax returns, control of tax contests, and other tax matters). The tax matters agreement also will provide for cooperation between Merck and Organon with respect to tax matters, the exchange of information and the retention of records that may affect the tax liabilities of the parties to the agreement.

The tax matters agreement will allocate responsibility for all U.S. federal income, state and foreign income, franchise, capital gain, withholding and similar taxes, as well as all non-income taxes. While general terms will apply to allocate responsibility for income taxes and non-income taxes between Merck and Organon, certain income and non-income taxes (or categories of income and non-income taxes) will be specifically addressed in the tax matters agreement. In particular, Merck generally will be responsible for any income taxes reportable on an originally filed consolidated, combined or unitary return that includes Merck or any of its subsidiaries (and Organon and/or any of our subsidiaries) for any periods or portions thereof ending on or prior to the distribution date. Organon generally will be responsible for any income taxes that are reportable on originally filed returns that include only Organon and/or any of its subsidiaries, for all tax periods. Additionally, as a general matter,

Merck will be responsible for certain income and non-income taxes imposed as the direct result of the separation or of an internal separation transaction. Organon will be responsible for certain taxes that exclusively relate to Organon's business and for taxes resulting from any breach of certain representations or covenants that Organon will make in the tax matters agreement.

Neither party's obligations under the agreement will be limited in amount or subject to any cap. Merck will be primarily responsible for preparing and filing any tax return with respect to the Merck affiliated group for U.S. federal income tax purposes and with respect to any consolidated, combined, unitary or similar group for U.S. state or local or foreign tax purposes that includes Merck or any of its subsidiaries (including those that also include Organon and/or any of its subsidiaries), as well as any tax return that includes only Merck and/or any of its subsidiaries (including such tax returns that reflect taxes attributable to Organon's business). Organon generally will be responsible for preparing and filing any tax returns that include only Organon and/or any of its subsidiaries. The party responsible for preparing a given tax return generally will have exclusive authority to control tax contests related to any such tax return. Organon generally will have exclusive authority to control tax contests with respect to tax returns that include only Organon and/or any of its subsidiaries.

The tax matters agreement will impose certain restrictions on Organon and its subsidiaries during the two-year period following the distribution that will be intended to prevent the distribution and certain related transactions from failing to qualify as tax-free for U.S. federal income tax purposes under Sections 355 and 368 of the Code or for other applicable non-U.S. income tax purposes. Specifically, during such period, Organon and its subsidiaries will be prohibited, except in specific circumstances, from, among other things, (1) ceasing to actively conduct certain businesses or causing our applicable affiliates to cease to actively conduct certain of their businesses; (2) entering into certain transactions or series of transactions pursuant to which all or a portion of the shares of Organon common stock would be acquired or all or a portion of certain assets of Organon and its subsidiaries would be acquired; (3) liquidating, partially liquidating, merging or consolidating with any other person; (4) issuing equity securities beyond certain thresholds; (5) repurchasing Organon stock other than in certain open-market transactions; (6) making certain amendments to Organon's certificate of incorporation and other organizational documents; and (7) taking or failing to take any other action that would cause the distribution or certain related transactions to fail to qualify as tax-free for U.S. federal income tax purposes under Sections 355 and 368 of the Code or for other applicable non-U.S. income tax purposes.

The tax matters agreement will provide special rules that allocate tax-related losses in the event that the separation, distribution or other related transactions that are intended to qualify as tax-free fail to so qualify. Under the tax matters agreement, each of Merck and Organon generally will be responsible for any tax-related losses imposed on Merck or Organon as a result of the failure of a transaction to qualify for tax-free treatment, to the extent that the failure to so qualify is attributable to actions, events or transactions relating to Merck's or Organon's respective stock, assets or business, or a breach of the relevant covenants made by Merck or Organon in the tax matters agreement. If such tax-related losses are not specifically allocable to Merck or Organon, each party will be responsible for a specified portion of such tax-related loss.

Employee Matters Agreement

Merck will also enter into an employee matters agreement with Organon. The employee matters agreement will allocate assets, liabilities and responsibilities relating to employee compensation and benefit plans and programs and other related matters in connection with the separation both in and outside of the United States.

The employee matters agreement will provide that, unless otherwise specified, Organon will be responsible for liabilities associated with employees who transfer to Organon, former employees whose last employment was with a manufacturing plant or entity located outside of the United States that wholly transfers to Organon, and individual independent contractors associated with Organon. Merck will be responsible for liabilities associated with employees retained by Merck, all other former employees, and all individual independent contractors associated with the Merck group or business.

Organon will adopt core employee benefits plans, generally consisting of retirement, separation pay, paid time off, medical (excluding retiree medical), dental, vision, life, short-term and long-term disability plans or coverage, as of or prior to the distribution date and Organon employees generally will be eligible to participate in such benefit plans as of the distribution date. In general, Organon core benefit plans will contain terms substantially comparable in the aggregate to those of the corresponding Merck plans; provided that Organon will not be required to implement any U.S.-defined benefit pension, deferred compensation, or retiree welfare benefit plans.

Merck will retain liability for U.S.-defined benefit pension, supplemental executive retirement, deferred compensation and retiree medical benefits for employees continuing with Merck, employees transferring to Organon and for former employees. The liability to employees transferred to Organon generally will be as to accrued benefits, but Merck will also provide service crediting to Organon employees transferred in connection with the Separation under these retained U.S.-defined benefit pension, supplemental executive retirement, and retiree medical plans for purposes of early retirement eligibility and subsidies, as well as for certain service crediting bridges for transferred Organon employees who would have otherwise met the eligibility requirements for such service crediting bridges on or prior to December 31, 2022. Although Merck will be responsible for providing these benefits, Organon will assume that portion of the aggregate incremental cost of providing early retirement subsidies, service crediting bridges, and retiree healthcare benefits under these programs that is attributable to future service, with such aggregate incremental cost as determined based on reasonable estimates in the discretion of the actuaries designated by Merck to calculate such amounts.

In general, Organon will provide, through December 31, 2022, each employee transferring to Organon in connection with the Separation with at least (i) the same rate of base salary, (ii) the same cash incentive and long-term incentive compensation opportunities, (iii) other core employee benefits that are substantially comparable in the aggregate to those provided prior to the earlier of the distribution date or the date as of which the comparable Organon core employee benefit plan is established or adopted, and (iv) the same separation pay and comparable post-termination medical, dental & life benefits continuation (excluding retiree medical and life insurance).

Equity Compensation Awards

The employee matters agreement will provide for the adjustment or conversion of all outstanding Merck equity awards as follows:

- *Options and RSU Awards.* As of the distribution date, all Merck stock options and time-based restricted stock unit (RSU) awards (whether then-vested or unvested) will be converted into (1) adjusted Merck awards for Merck employees, employees transferring to Organon at any time following the distribution date (each, a “Post-Distribution Organon Employee”) and any former employees or (2) Organon awards for Organon employees (other than Post-Distribution Organon Employees). Such adjusted awards will preserve the same intrinsic value and general terms and conditions (including vesting) as were in place immediately prior to the adjustments.
- Performance Share Units
 - For any Merck performance share unit (PSU) awards held by Merck employees, Post-Distribution Organon Employees and any former employees, the performance goals will be equitably adjusted to reflect the spin-off and the number of units subject to such awards will be determined on the same basis described above with respect to RSU awards. Such Merck PSU awards will otherwise settle in the ordinary course.
 - For any 2019 PSU awards with a 2019-2021 performance period held by Organon Employees (other than Post-Distribution Organon Employees), performance will be assessed based on a truncated performance period that ends on December 31, 2020 and attained performance through such date will be applied to 100% of the award. As of the distribution date, such earned award will

then be converted into a time-based Organon RSU award (on the same basis described above with respect to converted Organon RSU Awards) that otherwise vests in accordance with the previously applicable time-based vesting schedule.

- For any 2020 and 2021 PSU awards with a 2020-2022 or 2021-2023 performance period held by Organon employees (other than Post-Distribution Organon Employees), performance will be deemed to have been met at the target level. As of the distribution date, such award will then be converted into a time-based Organon RSU award (on the same basis described above with respect to converted Organon RSU Awards) that otherwise vests in accordance with the previously applicable time-based vesting schedule.
- *Adjusted Merck Phantom Shares & Deferred Stock Units.* Each Merck phantom share outstanding under the Merck Deferred Compensation Plan and each Merck deferred stock unit granted under the Merck Directors Plan as of immediately prior to the distribution date will be converted at the time of the distribution on the distribution date into an adjusted Merck phantom share or deferred stock unit, as applicable, with the number of units represented by such award adjusted to preserve the aggregate value of the original Merck phantom shares as measured immediately before and immediately after the distribution.

Annual Bonus

Organon will assume all obligations for post-distribution incentive compensation payments to transferring Organon employees, including for all 2021 annual bonuses.

Other Related Person Transactions

In January 2020, Merck entered into a consulting agreement with Carrie Cox, who will serve as Chairman of our Board of Directors upon the completion of the distribution. Under the consulting agreement, Ms. Cox is entitled to a monthly fee of \$9,500 in exchange for her performance of certain consulting services to Merck relating to her anticipated Chairmanship at Organon and reimbursement of reasonable out-of-pocket expenses. In addition, as a former employee of Merck, Ms. Cox received a non-qualified deferred compensation plan distributions from Merck (that is not conditioned on future services) of \$1,560,423 in 2019. No distributions were made in 2020 or are expected to be made in 2021. In addition, Ms. Cox currently holds retirement benefits in Merck's tax qualified 401(k) and pension plans, which are expected to be distributed commencing when she reaches age 65.

Procedures for Approval of Related Person Transactions

Effective upon the completion of this distribution, our Board of Directors will adopt a written policy regarding the review, approval, ratification or disapproval by the Audit Committee of transactions between us or any of our subsidiaries and any related person (to be defined in the policy to include our executive officers, directors or director nominees, any shareholder beneficially owning in excess of 5% of our stock or securities exchangeable for our stock and any immediate family member of any of the foregoing persons) in which the amount involved since the beginning of our last completed fiscal year will or may be expected to exceed \$120,000 and in which one or more of such related persons has a direct or indirect material interest. In approving or rejecting any such transaction, we expect that the Audit Committee will consider the relevant facts and circumstances available and deemed relevant to the committee. Any member of the Audit Committee who is a related person with respect to a transaction under review will not be permitted to participate in the deliberations or vote on approval, ratification or disapproval of the transaction.

Security Ownership of Certain Beneficial Owners and Management

Before the distribution, all of the outstanding shares of our common stock will be owned beneficially and of record by Merck. The following table sets forth information with respect to the expected beneficial ownership of our common stock upon the distribution by each expected director and named executive officer and all of Organon’s expected directors and named executive officers as a group. Organon based the share amounts on each person’s beneficial ownership of Merck’s common stock and stock options or other equity awards as of April 28, 2021 unless Merck indicates some other basis for the share amounts, and assume a distribution ratio of a one-tenth share of Organon’s common stock for every share of Merck’s common stock. The address of each director and executive officer shown in the table below is c/o Organon, 30 Hudson Street, 33rd Floor, Jersey City, New Jersey 07302.

Name	Shares Beneficially Owned	Stock Awards Currently Exercisable within 60 days of April 28, 2021	Percent of Class
Kevin Ali	4,108	16,383	*
Matthew Walsh	—	—	*
Kathryn DiMarco	803	—	*
Aaron Falcione	236	1,281	*
Susanne Fiedler	2,771	8,285	*
Sandra Milligan	1,973	10,202	*
Joseph T. Morrissey, Jr.	377	12,577	*
Vittorio Nisita	413	1,449	*
Geralyn S. Ritter	177	6,342	*
Rachel Stahler	—	—	*
Deborah H. Telman	—	—	*
Carrie S. Cox	—	—	*
Robert Essner	—	—	*
R. Alan Ezekowitz	—	—	*
Ma. Fatima D. Francisco	—	—	*
Helene D. Gayle	—	—	*
Rochelle B. Lazarus	635 ⁽¹⁾	—	*
Deborah R. Leone	11 ⁽²⁾	—	*
Martha E. McGarry	—	—	*
Phillip Ozuah	—	—	*
Cynthia M. Patton	—	—	*
Grace Puma	5 ⁽³⁾	—	*
Shalini Sharp	—	—	*
All directors and executive officers as a group (23 persons)	11,509	56,519	*

* None of the holdings represents holdings of more than 1% of Organon’s outstanding common stock.

- (1) Includes shares of common stock in which the beneficial owners share voting and/or investment power as follows: 175 shares held by Ms. Lazarus’ spouse.
- (2) Includes shares of common stock in which the beneficial owners share voting and/or investment power as follows: one share held in a joint trust.
- (3) Includes shares of common stock in which the beneficial owners share voting and/or investment power as follows: 5 shares held by Ms. Puma’s parent.

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The following table sets forth information with respect to the expected beneficial ownership of our common stock, upon the distribution, by each person who Organon believes will be a beneficial owner of 5% or more of Organon's outstanding common stock.

<u>Name and Address of Beneficial Owner</u>	<u>Amount and Nature of Beneficial Ownership of Organon's Common Stock</u>	<u>Percent of Class</u>
The Vanguard Group 100 Vanguard Blvd. Malvern, PA 19355	20,841,064(1)	8.2%
BlackRock, Inc. 55 East 52nd Street New York, NY 10055	19,621,380(2)	7.8%

- (1) Based on Amendment No. 6 to Schedule 13G (the "Vanguard filing") filed with the SEC on February 10, 2021 with respect to Merck common stock and applying the distribution ratio. According to the Vanguard filing, of the 208,410,644 shares of Merck common stock beneficially owned by The Vanguard Group ("Vanguard"), as of December 31, 2020, Vanguard has the shared power to vote or direct the vote with respect to 4,443,143 shares, sole power to dispose or to direct the disposition of 196,891,790 shares, and shared power to dispose or to direct the disposition of 11,518,854 shares.
- (2) As reported on Amendment No. 11 to Schedule 13G (the "BlackRock filing"), filed with the SEC on February 5, 2021 with respect to Merck common stock and applying the distribution ratio. According to the BlackRock filing, of the 196,213,804 shares of Merck common stock beneficially owned by BlackRock, Inc. ("BlackRock"), as of December 31, 2020, BlackRock has the sole power to vote or direct the vote with respect to 169,601,846 shares and sole power to dispose or to direct the disposition of 196,213,804 shares.

The Separation and Distribution

Background

On February 5, 2020, Merck announced that it intended to separate its women’s health, biosimilars and established brands businesses, and create a standalone pharmaceutical company. Merck announced that it intended to effect the separation through a pro rata distribution of all of the common stock of a new entity, which has since been named Organon and was formed to hold the assets and liabilities associated of the women’s health, biosimilars and established brands businesses.

On May 7, 2021, the Merck Board of Directors approved the distribution of all of Organon’s issued and outstanding shares of common stock to holders of shares of Merck common stock as of the close of business on May 17, 2021, the record date.

