As filed with the Securities and Exchange Commission on March 17, 2021

File No. 001-

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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	**85-2269702**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. employer Identification number)**
30 Hudson Street, Jersey City, NJ	**07302**
(Address of principal executive offices)	**(Zip Code)**

(551) 430-6000
(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
		Emerging growth company	☐

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

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:

Exhibit Number	Exhibit Description
2.1	Form of Separation and Distribution Agreement by and between Merck & Co., Inc. and Organon & Co.*
3.1	Form of Certificate of Incorporation of Organon & Co.
3.2	Form of 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
21.1	Subsidiaries of the Registrant*
99.1	Information Statement of Organon & Co., preliminary and subject to completion.

* To be filed by amendment.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 17, 2021

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

Exhibit 3.1

FORM OF AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

Organon & Co.
(a Delaware corporation)

Organon & Co., a corporation organized and existing under the laws of the State of Delaware, pursuant to Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware (the "DGCL"), as it may be amended, DOES HEREBY CERTIFY AS FOLLOWS:

1. The name of the corporation is Organon & Co.

2. The original certificate of incorporation of the corporation was filed with the Secretary of State of the State of Delaware on March 11, 2020 under the name "Organon & Co."

3. This Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), which restates, integrates and amends the certificate of incorporation of the corporation as heretofore in effect, has been adopted by the corporation in accordance with Sections 242 and 245 of the DGCL, and has been adopted by the consent of the stockholders of the corporation in accordance with Section 228 of the DGCL.

4. The text of the certificate of incorporation of the corporation is hereby amended and restated by this Certificate of Incorporation to read in its entirety as follows:

ARTICLE I
NAME

The name of the corporation is Organon & Co. (the "Corporation").

ARTICLE II
REGISTERED OFFICE; REGISTERED AGENT; OTHER OFFICES

(a) The address of the Corporation's registered office in the State of Delaware is 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

(b) The Corporation may have such other offices, either within or without the State of Delaware, as the Board of Directors of the Corporation (the "Board of Directors") may designate or as the business of the Corporation may from time to time require.

ARTICLE III
PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV
STOCK

Section 4.1 Authorized Stock. The total number of shares which the Corporation shall have authority to issue is , of which shall be designated as Common Stock, par value $0.01 per share (the "Common Stock"), and shall be designated as Preferred Stock, par value $0.01 per share (the "Preferred Stock").

Section 4.2 Common Stock.

(a) Except as required by law, each holder of Common Stock, as such, shall be entitled to one vote for each share of Common Stock held of record by such holder on all matters on which stockholders generally are entitled to vote; provided, however, that holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Certificate of Incorporation, including any certificate of designations relating to any series of Preferred Stock (each hereinafter referred to as a "Preferred Stock Designation"), that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation (including any Preferred Stock Designation).

(b) Dividends. Subject to the rights of the holders of any outstanding series of Preferred Stock, the holders of shares of Common Stock shall be entitled to receive dividends to the extent permitted by law when, as and if declared by the Board of Directors out of funds legally available therefor.

(c) Liquidation, Dissolution or Winding Up. Subject to the rights of the holders of any outstanding series of Preferred Stock, upon the dissolution, liquidation or winding up of the Corporation, whether voluntary or involuntary, the holders of shares of Common Stock shall be entitled to receive the assets of the Corporation available for distribution to its stockholders ratably in proportion to the number of shares held by them.

Section 4.3 Preferred Stock. Shares of Preferred Stock may be issued from time to time in one or more series. Subject to limitations prescribed by law and the provisions of this Article IV (including any Preferred Stock Designation), the Board of Directors (or such duly authorized committee thereof) is hereby authorized to provide, by resolution and by causing the filing of a Preferred Stock Designation for the issuance of the shares of Preferred Stock in one or more series, and, with respect to each such series, to establish from time to time the number of shares to be included in each such series, and to fix the designations, powers, preferences, and relative, participating, optional or other rights, if any, and the qualifications, limitations or restrictions, if any, of the shares of each such series.

Section 4.4 No Class Vote on Changes in Authorized Number of Shares of Stock. Subject to the rights of the holders of any outstanding series of Preferred Stock, the number of authorized shares of Common Stock or Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of at least a majority of the voting power of the stock of the Corporation outstanding and entitled to vote thereon irrespective of the provisions of Section 242(b)(2) of the DGCL.

ARTICLE V
BOARD OF DIRECTORS

Section 5.1 Number. Except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), the Board of Directors shall consist of such number of directors, not fewer than three nor more than fifteen directors, as may, from time to time, be determined solely by the Board of Directors in accordance with the Bylaws of the Corporation (as amended from time to time, the "Bylaws").

Section 5.2 Terms.

(a) Except as may be otherwise provided with respect to directors elected by the holders of any series of Preferred Stock provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation) (the "Preferred Stock Directors"), the Board of Directors shall be divided into three classes, as nearly equal in number as possible, designated Class I, Class II and Class III. Class I directors shall initially serve until the first annual meeting of stockholders following the time at which the initial classification of the Board of Directors becomes effective, expected to be held in 2022, and director nominees elected to succeed such Class I directors as Class I directors shall hold office for a three-year term and until the election and qualification of their respective successors in office or until any such director's earlier death, resignation, removal, retirement or disqualification. Directors designated as Class II directors shall initially serve until the second annual meeting of stockholders following the time at which the initial classification of the Board of Directors becomes effective, expected to be held in 2023, and director nominees elected to succeed such Class II directors as Class II directors shall hold office for a two-year term and until the election and qualification of their respective successors in office or until any such director's earlier death, resignation, removal, retirement or disqualification. Directors designated as Class III directors shall initially serve until the third annual meeting of stockholders following the time at which the initial classification of the Board of Directors becomes effective, expected to be held in 2024, and director nominees elected to succeed such Class III directors as Class III directors shall hold office for a one-year term and until the election and qualification of their respective successors in office or until any such director's earlier death, resignation, removal, retirement or disqualification. Commencing with the fourth annual meeting of stockholders following the time at which the initial classification of the Board of Directors becomes effective, expected to be held in 2025, directors of each class the term of which shall then or thereafter expire shall be elected to hold office for a one-year term and until the election and qualification of their respective successors in office or until any such director's earlier death, resignation, removal, retirement or disqualification. Prior to the fourth annual meeting of stockholders following the time at which the initial classification of the Board of Directors becomes effective, in case of any increase or decrease, from time to time, in the number of directors (other than Preferred Stock Directors), the number of directors in each class shall be apportioned as nearly equal as possible. The Board of Directors is authorized to assign members of the Board of Directors already in office to Class I, Class II or Class III, with such assignment becoming effective as of the time at which the initial classification of the Board of Directors becomes effective.

(b) Subject to the rights of the holders of any outstanding series of Preferred Stock, and unless otherwise required by law, newly created directorships resulting from any increase in the authorized number of directors and any vacancies in the Board of Directors resulting from death, resignation, retirement, disqualification, removal from office or other cause shall be filled solely by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Directors, or by the sole remaining director. Any director so chosen shall hold office until the next election of the class, if any, for which such director shall have been chosen and until his or her successor shall have been duly elected and qualified or until any such director's earlier death, resignation, removal, retirement or disqualification. Notwithstanding the foregoing, from and after the fourth annual meeting of stockholders following the time at which the initial classification of the Board of Directors becomes effective, expected to be held in 2025, any director so chosen shall hold office until the next election of directors and until his or her successor shall have been duly elected and qualified or until any such director's earlier death, resignation, removal, retirement or disqualification. No decrease in the authorized number of directors shall shorten the term of any incumbent director.

(c) Any director (other than any Preferred Stock Director) may be removed from office at any time, but only for cause and only by the affirmative vote of the holders of at least a majority of the voting power of the stock outstanding and entitled to vote thereon; provided, however, that from and after the fourth annual meeting of stockholders following the time at which the initial classification of the Board of Directors becomes effective, any director may be removed with or without cause and only by the affirmative vote of the holders of at least a majority of the voting power of the stock outstanding and entitled to vote thereon. Notwithstanding the foregoing, whenever the holders of any class or series are entitled to elect one or more directors by this Certificate of Incorporation (including any Preferred Stock Designation), with respect to the removal without cause of a director or directors so elected, the vote of the holders of the outstanding shares of that class or series and not the vote of the outstanding shares as a whole shall apply.

(d) During any period when the holders of any series of Preferred Stock have the right to elect additional directors as provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), and upon commencement and for the duration of the period during which such right continues: (i) the then otherwise total authorized number of directors of the Corporation shall automatically be increased by such number of directors that the holders of any series of Preferred Stock have a right to elect, and the holders of such Preferred Stock shall be entitled to elect the additional directors so provided for or fixed pursuant to said provisions; and (ii) each Preferred Stock Director shall serve until such Preferred Stock Director's successor shall have been duly elected and qualified, or until such director's right to hold such office terminates pursuant to said provisions, whichever occurs earlier, subject to his or her earlier death, disqualification, resignation or removal. Except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), whenever the holders of any series of Preferred Stock having such right to elect additional directors are divested of such right pursuant to said provisions, the terms of office of all Preferred Stock Directors elected by the holders of such Preferred Stock, or elected to fill any vacancies resulting from the death, resignation, disqualification or removal of such additional directors, shall forthwith terminate (in which case each such Preferred Stock Director shall cease to be qualified as a director and shall cease to be a director) and the total authorized number of directors of the Corporation shall be automatically reduced accordingly.