On June 2, 2021, the distribution date, each Merck shareholder will receive one-tenth of a share of Organon’s common stock for each share of Merck common stock held at the close of business on the record date. Merck shareholders will receive cash in lieu of any fractional shares of Organon common stock which they would have received after application of this ratio. Shareholders will not be required to make any payment, or surrender or exchange their shares of Merck common stock or take any other action to receive their shares of Organon’s common stock in the distribution. The distribution of Organon’s common stock as described in this information statement is subject to the satisfaction or waiver of certain conditions. For a more detailed description of these conditions, see the section entitled “—Conditions to the Distribution.”

Reasons for the Separation

The Merck Board of Directors believes that separating the women’s health, biosimilars and established brands businesses from the remainder of Merck is in the best interests of Merck and its shareholders for a number of reasons, including that it will:

- give each of Organon and Merck its own dedicated management team, focused on its unique business opportunities and capital needs, thereby allowing each business to pursue more effectively its own distinct operating priorities and strategies;
- give each of Organon and Merck its own source of capital dedicated to its own investment priorities, and allow each of Organon and Merck to implement a capital structure appropriate for its respective cash flow and growth profile;
- give each of Organon and Merck its own equity currency for use in connection with acquisitions; and
- enhance the ability of Organon and Merck to attract and retain qualified management and to better align incentive-based compensation with the performance of each of Organon and Merck’s separate businesses.

The Merck Board of Directors considered a number of potentially negative factors in evaluating the separation, including risks relating to the creation of a new public company and possible increased overall costs, as well as one-time separation costs, but concluded that the potential benefits of the separation outweighed these factors. For more information, see the sections entitled “The Separation and Distribution—Reasons for the Separation” and “Risk Factors” included elsewhere in this information statement.

When and How You Will Receive the Distribution

With the assistance of Equiniti Trust Company, Merck expects to distribute Organon common stock on June 2, 2021, the distribution date, to all holders of outstanding shares of Merck common stock as of the close of business on May 17, 2021, the record date. Equiniti Trust Company, which currently serves as the transfer agent and registrar for Merck’s common stock, will serve as the settlement and distribution agent in connection with the distribution and the transfer agent and registrar for Organon common stock.

For shareholders who own shares of Merck common stock as of the close of business on the record date, the shares of Organon's common stock that such shareholder is entitled to receive in the distribution will be issued electronically, as of the distribution date, to such shareholder in direct registration form or to such shareholder's bank or brokerage firm on the shareholder's behalf.

For shareholders who are registered holders, Equiniti Trust Company will then mail such shareholders a direct registration account statement that reflects such shares of Organon common stock. Direct registration form refers to a method of recording share ownership when no physical share certificates are issued to shareholders, as is the case in this distribution. Commencing on or shortly after the distribution date, for shareholders holding physical share certificates that represent their shares of Merck common stock and are the registered holder of the shares represented by those certificates, the distribution agent will mail to such shareholders an account statement that indicates the number of shares of Organon's common stock that have been registered in book-entry form in their names. Shareholders who elect to sell shares of Merck common stock in the "regular-way" market on or prior to the time of the distribution will be selling their right to receive shares of Organon common stock in the distribution.

Most Merck shareholders hold their common stock through a bank or brokerage firm. In such cases, the bank or brokerage firm would be said to hold the shares in "street name" and ownership would be recorded on the bank or brokerage firm's books. For shareholders holding their shares of Merck common stock through a bank or brokerage firm, such bank or brokerage firm will credit such shareholder's account for the Organon common stock that such shareholder is entitled to receive in the distribution. If you have any questions concerning the mechanics of having shares held in "street name," please contact your bank or brokerage firm.

Transferability of Organon Shares Received in the Distribution

Shares of Organon common stock distributed to shareholders in connection with the distribution will be transferable without registration under the Securities Act, except for shares received by persons who may be deemed to be Organon affiliates. Persons who may be deemed to be Organon affiliates after the distribution generally include individuals or entities that control, are controlled by or are under common control with Organon, which may include certain Organon executive officers, directors or principal shareholders. Securities held by Organon affiliates will be subject to resale restrictions under the Securities Act. Organon affiliates will be permitted to sell shares of Organon common stock only pursuant to an effective registration statement or an exemption from the registration requirements of the Securities Act, such as the exemption afforded by Rule 144 under the Securities Act.

The Number of Shares of Organon Common Stock You Will Receive

For each share of Merck common stock that you own at the close of business on May 17, 2021, the record date, you will receive one-tenth of a share of Organon common stock on the distribution date.

Merck will not distribute any fractional shares of Organon common stock to its shareholders. Instead, for holders of registered shares, Equiniti Trust Company will aggregate fractional shares into whole shares, sell the whole shares in the open market at prevailing market prices and distribute the aggregate cash proceeds (net of discounts and commissions) of the sales pro rata (based on the fractional share such holder would otherwise be entitled to receive) to each holder who otherwise would have been entitled to receive a fractional share in the distribution. The transfer agent, in its sole discretion, without any influence by Merck or Organon, will determine when, how, through which broker-dealer and at what price to sell the whole shares. Any broker-dealer used by the transfer agent will not be an affiliate of either Merck or Organon. Neither Organon nor Merck will be able to guarantee any minimum sale price in connection with the sale of these shares. Recipients of cash in lieu of fractional shares will not be entitled to any interest on the amounts of payment made in lieu of fractional shares.

The aggregate net cash proceeds of these sales will be taxable for U.S. federal income tax purposes. See "Material U.S. Federal Income Tax Consequences" for an explanation of the material U.S. federal income tax

consequences of the distribution. For a holder of physical certificates for shares of Merck common stock who is also the registered holder, such holder will receive a check from the distribution agent in an amount equal to your pro rata share of the aggregate net cash proceeds of the sales. Organon estimates that it will take approximately two weeks from the distribution date for the distribution agent to complete the distributions of the aggregate net cash proceeds. For a holder of shares of Merck common stock through a bank or brokerage firm, such holder's bank or brokerage firm will receive, on behalf of such holder, such holder's pro rata share of the aggregate net cash proceeds of the sales and will electronically credit such holder's account for such holder's share of such proceeds.

Results of the Distribution

After the distribution, Organon will be an independent, publicly traded company. The actual number of shares to be distributed will be determined at the close of business on May 17, 2021, the record date for the distribution, and will reflect any exercise of Merck options between the date the Merck Board of Directors declares the distribution and the record date for the distribution. The distribution will not affect the number of outstanding shares of Merck common stock or any rights of Merck's shareholders. Merck will not distribute any fractional shares of Organon common stock.

Organon will enter into the separation and distribution agreement with Merck and will enter into other agreements with Merck before the distribution to effect the separation and provide a framework for Organon's relationship with Merck after the distribution. These agreements will provide for the allocation between Merck and Organon of Merck's assets, liabilities and obligations (including investments, property, employee benefits and tax-related assets and liabilities) attributable to periods prior to Organon's separation from Merck and will govern the relationship between Merck and Organon after the distribution. For a more detailed description of these agreements, see "Certain Relationships and Related Party Transactions."

Market for Organon Common Stock

There is currently no public trading market for Organon's common stock. Organon intends to apply to list its common stock on the NYSE under the symbol "OGN." Organon has not and will not set the initial price of its common stock. The initial price will be established by the public markets.

Organon cannot predict the price at which its common stock will trade after the distribution. In fact, the combined trading prices, after the distribution, of the shares of Organon common stock that each Merck shareholder will receive in the distribution and the shares of Merck common stock held at the record date may not equal the "regular-way" trading price of a Merck share immediately prior to the distribution. The price at which Organon common stock trades may fluctuate significantly, particularly until an orderly public market develops. Trading prices for Organon common stock will be determined in the public markets and may be influenced by many factors. See "Risk Factors—Risks Related to Organon's Common Stock."

Trading Between the Record Date and Distribution Date

Beginning on or shortly before the record date and continuing until the time of the distribution, Merck expects that there will be two markets in shares of Merck common stock: a "regular-way" market and an "ex-dividend" market. Shares of Merck common stock that trade on the "regular-way" market will trade with an entitlement to Organon common stock distributed pursuant to the distribution. Shares of Merck common stock that trade on the "ex-dividend" market will trade without an entitlement to Organon common stock distributed pursuant to the distribution. Therefore, if a shareholder sells shares of Merck common stock in the "regular-way" market on or prior to the time of the distribution, such shareholder will be selling the right to receive Organon common stock in the distribution. If a shareholder owns shares of Merck common stock at the close of business on the record date and sells those shares on the "ex-dividend" market on or prior to the time of the distribution, such shareholder will receive the shares of Organon common stock that such shareholder is entitled to receive pursuant to such shareholder's ownership as of the record date of the shares of Merck common stock.

Furthermore, beginning on or shortly before the record date and continuing until the time of the distribution, Organon expects that there will be a “when-issued” market in its common stock. “When-issued” trading refers to a sale or purchase made conditionally because the security has been authorized but not yet issued. The “when-issued” trading market will be a market for Organon common stock that will be distributed to holders of Merck common stock on the distribution date. Shareholders who owned Merck common stock at the close of business on the record date are entitled to Organon common stock distributed pursuant to the distribution. Such a shareholder may trade this entitlement to shares of Organon common stock, without the shares of Merck common stock such shareholder owns, on the “when-issued” market. Upon completion of the distribution, “when-issued” trading with respect to Organon common stock will end, and “regular-way” trading will begin.

Conditions to the Distribution

The distribution is subject to a number of conditions, including, among others:

- the receipt of opinions from Merck’s Tax Advisors to the effect that the distribution and certain related transactions will qualify as tax-free to Merck and its shareholders under Sections 355 and 368 of the Code;
- the making of a distribution of approximately \$9.0 billion from Organon to Merck, and the determination by Merck in its sole discretion that following the separation Merck will have no further liability or obligation whatsoever with respect to any of the financing arrangements that Organon will be entering into in connection with the separation;
- the receipt of an opinion from an independent appraisal firm to the Merck Board of Directors confirming the solvency of Merck giving effect to the distribution of Organon and confirming the solvency of Organon giving effect to the cash dividend that is in form and substance acceptable to Merck in its sole discretion;
- the SEC declaring effective Organon’s registration statement on Form 10 of which this information statement forms a part, and the making available of the information statement to all holders of shares of Merck common stock as of the close of business on May 17, 2021, the record date;
- no order, injunction, or decree issued by any court of competent jurisdiction or other legal restraint or prohibition preventing the consummation of the separation, distribution or any of the related transactions shall be in effect;
- the shares of Organon common stock to be distributed shall have been accepted for listing on the NYSE, subject to official notice of distribution; and
- no other event or development existing or having occurred that, in the judgment of Merck’s Board of Directors, in its sole discretion, makes it inadvisable to effect the separation, distribution and other related transactions.

Merck and Organon cannot assure you that any or all of these conditions will be met. In addition, Merck will have the sole and absolute discretion to determine (and change) the terms of, and whether to proceed with, the distribution and, to the extent it determines to so proceed, to determine the record date and the distribution date and the distribution ratio. Merck does not intend to notify its shareholders of any modifications to the terms of the separation that, in the judgment of its Board of Directors, are not material. For example, the Merck Board of Directors might consider material such matters as significant changes to the distribution ratio, the assets to be contributed or the liabilities to be assumed in the separation. To the extent that the Merck Board of Directors determines that any modifications by Merck materially change the material terms of the distribution, Merck will notify Merck shareholders in a manner reasonably calculated to inform them about the modification as may be required by law, by, for example, publishing a press release, filing a current report on Form 8-K, or circulating a supplement to this information statement.

Material U.S. Federal Income Tax Consequences

The following is a summary of the material U.S. federal income tax consequences to Merck and to the holders of Merck common stock in connection with the spin-off (including the separation and distribution). This summary is based on the Code, the Treasury Regulations promulgated thereunder and judicial and administrative interpretations thereof, in each case as in effect and available as of the date of this information statement and all of which are subject to change at any time, possibly with retroactive effect. Any such change could affect the tax consequences described below.

This summary is limited to holders of Merck common stock that are U.S. Holders, as defined immediately below. A “U.S. Holder” is a beneficial owner of Merck common stock that is, for U.S. federal income tax purposes:

- an individual who is a citizen or a resident of the United States;
- a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized 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 its source; or
- a trust, if (i) a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (ii) it has a valid election in place under applicable Treasury Regulations to be treated as a United States person.

This summary also does not discuss all tax considerations that may be relevant to shareholders in light of their particular circumstances, nor does it address the consequences to shareholders subject to special treatment under the U.S. federal income tax laws, such as:

- dealers or traders in securities or currencies;
- regulated investment companies;
- real estate investment trusts;
- tax-exempt entities;
- banks, financial institutions or insurance companies;
- persons who acquired Merck common stock pursuant to the exercise of employee stock options or otherwise as compensation;
- shareholders who own, or are deemed to own, at least 10% or more, by voting power or value, of Merck equity;
- holders owning Merck common stock as part of a position in a straddle or as part of a hedging, conversion or other risk reduction transaction for U.S. federal income tax purposes;
- certain former citizens or long-term residents of the United States;
- holders who are subject to the alternative minimum tax; or
- a person that owns Merck common stock through partnerships or other pass-through entities.

This summary does not address the U.S. federal income tax consequences to Merck’s shareholders who do not hold Merck common stock as a capital asset. Moreover, this summary does not address any state, local or non-U.S. tax consequences or any estate, gift or other non-income tax consequences.

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds Merck common stock, the tax treatment of a partner in that partnership generally will depend on the status of the partner and the activities of the partnership. Such a partner or partnership should consult its own tax advisor as to its tax consequences.

YOU SHOULD CONSULT YOUR OWN TAX ADVISOR WITH RESPECT TO THE U.S. FEDERAL, STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES OF THE SPIN-OFF. THIS SUMMARY IS NOT INTENDED TO BE, NOR SHOULD IT BE CONSTRUED TO BE, LEGAL OR TAX ADVICE TO ANY PARTICULAR INVESTOR.

In connection with the spin-off, Merck expects to receive the Tax Opinions from its Tax Advisors to the effect that the distribution of 100% 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 Code. The Tax Opinions will be based on, among other things, current tax law, and assumptions and representations made by Organon and Merck, which if incorrect in any material respect, could jeopardize the conclusions reached in the Tax Opinions. The Tax Opinions received by Merck will not be binding on the IRS or the courts. The Tax Opinions will rely on certain facts, assumptions, representations and undertakings from Merck and Organon regarding the past and future conduct of Merck's and Organon's businesses and other matters. If any of these facts, assumptions, representations or undertakings is incorrect or not otherwise satisfied, Merck may not be able to rely on the Tax Opinions. Accordingly, notwithstanding the receipt of the Tax Opinions, we cannot assure you that the IRS will not assert, or that a court would not sustain, a position contrary to one or more of the conclusions set forth therein. In that event, the consequences described immediately below would not apply and holders of Merck common stock who receive shares of Organon common stock in the spin-off could be subject to significant U.S. federal income tax liability.

Assuming the spin-off satisfies the requirements necessary for tax-free treatment under Sections 355 and 368 of the Code, the following will describe the material U.S. federal income tax consequences of the spin-off to Merck, Organon and Merck's shareholders:

- no income, gain or loss will be recognized by, or be includible in the income of, a holder of Merck common stock, solely as a result of the receipt of Organon common stock, except with respect to any cash received in lieu of a fractional share;
- subject to the discussion below regarding Section 355(e), no gain or loss will be recognized by Merck as a result of the spin-off except for taxable income or gain possibly arising as a result of certain intercompany transactions;
- the aggregate tax basis of the Merck common stock, and Organon common stock received in the spin-off, in the hands of Merck's shareholders immediately after the spin-off, will be the same as the aggregate tax basis of the Merck common stock held by the holder immediately before the spin-off, allocated between the common stock of Merck and Organon common stock, including any fractional share interest for which cash is received, in proportion to such shares' relative fair market values on the date of the spin-off;
- the holding period of shares of the Organon common stock received by Merck's shareholders in the spin-off will include the holding period of their Merck common stock, provided that such Merck common stock is held as a capital asset on the date of the spin-off; and
- a Merck shareholder who receives cash in lieu of a fractional share of Organon common stock in the spin-off will be treated as having sold such fractional share for the amount of cash received and generally will recognize capital gain or loss in an amount equal to the difference between the amount of such cash received and such shareholder's adjusted tax basis in the fractional share. That gain or loss will be long-term capital gain or loss if the shareholder's holding period for its Merck common stock exceeds one year.

Merck's shareholders that have acquired different blocks of Merck common stock at different times or at different prices should consult their tax advisors regarding the allocation of their aggregate adjusted basis among, and their holding period of, Organon common stock distributed with respect to such blocks of Merck common stock.

U.S. Treasury Regulations require certain shareholders that receive stock in a spin-off to attach to their respective U.S. federal income tax returns, for the year in which the spin-off occurs, a detailed statement setting forth certain information relating to the spin-off. Within a reasonable period of time after the distribution, Merck expects to make available to its shareholders information pertaining to compliance with this requirement.

If the spin-off were not to qualify as tax-free for U.S. federal income tax purposes, each Merck shareholder that receives shares of Organon common stock in the spin-off would be treated as receiving a distribution in an amount equal to the fair market value of such shares, which generally would be treated in the following manner:

- first as a taxable dividend to the extent of such shareholder's pro rata share of Merck's current and accumulated earnings and profits;
- then as a non-taxable return of capital to the extent of such shareholder's tax basis in its Merck common stock; and
- thereafter as capital gain with respect to any remaining value.

Additionally, each shareholder's basis in the Organon common stock would be equal to the fair market value of such stock on the date of the distribution and its holding period in the Organon common stock would begin on the date of the distribution. Furthermore, Merck would recognize a taxable gain on the Organon common stock to the extent the fair market value of Organon common stock exceeds Merck's tax basis therein. Even if the spin-off otherwise qualifies for tax-free treatment under Section 355 of the Code, it may be taxable to Merck (but not Merck's shareholders) under Section 355(e) of the Code if 50% or more, by vote or value, of the shares of Organon common stock or Merck common stock are acquired or issued as part of a plan or series of related transactions that includes the spin-off. For this purpose, any acquisitions or issuances of Merck common stock within two years before the spin-off, and any acquisitions or issuances of Organon common stock or Merck common stock within two years after the spin-off, generally are presumed to be part of such a plan, although Organon or Merck may be able to rebut that presumption. Even if Section 355(e) of the Code were to apply to cause the spin-off to be taxable to Merck, the receipt of the shares of Organon common stock in the spin-off would remain tax-free to the Merck shareholders.

Tax Matters Agreement

In connection with the distribution, Merck and Organon will enter into a tax matters agreement pursuant to which Organon will agree to be responsible for certain liabilities and obligations following the distribution. In general, under the terms of the tax matters agreement, in the event the distribution were to fail to qualify for U.S. federal income tax purposes under Sections 355 and 368 of the Code (including as a result of Section 355(e) of the Code) and if such failure were the result of actions taken by Organon after the distribution, Organon would be responsible for all taxes imposed on Merck to the extent such taxes result from such actions. Further, if such failure were the result of any acquisition of Organon shares or assets or any of Organon's representations or undertakings being incorrect or breached, Organon would be responsible for all taxes imposed on Merck as a result. For a more detailed discussion, see "Certain Relationships and Related Party Transactions—Tax Matters Agreement." Our indemnification obligations to Merck and its subsidiaries, officers and directors are not limited in amount or subject to any cap. If we are required to indemnify Merck and its subsidiaries and their respective officers and directors under the circumstances set forth in the tax matters agreement, we may be subject to substantial liabilities.

Information Reporting and Backup Withholding

U.S. Treasury regulations require certain shareholders who receive stock in a distribution to attach to the shareholder's U.S. federal income tax return for the year in which the distribution occurs a detailed statement setting forth certain information relating to the tax-free nature of the distribution. In addition, payments of cash to a Merck shareholder in lieu of fractional shares of Organon common stock in the distribution may be subject to

information reporting, unless the shareholder provides proof of an applicable exemption. Such payments that are subject to information reporting may also be subject to backup withholding (currently at a rate of 24%), unless the shareholder provides a correct taxpayer identification number and otherwise complies with the requirements of the backup withholding rules. Backup withholding does not constitute an additional tax, but merely an advance payment, which may be refunded or credited against a shareholder's U.S. federal income tax liability, provided the required information is timely supplied to the IRS.

The preceding summary of the anticipated U.S. federal income tax consequences of the spin-off is for general informational purposes only. Merck's shareholders should consult their own tax advisors as to the specific tax consequences of the spin-off to them, including the application and effect of state, local or non-U.S. tax laws and of changes in applicable tax laws.

Description of Certain Indebtedness

The following summary sets forth information based on Organon's current expectations about the financing arrangements anticipated to be entered into prior to the separation. However, Organon has not yet entered into any definitive agreements with respect to such financing arrangements, and, accordingly, the terms of such financing arrangements have not yet been determined, remain under discussion and are subject to change, including as a result of market conditions.

Senior Notes Issuances

In April 2021, Organon Finance 1 LLC, a subsidiary of Merck, issued €1.25 billion aggregate principal amount of 2.875% senior secured notes due 2028, \$2.1 billion aggregate principal amount of 4.125% senior secured notes due 2028 and \$2.0 billion aggregate principal amount of 5.125% senior unsecured notes due 2031 (collectively, the notes), in connection with the spin-off of Organon. The notes were issued to “qualified institutional buyers” in reliance on Rule 144A and Regulation S under the Securities Act. The proceeds of the notes offering will be held in escrow until satisfaction of the conditions precedent to the spin-off and certain other escrow release conditions.

As part of the spin-off, Organon and a wholly-owned Dutch subsidiary of Organon will assume the notes as co-issuers. Organon's debt balance as of the distribution date will be determined based on internal capital planning and take into account factors and assumptions including the anticipated business plan, optimal debt levels, operating activities, general economic contingencies, credit rating and desired financing capacity. Nothing in this summary or otherwise herein shall constitute or be deemed to constitute an offer to sell or the solicitation of an offer to buy the notes.

Senior Credit Facilities

In connection with the spin-off, we expect to enter into a credit agreement with JPMorgan Chase Bank, N.A., as administrative agent and collateral agent (the “Senior Credit Agreement”), providing for:

- a Term Loan B Facility (“Term Loan B Facility”), consisting of (i) a U.S. dollar denominated senior secured “tranche B” term loan in the amount of \$3,000 million, and (ii) a Euro denominated senior secured “tranche B” term loan in the Euro equivalent amount of €750 million, in each case with a seven-year term that matures in 2028; and
- a Revolving Credit Facility (“Revolving Credit Facility” and, together with the Term Loan B Facility, the “Senior Credit Facilities”), in an aggregate principal amount of up to \$1,000 million, with a five-year term that matures in 2026.

The following is a summary description of certain terms of the Senior Credit Facilities. The terms of the Senior Credit Agreement and related documentation for the Senior Credit Facilities are subject to ongoing negotiation, and accordingly their definitive terms may vary from those described below.

We expect the Revolving Credit Facility to be undrawn on the spin date, and do not expect to have outstanding letters of credit under the Revolving Credit Facility on the spin date.

We expect borrowings made under the Senior Credit Agreement to initially bear interest, in the case of

- revolving loans under the Revolving Credit Facility (i) in U.S. Dollars, at 2.00% in excess of an adjusted London Interbank Offered Rate or 1.00% in excess of an alternate base rate, at our option and (ii) in Euros, at 2.00% in excess of an adjusted Euro Interbank Offer Rate; and
- term loans under the Term Loan B Facility (i) denominated in U.S. Dollars, at 3.00% in excess of Adjusted LIBOR or 2.00% in excess of ABR, at our option and (ii) denominated in Euros, at 3.00% in excess of Adjusted EURIBOR.

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We expect the interest rate on the revolving loans under the Revolving Credit Facility to be subject to a step-down based on meeting a leverage ratio target. A commitment fee applies to the unused portion of the revolving facility that is expected to initially be 0.50%, and to be subject to a step-down to 0.375% based on meeting a leverage ratio target.

The Revolving Credit Facility will be subject to a financial covenant whereby the total leverage ratio, which measures the ratio of (i) consolidated total debt to (ii) consolidated earnings before interest, taxes, depreciation and amortization, and subject to other adjustments, must meet certain defined limits which are tested on a quarterly basis (commencing with the quarterly period ending on September 30, 2021) in accordance with the terms of the Senior Credit Facilities. In addition, the Senior Credit Agreement will contain covenants that will limit, among other things, our ability to prepay, redeem or repurchase our subordinated and junior lien debt, incur additional debt, make acquisitions, merge with other entities, pay dividends or distributions, redeem or repurchase equity interests, and create or become subject to liens.

Description of Capital Stock

Organon's certificate of incorporation and bylaws will be amended and restated prior to the distribution. The following is a summary of the material terms of Organon's capital stock that will be contained in the amended and restated certificate of incorporation and bylaws. The summaries and descriptions below do not purport to be complete statements of the relevant provisions of the certificate of incorporation or of the bylaws to be in effect at the time of the distribution. The summary is qualified in its entirety by reference to these documents, which you must read (along with the applicable provisions of Delaware law) for complete information on Organon's capital stock as of the time of the distribution. The certificate of incorporation and bylaws to be in effect at the time of the distribution will be included as exhibits to Organon's registration statement on Form 10, of which this information statement forms a part.

General

Organon's authorized capital stock consists of 500,000,000 shares of common stock, par value \$0.01 per share and 25,000,000 shares of preferred stock, par value \$0.01 per share. Organon's Board of Directors may establish the rights and preferences of the preferred stock from time to time. Immediately following the distribution, and based on the number of Merck shares outstanding on March 31, 2021 and the distribution ratio, Organon expects that approximately 253,130,375 shares of its common stock will be issued and outstanding (based on the number of shares of Merck outstanding on March 31, 2021) and that no shares of preferred stock will be issued and outstanding.

Common Stock

Each holder of Organon common stock will be entitled to one vote for each share on all matters to be voted upon by the holders of Organon common stock, and there will be no cumulative voting rights. Subject to any preferential rights of any outstanding preferred stock, holders of Organon common stock will be entitled to receive ratably the cash dividends, if any, as may be declared from time to time by its Board of Directors out of funds legally available for that purpose. If there is a liquidation, dissolution or winding up of Organon, holders of its common stock would be entitled to ratably distribution of its assets remaining after the payment in full of liabilities and any preferential rights of any then-outstanding preferred stock.

Holders of Organon common stock will have no preemptive or conversion rights or other subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. After the distribution, all outstanding shares of Organon common stock will be fully paid and non-assessable. The rights, preferences and privileges of the holders of Organon common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that Organon may designate and issue in the future.

Preferred Stock

Under the terms of Organon's amended and restated certificate of incorporation, its Board of Directors will be authorized, subject to limitations prescribed by the Delaware General Corporation Law, or the DGCL, and by its amended and restated certificate of incorporation, to issue preferred stock in one or more series without further action by the holders of its common stock. Organon's Board of Directors will have the discretion, subject to limitations prescribed by the DGCL and by Organon's amended and restated certificate of incorporation, to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. Certain provisions of the tax matters agreement, which are intended to preserve the intended tax treatment of the separation and certain related transactions, may prevent certain issuances of our stock for a period of time following the closing of the transactions.

Anti-Takeover Effects of Various Provisions of DGCL and our Amended and Restated Certificate of Incorporation and Bylaws

Certain provisions in our proposed amended and restated certificate of incorporation and our proposed amended and restated bylaws summarized below may be deemed to have an anti-takeover effect and may delay, deter or prevent a tender offer or takeover attempt that a shareholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by shareholders. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our Board of Directors and in the policies formulated by our Board of Directors and to discourage certain types of transactions that may involve an actual or threatened change of control.

- *Classified Board.* Our amended and restated certificate of incorporation will provide that, until the annual shareholder meeting in 2025, our Board of Directors will be divided into three classes, with each class consisting, as nearly as may be possible, of one-third of the total number of directors. The directors designated as Class I directors will have terms expiring at the first annual meeting of shareholders following the distribution, which we expect to hold in 2022, and will be up for re-election at that meeting for a three-year term to expire at the 2025 annual meeting of shareholders; the directors designated as Class II directors will have terms expiring at the following year's annual meeting of shareholders, which we expect to hold in 2023, and will be up for re-election at that meeting for a two-year term to expire at the 2025 annual meeting of shareholders; and the directors designated as Class III directors will have terms expiring at the following year's annual meeting of shareholders which we expect to hold in 2024, and will be up for re-election at that meeting for a one-year term to expire at the 2025 annual meeting of shareholders. Commencing with the 2025 annual meeting of shareholders, directors will be elected annually and for a term of office to expire at the next annual meeting of shareholders, and our Board of Directors will thereafter no longer be divided into classes. Before our Board of Directors is declassified, it would take at least three years after the completion of the distribution for any individual or group to gain control of our Board of Directors. Accordingly, while the Board of Directors is divided into classes, these provisions could discourage a third party from initiating a proxy contest, making a tender offer or otherwise attempting to control us.
- *Removal and Vacancies.* Our amended and restated certificate of incorporation will provide that (i) prior to our Board of Directors being declassified as discussed above, our shareholders may remove directors only for cause and (ii) after our Board of Directors has been fully declassified, our shareholders may remove directors with or without cause. Removal will require the affirmative vote of holders of at least a majority of the voting power of our stock outstanding and entitled to vote on such removal. Vacancies occurring on the Board of Directors, whether due to death, resignation, removal, retirement, disqualification or for any other reason, and newly created directorships resulting from an increase in the authorized number of directors, shall be filled solely by a majority of the remaining members of the Board of Directors or by a sole remaining director.
- *Blank Check Preferred Stock.* Our amended and restated certificate of incorporation will authorize our Board to designate and issue, without any further vote or action by the shareholders, up to 25,000,000 shares of preferred stock from time to time in one or more series and, with respect to each such series, to fix the number of shares constituting the series and the designation of the series, the voting powers (if any) of the shares of the series, and the preferences and relative, participating, optional and other rights, if any, and any qualifications, limitations or restrictions, of the shares of such series. The ability to issue such preferred stock could discourage potential acquisition proposals and could delay or prevent a change in control.
- *No Shareholder Action by Written Consent.* Our amended and restated certificate of incorporation will expressly exclude the right of our shareholders to act by written consent. Shareholder action must take place at an annual meeting or at a special meeting of our shareholders.