Section 5.3 Powers. Except as otherwise required by the DGCL or as provided in this Certificate of Incorporation (including any Preferred Stock Designation), the business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

Section 5.4 Election; Annual Meeting of Stockholders.

(a) Ballot Not Required. The directors of the Corporation need not be elected by written ballot unless the Bylaws so provide.

(b) Notice. Advance notice of nominations for the election of directors, and of business other than nominations, to be proposed by stockholders for consideration at a meeting of stockholders of the Corporation shall be given in the manner and to the extent provided in or contemplated by the Bylaws.

(c) Annual Meeting. Any annual meeting of stockholders, for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly come before the meeting, shall be held at such place, if any, either within or without the State of Delaware, on such date, and at such time as the Board of Directors shall fix. The Board of Directors may postpone, reschedule or cancel any annual meeting of stockholders previously scheduled by the Board of Directors.

ARTICLE VI
STOCKHOLDER ACTION

Except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), no action that is required or permitted to be taken by the stockholders of the Corporation may be effected by consent of stockholders in lieu of a meeting of stockholders.

ARTICLE VII
SPECIAL MEETINGS OF STOCKHOLDERS

Except as otherwise required by law, and except as otherwise provided for or fixed pursuant to the provisions of Article IV hereof (including any Preferred Stock Designation), a special meeting of the stockholders of the Corporation may be called at any time only by the Board of Directors. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the Board of Directors.

ARTICLE VIII
EXISTENCE

The Corporation shall have perpetual existence.

ARTICLE IX
AMENDMENT

Section 9.1 Amendment of the Certificate of Incorporation. The Corporation reserves the right at any time, and from time to time, to amend, alter, change or repeal any provision contained in this Certificate of Incorporation (including any Preferred Stock Designation), and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by the laws of the State of Delaware, and all powers, preferences and rights of any nature conferred upon stockholders, directors or any other persons by and pursuant to this Certificate of Incorporation (including any Preferred Stock Designation) in its present form or as hereafter amended are granted subject to this reservation.

Section 9.2 Amendment of Bylaws. In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, but subject to the terms of any series of Preferred Stock then outstanding, the Board of Directors is expressly authorized to adopt, amend or repeal the Bylaws. Except as otherwise provided in this Certificate of Incorporation (including the terms of any Preferred Stock Designation) or the Bylaws, and in addition to any requirements of law, the affirmative vote of the holders of at least a majority of the voting power of the stock outstanding and entitled to vote thereon, voting together as a single class, shall be required for the stockholders to adopt, amend or repeal the Bylaws.

ARTICLE X
LIABILITY OF DIRECTORS

Section 10.1 No Personal Liability. To the fullest extent permitted by the DGCL as the same exists or as may hereafter be amended, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director.

Section 10.2 Amendment or Repeal. Any amendment, alteration or repeal of this Article X, or the adoption of any provision of the Certificate of Incorporation inconsistent with this Article X, shall not affect its application with respect to an action or omission by a director occurring before such amendment, alteration, adoption or repeal. If the DGCL hereafter is amended to eliminate or limit the liability of a director, then a director of the Corporation, in addition to the circumstances in which a director is not personally liable as set forth in the preceding sentence, shall not be liable to the fullest extent permitted by the amended DGCL.

***

This Amended and Restated Certificate of Incorporation shall become effective at Eastern Time on , 2021.

[*The remainder of this page has been intentionally left blank.*]

IN WITNESS WHEREOF, this Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of the Corporation on this day of , 2021.

By: _____
Name:
Title:

Exhibit 3.2

FORM OF AMENDED AND RESTATED BYLAWS

of
Organon & Co.
(a Delaware corporation)

ARTICLE I
CORPORATE OFFICES

Section 1.1 Registered Office. The registered office of Organon & Co. (the "Corporation") shall be fixed in the Certificate of Incorporation of the Corporation (as the same may be amended and/or restated from time to time, the "Certificate of Incorporation").

Section 1.2 Other Offices. The Corporation may also have an office or offices, and keep the books and records of the Corporation, except as otherwise required by law, at such other place or places, either within or without the State of Delaware, as the Board of Directors may designate or as the business of the Corporation may from time to time require.

ARTICLE II
MEETINGS OF STOCKHOLDERS

Section 2.1 Annual Meeting. Any annual meeting of stockholders, for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly come before the meeting, shall be held at such place, if any, either within or without the State of Delaware, on such date, and at such time as the Board of Directors shall fix. The Board of Directors may postpone, reschedule or cancel any annual meeting of stockholders previously scheduled by the Board of Directors.

Section 2.2 Special Meeting.

(a) General. Except as otherwise required by law, and except as otherwise provided for or fixed pursuant to the Certificate of Incorporation, including any certificate of designations relating to any series of Preferred Stock (each hereinafter referred to as a "Preferred Stock Designation"), special meetings of the stockholders for any purpose or purposes may be called at any time only by the Board of Directors. The Board of Directors may postpone, reschedule or cancel any special meeting of stockholders previously scheduled by the Board of Directors. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the Board of Directors.

Section 2.3 Notice of Stockholders' Meetings.

(a) Whenever stockholders are required or permitted to take any action at a meeting, notice of the place, if any, date and time of the meeting of stockholders, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for determining the stockholders entitled to notice of the meeting), the means of

remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting and, if the meeting is to be held solely by means of remote communications, the means for accessing the list of stockholders contemplated by Section 2.5 of these Bylaws, shall be given. The notice shall be given not less than 10 nor more than 60 days before the date on which the meeting is to be held, to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting, except as otherwise provided by law, the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws. In the case of a special meeting, the purpose or purposes for which the meeting is called also shall be set forth in the notice.

(b) Except as otherwise required by law, notice may be given in writing directed to a stockholder's mailing address as it appears on the records of the Corporation and shall be given: (i) if mailed, when notice is deposited in the U.S. mail, postage prepaid; and (ii) if delivered by courier service, the earlier of when the notice is received or left at such stockholder's address.

(c) So long as the Corporation is subject to the Securities and Exchange Commission (the "SEC")'s proxy rules set forth in Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), notice shall be given in the manner required by such rules. To the extent permitted by such rules, notice may be given by electronic transmission directed to the stockholder's electronic mail address, and if so given, shall be given when directed to such stockholder's electronic mail address unless the stockholder has notified the Corporation in writing or by electronic transmission of an objection to receiving notice by electronic mail or such notice is prohibited by Section 232(e) of the General Corporation Law of the State of Delaware (the "DGCL"). If notice is given by electronic mail, such notice shall comply with the applicable provisions of Sections 232(a) and 232(d) of the DGCL.

(d) Notice may be given by other forms of electronic transmission with the consent of a stockholder in the manner permitted by Section 232(b) of the DGCL, and shall be deemed given as provided therein.

(e) An affidavit that notice has been given, executed by the Secretary of the Corporation, Assistant Secretary or any transfer agent or other agent of the Corporation, shall be *prima facie* evidence of the facts stated in the notice in the absence of fraud. Notice shall be deemed to have been given to all stockholders who share an address if notice is given in accordance with the "householding" rules set forth in Rule 14a-3(e) under the Exchange Act and Section 233 of the DGCL.

(f) When a meeting is adjourned to another time or place, notice need not be given of the adjourned meeting if the place, if any, date and time thereof, and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting, are announced at the meeting at which the adjournment is taken; provided, however, that if the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the Board of Directors shall fix a new record date for notice of such adjourned meeting in accordance with Section 7.6(a), and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

Section 2.4 Organization and Conduct of Meetings.

(a) Unless otherwise determined by the Board of Directors, meetings of stockholders shall be presided over by the Chairman of the Board of Directors, or in his or her absence, by the Chief Executive Officer or, in his or her absence, by another person designated by the Board of Directors. The Secretary of the Corporation, or in his or her absence, an Assistant Secretary, or in the absence of the Secretary of the Corporation and all Assistant Secretaries, a person whom the chairman of the meeting shall appoint, shall act as secretary of the meeting and keep a record of the proceedings thereof.

(b) The date and time of the opening and the closing of the polls for each matter upon which the stockholders shall vote at a meeting of stockholders shall be announced at the meeting by the chairman of the meeting. The Board of Directors may adopt such rules and regulations for the conduct of any meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board of Directors, the chairman of the meeting shall have the authority to adopt and enforce such rules and regulations for the conduct of any meeting of stockholders and the safety of those in attendance as, in the judgment of the chairman, are necessary, appropriate or convenient for the conduct of the meeting. Rules and regulations for the conduct of meetings of stockholders, whether adopted by the Board of Directors or by the chairman of the meeting, may include, without limitation, establishing: (i) an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies and such other persons as the chairman of the meeting shall permit; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; (v) limitations on the time allotted for consideration of each agenda item and for questions and comments by participants; (vi) regulations for the opening and closing of the polls for balloting and matters which are to be voted on by ballot (if any); and (vii) procedures (if any) requiring attendees to provide the Corporation advance notice of their intent to attend the meeting. Subject to any rules and regulations adopted by the Board of Directors, the chairman of the meeting may convene and, for any or no reason, from time to time, adjourn and/or recess any meeting of stockholders pursuant to Section 2.7. The chairman of the meeting, in addition to making any other determinations that may be appropriate to the conduct of the meeting, shall declare that a nomination or other business was not properly brought before the meeting if the facts warrant (including if a determination is made, pursuant to Section 2.10(c)(i) of these Bylaws, that a nomination or other business was not made or proposed, as the case may be, in accordance with Section 2.10 of these Bylaws), and if such chairman should so declare, such nomination shall be disregarded or such other business shall not be transacted.

Section 2.5 List of Stockholders. The Corporation shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; provided, however, that if the record date for determining the stockholders entitled to vote is less than 10 days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the 10th day before the meeting date. Such list shall be arranged in

alphabetical order and shall show the address of each stockholder and the number of shares registered in the name of each stockholder. Nothing in this Section 2.5 shall require the Corporation to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting at least 10 days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of meeting; or (b) during ordinary business hours at the principal place of business of the Corporation. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then a list of stockholders entitled to vote at the meeting shall be produced and kept at the time and place of the meeting during the whole time thereof and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting. Except as otherwise required by law, the stock ledger shall be the only evidence as to who are the stockholders entitled to examine the list of stockholders required by this Section 2.5 or to vote in person or by proxy at any meeting of stockholders.

Section 2.6 Quorum. Except as otherwise required by law, the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws, at any meeting of stockholders, the holders of a majority of the voting power of the stock outstanding and entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum for the transaction of business; provided, however, that where a separate vote by a class or series or classes or series is required, the holders of a majority of the voting power of the stock of such class or series or classes or series outstanding and entitled to vote on that matter, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to such matter. If a quorum is not present or represented at any meeting of stockholders, then the chairman of the meeting, or the holders of a majority of the voting power of the stock present in person or represented by proxy at the meeting and entitled to vote thereon, shall have power to adjourn the meeting from time to time in accordance with Section 2.7, until a quorum is present or represented. Subject to applicable law, if a quorum initially is present at any meeting of stockholders, the stockholders may continue to transact business until adjournment or recess, notwithstanding the withdrawal of enough stockholders to leave less than a quorum, but if a quorum is not present at least initially, no business other than adjournment or recess may be transacted.

Section 2.7 Adjourned or Recessed Meeting. Any annual or special meeting of stockholders, whether or not a quorum is present, may be adjourned or recessed for any or no reason from time to time by the chairman of the meeting, subject to any rules and regulations adopted by the Board of Directors pursuant to Section 2.4(b). Any such meeting may be adjourned for any or no reason from time to time by the holders of a majority of the voting power of the stock present in person or represented by proxy at the meeting and entitled to vote thereon. At any such adjourned or recessed meeting at which a quorum is present, any business may be transacted that might have been transacted at the meeting as originally called.

Section 2.8 Voting.

(a) Except as otherwise required by law or the Certificate of Incorporation (including any Preferred Stock Designation), each holder of stock of the Corporation entitled to vote at any meeting of stockholders shall be entitled to one vote for each share of such stock held of record by such holder that has voting power upon the subject matter in question.

(b) At each meeting of stockholders at which a quorum is present, all corporate actions to be taken by vote of the stockholders shall be authorized by the affirmative vote of the holders of at least a majority of the voting power of the stock present in person or represented by proxy and entitled to vote on the subject matter, unless a different or minimum vote is required by law, the Certificate of Incorporation (including any Preferred Stock Designation), these Bylaws, the rules and regulations of any stock exchange applicable to the Corporation, or any law, rule or regulation applicable to the Corporation or its securities, in which case such different or minimum vote shall be the applicable vote on the matter. Where a separate vote by a class or series or classes or series is required, if a quorum of such class or series or classes or series is present, such act shall be authorized by the affirmative vote of the holders of at least a majority of the voting power of the stock of such class or series or classes or series present in person or represented by proxy and entitled to vote on the subject matter. Voting at meetings of stockholders need not be by written ballot.

Section 2.9 Submission of Information by Director Nominees.

(a) To be eligible to be a nominee for election or re-election as a director of the Corporation, a person must deliver to the Secretary of the Corporation at the principal executive offices of the Corporation the following information:

(i) a written representation and agreement, which shall be signed by such person and pursuant to which such person shall represent and agree that such person: (A) consents to serving as a director if elected and (if applicable) to being named in the Corporation's proxy statement and form of proxy as a nominee, and currently intends to serve as a director for the full term for which such person is standing for election; (B) is not and will not become a party to any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity: (1) as to how the person, if elected as a director, will act or vote on any issue or question that has not been disclosed to the Corporation; or (2) that could limit or interfere with the person's ability to comply, if elected as a director, with such person's fiduciary duties under applicable law; (C) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director or nominee that has not been disclosed to the Corporation; and (D) if elected as a director, will comply with all of the Corporation's corporate governance, conflict of interest, confidentiality, and stock ownership and trading policies and guidelines, and any other Corporation policies and guidelines applicable to directors (which will be promptly provided following a request therefor); and

(ii) all completed and signed questionnaires prepared by the Corporation (including those questionnaires required of the Corporation's directors and any other questionnaire the Corporation determines is necessary or advisable to assess whether a nominee will satisfy any qualifications or requirements imposed by the Certificate of Incorporation or these Bylaws, any law, rule, regulation or listing standard that may be applicable to the Corporation, and the Corporation's corporate governance policies and guidelines) (all of the foregoing, the "Questionnaires"). The Questionnaires will be promptly provided following a request therefor.

(b) A nominee for election or re-election as a director of the Corporation shall also provide to the Corporation such other information as it may reasonably request. The Corporation may request such additional information as necessary to permit the Corporation to determine the eligibility of such person to serve as a director of the Corporation, including information relevant to a determination whether such person can be considered an independent director.

(c) All written and signed representations and agreements, and the Questionnaires described in Section 2.9(a)(ii) above, shall be considered timely for a nominee for election or re-election as a director of the Corporation under Section 2.10 or Section 2.11, as applicable, if provided to the Corporation by the deadlines specified in Section 2.10 or Section 2.11, as applicable. All information provided pursuant to this Section 2.9 shall be deemed part of the stockholder's notice submitted pursuant to Section 2.10 or a Stockholder Notice (as defined in Section 2.11 below), as applicable.

Section 2.10 Notice of Stockholder Business and Nominations.

(a) Annual Meeting.

(i) Nominations of persons for election to the Board of Directors and the proposal of business other than nominations to be considered by the stockholders may be made at an annual meeting of stockholders only: (A) pursuant to the Corporation's notice of meeting (or any supplement thereto); (B) by or at the direction of the Board of Directors (or any authorized committee thereof); (C) by any stockholder of the Corporation who is a stockholder of record at the time the notice provided for in this Section 2.10(a) is delivered to the Secretary of the Corporation, who is entitled to vote at the meeting and who complies with the notice procedures set forth in this Section 2.10(a); or (D) with respect to nominations of persons for election to the Board of Directors, by any Eligible Stockholder (as defined in Section 2.11) whose Stockholder Nominee (as defined in Section 2.11) is included in the Corporation's proxy materials for the relevant annual meeting. For the avoidance of doubt, the foregoing clauses (C) and (D) shall be the exclusive means for a stockholder to make director nominations, and the foregoing clause (C) shall be the exclusive means for a stockholder to propose other business at an annual meeting of stockholders (other than a proposal included in the Corporation's proxy statement pursuant to and in compliance with Rule 14a-8 under the Exchange Act).