- *No Shareholder Ability to Call Special Meetings of Shareholders.* Our amended and restated certificate of incorporation and bylaws will provide that only the Board of Directors will be able to call a special meeting of shareholders.
- *Requirements for Advance Notification of Shareholder Nominations and Proposals.* Our amended and restated bylaws will require shareholders seeking to nominate persons for election as directors at an annual or special meeting of shareholders, or to bring other business before an annual or special meeting (other than a proposal submitted under Rule 14a-8 under the Exchange Act), to provide timely notice in writing. A shareholder’s notice to our Corporate Secretary must be in proper written form and must set forth certain information, as required under our amended and restated bylaws, related to the shareholder giving the notice, the beneficial owner (if any) on whose behalf the nomination is made as well as their control persons and information about the proposal or nominee for election to the Board of Directors.
- *Exclusive Forum.* Our amended and restated bylaws will provide that, unless we select or consent to the selection, in writing, of another forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court or a federal court located within the State of Delaware) shall be the exclusive forum for any “internal corporate claims,” which include claims in the right of our company (i) that are based upon a violation of a duty by a current or former director, officer, employee or shareholder in such capacity; or (ii) as to which the DGCL confers jurisdiction upon the Court of Chancery. Furthermore, unless we select or consent to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. It is possible that a court could find our exclusive forum provision to be inapplicable or unenforceable. Although we believe this provision benefits us by providing increased consistency in the application of law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.
- *Business Combinations with Interested Shareholder.* We are subject to Section 203 of the DGCL, which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any business combination with any interested shareholder for a period of three years following the date that such shareholder became an interested shareholder.

Limitation on Liability of Directors and Indemnification of Directors and Officers

Our amended and restated bylaws will generally provide indemnification and advancement of expenses for our directors and officers to the fullest extent permitted by the DGCL. Prior to the completion of the distribution, we also intend to enter into indemnification agreements with each of our directors and executive officers that may, in some cases, be broader than the specific indemnification and advancement of expenses provisions contained under Delaware law. In addition, as permitted by Delaware law, our amended and restated certificate of incorporation will include a provision that eliminates the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our shareholders in derivative suits to recover monetary damages against a director for breach of fiduciary duties as a director, except that under Delaware law, we may not eliminate the personal liability of a director for:

- any breach of his duty of loyalty to us or our shareholders;
- acts or omissions not in good faith, or which involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or

- any transaction from which the director derived an improper personal benefit; or improper distributions to shareholders.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Equiniti Trust Company.

Listing

We have applied to list our common stock on the NYSE, under the ticker symbol “OGN.”

Where You Can Find More Information

Organon has filed a registration statement on Form 10 with the SEC with respect to the shares of Organon common stock being distributed as contemplated by this information statement. This information statement is a part of, and does not contain all of the information set forth in, the registration statement and the exhibits and schedules to the registration statement. For further information with respect to Organon and its common stock, please refer to the registration statement, including its exhibits and schedules. Statements made in this information statement relating to any contract or other document are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract or document. You may review a copy of the registration statement, including its exhibits and schedules, by calling the SEC at 1-800-SEC-0330 as well as on the Internet website maintained by the SEC at www.sec.gov. Information contained on any website referenced in this information statement is not incorporated by reference in this information statement.

As a result of the distribution, Organon will become subject to the information and reporting requirements of the Exchange Act and, in accordance with the Exchange Act, will file periodic reports, proxy statements and other information with the SEC.

Organon intends to furnish holders of its common stock with annual reports containing consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles and audited and reported on, with an opinion expressed, by an independent registered public accounting firm.

You should rely only on the information contained in this information statement or to which this information statement has referred you. Organon has not authorized any person to provide you with different information or to make any representation not contained in this information statement.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Merck & Co., Inc.

Opinion on the Financial Statements

We have audited the accompanying combined balance sheets of Organon & Co. (a business of Merck & Co., Inc.) (the “Company”) as of December 31, 2020 and 2019, and the related combined 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 “combined financial statements”). In our opinion, the combined financial statements 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.

Change in Accounting Principle

As discussed in Note 3 to the combined financial statements, the Company changed the manner in which it accounts for the income tax consequences of intra-entity transfers of assets other than inventory in 2018.

Basis for Opinion

These combined financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s combined financial statements 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 of these combined financial statements in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the combined financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the combined 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 combined 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 combined financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the combined 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 combined 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 combined 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 and Managed Care Rebates

As described in Note 3 to the combined 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 \$302 million 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) 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 and Managed Care 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 combined financial statements. These procedures 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.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
March 17, 2021

We have served as the Company's auditor since 2019.

[Table of Contents](#)**Combined Statement of Income**

Organon & Co.

Years Ended December 31

(\$ in millions)

	<u>2020</u>	<u>2019</u>	<u>2018</u>
Sales ⁽¹⁾	<u>\$ 8,096</u>	<u>\$ 9,530</u>	<u>\$ 9,777</u>
Costs, Expenses and Other			
Cost of sales ⁽²⁾	<u>3,347</u>	3,621	4,693
Selling, general and administrative	<u>1,666</u>	1,922	2,013
Research and development	<u>304</u>	332	365
Restructuring costs	<u>70</u>	101	119
Other (income) expense, net	<u>29</u>	(1)	(142)
	<u>5,416</u>	<u>5,975</u>	<u>7,048</u>
Income Before Taxes	<u>2,680</u>	<u>3,555</u>	<u>2,729</u>
Taxes on Income	<u>520</u>	<u>337</u>	<u>576</u>
Net Income	<u>\$2,160</u>	<u>\$3,218</u>	<u>\$2,153</u>

(1) Includes related party sales of \$599 million in 2020, \$501 million in 2019 and \$432 million in 2018.

(2) Includes costs for inventory purchases from related parties of \$1.0 billion in 2020, \$1.1 billion in 2019 and \$923 million in 2018.

Combined Statement of Comprehensive Income

Organon & Co.

Years Ended December 31

(\$ in millions)

	<u>2020</u>	<u>2019</u>	<u>2018</u>
Net Income	<u>\$2,160</u>	<u>\$3,218</u>	<u>\$2,153</u>
Other Comprehensive Loss, Net of Taxes:			
Benefit plan net loss and prior service cost, net of amortization	<u>(143)</u>	(60)	(59)
Cumulative translation adjustment	<u>(30)</u>	54	(125)
	<u>(173)</u>	<u>(6)</u>	<u>(184)</u>
Comprehensive Income	<u>\$1,987</u>	<u>\$3,212</u>	<u>\$1,969</u>

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

[Table of Contents](#)**Combined Balance Sheet**

Organon & Co.

December 31

(\$ in millions)

	2020	2019
Assets		
Current Assets		
Cash and cash equivalents	\$ 70	\$ 319
Accounts receivable (net of allowance for doubtful accounts of \$18 in 2020 and \$20 in 2019)	1,360	1,474
Inventories (excludes inventories of \$127 in 2020 and \$93 in 2019 classified in Other assets—see Note 7)	971	1,071
Due from related party	—	13
Other current assets	977	1,078
Total current assets	<u>3,378</u>	<u>3,955</u>
Property, Plant and Equipment (at cost)		
Land	15	7
Buildings	653	382
Machinery, equipment and office furnishings	803	824
Construction in progress	362	143
	<u>1,833</u>	<u>1,356</u>
Less: accumulated depreciation	835	676
	<u>998</u>	<u>680</u>
Goodwill	4,603	4,603
Other Intangibles, Net	503	569
Other Assets	438	741
	<u>\$9,920</u>	<u>\$10,548</u>
Liabilities and Equity		
Current Liabilities		
Trade accounts payable	\$ 294	\$ 258
Accrued and other current liabilities	752	807
Due to related party	1,150	34
Income taxes payable	288	242
Total current liabilities	<u>2,484</u>	<u>1,341</u>
Deferred Income Taxes	128	139
Related Party Loans Payable	—	70
Other Noncurrent Liabilities	1,822	1,963
Organon & Co. Equity		
Net investment from Parent	6,108	7,949
Accumulated other comprehensive loss	(622)	(914)
Total equity	<u>5,486</u>	<u>7,035</u>
	<u>\$9,920</u>	<u>\$10,548</u>

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

Combined Statement of Equity

Organon & Co.

Years Ended December 31

(\$ in millions)

	Net Investment from Parent	Accumulated Other Comprehensive Loss	Total
Balance January 1, 2018	<u>\$ 8,941</u>	<u>\$ (724)</u>	<u>\$8,217</u>
Net income	2,153	—	2,153
Adoption of new accounting standard (see Note 3)	329	—	329
Other comprehensive loss, net of taxes	—	(184)	(184)
Net transfers to Parent	(4,167)	—	(4,167)
Balance December 31, 2018	<u>7,256</u>	<u>(908)</u>	<u>6,348</u>
Net income	3,218	—	3,218
Other comprehensive loss, net of taxes	—	(6)	(6)
Net transfers to Parent	(2,525)	—	(2,525)
Balance December 31, 2019	<u>7,949</u>	<u>(914)</u>	<u>7,035</u>
Net income	2,160	—	2,160
Other comprehensive loss, net of taxes	—	(173)	(173)
Net transfers to Parent	(4,001)	465	(3,536)
Balance December 31, 2020	<u><u>\$ 6,108</u></u>	<u><u>\$ (622)</u></u>	<u><u>\$ 5,486</u></u>

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

[Table of Contents](#)**Combined Statement of Cash Flows**

Organon & Co.

Years Ended December 31

(\$ in millions)

	2020	2019	2018
Cash Flows from Operating Activities			
Net income	\$ 2,160	\$ 3,218	\$ 2,153
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	157	354	1,673
Deferred income taxes	6	66	37
Share-based compensation	54	52	56
Unrealized foreign exchange loss (gain)	7	(11)	(68)
Other	—	—	10
Net changes in assets and liabilities:			
Accounts receivable	159	35	250
Inventories	(29)	(112)	44
Other current assets	108	(101)	(161)
Trade accounts payable	27	(31)	20
Accrued and other current liabilities	(118)	(16)	(170)
Income taxes payable	(118)	(590)	(166)
Due from/due to related party	(126)	(3)	78
Other	(100)	(94)	(69)
Net Cash Provided by Operating Activities	<u>2,187</u>	<u>2,767</u>	<u>3,687</u>
Cash Flows from Investing Activities			
Capital expenditures	(278)	(109)	(101)
Proceeds from sale of property, plant and equipment	20	7	32
Net Cash Used in Investing Activities	<u>(258)</u>	<u>(102)</u>	<u>(69)</u>
Cash Flows from Financing Activities			
(Payments) proceeds from related party loans, net	(79)	(44)	18
Short-term borrowings from Parent, net	1,244	—	41
Net transfers to Parent	(3,340)	(2,577)	(4,223)
Net Cash Used in Financing Activities	<u>(2,175)</u>	<u>(2,621)</u>	<u>(4,164)</u>
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(3)	31	19
Net (Decrease) Increase in Cash and Cash Equivalents	<u>(249)</u>	<u>75</u>	<u>(527)</u>
Cash and Cash Equivalents at Beginning of Year	319	244	771
Cash and Cash Equivalents at End of Year	<u>\$ 70</u>	<u>\$ 319</u>	<u>\$ 244</u>

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

Notes to Combined Financial Statements

Organon & Co.
(\$ in millions)

1. Background and Nature of Operations

On February 5, 2020, Merck & Co., Inc. (Merck or Parent) announced its intent to spin-off its women's health, biosimilars and established brands businesses into a new, independent publicly traded company, Organon & Co. (Organon or the Company), through a distribution of Organon's publicly traded stock to Merck shareholders. These combined financial statements reflect the combined historical results of operations, financial position and cash flows of the Company.

Completion of the spin-off is subject to certain conditions, including receipt of an opinion from tax counsel or other third-party adviser that the distribution and certain related transactions will qualify as tax-free to Merck and its shareholders under sections 355 and 368 of the Internal Revenue Code.

The Company's operations are principally managed on a products basis and include two operating segments, the Organon Products segment and the Merck Retained Products segment.

The Organon Products segment is engaged in developing and delivering innovative health solutions through its portfolio of prescription therapies within women's health, biosimilars, and established brands (Organon Products). The Company sells these 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. The Company expects to operate six manufacturing facilities in Belgium, Brazil, Indonesia, Mexico, the Netherlands and the United Kingdom (UK).

The Organon Products segment portfolio includes:

- *Women's Health*: the Company has innovative contraception and fertility brands, such as *Nexplanon/Implanon*, a long-acting reversible contraceptive, a class of contraceptives which are recognized as the most effective type of hormonal contraception available to patients with a lower long-term average cost.
- *Biosimilars*: the Company's current portfolio spans immunology and oncology treatments. All five of the biosimilars in Organon's portfolio have launched in certain countries globally, including two biosimilars in the United States.
- *Established Brands*: the Company has a portfolio of established brands, which generally are beyond market exclusivity, including leading brands in cardiovascular, respiratory, dermatology and non-opioid pain management.

The Merck Retained Products segment reflects the results of certain Merck non-U.S. legal entities that will be contributed to Organon in connection with the spin-off (Transferring Entities and each, a Transferring Entity). The Transferring Entities include operations related to other Merck products that will be retained by Merck (Merck Retained Products) (see Note 2).

2. Basis of Presentation

The Company's historical combined financial statements have been prepared on a standalone basis and are derived from Merck's consolidated financial statements and accounting records. The combined financial statements reflect the Company's financial position, results of operations and cash flows as it was operated as part of Merck prior to the spin-off, in conformity with U.S. generally accepted accounting principles (GAAP). The assets, liabilities, revenue and expenses of the Company have been reflected in our combined financial statements on a historical cost basis, as included in the consolidated financial statements of Merck, using the

historical accounting policies applied by Merck. These combined financial statements do not purport to reflect what the Company's results of operations, comprehensive income, financial position, equity or cash flows would have been had the Company operated as a standalone public company during the periods presented.