(ii) For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to clause (C) of the foregoing paragraph, the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation and, in the case of business other than nominations, such business must be a proper subject for stockholder action. To be timely, a stockholder's notice must be delivered to the Secretary of the Corporation at the

principal executive offices of the Corporation not later than the close of business (as defined in Section 2.10(c)(ii) below) on the 120th day nor earlier than the close of business on the 150th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is more than 30 days before or more than 30 days after such anniversary date, or if no annual meeting was held or deemed to have been held in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the 150th day prior to such annual meeting and not later than the close of business on the later of the 120th day prior to such annual meeting or the 10th day following the date on which public announcement (as defined in Section 2.10(c)(ii) below) of the date of such meeting is first made by the Corporation. In no event shall an adjournment or recess of an annual meeting, or a postponement of an annual meeting for which notice of the meeting has already been given to stockholders or a public announcement of the meeting date has already been made, commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above. The number of nominees a stockholder may nominate for election at the annual meeting (or in the case of a stockholder giving the notice on behalf of a beneficial owner, the number of nominees a stockholder may nominate for election at the annual meeting on behalf of the beneficial owner) shall not exceed the number of directors to be elected at such annual meeting. For purposes of this Section 2.10, the 2021 annual meeting of stockholders shall be deemed to have been held on , 2021. Such stockholder's notice shall set forth:

(A) as to each person whom the stockholder proposes to nominate for election or re-election as a director: (1) all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required, in each case pursuant to and in accordance with Regulation 14A under the Exchange Act; and (2) the information required to be submitted by nominees pursuant to Section 2.9(a) above, including all completed and signed Questionnaires described in Section 2.9(a)(ii) above, which will be promptly provided following a request therefor;

(B) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend these Bylaws, the language of the proposed amendment), the reasons for conducting such business at the meeting and any substantial interest (within the meaning of Item 5 of Schedule 14A under the Exchange Act) in such business of such stockholder and the beneficial owner (within the meaning of Section 13(d) of the Exchange Act), if any, on whose behalf the proposal is made;

(C) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is made or the other business is proposed:

(1) the name and address of such stockholder, as they appear on the Corporation's books, and the name and address of such beneficial owner;

(2) the class or series and number of shares of stock of the Corporation which are owned of record by such stockholder and such beneficial owner as of the date of the notice, and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of the class or series and number of shares of stock of the Corporation owned of record by the stockholder and such beneficial owner as of the record date for the meeting; and

(3) a representation that the stockholder (or a qualified representative of the stockholder) intends to appear at the meeting to make such nomination or propose such business;

(D) as to the stockholder giving the notice or, if the notice is given on behalf of a beneficial owner on whose behalf the nomination is made or the other business is proposed, as to such beneficial owner, and if such stockholder or beneficial owner is an entity, as to each director, executive, managing member or control person of such entity (any such individual or control person, a "control person"):

(1) the class or series and number of shares of stock of the Corporation which are beneficially owned (as defined in Section 2.10(c)(ii) below) by such stockholder or beneficial owner and by any control person as of the date of the notice, and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of the class or series and number of shares of stock of the Corporation beneficially owned by such stockholder or beneficial owner and by any control person as of the record date for the meeting;

(2) a description of any agreement, arrangement or understanding with respect to the nomination or other business between or among such stockholder, beneficial owner or control person and any other person, including, without limitation any agreements that would be required to be disclosed pursuant to Item 5 or Item 6 of Exchange Act Schedule 13D (regardless of whether the requirement to file a Schedule 13D is applicable) and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of any such agreement, arrangement or understanding in effect as of the record date for the meeting;

(3) a description of any agreement, arrangement or understanding (including, without limitation, any derivative or short positions, profit interests, options, hedging transactions, and borrowed or loaned shares) that has been entered into as of the date of the stockholder's notice by, or on behalf of, such stockholder, beneficial owner or control person, the effect or intent of which is to mitigate loss, manage risk or benefit from changes in the share price of any class or series of the Corporation's stock, or maintain, increase or decrease the voting power of the stockholder, beneficial owner or control person with respect to securities of the Corporation, and a representation that the stockholder will notify the Corporation in writing within five business days after the record date for such meeting of any such agreement, arrangement or understanding in effect as of the record date for the meeting; and

(4) a representation whether the stockholder or the beneficial owner, if any, will engage in a solicitation with respect to the nomination or other business and, if so, the name of each participant in such solicitation (as defined in Item 4 of Schedule 14A under the Exchange Act) and whether such person intends or is part of a group which intends to deliver a proxy statement and/or form of proxy to holders of shares representing at least 50% of the voting power of the stock entitled to vote generally in the election of directors in the case of a nomination, or holders of at least the percentage of the Corporation's stock required to approve or adopt the business to be proposed in the case of other business.

(iii) Notwithstanding anything in Section 2.10(a)(ii) above or Section 2.10(b) below to the contrary, if the record date for determining the stockholders entitled to vote at any meeting of stockholders is different from the record date for determining the stockholders entitled to notice of the meeting, a stockholder's notice required by this Section 2.10 shall set forth a representation that the stockholder will notify the Corporation in writing within five business days after the record date for determining the stockholders entitled to vote at the meeting, or by the opening of business on the date of the meeting (whichever is earlier), of the information required under clauses (ii)(C)(2) and (ii)(D)(1)-(3) of this Section 2.10, and such information when provided to the Corporation shall be current as of the record date for determining the stockholders entitled to vote at the meeting.

(iv) This Section 2.10(a) shall not apply to a proposal proposed to be made by a stockholder if the stockholder has notified the Corporation of his or her intention to present the proposal at an annual or special meeting only pursuant to and in compliance with Rule 14a-8 under the Exchange Act and such proposal has been included in a proxy statement that has been prepared by the Corporation to solicit proxies for such meeting.

(v) Notwithstanding anything in this Section 2.10(a) to the contrary, in the event that the number of directors to be elected to the Board of Directors at an annual meeting is increased and there is no public announcement by the Corporation naming all of the nominees for directors or specifying the size of the increased Board of Directors made by the Corporation at least 10 days prior to the last day a stockholder may deliver a notice in accordance with Section 2.10(a)(ii) above, a stockholder's notice required by this Section 2.10(a) shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation not later than the close of business on the 10th day following the day on which such public announcement is first made by the Corporation.

(b) Special Meeting. Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation's notice of meeting: (i) by or at the direction of the Board of Directors (or any authorized committee thereof); or (ii) provided that the Board of Directors has determined that one or more directors are to be elected at such meeting, by any stockholder of the Corporation who is a stockholder of record at the time the notice provided for in this Section 2.10(b) is delivered to the Secretary of the Corporation, who is entitled to vote at the meeting and upon such election and who delivers notice thereof in writing setting forth the information required by Section 2.10(a) above and provides the additional information required by Section 2.9 above. In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board of Directors, any stockholder entitled to vote in such election of directors may nominate a person or persons (as the case may be) for election to such position(s) as specified in the Corporation's notice of meeting, if the notice required by this Section 2.10(b) shall be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation not earlier than the close of business on the 150th day prior to such special meeting and not later than the close of business on the later of the 120th day prior to such

special meeting or the 10th day following the date on which public announcement of the date of the special meeting and of the nominees to be elected at such meeting is first made by the Corporation. The number of nominees a stockholder may nominate for election at the special meeting (or in the case of a stockholder giving the notice on behalf of a beneficial owner, the number of nominees a stockholder may nominate for election at the annual meeting on behalf of such beneficial owner) shall not exceed the number of directors to be elected at such special meeting. In no event shall an adjournment, recess or postponement of a special meeting commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

(c) General.

(i) Except as otherwise required by law, only such persons who are nominated in accordance with the procedures set forth in this Section 2.10 shall be eligible to be elected at any meeting of stockholders of the Corporation to serve as directors and only such other business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 2.10. Except as otherwise required by law, each of the Chairman of the Board of Directors, the Board of Directors or the chairman of the meeting shall have the power to determine whether a nomination or any other business proposed to be brought before the meeting was made or proposed, as the case may be, in accordance with the procedures set forth in this Section 2.10 (including whether a stockholder or beneficial owner solicited (or is part of a group which solicited) or did not so solicit, as the case may be, proxies in compliance with such stockholder's representation as required by clause (a)(ii)(D)(4) of this Section 2.10). If any proposed nomination or other business is not in compliance with this Section 2.10, then except as otherwise required by law, the chairman of the meeting shall declare that such nomination shall be disregarded or that such other business shall not be transacted. Notwithstanding the foregoing provisions of this Section 2.10, unless otherwise required by law, if the stockholder does not provide the information required under Section 2.9 or clauses (a)(ii)(C)(2) and (a)(ii)(D)(1)-(3) of this Section 2.10 to the Corporation within the time frames specified herein, any such nomination shall be disregarded and any such other business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. Notwithstanding the foregoing provisions of this Section 2.10, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual or special meeting of stockholders of the Corporation to present a nomination or other business, such nomination shall be disregarded and such other business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. To be considered a qualified representative of a stockholder pursuant to the preceding sentence, a person must be a duly authorized officer, manager or partner of such stockholder or authorized by a writing executed by such stockholder (or a reliable reproduction of the writing) delivered to the Corporation prior to the making of such nomination or proposal at such meeting (and in any event not fewer than five business days before the meeting) stating that such person is authorized to act for such stockholder as proxy at the meeting of stockholders.

(ii) For purposes of these Bylaws, the "close of business" shall mean 6:00 p.m. local time at the principal executive offices of the Corporation on any calendar day, whether or not the day is a business day, and a "public announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the Corporation with the SEC pursuant to Sections 13, 14 or 15(d) of the Exchange Act. For purposes of clause (a)(ii)(D)(1) of this Section 2.10, shares shall be treated as "beneficially owned" by a person if the person beneficially owns such shares, directly or indirectly, for purposes of Section 13(d) of the Exchange Act and Regulations 13D and 13G thereunder or has or shares pursuant to any agreement, arrangement or understanding (whether or not in writing): (A) the right to acquire such shares (whether such right is exercisable immediately or only after the passage of time or the fulfillment of a condition or both); (B) the right to vote such shares, alone or in concert with others; and/or (C) investment power with respect to such shares, including the power to dispose of, or to direct the disposition of, such shares.

(iii) Nothing in this Section 2.10 shall be deemed to affect any rights of the holders of any series of Preferred Stock to elect directors pursuant to any applicable provisions of the Certificate of Incorporation (including any Preferred Stock Designation).

Section 2.11 Proxy Access for Director Nominations.

(a) Eligibility. Subject to the terms and conditions of these Bylaws, in connection with an annual meeting of stockholders at which directors are to be elected, the Corporation (x) shall include in its proxy statement and on its form of proxy the names of, and (y) shall include in its proxy statement the "Additional Information" (as defined in Section 2.11(b)(iii) below) relating to, a number of nominees specified pursuant to Section 2.11(b)(i) (the "Authorized Number") for election to the Board of Directors submitted pursuant to this Section 2.11 (each, a "Stockholder Nominee"), if:

(i) the Stockholder Nominee satisfies the eligibility requirements in this Section 2.11;

(ii) the Stockholder Nominee is identified in a timely notice (the "Stockholder Notice") that satisfies this Section 2.11 and is delivered by a stockholder that qualifies as, or is acting on behalf of, an Eligible Stockholder (as defined Section 2.11(b)(ii) below);

(iii) the Eligible Stockholder satisfies the requirements in this Section 2.11 and expressly elects at the time of the delivery of the Stockholder Notice to have the Stockholder Nominee included in the Corporation's proxy materials pursuant to this Section 2.11; and

(iv) the additional requirements of these Bylaws are met.

(b) Definitions.

(i) The maximum number of Stockholder Nominees appearing in the Corporation's proxy materials with respect to an annual meeting of stockholders (the "Authorized Number") shall not exceed the greater of (i) two or (ii) 20% of the number of directors in office as of the last day on which a Stockholder Notice may be delivered pursuant to this Section 2.11 with respect to the annual meeting, or if such amount is not a whole number, the closest whole number (rounding down) below 20%; provided that the Authorized Number shall be reduced, but not below one, (A) by any Stockholder Nominee whose name was submitted for inclusion in the Corporation's proxy materials pursuant to this Section 2.11 but

whom the Board of Directors decides to nominate as a Board nominee; (B) by any directors in office or director nominees that in either case shall be included in the Corporation's proxy materials with respect to the annual meeting as an unopposed (by the Corporation) nominee pursuant to an agreement, arrangement or other understanding between the Corporation and a stockholder or group of stockholders (other than any such agreement, arrangement or understanding entered into in connection with an acquisition of capital stock, by the stockholder or group of stockholders, from the Corporation); and (C) by any nominees who were previously elected to the Board as Stockholder Nominees at any of the preceding two annual meetings and who are nominated for election at the annual meeting by the Board as a Board nominee. In the event that one or more vacancies for any reason occurs after the date of the Stockholder Notice but before the annual meeting and the Board resolves to reduce the size of the Board in connection therewith, the Authorized Number shall be calculated based on the number of directors in office as so reduced.

(ii) To qualify as an "Eligible Stockholder," a stockholder or a group as described in this Section 2.11 must:

(A) own and have owned (as defined below), continuously for at least three years as of the date of the Stockholder Notice, a number of shares (as adjusted to account for any stock dividend, stock split, subdivision, combination, reclassification or recapitalization of outstanding shares of the Corporation that are entitled to vote generally in the election of directors) that represents at least 3% of the combined voting power of the then-outstanding shares of all classes and series of capital stock of the Corporation entitled to vote generally in the election of directors of the Corporation, voting as a single class, as of the date of the Stockholder Notice (the "Required Shares"); and

(B) thereafter continue to own the Required Shares through such annual meeting of stockholders.

For purposes of satisfying the ownership requirements of this Section 2.11(b)(ii), a group of not more than 20 stockholders and/or beneficial owners may aggregate the number of outstanding shares of the Corporation that are entitled to vote generally in the election of directors that each group member has individually owned continuously for at least three years as of the date of the Stockholder Notice if all other requirements and obligations for an Eligible Stockholder set forth in this Section 2.11 are satisfied by and as to each stockholder or beneficial owner comprising the group whose shares are aggregated. No shares may be attributed to more than one Eligible Stockholder, and no stockholder or beneficial owner, alone or together with any of its affiliates, may individually or as a member of a group qualify as or constitute more than one Eligible Stockholder under this Section 2.11. A group of any two or more funds shall be treated as only one stockholder or beneficial owner for this purpose if they are (1) under common management and investment control, or (2) part of a family of funds, meaning a group of publicly offered funds that are part of the same family of funds (whether organized in the U.S. or outside the U.S.) that hold themselves out to investors as related companies for purposes of investment and investor services. For purposes of this Section 2.11, the term "affiliate" or "affiliates" shall have the meanings ascribed thereto under the rules and regulations promulgated under the Exchange Act.

(iii) For purposes of this Section 2.11:

(A) A stockholder or beneficial owner is deemed to "own" only those outstanding shares of the Corporation that are entitled to vote generally in the election of directors as to which the person possesses both (1) the full voting and investment rights pertaining to the shares and (2) the full economic interest in (including the opportunity for profit and risk of loss on) such shares, except that the number of shares calculated in accordance with clauses (1) and (2) shall not include any shares (i) sold by such person in any transaction that has not been settled or closed, (ii) borrowed by the person for any purposes or purchased by the person pursuant to an agreement to resell, or (iii) subject to any option, warrant, forward contract, swap, contract of sale, or other derivative or similar agreement entered into by the person, whether the instrument or agreement is to be settled with shares or with cash based on the notional amount or value of outstanding shares of the Corporation that are entitled to vote generally in the election of directors, if the instrument or agreement has, or is intended to have, or if exercised would have, the purpose or effect of (x) reducing in any manner, to any extent or at any time in the future, the person's full right to vote or direct the voting of the shares, and/or (y) hedging, offsetting or altering to any degree any gain or loss arising from the full economic ownership of the shares by the person. The terms "owned," "owning" and other variations of the word "own," when used with respect to a stockholder or beneficial owner, have correlative meanings. For purposes of clauses (i) through (iii), the term "person" includes its affiliates.

(B) A stockholder or beneficial owner "owns" shares held in the name of a nominee or other intermediary so long as the person retains both (1) the full voting and investment rights pertaining to the shares and (2) the full economic interest in the shares. The person's ownership of shares is deemed to continue during any period in which the person has delegated any voting power by means of a proxy, power of attorney, or other instrument or arrangement that is revocable at any time by the stockholder.

(C) A stockholder or beneficial owner's ownership of shares shall be deemed to continue during any period in which the person has loaned the shares if the person has the power to recall the loaned shares on not more than five business days' notice and (1) the person recalls the loaned shares within five business days of the last date on which a timely Stockholder Notice may be delivered for the relevant annual meeting or the record date for the relevant annual meeting, and (2) the person holds the recalled shares through the annual meeting.

(iv) For purposes of this Section 2.11, the "Additional Information" referred to in Section 2.11(a) that the Corporation will include in its proxy statement is:

(A) the information set forth in the Schedule 14N provided with the Stockholder Notice concerning each Stockholder Nominee and the Eligible Stockholder that is required to be disclosed in the Corporation's proxy statement by the applicable requirements of the Exchange Act and the rules and regulations thereunder; and

(B) if the Eligible Stockholder so elects, a written statement of the Eligible Stockholder (or, in the case of a group, a written statement of the group), not to exceed 500 words, in support of its Stockholder Nominee(s), which must be provided at the same time as the Stockholder Notice for inclusion in the Corporation's proxy statement for the annual meeting (the "Statement").

Notwithstanding anything to the contrary contained in this Section 2.11, the Corporation may omit from its proxy materials any information or Statement that it, in good faith, believes is untrue in any material respect (or omits a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading) or would violate any applicable law, rule, regulation or listing standard. Nothing in this Section 2.11 shall limit the Corporation's ability to solicit against and include in its proxy materials its own statements relating to any Eligible Stockholder or Stockholder Nominee.

(c) Stockholder Notice and Other Informational Requirements.