These combined financial statements were prepared following a legal entity approach, which resulted in the inclusion of the following:

- Certain assets and liabilities, results of operations and cash flows attributable to the sales of products in the Organon Products segment that will be contributed to Organon prior to the consummation of the spin-off, and
- The Transferring Entities, which have historically included the results from the sales of products included both in the Organon Products segment and the Merck Retained Products segment. Each Transferring Entity's historical operations, including its results of operations, assets and liabilities, and cash flows have been fully reflected in these combined financial statements; however, prior to the consummation of the spin-off, the products in the Merck Retained Products segment will be contributed to newly formed Merck entities that will be retained by Merck. Upon full contribution of the Merck Retained Products by the Company to Merck and its affiliates, the historical results of operations of such products in the Merck Retained Products segment will be reflected as discontinued operations in the Organon financial statements.

During the fourth quarter of 2020, in contemplation of the spin-off:

- The Merck Retained Products business in certain Transferring Entities was distributed to Merck affiliates (MRP Distribution) and the Merck Retained Products segment's results of operations, assets and liabilities, and cash flows for such Transferring Entities are included in these combined financial statements through the date of distribution to Merck affiliates.
- The Organon Products business in certain jurisdictions has been transferred by Merck affiliates to legal entities established to operate the Organon Products business and, as noted above, such entities will be contributed to Organon (Organon Entities).

The Company's businesses have historically functioned together with the other businesses controlled by Merck. Accordingly, the Company relied on Merck's corporate and other support functions for its business. Therefore, certain corporate and shared costs have been allocated to the Company including:

(i) expenses related to Merck support functions that are provided on a centralized basis within Merck, including expenses for facilities, executive oversight, treasury, finance, legal, human resources, shared services, compliance, procurement, information technology and other corporate functions. These expenses have been allocated to the Company based on a specific identification basis or, when specific identification is not practicable, a proportional cost allocation method primarily based on revenue or directly identifiable actual costs, depending on the nature of the services.

(ii) certain manufacturing and supply costs incurred by Merck's manufacturing division, including facility management, distribution, logistics, planning and global quality. These costs include material, manufacturing costs and variances, distribution expenses, supply chain management, contract manufacturing and quality charges, among others. These costs have been allocated based on a specific identification basis, or when specific identification is not practicable, a proportional cost allocation method based on directly identifiable manufacturing costs, depending on the nature of the costs.

(iii) certain costs incurred by Merck's human health division in relation to selling and marketing activities, and related administrative support functions, that are not routinely allocated to therapeutic areas. Human health division costs have been allocated either based on product specific identification, or when specific identification is not practicable, a proportional cost allocation method based on associated selling and marketing costs, depending on the nature of the costs.

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(iv) costs incurred by Merck's research laboratories for activities related to drug discovery and development, as well as medical and regulatory affairs. Such costs have been allocated based on a specific identification basis, or when specific identification is not practicable, a proportional cost allocation method based on directly identifiable employee activities.

(v) restructuring costs (see Note 5) and share-based compensation expenses (see Note 11).

(vi) certain compensation expenses maintained on a centralized basis such as certain employee benefit expenses.

Management believes these cost allocations are a reasonable reflection of the utilization of services provided to, or the benefit derived by, the Company during the periods presented, though the allocations may not be indicative of the actual costs that would have been incurred had the Company operated as a standalone public company. Actual costs that may have been incurred if the Company had been a standalone company would depend on a number of factors, including the chosen organizational structure, whether functions were outsourced or performed by Company's employees, and strategic decisions made in areas such as manufacturing, selling and marketing, research and development, information technology and infrastructure.

Following the spin-off, certain functions that Merck provided to the Company prior to the spin-off will either continue to be provided to the Company by Merck under a transition services agreement or will be performed using the Company's own resources or third-party service providers. Additionally, under manufacturing and supply agreements, the Company will manufacture certain products for Merck or its applicable affiliate and Merck will manufacture certain products for the Company or its applicable affiliate. The Company expects to incur certain costs in its establishment as a standalone public company, as well as ongoing additional costs associated with operating as an independent, publicly traded company.

The combined balance sheet reflects all of the assets and liabilities that are either specifically identifiable or are directly attributable to the Company and its operations, as well as assets and liabilities attributable to the Merck Retained Products in the Transferring Entities. However, the balance sheet at December 31, 2020 excludes the assets and liabilities of the Merck Retained Products in certain Transferring Entities that were distributed to the Parent in the fourth quarter of 2020 as part of the MRP Distribution. The assets and liabilities in the remaining Transferring Entities attributable to Merck Retained Products will be distributed to the Parent prior to the spin-off. Property, plant and equipment reflected in the combined balance sheet is primarily attributable to the six manufacturing facilities the Company expects to operate. No assets or liabilities are reflected in the combined balance sheet for amounts related to derivatives and hedging activities.

Merck maintains various employee benefit plans which the Company's employees participate in, and a portion of the costs associated with these plans has been included in the Company's combined financial statements. The combined balance sheet only includes assets and liabilities relating to plans for which the entity being transferred is the plan sponsor; most of these plans are on the Transferring Entities and substantially all of the related assets and liabilities were transferred to Merck as part of the MRP Distribution in the fourth quarter of 2020 or will be prior to the spin-off.

Income tax expense and deferred tax balances in the combined financial statements have been calculated on a separate tax return basis. The Company's operations are included in the tax returns of certain Organon Entities, Transferring Entities or the respective Merck entities of which the Company's business is a part. In the future, as a standalone entity, the Company will file tax returns on its own behalf, and its deferred taxes and effective income tax rate may differ from those in the historical periods.

Merck utilizes a centralized approach to cash management and the financing of its operations. Cash generated by the Company is routinely transferred into accounts managed by Merck's centralized treasury function and cash disbursements for the Company's operations are funded as needed by Merck. Cash and cash

equivalents of the Organon Entities and the Transferring Entities are reflected in the Company's combined balance sheet. Balances held by the Organon Entities and the Transferring Entities with Merck for cash transfers and loans are reflected as *Due from related party*, *Due to related party*, or *Related Party Loans Payable*. All other cash, cash equivalents, short-term investments and related transfers between Merck and the Company are generally held centrally through accounts controlled and maintained by Merck and are not specifically identifiable to the Company. Accordingly, such balances have been accounted for through *Net investment from Parent*. Merck's third-party debt and related interest expense have not been attributed to the Company because the Company is not the legal obligor of the debt and the borrowings are not specifically identifiable to the Company. However, in connection with the spin-off, the Company expects to incur indebtedness and such indebtedness would cause the Company to record additional interest expense in future periods.

As the separate legal entities that make up the Company's business were not historically held by a single legal entity, *Net investment from Parent* is shown in lieu of shareholders' equity in these combined financial statements. *Net investment from Parent* represents Merck's interest in the recorded assets of the Company and the cumulative investment by Merck in the Company through the periods presented, inclusive of operating results.

All intercompany transactions and accounts within Organon have been eliminated. For the Organon Entities and the Transferring Entities, transactions with Merck affiliates attributable to the Merck Retained Products are included in the combined statement of income and related balances are reflected as *Due to related party*, *Due from related party* or *Related Party Loans Payable*. Other balances between the Company and Merck are considered to be effectively settled in the combined financial statements at the time the transactions are recorded. The total net effect of these intercompany transactions considered to be settled is reflected in the combined statement of cash flows within financing activities and in the combined statement of equity as *Net transfers to Parent*. See Note 17 for additional details.

3. Summary of Accounting Policies

Revenue Recognition — Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. The Company acts as the principal in its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts 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.

Revenues from sales of products, including sales of Merck Retained Products to affiliates by the Organon Entities and the Transferring Entities, 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 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 \$1.8 billion in 2020, \$1.9 billion in 2019 and \$2.0 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 \$41 million and \$302 million, respectively, at December 31, 2020 and were \$52 million and \$313 million, 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. 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.

The Company's payment terms for U.S. customers are typically 36 days from receipt of invoice. Outside of the United States, payment terms are typically 30 days to 90 days, although certain markets have longer payment terms.

See Note 16 for disaggregated revenue disclosures.

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

Inventories — Inventories are valued at the lower of cost or net realizable value. The cost of a substantial majority of U.S. 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.

Value Added Tax — The Company's purchases, sales and intercompany transfers of goods are subject to value added tax (VAT) and VAT receivables are recognized for amounts that represent credits against future VAT obligations. VAT receivables included in *Other current assets* were \$348 million and \$187 million as of December 31, 2020 and 2019, respectively. VAT payables included in *Accrued and other current liabilities* were \$38 million and \$46 million as of December 31, 2020 and 2019, respectively.

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Depreciation — Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. 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 \$72 million in 2020, \$69 million in 2019 and \$68 million in 2018.

Advertising and Promotion Costs — Advertising and promotion costs are expensed as incurred. The Company recorded advertising and promotion expenses of \$217 million, \$298 million and \$322 million in 2020, 2019 and 2018, respectively.

Goodwill — Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses acquired. Substantially all of the goodwill attributed to Organon in the Company's financial statements resulted from Merck's merger with Schering-Plough Corporation (Schering-Plough) in 2009. Goodwill was attributed to Organon based on the fair value of the Organon business as of the acquisition date relative to the total fair value of Schering-Plough. Goodwill, attributable only to the Organon Products reporting unit, is 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 fair value is less than carrying value. If the Company concludes it is more likely than not that fair value is less than carrying value, a quantitative fair value test is performed. If carrying value is greater than fair value, a goodwill impairment charge will be recorded for the difference (up to the carrying value of goodwill). As of the most recent goodwill impairment testing date, the reporting unit's fair value exceeded its carrying value by a substantial amount.

Acquired Intangibles — Acquired intangibles include products and product rights and licenses, which are initially recorded at fair value, assigned an estimated useful life, and amortized on a straight-line basis over their estimated useful lives. Substantially all of the products and product rights intangible assets attributed to Organon in the Company's financial statements resulted from Merck's merger with Schering-Plough. The intangible assets attributable to the Company's operations have been reflected in the combined financial statements based on Merck's historical cost. Licenses include milestone payments made to collaborative partners upon or subsequent to regulatory approval. The estimated useful lives of acquired intangibles range from 5 to 15 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.

Research and Development — Research and development costs are expensed as incurred. Research and development costs also include upfront and milestone payments related to licensing or collaborative arrangements involving clinical development programs that have not yet received regulatory approval.

Foreign Currency Translation — The net assets of international operations 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 loss* and reflected as a separate component of equity. For those operations that operate in highly inflationary economies and for those operations 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*.

Merck calculates foreign currency translation on its consolidated assets and liabilities, which include assets and liabilities of the Company. These combined financial statements include Merck's foreign currency translation for the Organon entities and the Transferring Entities. Other than for the Organon Entities and the

Transferring Entities, since the Company has not historically recorded foreign currency translation on its own assets and liabilities, foreign currency translation recorded in these combined financial statements, is based on currency movements specific to the Company's combined financial statements during the periods presented.

Share-Based Compensation — Certain of the Company's employees have historically participated in Merck's share-based compensation plans. Share-based compensation expense has been allocated to the Company based on a proportionate cost allocation method. The Company expenses all share-based payments to employees over the requisite service period based on the grant-date fair value of the awards.

Pension Benefits — The defined benefit plans in which the Company participates relate primarily to plans sponsored by Merck and for which other businesses of Merck also participate (Shared Plans). The Company accounts for the Shared Plans as multiemployer plans and therefore the related assets and liabilities are not reflected in the combined balance sheet. The combined statement of income reflects a proportional allocation of net periodic benefit cost for the Shared Plans associated with the Company. For certain defined benefit plans attributable to the Organon Entities and the Transferring Entities, the overfunded or underfunded status of the plan is recognized as an asset or liability on the combined balance sheet.

Restructuring Costs — Costs associated with exit or disposal activities are recognized in the period in which they are incurred. 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. The combined financial statements include restructuring costs directly identifiable to the Organon Entities and the Transferring Entities and a proportional allocation of Merck's restructuring costs associated with the Company. The Company has recorded liabilities for costs associated with restructuring activities related to the Organon Entities and the Transferring Entities. When accruing these costs, the Company recognizes 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 with the range.

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 — Income tax expense and deferred tax balances have been calculated on a separate tax return basis. The Company's operations are included in the tax returns of certain Organon Entities, Transferring Entities or the respective Merck entities of which the Company's business is a part. In the future, as a standalone entity, the Company will file tax returns on its own behalf and its deferred taxes and effective tax rate may differ from those in the historical periods. 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 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.

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* in the combined statement of 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. The Company does not maintain an income taxes payable to or from account as it is deemed to be settled with the tax paying entities in the respective jurisdictions. These settlements are reflected as changes in *Net investment from Parent* on the combined balance sheet. However, the Company's combined balance sheet reflects balances with taxing authorities for certain Organon Entities and

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Transferring Entities and the one-time transition tax resulting from the Tax Cuts and Jobs Act of 2017 (TCJA), as well as for unrecognized income tax benefits along with related interest and penalties. The Company and Merck will enter into a tax matters agreement prior to the separation.

Use of Estimates — The combined 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 in determining the allocation of costs and expenses from Merck, and are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, valuation of goodwill and intangibles, amounts recorded for contingencies, environmental liabilities and other reserves, pension and share-based compensation assumptions, restructuring costs, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

Net Investment from Parent — *Net investment from Parent* in the combined balance sheet represents Merck's historical investment in the Company, the accumulated net earnings after taxes and the net effect of the transactions with and allocations from Merck. See Notes 2 and 17 for additional information.

Recently Adopted Accounting Standards — In May 2014, the Financial Accounting Standards Board (FASB) issued amended accounting guidance on revenue recognition that applies to all contracts with customers. The objective of the new guidance is to improve comparability of revenue recognition practices across entities and to provide more useful information to users of financial statements through improved disclosure requirements. The new standard permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of adopting the guidance being recognized at the date of initial application (modified retrospective method). The new standard was effective as of January 1, 2018 and was adopted using the modified retrospective method. The adoption of the new standard had a *de minimis* impact on the Company's combined financial statements.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. The new guidance requires the recognition of the income tax consequences of an intra-entity transfer of an asset (with the exception of inventory) when the intra-entity transfer occurs, replacing the prohibition against doing so. The current exception to defer the recognition of any tax impact on the transfer of inventory within the consolidated entity until it is sold to a third party remains unaffected. The new standard was effective as of January 1, 2018 and was adopted using a modified retrospective approach. The Company recorded a cumulative-effect adjustment upon adoption increasing *Net investment from Parent* by \$329 million with a corresponding decrease to *Deferred Income Taxes*.

In February 2018, the FASB issued an accounting standards update to address a narrow-scope financial reporting issue that arose as a consequence of the TCJA. The new standard allows a company to make a one-time election to reclassify stranded tax effects resulting from the TCJA from accumulated other comprehensive income to retained earnings. The new standard also requires companies to disclose their accounting policy for releasing stranded income tax effects from accumulated other comprehensive income. The Company has elected not to reclassify stranded tax effects resulting from the TCJA. The Company's policy for releasing disproportionate income tax effects from *Accumulated other comprehensive loss* is to utilize the item-by-item approach.