(i) The Stockholder Notice shall set forth all information, representations and agreements required under Sections 2.9 and 2.10 above, including the information and Questionnaires, as applicable, required with respect to (i) any nominee for election as a director, (ii) any stockholder giving notice of an intent to nominate a candidate for election, and (iii) any stockholder, beneficial owner or other person on whose behalf the nomination is made under this Section 2.11. In addition, such Stockholder Notice shall include:

(A) a copy of the Schedule 14N that has been or concurrently is filed with the SEC under the Exchange Act;

(B) a written statement of the Eligible Stockholder (and in the case of a group, the written statement of each stockholder or beneficial owner whose shares are aggregated for purposes of constituting an Eligible Stockholder), which statement(s) shall also be included in the Schedule 14N filed with the SEC: (1) setting forth and certifying to the number of outstanding shares of the Corporation that are entitled to vote generally in the election of directors the Eligible Stockholder owns and has owned continuously for at least three years as of the date of the Stockholder Notice; (2) agreeing to continue to own such shares through the annual meeting; and (3) regarding whether or not it intends to maintain ownership of the Required Shares for at least one year following the annual meeting;

(C) the written agreement of the Eligible Stockholder (and in the case of a group, the written agreement of each stockholder or beneficial owner whose shares are aggregated for purposes of constituting an Eligible Stockholder) addressed to the Corporation, setting forth the following additional agreements, representations, and warranties:

(1) it shall provide (i) within five business days after the date of the Stockholder Notice, one or more written statements from the record holder(s) of the Required Shares and from each intermediary through which the Required Shares are or have been held, in each case during the requisite three-year holding period, specifying the number of shares that the Eligible Stockholder owns, and has owned continuously in compliance with this Section 2.11; (ii) within five business days after the record date for determining stockholders entitled to vote at the annual meeting, both the information required under Section 2.10(a)(ii)(C)(2) and Section 2.10(a)(ii)(D)(1)-(3) and written statements from the record holder(s) and intermediaries as required under clause (B)(1) of this Section 2.11(c)(1) verifying the Eligible Stockholder's continuous ownership of the Required Shares, in each case, as of such date; and (iii) immediate notice to the Corporation if the Eligible Stockholder ceases to own any of the Required Shares prior to the annual meeting;

(2) it (i) acquired the Required Shares in the ordinary course of business and not with the intent to change or influence control at the Corporation, and does not presently have this intent; (ii) has not nominated and shall not nominate for election to the Board at the annual meeting any person other than the Stockholder Nominee(s) being nominated pursuant to this Section 2.11; (iii) has not engaged and shall not engage in, and has not been and shall not be a participant (as defined in Item 4 of Exchange Act Schedule 14A) in, a solicitation within the meaning of Exchange Act Rule 14a-1(l), in support of the election of any individual as a director at the annual meeting other than its Stockholder Nominee(s) or any nominee(s) of the Board; and (iv) shall not distribute to any stockholder any form of proxy for the annual meeting other than the form distributed by the Corporation; and

(3) it will (i) assume all liability stemming from any legal or regulatory violation arising out of the Eligible Stockholder's communications with the stockholders of the Corporation or out of the information that the Eligible Stockholder provided to the Corporation; (ii) indemnify and hold harmless the Corporation and each of its directors, officers and employees individually against any liability, loss or damages in connection with any threatened or pending action, suit or proceeding, whether legal, administrative or investigative, against the Corporation or any of its directors, officers or employees arising out of the nomination or solicitation process pursuant to this Section 2.11; (iii) comply with all laws, rules, regulations and listing standards applicable to its nomination or any solicitation in connection with the annual meeting; (iv) file with the SEC any solicitation or other communication by or on behalf of the Eligible Stockholder relating to the Corporation's annual meeting of stockholders, one or more of the Corporation's directors or director nominees or any Stockholder Nominee, regardless of whether the filing is required under Exchange Act Regulation 14A, or whether any exemption from filing is available for the materials under Exchange Act Regulation 14A, and (v) at the request of the Corporation, promptly, but in any event within five business days after such request (or by the day prior to the day of the annual meeting, if earlier), provide to the Corporation such additional information as reasonably requested by the Corporation; and

(D) in the case of a nomination by a group, the designation by all group members of one group member that is authorized to act on behalf of all members of the group with respect to the nomination and matters related thereto, including withdrawal of the nomination, and the written agreement, representation, and warranty of the Eligible Stockholder that it shall provide, within five business days after the date of the Stockholder Notice, documentation reasonably satisfactory to the Corporation demonstrating that the number of stockholders and/or beneficial owners within such group does not exceed 20, including whether a group of funds qualifies as one stockholder or beneficial owner within the meaning of Section 2.11(b)(ii).

All information provided pursuant to this Section 2.11(c) shall be deemed part of the Stockholder Notice for purposes of this Section 2.11.

(ii) To be timely under this Section 2.11, the Stockholder Notice must be delivered by a stockholder to the Secretary of the Corporation at the principal executive offices of the Corporation not later than the close of business (as defined in Section 2.10(c)(ii) above) on the 120th day nor earlier than the close of business on the 150th day prior to the first anniversary of the date (as stated in the Corporation's proxy materials) the definitive proxy statement was first released to stockholders in connection with the preceding year's annual meeting of stockholders; provided, however, that in the event the annual meeting is more than 30 days before or after the anniversary of the previous year's annual meeting, or if no annual meeting was held or deemed to have been held in the preceding year, to be timely, the Stockholder Notice must be so delivered not earlier than the close of business on the 150th day prior to such annual meeting and not later than the close of business on the later of the 120th day prior to such annual meeting or the 10th day following the day on which public announcement (as defined in Section 2.10(c)(ii) above) of the date of such meeting is first made by the Corporation. In no event shall an adjournment of an annual meeting, or a postponement of an annual meeting for which notice of the meeting has already been given to stockholders or a public announcement of the meeting date has already been made, commence a new time period (or extend any time period) for the giving of the Stockholder Notice as described above. For purposes of this Section 2.11, the definitive proxy statement for the 2021 annual meeting of stockholders shall be deemed to have been first released to stockholders on , 2021.

(iii) At the request of the Corporation, a Stockholder Nominee shall promptly, but in any event within five business days after such request (or by the day prior to the day of the annual meeting, if earlier), provide to the Corporation such additional information as the Corporation may reasonably request. The Corporation may request such additional information as necessary to permit the Corporation to determine if a Stockholder Nominee satisfies the requirements of this Section 2.11, including information relevant to a determination whether the Stockholder Nominee can be considered an independent director.

(iv) In the event that any information or communications provided by the Eligible Stockholder or any Stockholder Nominees to the Corporation or its stockholders is not, when provided, or thereafter ceases to be, true, correct and complete in all material respects (including omitting a material fact necessary to make the statements made, in light of the circumstances under which they were made, not misleading), such Eligible Stockholder or Stockholder Nominee, as the case may be, shall promptly notify the Secretary of the Corporation and provide the information that is required to make such information or communication true, correct, complete and not misleading; it being understood that providing any such notification shall not be deemed to cure any defect or limit the Corporation's right to omit a Stockholder Nominee from its proxy materials as provided in this Section 2.11.

(d) Proxy Access Procedures.

(i) Notwithstanding anything to the contrary contained in this Section 2.11, the Corporation may omit from its proxy materials any Stockholder Nominee, and such nomination shall be disregarded and no vote on such Stockholder Nominee shall occur, notwithstanding that proxies in respect of such vote may have been received by the Corporation, if:

(A) the Eligible Stockholder or Stockholder Nominee breaches any of its agreements, representations or warranties set forth in the Stockholder Notice or otherwise submitted pursuant to this Section 2.11, any of the information in the Stockholder Notice or otherwise submitted pursuant to this Section 2.11 was not, when provided, true, correct and complete, or the Eligible Stockholder or applicable Stockholder Nominee otherwise fails to comply with its obligations pursuant to these Bylaws, including, but not limited to, its obligations under this Section 2.11;

(B) the Stockholder Nominee (1) is not independent under any applicable listing standards, any applicable rules of the SEC and any publicly disclosed standards used by the Board in determining and disclosing the independence of the Corporation's directors, (2) is or has been, within the past three years, an officer or director of a competitor, as defined for purposes of Section 8 of the Clayton Antitrust Act of 1914, as amended, (3) is a named subject of a pending criminal proceeding (excluding traffic violations and other minor offenses) or has been convicted in a criminal proceeding (excluding traffic violations and other minor offenses) within the past ten years, or (4) is subject to any order of the type specified in Rule 506(d) of Regulation D promulgated under the Securities Act of 1933, as amended (the "Securities Act");

(C) the Corporation has received a notice (whether or not subsequently withdrawn) that a stockholder intends to nominate any candidate for election to the Board pursuant to the advance notice requirements set forth in Section 2.10 of this Article II; or

(D) the election of the Stockholder Nominee to the Board would cause the Corporation to violate the Certificate of Incorporation, these Bylaws, or any applicable law, rule, regulation or listing standard.

(ii) An Eligible Stockholder submitting more than one Stockholder Nominee for inclusion in the Corporation's proxy materials pursuant to this Section 2.11 shall rank such Stockholder Nominees based on the order that the Eligible Stockholder desires such Stockholder Nominees to be selected for inclusion in the Corporation's proxy materials and include such assigned rank in its Stockholder Notice submitted to the Corporation. In the event that the number of Stockholder Nominees submitted by Eligible Stockholders pursuant to this Section 2.11 exceeds the Authorized Number, the Stockholder Nominees to be included in the Corporation's proxy materials shall be determined in accordance with the following provisions: one Stockholder Nominee who satisfies the eligibility requirements in this Section 2.11 shall be selected from each Eligible Stockholder for inclusion in the Corporation's proxy materials until the Authorized Number is reached, going in order of the amount (largest to smallest) of shares of the Corporation each Eligible Stockholder disclosed as owned in its Stockholder Notice submitted to the Corporation and going in the order of the rank (highest to lowest) assigned to each Stockholder Nominee by such Eligible Stockholder. If the Authorized Number is not reached after one Stockholder Nominee who satisfies the eligibility requirements in this Section 2.11 has been selected from each Eligible Stockholder, this selection process shall continue as many times as necessary, following the same order each time, until the Authorized Number is reached. Following such determination, if any Stockholder Nominee who satisfies the eligibility requirements in this Section 2.11 thereafter is nominated by the Board, thereafter is not included in the Corporation's proxy materials or thereafter is not submitted for director election for any reason (including the Eligible Stockholder's or Stockholder Nominee's failure to comply with this Section 2.11), no other nominee or nominees shall be included in the Corporation's proxy materials or otherwise submitted for election as a director at the applicable annual meeting in substitution for such Stockholder Nominee.