In January 2017, the FASB issued guidance that provides for the elimination of Step 2 from the goodwill impairment test. Under the new guidance, impairment charges are recognized to the extent the carrying amount of a reporting unit exceeds its fair value with certain limitations. The Company adopted the new standard in 2018. The adoption of the new guidance had an immaterial effect on its combined financial statements.

In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases and subsequently issued several updates to the new guidance (new leasing guidance). The new leasing guidance requires that lessees recognize a right-of-use asset and a lease liability for each of its leases (other than leases that

meet the definition of a short-term lease). Leases are classified as either operating or finance. Operating leases result in straight-line expense in the income statement (similar to previous operating leases), while finance leases result in more expense being recognized in the earlier years of the lease term (similar to previous capital leases). The Company adopted the new standard on January 1, 2019 using a modified retrospective approach and elected the transition method that allows for application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented in the financial statements. The Company also elected available practical expedients. Upon adoption, the Company recognized \$67 million of additional assets and related liabilities on its combined balance sheet. The adoption of the new leasing guidance did not impact the Company's combined statements of income or of cash flows.

In August 2018, the FASB issued new guidance modifying the disclosure requirements for employers that sponsor defined benefit pension or other postretirement plans. The new guidance removes disclosures that no longer are considered cost beneficial, clarifies the specific requirements of certain disclosures, and adds disclosure requirements identified as relevant. The Company elected to early adopt the new guidance in 2019 and has incorporated the new guidance into its employee benefit plan disclosures (see Note 12).

Also, in August 2018, the FASB issued new guidance on fair value measurements that adds, removes, and modifies certain disclosure requirements. The Company elected to early adopt the new guidance in 2019. There were no changes to the Company's existing fair value disclosures upon adoption.

In June 2016, the 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 combined 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. The Company adopted the new guidance effective January 1, 2020. There was no impact to the Company's combined financial statements upon adoption.

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 combined financial statements upon adoption.

4. Samsung Collaboration

In 2013, Merck entered into an agreement with Samsung Bioepis Co., Ltd. (Samsung Bioepis) to develop and commercialize multiple pre-specified biosimilar candidates, which have since launched and are part of the Company's product portfolio. Under the agreement, Samsung Bioepis is responsible for preclinical and clinical development, process development and manufacturing, clinical trials and registration of product candidates, and the Company has an exclusive license for worldwide commercialization with certain geographic exceptions specified on a product-by-product basis. The Company's access rights to each product under the agreement last for 10 years from each product's launch date on a market-by-market basis. Gross profits are shared equally in all markets with the exception of Brazil where gross profits are shared 65% to Samsung Bioepis and 35% to the Company. Since the Company 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. Generally, profit sharing adjustments are recorded either to *Cost of sales* (after commercialization) or *Selling, general and administrative* expenses (prior to commercialization).

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In addition to an upfront payment upon execution of the arrangement, Samsung Bioepis is eligible for additional payments associated with pre-specified clinical and regulatory milestones. Milestone payments made to Samsung Bioepis were \$25 million in 2020 and \$50 million in 2019. At December 31, 2020, potential future regulatory milestone payments of \$25 million remain under the agreement.

Summarized information related to this collaboration is as follows:

<u>Years Ended December 31</u>	<u>2020</u>	<u>2019</u>	<u>2018</u>
Sales	\$330	\$252	\$ 64
Cost of sales	208	152	40
Selling, general and administrative	87	91	47
<u>December 31</u>		<u>2020</u>	<u>2019</u>
Receivables from Samsung included in <i>Other current assets</i>		\$ 52	\$ 86
Payables to Samsung included in <i>Trade Accounts Payable</i>		13	—

5. Restructuring

Certain of the Company's operations have been affected by restructuring plans initiated by Merck. These restructuring plans include a global restructuring program approved in 2019 focused primarily on further optimizing Merck's manufacturing and supply network and reducing its global real estate footprint. The Company's operations were also affected by previous restructuring plans designed to streamline Merck's cost structure, which included the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities.

The following table summarizes the charges directly attributed to the Organon Entities and the Transferring Entities as well as charges allocated to the Company related to these restructuring program activities by type of cost:

	<u>Separation Costs</u>	<u>Accelerated Depreciation</u>	<u>Other</u>	<u>Total</u>
<u>Year Ended December 31, 2020</u>				
Cost of sales	\$ —	\$ —	\$ 3	\$ 3
Restructuring costs	33	—	37	70
	<u>\$ 33</u>	<u>\$ —</u>	<u>\$ 40</u>	<u>\$ 73</u>
<u>Year Ended December 31, 2019</u>				
Cost of sales	\$ —	\$ 7	\$—	\$ 7
Restructuring costs	87	—	14	101
	<u>\$ 87</u>	<u>\$ 7</u>	<u>\$ 14</u>	<u>\$108</u>
<u>Year Ended December 31, 2018</u>				
Cost of sales	\$ —	\$ 5	\$ 2	\$ 7
Restructuring costs	86	—	33	119
	<u>\$ 86</u>	<u>\$ 5</u>	<u>\$ 35</u>	<u>\$126</u>

Restructuring costs allocated to the Company were \$58 million, \$73 million and \$96 million in 2020, 2019 and 2018, respectively. Separation costs are associated with actual headcount reductions made by Merck, as well as those headcount reductions which were probable and could be reasonably estimated. Other activity represents costs associated with facilities to be sold or closed including allocated accelerated depreciation expense for facilities retained by Merck, asset abandonment, shut-down and other related costs.

The Company has recorded liabilities for costs associated with restructuring activities related to the Organon Entities and the Transferring Entities included primarily in *Accrued and other current liabilities*, which were \$18 million and \$10 million at December 31, 2020 and 2019, respectively.

6. Financial Instruments

Merck manages the impact of foreign exchange rate movements on its affiliates' earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments. Merck has established revenue hedging and balance sheet risk management programs to protect against the volatility of future foreign currency cash flows and changes in fair value caused by volatility in exchange rates that the Company participates in. Accordingly, the combined statement of income includes the impact of Merck's derivative financial instruments that is deemed to be associated with the Company's operations and has been allocated to the Company utilizing a proportional allocation method. In 2020, the recognized amount allocated to *Sales* was *de minimis*. In 2019 and 2018, the Company recognized allocated net (gains) losses of \$(73) million and \$44 million, respectively, in *Sales*. In 2020, 2019 and 2018, the Company recognized allocated net losses (gains) of \$52 million, \$3 million and \$(107) million, respectively, in *Other (income) expense, net*. Additionally, direct and allocated foreign currency transaction gains and losses included in *Other (income) expense, net* in 2020, 2019 and 2018 were net losses of \$18 million, \$61 million and \$167 million, respectively.

Concentrations of Credit Risk

On an ongoing basis, the Company's operations form part of Merck's monitoring of concentrations of credit risk associated with corporate and government issuers of securities and financial institutions with which Merck conducts business. Credit exposure limits are established to limit a concentration with any single issuer or institution.

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's customers with the largest accounts receivable balances are AAH Pharmaceuticals LTD (headquartered in the UK), McKesson Corporation, AmerisourceBergen Corporation, and Cardinal Health, Inc., which represented, in aggregate, approximately 30% of total accounts receivable at December 31, 2020. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

Merck has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. Merck factored \$227 million and \$488 million of accounts receivable related to the Company 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 combined statement of cash flows.

7. Inventories

Inventories at December 31 consisted of:

	<u>2020</u>	<u>2019</u>
Finished goods	\$ 409	\$ 463
Raw materials and work in process	630	632
Supplies	60	73
Total (approximates current cost)	1,099	1,168
Decrease to LIFO cost	(1)	(4)
	<u>\$1,098</u>	<u>\$1,164</u>
Recognized as:		
Inventories	\$ 971	\$1,071
Other assets	127	93

Inventories valued under the LIFO method comprised \$48 million and \$62 million at December 31, 2020 and 2019, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories not expected to be sold within one year.

8. Other Intangibles

Other intangibles at December 31 consisted of:

	<u>2020</u>			<u>2019</u>		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	\$24,159	\$ 23,787	\$372	\$24,159	\$ 23,715	\$444
Licenses	201	70	131	176	51	125
	<u>\$ 24,360</u>	<u>\$ 23,857</u>	<u>\$ 503</u>	<u>\$ 24,335</u>	<u>\$ 23,766</u>	<u>\$ 569</u>

Acquired intangibles include products and products rights, and licenses, which are initially recorded at fair value, assigned an estimated useful life, and amortized on a straight-line basis over their estimated useful lives. At December 31, 2020, the Company's most significant acquired intangible asset balance included in products and product rights above related to *Nexplanon/Implanon*, which had a net balance of \$354 million. At December 31, 2020, the most significant amounts within licenses relate to capitalized milestone payments associated with the Samsung Bioepis collaboration (see Note 4), which had a net balance of \$113 million in the aggregate.

Aggregate amortization expense recorded within *Cost of sales* was \$85 million in 2020, \$285 million in 2019 and \$1.6 billion in 2018. The estimated aggregate amortization expense for each of the next five years is as follows: 2021, \$83 million; 2022, \$82 million; 2023, \$78 million; 2024, \$73 million; 2025, \$73 million.

9. Leases

The Company has operating leases primarily for real estate. 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 the Company 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 the Company will exercise that option. Real estate leases for facilities have an average remaining lease term of 6.8 years, which for

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one lease includes an option to extend for 5 years. The Company has made an accounting policy election not to record short-term leases (leases with an initial term of 12 months or less) on the balance sheet; however, the Company 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 most of the Company's leases do not have a readily determinable implicit discount rate, the Company uses Merck's incremental borrowing rate to calculate the present value of lease payments. On a quarterly basis, an updated incremental borrowing rate is determined based on the average remaining lease term of each asset class and Merck'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. The Company 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). Direct and allocated operating lease cost was \$49 million in 2020 and \$57 million in 2019. Direct and allocated rental expense under operating leases for periods prior to the adoption of the new leasing guidance was \$58 million in 2018.

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 is immaterial and there are no sale-leaseback transactions. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Supplemental balance sheet information related to operating leases is as follows:

<u>December 31</u>	<u>2020</u>	<u>2019</u>
Assets		
Other Assets	\$ 91	\$ 82
Liabilities		
Accrued and other current liabilities	20	14
Other Noncurrent Liabilities	71	68
	<u>\$ 91</u>	<u>\$ 82</u>
Weighted-average remaining lease term (years)	6.8	8.3
Weighted-average discount rate	2.7%	3.3%

Maturities of operating leases liabilities are as follows:

2021	\$22
2022	19
2023	16
2024	10
2025	9
Thereafter	23
Total lease payments	99
Less: Imputed interest	8
	<u>\$ 91</u>

At December 31, 2020, the Company had entered into real estate operating leases that had not yet commenced. The obligations associated with these leases total \$280 million, of which \$115 million relates to a lease for Organon's corporate headquarters that will commence in March 2021 and has a lease term of 11 years.

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

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

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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 in a N.J. coordinated proceeding. 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.

Nexplanon/Implanon

Merck is a defendant in lawsuits brought by individuals relating to the use of Implanon and Nexplanon. In the United States, as of December 31, 2020, there were two filed product liability actions involving Implanon, both of which are pending in the Northern District of Ohio. In addition, there are 55 unfiled cases alleging similar injuries, which have been tolled under a written tolling agreement. There is one filed action related to Nexplanon in the United States seeking compensation for alleged injuries or medical bills involving complicated removals of Nexplanon. As of December 31, 2020, Merck had 21 cases pending outside the United States pertaining to insertion and removal related events, of which 15 relate to Implanon and six relate to Nexplanon.

Propecia/Proscar

Merck is a defendant in product liability lawsuits in the United States involving Propecia and/or Proscar. The lawsuits were filed in various federal courts and in state court in New Jersey. The federal lawsuits were then consolidated for pretrial purposes in a federal multidistrict litigation in the Eastern District of New York (the MDL), and Judge Brian Cogan now presides over these matters. The matters pending in state court in New Jersey were consolidated in Middlesex County (N.J. Coordinated Proceedings). Merck is also defending a Propecia matter in state court in Los Angeles, California.

In 2018, Merck and the Plaintiffs' Executive Committee in the MDL and the Plaintiffs' Liaison Counsel in the N.J. Coordinated Proceedings entered into an agreement to resolve the above mentioned Propecia/Proscar lawsuits for an aggregate amount of \$4.3 million. The settlement was subject to certain contingencies, including 95% plaintiff participation and a per plaintiff clawback if the participation rate was less than 100%. The contingencies were satisfied and the settlement agreement has been finalized. At December 31, 2020, fewer than 10 cases remain pending in the United States. The Company is also defending 16 product liability cases outside the United States.

Vioxx

Merck Sharp & Dohme Farmaceutica Ltda. is a named defendant in product liability cases in Brazil alleging personal injury or economic loss as a result of the purchase or use of Vioxx, including two individual actions and seven putative class action proceedings. Organon will not be liable for the results of the Vioxx litigation.

Governmental Proceedings

Merck'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. Merck's policy is to cooperate with these authorities and to provide responses as appropriate.

From time to time, Merck's subsidiaries receive 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

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.

Organon will not be liable for the results of the *Zetia* Antitrust litigation.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications (NDAs) with the U.S. Food and Drug Administration (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, potential payment of damages and legal fees, and, with respect to products acquired through acquisitions, potentially significant intangible asset impairment charges.

Nasonex — *Nasonex* lost market exclusivity in the United States in 2016. Prior to that, in April 2015, Merck filed a patent infringement lawsuit against Apotex Inc. and Apotex Corp. (Apotex) in respect of Apotex's marketed product that Merck believed was infringing. In January 2018, Merck and Apotex settled this matter with Apotex agreeing to pay \$115 million plus certain other consideration.

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 *Inter Partes* Review (IPR) proceedings in the United States Patent and Trademark Office (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 \$35 million and \$40 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

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled \$24 million and \$21 million at December 31, 2020 and 2019, respectively. 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 \$20 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. Share-Based Compensation Plans

Merck has share-based compensation plans under which it grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors of Merck may be granted options to purchase shares of Merck's common stock at the fair market value at the time of grant.

For the periods presented, since the Company operated together with other Merck businesses, the Company has determined that it is not practicable to specifically identify share-based compensation expense for Merck awards related to the Company's employees. Accordingly, such expense, as well as expense related to Merck's corporate and shared functional employees, has been allocated to the Company on a proportional cost allocation method, primarily based on revenue or directly identifiable costs, depending on the employee's function. The amounts presented are not necessarily indicative of future awards and do not necessarily reflect the costs that the Company would have incurred as an independent company for the periods presented.

Total allocated share-based compensation expense and the associated income tax benefits recognized by the Company in the combined statement of income are as follows:

<i>Years Ended December 31</i>	<u>2020</u>	<u>2019</u>	<u>2018</u>
Share-based compensation expense	\$ 54	\$ 52	\$ 56
Income tax benefits	11	11	12

12. Pension and Other Postretirement Benefit Plans

The Organon Entities and the Transferring Entities are the plan sponsors for certain defined benefit pension plans and these combined financial statements reflect the periodic benefit costs and funded status of such plans. The Company uses December 31 as the year-end measurement date for these plans.

Further, Merck has defined benefit pension plans covering eligible employees in the United States and in certain of its international subsidiaries. Merck also provides medical benefits, principally to its eligible U.S. retirees and their dependents through its other postretirement benefit plans. Liabilities associated with these plans are not reflected in the Company's combined balance sheet. The combined statement of income includes expense allocations for these benefits which were determined using a proportional allocation method. Total benefit plan expense allocated to the Company amounted to \$55 million, \$29 million and \$42 million for the years ended 2020, 2019 and 2018, respectively.

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The following tables provide disclosures for pension plans of the Organon Entities and the Transferring Entities:

Net Periodic Benefit Cost

The net periodic benefit (credit) cost for pension plans consisted of the following components:

<i>Years Ended December 31</i>	<u>2020</u>	<u>2019</u>	<u>2018</u>
Service cost	\$ 36	\$ 28	\$ 30
Interest cost	35	51	51
Expected return on plan assets	(97)	(117)	(121)
Amortization of unrecognized prior service cost	(3)	(2)	(3)
Net loss amortization	18	9	15
Settlements	2	—	1
Net periodic benefit credit	<u>\$ (9)</u>	<u>\$ (31)</u>	<u>\$ (27)</u>

The components of net periodic benefit (credit) cost other than the service cost component for the pension plans of the Organon Entities and the Transferring Entities are included in *Other (income) expense, net* (see Note 13).

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:

	<u>2020</u>	<u>2019</u>
Fair value of plan assets January 1	\$ 2,864	\$2,433
Actual return on plan assets	128	414
Company contributions	34	27
Effects of exchange rate changes	161	30
Benefits paid	(46)	(43)
Other	5	3
Net transfer of plan assets to Merck affiliates	(2,710)	—
Fair value of plan assets December 31	\$ 436	\$2,864
Benefit obligation January 1	\$ 2,746	\$2,326
Service cost	36	28
Interest cost	35	51
Actuarial losses	207	363
Benefits paid	(46)	(43)
Effects of exchange rate changes	155	18
Other	4	3
Net transfer of benefit obligations to Merck affiliates	(2,646)	—
Benefit obligation December 31	\$ 491	\$2,746
Funded status December 31	<u>\$ (55)</u>	<u>\$ 118</u>
Recognized as:		
Other assets	\$ —	\$ 177
Other Noncurrent Liabilities	(55)	(59)

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During the fourth quarter of 2020, (i) certain Transferring Entities transferred net pension assets of \$61 million, reflecting plan assets of \$2.7 billion and benefit obligations of \$2.6 billion from the Merck Retained Products business to Merck affiliates related to plan participants that will remain with the Parent, and (ii) \$3 million of benefit obligations were contributed by Merck affiliates to the Organon Entities related to participants of Merck sponsored plans that were transferred to the Company in 2020.

At December 31, 2020 and 2019, the accumulated benefit obligation for the pension plans was \$429 million and \$1.1 billion, respectively. The decline in 2020 resulted primarily from the transfers noted above.

Information related to the funded status of selected pension plans at December 31 is as follows:

	2020	2019
Pension plans with a projected benefit obligation in excess of plan assets		
Projected benefit obligation	\$491	\$1,178
Fair value of plan assets	435	1,118
Pension plans with an accumulated benefit obligation in excess of plan assets		
Accumulated benefit obligation	\$ 54	\$ 45
Fair value of plan assets	38	34

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.

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.

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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	Total	Level 1	Level 2	Level 3	Total
	2020				2019			
Cash and cash equivalents	\$ —	\$ —	\$ —	\$ —	\$ 4	\$ —	\$ —	\$ 4
<i>Investment funds</i>								
Developed markets equities	—	198	—	198	—	1,332	—	1,332
Government and agency obligations	—	198	—	198	—	1,018	—	1,018
Emerging markets equities	—	—	—	—	—	96	—	96
<i>Fixed income securities</i>								
Government and agency obligations	—	5	—	5	—	—	—	—
<i>Other investments</i>								
Insurance contracts	—	34	—	34	—	32	382	414
Other	—	1	—	1	—	—	—	—
Plan assets at fair value	<u>\$ —</u>	<u>\$ 436</u>	<u>\$ —</u>	<u>\$ 436</u>	<u>\$ 4</u>	<u>\$ 2,478</u>	<u>\$ 382</u>	<u>\$ 2,864</u>

The targeted investment portfolio for the Company's pension plans that are sponsored outside the United States varies based on the duration of pension liabilities and local government rules and regulations.

The table below provides a summary of the changes in fair value 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	Insurance Contracts
Balance January 1	\$ 382	\$ 357
Actual return on plan assets still held at December 31	—	42
Purchases and sales, net	—	(17)
Transfer of plan assets to Merck affiliates	(382)	—
Balance December 31	<u>\$ —</u>	<u>\$ 382</u>

Expected Contributions

Expected contributions during 2021 are approximately \$15 million for the pension plans of the Organon Entities and the Transferring Entities.

Expected Benefit Payments

Expected benefit payments are follows: 2021, \$1 million; 2022, \$2 million; 2023, \$4 million; 2024, \$4 million; 2025, \$3 million; 2026-2030, \$32 million. 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.

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<i>Years Ended December 31</i>	<u>2020</u>	<u>2019</u>	<u>2018</u>
Net loss arising during the period	<u>\$ (186)</u>	<u>\$ (75)</u>	<u>\$ (96)</u>
Prior service cost arising during the period	<u>(1)</u>	<u>—</u>	<u>(7)</u>
	<u>\$ (187)</u>	<u>\$ (75)</u>	<u>\$ (103)</u>
Net loss amortization included in benefit cost	<u>\$ 18</u>	<u>\$ 9</u>	<u>\$ 15</u>
Prior service credit amortization included in benefit cost	<u>(3)</u>	<u>(2)</u>	<u>(3)</u>
	<u>\$ 15</u>	<u>\$ 7</u>	<u>\$ 12</u>

Actuarial Assumptions

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining pension plan information are as follows:

<i>December 31</i>	<u>2020</u>	<u>2019</u>	<u>2018</u>
Net periodic benefit cost			
Discount rate	<u>1.75%</u>	<u>2.51%</u>	<u>2.36%</u>
Expected rate of return on plan assets	<u>4.35%</u>	<u>4.95%</u>	<u>5.40%</u>
Salary growth rate	<u>2.22%</u>	<u>3.14%</u>	<u>3.13%</u>
Benefit obligation			
Discount rate	<u>0.93%</u>	<u>1.63%</u>	<u>2.39%</u>
Salary growth rate	<u>2.68%</u>	<u>3.03%</u>	<u>3.13%</u>

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 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.

Savings Plan

Merck also maintains defined contribution savings plans in the United States, which the Company participates in. The Company matches a percentage of employees' contributions. The amount allocated for total employer contributions in 2020, 2019, and 2018 was \$18 million, \$18 million, and \$21 million, respectively, which is recognized as an expense in the combined statement of income.

13. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

<i>Years Ended December 31</i>	<u>2020</u>	<u>2019</u>	<u>2018</u>
Interest income	<u>\$ (16)</u>	<u>\$ (19)</u>	<u>\$ (21)</u>
Interest expense	<u>6</u>	<u>6</u>	<u>6</u>
Exchange losses	<u>70</u>	<u>64</u>	<u>60</u>
Net periodic defined benefit plan credit other than service cost	<u>(45)</u>	<u>(59)</u>	<u>(57)</u>
Cost reimbursements and fees to (from) Merck affiliates	<u>22</u>	<u>19</u>	<u>(26)</u>
Other, net	<u>(8)</u>	<u>(12)</u>	<u>(104)</u>
	<u>\$ 29</u>	<u>\$ (1)</u>	<u>\$ (142)</u>

Other, net (as presented in the table above) in 2018 includes a gain of \$115 million related to the settlement of certain patent litigation (see Note 10).

14. Taxes on Income

For purposes of these combined financial statements, income taxes have been calculated as if the Company filed income tax returns on a standalone basis. The Company believes the assumptions supporting its allocation and presentation of income taxes on a separate return basis are reasonable. One of these assumptions is that the Company on a standalone basis will not benefit from certain tax incentives that historically benefited Merck. However, the taxes recognized in the combined financial statements and resulting effective tax rates may not be reflective of the taxes that the Company expects to recognize in the future as a standalone entity.

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	\$ 563	21.0%	\$ 747	21.0%	\$ 573	21.0%
Differential arising from:						
Foreign earnings	(54)	(2.0)	(166)	(4.7)	(121)	(4.6)
Tax settlements	—	—	(264)	(7.4)	(20)	(0.7)
Amortization of intangible assets	12	0.4	22	0.6	116	4.3
Other ⁽¹⁾	(1)	—	(2)	—	28	1.1
	<u>\$ 520</u>	<u>19.4%</u>	<u>337</u>	<u>9.5%</u>	<u>576</u>	<u>21.1%</u>

(1) Other includes impact of the TCJA, state taxes, the tax effects of tax-deductible expenses and miscellaneous items.

The Company's remaining transition tax liability under the TCJA that was enacted in 2017, which has been reduced by payments, was \$1.5 billion and \$1.7 billion at December 31, 2020 and 2019, respectively. Of these amounts, \$161 million is included in *Income Taxes Payable* at both December 31, 2020 and 2019, and the remainder of \$1.3 billion and \$1.5 billion at December 31, 2020 and 2019, respectively, is included in *Other Noncurrent Liabilities*. As a result of the TCJA, the Company has made a determination it is no longer indefinitely reinvested with respect to its previously taxed undistributed earnings from foreign subsidiaries and provided for a deferred tax liability for withholding taxes due upon future remittances, net of certain foreign income tax credits. The Company has continued to accrue for income taxes that will be due upon future remittances of undistributed foreign earnings in the amount of \$79 million and \$32 million as of December 31, 2020 and 2019, respectively, for withholding taxes due and taxable currency gains and losses, net of certain foreign income tax credits.

The tax effects of foreign earnings in the tax rate reconciliation above primarily reflect the effects of operations in jurisdictions with different tax rates than the United States 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 a newly active legal entity.

Income before taxes consisted of:

<u>Years Ended December 31</u>	<u>2020</u>	<u>2019</u>	<u>2018</u>
Domestic	\$ 528	\$ 516	\$ 414
Foreign	2,152	3,039	2,315
	<u>\$ 2,680</u>	<u>\$ 3,555</u>	<u>\$ 2,729</u>

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Taxes on income consisted of:

<u>Years Ended December 31</u>	<u>2020</u>	<u>2019</u>	<u>2018</u>
<i>Current provision</i>			
Federal	\$ 101	\$(164)	\$ 152
Foreign	412	480	395
State	1	(45)	(8)
	<u>\$514</u>	<u>\$271</u>	<u>\$539</u>
<i>Deferred provision</i>			
Federal	\$ 9	\$ 3	\$ (44)
Foreign	(4)	44	65
State	1	19	16
	<u>\$ 6</u>	<u>\$ 66</u>	<u>\$ 37</u>
	<u>\$ 520</u>	<u>\$ 337</u>	<u>\$ 576</u>

Deferred income taxes at December 31 consisted of:

	<u>2020</u>		<u>2019</u>	
	<u>Assets</u>	<u>Liabilities</u>	<u>Assets</u>	<u>Liabilities</u>
Product intangibles and licenses	\$ 24	\$ —	\$ 22	\$ —
Inventory related	—	10	—	32
Reserves and allowances	50	—	41	—
Unrecognized tax benefits	18	—	17	—
Unremitted foreign earnings	—	79	—	32
Net operating losses and other tax credit carryforwards	72	—	80	—
Other	43	—	48	—
Subtotal	207	89	208	64
Valuation allowance	(81)	—	(86)	—
Total deferred taxes	<u>\$ 126</u>	<u>\$ 89</u>	<u>\$ 122</u>	<u>\$ 64</u>
Net deferred income taxes	<u>\$ 37</u>	—	<u>\$ 58</u>	—
Recognized as:				
Other Assets	\$ 165	—	\$ 197	—
Deferred Income Taxes	—	\$ 128	—	\$ 139

The Company has recognized \$67 million and \$78 million of deferred taxes on net operating loss (NOL) carryforwards in Brazil as of December 31, 2020 and December 31, 2019, respectively. Valuation allowances of \$81 million and \$86 million have been established on these foreign NOL carryforwards and other deferred tax assets in Brazil as of December 31, 2020 and December 31, 2019, respectively. The Company has no NOL carryforwards relating to U.S. jurisdictions.

Income taxes paid in 2020, 2019 and 2018 were \$391 million, \$920 million and \$678 million, respectively.

As of December 31, 2020 and 2019, the Company deferred the income tax consequences resulting from intra-entity transfers of inventory totaling \$421 million and \$657 million, respectively. These amounts are reflected in *Other current assets*.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	<u>2020</u>	<u>2019</u>	<u>2018</u>
Balance January 1	\$213	\$ 619	\$659
Additions related to current year tax positions	15	12	29
Additions related to prior year tax positions	23	4	3
Reductions for tax positions of prior years ⁽¹⁾	(3)	(274)	(6)
Settlements ⁽¹⁾	(19)	(140)	(49)
Lapse of statute of limitations	(10)	(8)	(17)
Balance December 31	<u>\$219</u>	<u>\$ 213</u>	<u>\$619</u>

⁽¹⁾ Amounts in 2019 reflect the settlement with the IRS discussed below.

If the Company were to recognize the unrecognized tax benefits of \$219 million at December 31, 2020, the income tax provision would reflect a favorable net impact of \$211 million.

The Company is part of Merck's consolidated U.S. federal income tax return, as well as separate and combined Merck income tax returns in numerous state and international jurisdictions. Merck 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 \$52 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 Merck'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 \$12 million in 2020, \$(48) million in 2019 and \$21 million in 2018. These amounts reflect the beneficial impacts of various tax settlements, including those discussed below. Liabilities for accrued interest and penalties were \$68 million and \$61 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 reflected a payment of \$142 million in the combined financial statements. 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 net tax benefit of \$258 million 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 Merck's tax returns for the years 2015 and 2016. In addition, various state and foreign tax examinations are in progress and for these jurisdictions, Merck's income tax returns are open for examination for the period 2003 through 2020.