(iii) Any Stockholder Nominee who is included in the Corporation's proxy materials for a particular annual meeting of stockholders but either (A) withdraws from or becomes ineligible or unavailable for election at the annual meeting for any reason, including for the failure to comply with any provision of these Bylaws (provided that in no event shall any such withdrawal, ineligibility or unavailability commence a new time period (or extend any time period) for the giving of a Stockholder Notice) or (B) does not receive a number of votes cast in favor of his or her election that is at least equal to 25% of the shares present in person or represented by proxy and entitled to vote in the election of directors, shall be ineligible to be a Stockholder Nominee pursuant to this Section 2.11 for the next two annual meetings.

(iv) Notwithstanding the foregoing provisions of this Section 2.11, unless otherwise required by law or otherwise determined by the chairman of the meeting or the Board, if the stockholder delivering the Stockholder Notice (or a qualified representative of the stockholder, as defined in Section 2.10(c)(i)) does not appear at the annual meeting of stockholders of the Corporation to present its Stockholder Nominee or Stockholder Nominees, such nomination or nominations shall be disregarded, notwithstanding that proxies in respect of the election of the Stockholder Nominee or Stockholder Nominees may have been received by the Corporation. Without limiting the Board's power and authority to interpret any other provisions of these Bylaws, the Board (and any other person or body authorized by the Board) shall have the power and authority to interpret this Section 2.11 and to make any and all determinations necessary or advisable to apply this Section 2.11 to any persons, facts or circumstances, in each case acting in good faith. This Section 2.11 shall be the exclusive method for stockholders to include nominees for director election in the Corporation's proxy materials.

Section 2.12 No Action by Consent. Except as otherwise provided for or fixed pursuant to the Certificate of Incorporation (including any Preferred Stock Designation), no action that is required or permitted to be taken by the stockholders of the Corporation may be effected by consent of stockholders in lieu of a meeting of stockholders.

Section 2.13 Inspectors of Election. Before any meeting of stockholders, the Corporation may, and shall if required by law, appoint one or more inspectors of election to act at the meeting and make a written report thereof. Inspectors may be employees of the Corporation. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the chairman of the meeting may, and shall if required by law, appoint one or more inspectors to act at the meeting. Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his or her ability. Inspectors need not be stockholders. No director or nominee for the office of director at an election shall be appointed as an inspector at such election.

Such inspectors shall:

(a) determine the number of shares outstanding and the voting power of each, the number of shares represented at the meeting, the existence of a quorum, and the validity of proxies and ballots;

(b) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors;

(c) count and tabulate all votes and ballots; and

(d) certify their determination of the number of shares represented at the meeting, and their count of all votes and ballots.

Section 2.14 Meetings by Remote Communications. The Board of Directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication in accordance with Section 211(a)(2) of the DGCL. If authorized by the Board of Directors in its sole discretion, and subject to such guidelines and procedures as the Board of Directors may adopt, stockholders and proxyholders not physically present at a meeting of stockholders may, by means of remote communication: (a) participate in a meeting of stockholders; and (b) be deemed present in person and vote at a meeting of stockholders whether such meeting is to be held at a designated place or solely by means of remote communication, provided that: (i) the Corporation shall implement reasonable measures to verify that each person deemed present and permitted to vote at the meeting by means of remote communication is a stockholder or proxyholder; (ii) the Corporation shall implement reasonable measures to provide such stockholders and proxyholders a reasonable opportunity to participate in the meeting and to vote on matters submitted to the stockholders, including an opportunity to read or hear the proceedings of the meeting substantially concurrently with such proceedings; and (iii) if any stockholder or proxyholder votes or takes other action at the meeting by means of remote communication, a record of such vote or other action shall be maintained by the Corporation.

Section 2.15 Delivery to the Corporation. Whenever this Article II requires one or more persons (including a record or beneficial owner of stock) to deliver a document or information (other than a document authorizing another person to act for a stockholder by proxy at a meeting of stockholders pursuant to Section 212 of the DGCL) to the Corporation or any officer, employee or agent thereof (including any notice, request, questionnaire, revocation, representation or other document or agreement), the Corporation shall not be required to accept delivery of such document or information unless the document or information is in writing exclusively (and not in an electronic transmission) and delivered exclusively by hand (including, without limitation, overnight courier service) or by certified or registered mail, return receipt requested. For the avoidance of doubt, the Corporation expressly opts out of Section 116 of the DGCL with respect to the delivery of information and documents (other than a document authorizing another person to act for a stockholder by proxy at a meeting of stockholders pursuant to Section 212 of the DGCL) to the Corporation required by this Article II.

ARTICLE III
DIRECTORS

Section 3.1 Powers. Except as otherwise required by the DGCL or as provided in the Certificate of Incorporation (including any Preferred Stock Designation), the business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. In addition to the powers and authorities these Bylaws expressly confer upon it, the Board of Directors may exercise all such powers of the Corporation and do all such lawful acts and things as are not by law or the Certificate of Incorporation (including any Preferred Stock Designation) required to be exercised or done by the stockholders.

Section 3.2 Number and Election. Except as otherwise provided for or fixed pursuant to the Certificate of Incorporation (including any Preferred Stock Designation), the Board of Directors shall consist of such number of directors, not fewer than three nor more than fifteen directors, the exact number to be determined from time to time solely by resolution adopted by the affirmative vote of the majority of the total number of directors then authorized (the "Whole Board").

At any meeting of stockholders at which directors are to be elected, each nominee for election as a director in an uncontested election shall be elected if the number of votes cast for the nominee's election exceeds the number of votes cast against the nominee's election. In all director elections other than uncontested elections, the nominees for election as a director shall be elected by a plurality of the votes cast. For purposes of this Section 3.2, an "uncontested election" means any meeting of stockholders at which the number of candidates does not exceed the number of directors to be elected and with respect to which: (a) no stockholder has submitted notice of an intent to nominate a candidate for election at such meeting in accordance with Section 2.10 or no Eligible Stockholder has submitted a Stockholder Notice nominating a Stockholder Nominee at such meeting in accordance with Section 2.11; or (b) such a notice has been submitted, and on or before the fifth business day prior to the date that the Corporation files its definitive proxy statement relating to such meeting with the SEC (regardless of whether thereafter revised or supplemented), the notice has been: (i) withdrawn in writing to the Secretary of the Corporation; (ii) determined not to be a valid notice of nomination, with such determination to be made by the Board of Directors (or a committee thereof) pursuant to Section 2.10 or 2.11, as applicable, or if challenged in court, by a final court order; or (iii) determined by the Board of Directors (or a committee thereof) not to create a *bona fide* election contest.

Directors need not be stockholders unless so required by the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws, wherein other qualifications for directors may be prescribed.

Section 3.3 Vacancies and Newly Created Directorships. Newly created directorships resulting from any increase in the authorized number of directors or any vacancies on the Board of Directors resulting from the death, resignation, disqualification, removal from office or other cause shall be filled as set forth in the Certificate of Incorporation.

Section 3.4 Resignations and Removal. Any director may resign at any time upon notice given in writing or by electronic transmission to the Board of Directors, the Chairman of the Board of Directors or the Secretary of the Corporation. Such resignation shall take effect upon delivery, unless the resignation specifies a later effective date or time or an effective date or time determined upon the happening of an event or events. Unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective. Directors of the Corporation may be removed only as expressly provided in the Certificate of Incorporation.

Section 3.5 Regular Meetings. Regular meetings of the Board of Directors shall be held at such place or places, within or without the State of Delaware, on such date or dates and at such time or times, as shall have been established by the Board of Directors and publicized among all directors. A notice of each regular meeting shall not be required.

Section 3.6 Special Meetings. Special meetings of the Board of Directors for any purpose or purposes may be called at any time by the Chairman of the Board of Directors, the Chief Executive Officer or a majority of the directors then in office. The person or persons authorized to call special meetings of the Board of Directors may fix the place, within or without the State of Delaware, date and time of such meetings. Notice of each such meeting shall be given to each director, if by mail, addressed to such director at his or her residence or usual place of business, at least five days before the day on which such meeting is to be held, or shall be sent to such director by electronic transmission, or be delivered personally or by telephone, in each case at least 24 hours prior to the time set for such meeting. A notice of special meeting need not state the purpose of such meeting, and, unless indicated in the notice thereof, any and all business may be transacted at a special meeting.

Section 3.7 Participation in Meetings by Conference Telephone. Members of the Board of Directors, or of any committee thereof, may participate in a meeting of such Board of Directors or committee by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation shall constitute presence in person at such meeting.