15. Other Comprehensive Income (Loss)

Changes in *Accumulated other comprehensive loss* by component are as follows:

	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Loss
Balance January 1, 2018, net of taxes	\$ (235)	\$ (489)	\$ (724)
Other comprehensive income (loss), pretax	(91)	(125)	(216)
Tax	32	—	32
Other comprehensive income (loss), net of taxes	(59)	(125)	(184)
Balance at December 31, 2018, net of taxes	(294)	(614)	(908)
Other comprehensive income (loss), pretax	(68)	54	(14)
Tax	8	—	8
Other comprehensive income (loss), net of taxes	(60)	54	(6)
Balance at December 31, 2019, net of taxes	(354)	(560)	(914)
Other comprehensive income (loss), pretax	(172)	(30)	(202)
Tax	29	—	29
Other comprehensive income (loss), net of taxes	(143)	(30)	(173)
Transfer of benefit plans to Merck affiliates	465	—	465
Balance at December 31, 2020, net of taxes	\$ (32)	\$ (590)	\$ (622)

During the fourth quarter of 2020, corresponding to the transfer of net pension assets of \$61 million from the Merck Retained Products business of certain Transferring Entities to Merck affiliates, the Company derecognized the related amounts recognized in *Other Comprehensive Income* as *Net transfers to Parent* in the combined statement of equity.

16. Segment Reporting

The Company's operations are principally managed on a products basis and include two operating segments, the Organon Products segment and the Merck Retained Products segment. The Organon Products segment is engaged in developing and delivering innovative health solutions through its portfolio of prescription therapies within women's health, biosimilars and established brands. The Merck Retained Products segment reflects the results of the Transferring Entities with respect to other Merck products that will be retained by the Parent. For certain Transferring Entities that distributed the Merck Retained Products business to the Parent in the fourth quarter of 2020, the Merck Retained Products segment reflects results up to the date of distribution.

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Sales of the Company's products were as follows:

Years Ended December 31	2020			2019			2018		
	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Organon Products segment									
Women's Health									
Nexplanon/Implanon	\$ 488	\$ 192	\$ 680	\$ 568	\$ 219	\$ 787	\$ 495	\$ 208	\$ 703
NuvaRing	110	127	236	742	136	879	722	180	902
Follistim AQ	84	109	193	103	138	241	115	153	268
Orgalutran	11	69	81	25	86	112	48	93	141
Cerazette	—	67	67	—	71	71	—	90	90
Biosimilars									
Renflexis	122	13	135	94	3	97	26	1	27
Ontruzant	3	113	115	—	83	83	—	20	20
Brenzys	—	74	74	—	72	72	—	16	16
Established Brands									
<i>Cardiovascular</i>									
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
Rosuzet	—	130	130	—	120	120	—	58	58
Cozaar/Hyzaar	21	365	386	24	418	442	23	431	453
Zocor	2	75	77	6	107	112	5	116	121
<i>Respiratory</i>									
Singulair	18	444	462	29	669	698	20	688	708
Dulera	188	35	222	188	30	217	199	28	227
Nasonex	12	206	218	9	284	293	23	353	376
Clarinx	7	123	130	8	133	142	10	145	155
Asmanex	75	8	83	84	10	94	100	13	113
<i>Non-Opioid Pain, Bone and Dermatology</i>									
Arcoxia	—	258	258	—	288	288	—	335	335
Fosamax	4	176	180	9	188	197	4	205	209
Diprosan	—	118	118	—	102	102	—	102	102
Diprosone	1	82	83	1	83	84	(1)	92	91
<i>Other</i>									
Proscar	2	174	176	2	202	203	2	183	185
Propecia	10	119	129	11	120	131	12	119	131
Sinemet	(1)	78	77	1	78	79	4	98	102
Remeron	2	61	64	3	79	82	2	130	132
Other Organon Products segment ⁽¹⁾	232	807	1,041	60	826	885	131	793	926
Total Organon Products segment sales	1,402	5,130	6,532	1,997	5,780	7,777	1,995	6,297	8,292
Merck Retained Products Segment									
Keytruda	—	529	529	—	493	493	—	309	309
Januvia/Janumet	—	76	76	—	110	110	—	113	113
Gardasil/Gardasil 9	—	52	52	—	70	70	—	63	63
Zostavax	—	50	50	—	65	65	—	76	76
Simponi	—	49	49	—	69	69	—	92	92
Varivax	—	1	1	—	93	93	—	19	19
Supply sales to Merck affiliates	—	542	542	—	501	501	—	432	432
Other Merck Retained Products segment ⁽¹⁾	—	265	265	—	352	352	—	381	381
Total Merck Retained Products segment sales	—	1,564	1,564	—	1,753	1,753	—	1,485	1,485
	\$1,402	\$6,694	\$8,096	\$1,997	\$7,533	\$9,530	\$1,995	\$7,782	\$9,777

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

⁽¹⁾ Includes sales of products not listed separately, revenue resulting from an arrangement for the sale of generic etonogestrel/ethinyl estradiol vaginal ring, allocated amounts from revenue hedging activities, and manufacturing sales to Merck and third parties.

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Combined sales by geographic area where derived are as follows:

<i>Years Ended December 31</i>	2020			2019			2018		
	Organon Products	Merck Retained Products	Total	Organon Products	Merck Retained Products	Total	Organon Products	Merck Retained Products	Total
Europe, Middle East and Africa	\$ 2,092	\$ 1,000	\$3,092	\$ 2,222	\$ 1,149	\$3,371	\$ 2,707	\$ 1,031	\$3,738
United States	1,402	—	1,402	1,997	—	1,997	1,995	—	1,995
Latin America	434	490	924	472	547	1,019	535	402	937
China	873	—	873	1,027	—	1,027	908	—	908
Other Asia Pacific	774	74	848	816	42	858	888	55	943
Japan	765	—	765	1,015	—	1,015	1,120	—	1,120
Canada	185	—	185	170	—	170	175	—	175
Other	7	—	7	58	15	73	(36)	(3)	(39)
	<u>\$ 6,532</u>	<u>\$ 1,564</u>	<u>\$8,096</u>	<u>\$ 7,777</u>	<u>\$ 1,753</u>	<u>\$9,530</u>	<u>\$ 8,292</u>	<u>\$ 1,485</u>	<u>\$9,777</u>

Income Before Taxes by segment is as follows:

<i>Years Ended December 31</i>	2020			2019			2018		
	Organon Products	Merck Retained Products	Total	Organon Products	Merck Retained Products	Total	Organon Products	Merck Retained Products	Total
Sales	\$ 6,532	\$ 1,564	\$8,096	\$ 7,777	\$ 1,753	\$9,530	\$ 8,292	\$ 1,485	\$9,777
Costs, Expenses and Other									
Cost of sales	2,119	1,228	3,347	2,274	1,347	3,621	3,541	1,152	4,693
Selling, general and administrative	1,356	310	1,666	1,443	479	1,922	1,567	446	2,013
Research and development	210	94	304	220	112	332	262	103	365
Restructuring costs	60	10	70	78	23	101	108	11	119
Other (income) expense, net	35	(6)	29	66	(67)	(1)	(51)	(91)	(142)
Income (Loss) Before Taxes	<u>\$ 2,752</u>	<u>\$ (72)</u>	<u>\$2,680</u>	<u>\$ 3,696</u>	<u>\$ (141)</u>	<u>\$3,555</u>	<u>\$ 2,865</u>	<u>\$ (136)</u>	<u>\$2,729</u>

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Interest income, interest expense and depreciation and amortization by segment is as follows:

<i>Years Ended December 31</i>	Organon			Merck			Organon			Merck		
	Products	Retained Products	Total	Products	Retained Products	Total	Products	Retained Products	Total	Products	Retained Products	Total
	2020			2019			2018					
Interest income	\$ (1)	\$ (15)	\$ (16)	\$ —	\$ (19)	\$ (19)	\$ —	\$ (21)	\$ (21)			
Interest expense	1	5	6	—	6	6	—	6	6			
Depreciation and amortization	142	15	157	333	21	354	1,655	18	1,673			

Property, plant and equipment, net, by geographic area where located is as follows:

<i>December 31</i>	2020	2019	2018
Europe, Middle East and Africa	\$749	\$564	\$534
North America	132	—	—
Latin America	91	96	97
Asia Pacific	23	19	18
Other	3	1	2
	\$998	\$680	\$651

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

17. Related Party Disclosures

The Company has not historically operated as a standalone business and the combined financial statements are derived from the consolidated financial statements and accounting records of Merck. The following disclosure summarizes activity between the Company and Merck, including the affiliates of Merck that are not part of the planned spin-off.

Cost Allocations from Merck

Merck provides significant corporate, manufacturing, selling, marketing, administrative, research services and resources to the Company. Some of these services will continue to be provided by Merck to the Company on a temporary basis after the separation is completed under a transition services agreement. The combined financial statements reflect an allocation of these costs. See Note 2 for a discussion of these costs and the methodology used to allocate them.

These allocations are reflected in the combined statement of income as follows:

<i>Years Ended December 31</i>	2020	2019	2018
Cost of sales	\$ 466	\$ 528	\$ 453
Selling, general and administrative	765	837	879
Research and development	153	200	251
	\$ 1,384	\$ 1,565	\$ 1,583

Management believes these cost allocations are a reasonable reflection of the utilization of services provided to, or the benefit derived by, the Company during the periods presented. The allocations may not, however, be indicative of the actual expenses that would have been incurred had the Company operated as a

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standalone public company. Actual costs that may have been incurred if the Company had been a standalone public company would depend on a number of factors, including the chosen organizational structure, whether functions were outsourced or performed by Company's employees, and strategic decisions made in areas such as manufacturing, selling and marketing, research and development, information technology and infrastructure.

Related Party Transactions

The Organon Entities and the Transferring Entities have entered into the following transactions with other Merck affiliates:

<i>Years Ended December 31</i>	<u>2020</u>	<u>2019</u>	<u>2018</u>
Supply sales to Merck affiliates	\$ 599	\$ 501	\$432
Purchases from Merck affiliates	1,039	1,087	923
Interest expense, net, on loans and advances with Merck affiliates	2	3	2
Cost reimbursements and fees from (to) Merck affiliates	22	19	(26)

The Company had the following balances with Merck affiliates:

<i>December 31</i>	<u>2020</u>	<u>2019</u>
Trade receivables, net	\$—	\$ 32
Less: Short term borrowings, net	—	(19)
Due from related party	<u>\$—</u>	<u>\$ 13</u>

<i>December 31</i>	<u>2020</u>	<u>2019</u>
Short term borrowings, net	\$1,266	\$—
Short term loans and notes payable, net	25	34
Less: Trade receivables, net	(141)	—
Due to related party	<u>\$1,150</u>	<u>\$ 34</u>

<i>December 31</i>	<u>2020</u>	<u>2019</u>
Related Party Loans Payable	\$—	\$70

Short term borrowings, net, reflects balances from temporary cash transfers between the Company and Merck affiliates under Merck's centralized cash management that are held in Organon Entities and the Transferring Entities, and as of December 31, 2020, primarily represent balances resulting from transfers between Organon Entities, the Transferring Entities and Merck affiliates during the fourth quarter of 2020 (see Note 2) that will be settled between the entities prior to the completion of the spin-off.

Net Transfers to Parent

Net transfers to Parent are included within *Net investment from Parent* in the combined statement of equity and within financing activities in the combined statement of cash flows and represent the net effect of transactions between the Company and Merck. The components of net transfers to Parent are as follows:

<i>Years Ended December 31</i>	<u>2020</u>	<u>2019</u>	<u>2018</u>
Cash pooling and general financing activities	\$ 5,107	\$ 4,845	\$ 6,332
Cost allocations, excluding non-cash share-based compensation	(1,330)	(1,513)	(1,527)
Taxes deemed settled with the Parent	(384)	(825)	(645)
Allocated derivative and hedging (losses) gains	(53)	70	63
Net transfers to Parent as reflected in the Combined Statement of Cash Flows	<u>3,340</u>	<u>2,577</u>	<u>4,223</u>
Share-based compensation expense	(54)	(52)	(56)
Net assets distributed to Merck affiliates	250	—	—
Derecognition of amounts recognized in <i>Accumulated other comprehensive loss</i> related to employee benefit plan transfers to Merck affiliates	465	—	—
Net transfers to Parent as reflected in the Combined Statement of Equity	<u>\$ 4,001</u>	<u>\$ 2,525</u>	<u>\$ 4,167</u>

During the fourth quarter of 2020, transfers between the Organon Entities, the Transferring Entities and Merck affiliates were recognized in *Net transfers to Parent* in the combined statement of equity at Merck's historical cost (see Note 2) and consisted of (i) the distribution of assets related to the Merck Retained Products business from the Transferring Entities to Merck affiliates, including property, plant and equipment, net, of \$100 million, net pension assets of \$61 million, inventories of \$135 million and other noncurrent assets of \$160 million, partially offset by (ii) the contribution of assets and liabilities related to the Organon Products business from Merck affiliates to Organon Entities, including property, plant and equipment, net, of \$198 million historically operated by Transferring Entities and other assets, net, of \$8 million.

18. Subsequent Events

These combined financial statements were derived from the financial statements of Merck, which issued its annual financial statements for the fiscal year ended December 31, 2020 on February 25, 2021. Accordingly, the Company has evaluated transactions for consideration as recognized subsequent events in these financial statements through the date of February 25, 2021.

Events Subsequent to the Original Issuance of the Combined Financial Statements (Unaudited)

The Company has evaluated transactions that occurred through April 29, 2021, the date these financial statements were available for reissuance, for the purposes of unrecognized subsequent events.

In March 2021, Merck and Alydia Health announced a definitive agreement pursuant to which, after the spin-off, Organon will acquire Alydia Health for up to \$240 million in total consideration, subject to customary purchase price adjustments. Total consideration includes a \$215 million upfront payment plus a \$25 million sales-based contingent milestone payment. Alydia Health is a commercial-stage medical device company focused on preventing maternal morbidity and mortality caused by postpartum hemorrhage or abnormal postpartum uterine bleeding. Of the \$215 million upfront payment, \$50 million was paid by Merck and the remaining \$165 million will be paid by Organon upon the closing of the acquisition, which remains subject to customary closing conditions and completion of the spin-off of Organon from Merck. The \$25 million contingent milestone payment will be paid by Organon upon achievement of the milestone.

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In April 2021, Organon Finance 1 LLC, a subsidiary of Merck, issued €1.25 billion aggregate principal amount of 2.875% senior secured notes due 2028, \$2.1 billion aggregate principal amount of 4.125% senior secured notes due 2028 and \$2.0 billion aggregate principal amount of 5.125% senior unsecured notes due 2031 (collectively, the notes), in connection with the spin-off of Organon. As part of the spin-off, the notes will be assumed by Organon and a Dutch private limited company, a wholly owned subsidiary of Organon, which acted as co-issuer of the notes. The proceeds of the notes offering will be held in escrow until satisfaction of the conditions precedent to the spin-off and certain other escrow release conditions.