Section 3.8 Quorum and Voting. Except as otherwise required by law, the Certificate of Incorporation or these Bylaws, a majority of the Whole Board shall constitute a quorum for the transaction of business at any meeting of the Board of Directors, and the vote of a majority of the directors present at a duly held meeting at which a quorum is present shall be the act of the Board of Directors. The chairman of the meeting or a majority of the directors present may adjourn the meeting to another time and place whether or not a quorum is present. At any adjourned meeting at which a quorum is present, any business may be transacted which might have been transacted at the meeting as originally called.

Section 3.9 Board of Directors Action by Written Consent Without a Meeting. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors, or any committee thereof, may be taken without a meeting, provided that all members of the Board of Directors or committee, as the case may be, consent in writing or by electronic transmission to such action. After an action is taken, the consent or consents relating thereto shall be filed with the minutes or proceedings of the Board of Directors or committee in the same paper or electronic form as the minutes are maintained. Any person (whether or not then a director) may provide, whether through instruction to an agent or otherwise, that a consent to action shall be effective at a future time

(including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made and such consent shall be deemed to have been given at such effective time so long as such person is then a director and did not revoke the consent prior to such time. Any such consent shall be revocable prior to its becoming effective.

Section 3.10 Chairman of the Board of Directors. The Chairman of the Board of Directors shall preside at meetings of stockholders and at meetings of the Board of Directors and shall perform such other duties as the Board of Directors may from time to time determine. If the Chairman of the Board of Directors is not present at a meeting of stockholders, the Chief Executive Officer shall preside at such meeting or, in his or her absence, another person designated by the Board of Directors. If the Chairman of the Board of Directors is not present at a meeting of the Board of Directors, another director chosen by the Board of Directors shall preside.

Section 3.11 Rules and Regulations. The Board of Directors shall adopt such rules and regulations not inconsistent with the provisions of law, the Certificate of Incorporation or these Bylaws for the conduct of its meetings and management of the affairs of the Corporation as the Board of Directors shall deem proper.

Section 3.12 Fees and Compensation of Directors. Unless otherwise restricted by the Certificate of Incorporation, directors may receive such compensation, if any, for their services on the Board of Directors and its committees, and such reimbursement of expenses, as may be fixed or determined by resolution of the Board of Directors.

Section 3.13 Emergency Bylaws. This Section 3.13 shall be operative during any emergency condition as contemplated by Section 110 of the DGCL (an "Emergency"), notwithstanding any different or conflicting provisions in these Bylaws, the Certificate of Incorporation or the DGCL. In the event of any Emergency, or other similar emergency condition, the director or directors in attendance at a meeting of the Board of Directors or a standing committee thereof shall constitute a quorum. Such director or directors in attendance may further take action to appoint one or more of themselves or other directors to membership on any standing or temporary committees of the Board of Directors as they shall deem necessary and appropriate. Except as the Board of Directors may otherwise determine, during any Emergency, the Corporation and its directors and officers may exercise any authority and take any action or measure contemplated by Section 110 of the DGCL.

ARTICLE IV
COMMITTEES

Section 4.1 Committees of the Board of Directors. The Board of Directors may designate one or more committees, each such committee to consist of one or more of the directors of the Corporation. The Board of Directors may designate one or more directors as alternate members of any committee to replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members present at any meeting and not disqualified from voting, whether or not he, she or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to

the extent permitted by law and provided in the resolution of the Board of Directors establishing such committee, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to the following matters: (a) approving or adopting, or recommending to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval; or (b) adopting, amending or repealing any bylaw of the Corporation. All committees of the Board of Directors shall keep minutes of their meetings and shall report their proceedings to the Board of Directors when requested or required by the Board of Directors.

Section 4.2 Meetings and Action of Committees. Unless the Board of Directors provides otherwise by resolution, any committee of the Board of Directors may adopt, alter and repeal such rules and regulations not inconsistent with the provisions of law, the Certificate of Incorporation or these Bylaws for the conduct of its meetings as such committee may deem proper. A majority of the directors then serving on a committee shall constitute a quorum for the transaction of business by the committee except as otherwise required by law, the Certificate of Incorporation or these Bylaws, and except as otherwise provided in a resolution of the Board of Directors; provided, however, that in no case shall a quorum be less than one-third of the directors then serving on the committee. Unless the Certificate of Incorporation, these Bylaws or a resolution of the Board of Directors requires a greater number, the vote of a majority of the members of a committee present at a meeting at which a quorum is present shall be the act of the committee.

ARTICLE V
OFFICERS

Section 5.1 Officers. The officers of the Corporation shall consist of a Chief Executive Officer and a Secretary of the Corporation. The Board of Directors, in its sole discretion, may also elect one or more Chief Financial Officers, Chief Operating Officers, Presidents, General Counsel, Treasurers, Controllers, Assistant Secretaries, Assistant Treasurers and such other officers as the Board of Directors may from time to time determine, each of whom shall be elected by the Board of Directors, each to have such authority, functions or duties as set forth in these Bylaws or as determined by the Board of Directors and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board of Directors. Each officer shall be elected by the Board of Directors and shall hold office for such term as may be prescribed by the Board of Directors and until such person's successor shall have been duly elected and qualified, or until such person's earlier death, disqualification, resignation or removal. Any number of offices may be held by the same person; provided, however, that no officer shall execute, acknowledge or verify any instrument in more than one capacity if such instrument is required by law, the Certificate of Incorporation or these Bylaws to be executed, acknowledged or verified by two or more officers.

Section 5.2 Compensation. The salaries of the officers of the Corporation and the manner and time of the payment of such salaries shall be fixed and determined by the Board of Directors or by a duly authorized officer and may be altered by the Board of Directors from time to time as it deems appropriate, subject to the rights, if any, of such officers under any contract of employment.

Section 5.3 Removal, Resignation and Vacancies. Any officer of the Corporation may be removed, with or without cause, by the Board of Directors or by a duly authorized officer, without prejudice to the rights, if any, of such officer under any contract to which it is a party. Any officer may resign at any time upon notice given in writing or by electronic transmission to the Corporation, without prejudice to the rights, if any, of the Corporation under any contract to which such officer is a party. If any vacancy occurs in any office of the Corporation, the Board of Directors may elect a successor to fill such vacancy for the remainder of the unexpired term and until a successor shall have been duly elected and qualified.

Section 5.4 Chief Executive Officer. The Chief Executive Officer shall have general supervision and direction of the business and affairs of the Corporation, shall be responsible for corporate policy and strategy, and shall report directly to the Board of Directors. Unless otherwise provided in these Bylaws or determined by the Board of Directors, all other officers of the Corporation shall report directly to the Chief Executive Officer or as otherwise determined by the Chief Executive Officer. The Chief Executive Officer shall, if present and in the absence of the Chairman of the Board of Directors, preside at meetings of the stockholders.

Section 5.5 Chief Financial Officer. The Chief Financial Officer shall exercise all the powers and perform the duties of the office of the chief financial officer and in general have overall supervision of the financial operations of the Corporation. The Chief Financial Officer shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors or the Chief Executive Officer may from time to time determine.

Section 5.6 General Counsel. The General Counsel will be the chief consultant of the Corporation on legal matters, will supervise all matters of legal import concerning the interests of the Corporation and shall exercise all other powers and perform the duties of the office of the General Counsel. The General Counsel shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors or the Chief Executive Officer may from time to time determine.

Section 5.7 Treasurer. The Treasurer shall supervise and be responsible for all the funds and securities of the Corporation, the deposit of all moneys and other valuables to the credit of the Corporation in depositories of the Corporation, borrowings and compliance with the provisions of all indentures, agreements and instruments governing such borrowings to which the Corporation is a party, the disbursement of funds of the Corporation and the investment of its funds, and in general shall perform all of the duties incident to the office of the Treasurer. The Treasurer shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer or the Chief Financial Officer may from time to time determine.

Section 5.8 Controller. The Controller shall, when requested, counsel with and advise the other officers of the Corporation and shall perform such other duties as the Board of Directors, the Chief Executive Officer, the Chief Financial Officer, or the Treasurer may from time to time determine.

Section 5.9 Secretary. The Secretary shall keep in safe custody the seal of the Corporation and affix it to any instrument when authorized by the Board of Directors, and shall perform all other duties incident to the office of Secretary and such other duties as may be prescribed by the Board of Directors or the Chief Executive Officer. The Secretary (or in such officer's absence, an Assistant Secretary, but if neither is present, another person selected by the chairperson for the meeting) shall have the duty to record the proceedings of the meetings of stockholders, the Board of Directors and of the committees of the Board of Directors in a book to be kept for that purpose.

Section 5.10 Additional Matters. The Chief Executive Officer and the Chief Financial Officer of the Corporation shall have the authority to designate employees of the Corporation to have the title of Vice President, Assistant Vice President, Assistant Treasurer or Assistant Secretary. Any employee so designated shall have the powers and duties determined by the officer making such designation. The persons upon whom such titles are conferred shall not be deemed officers of the Corporation unless elected by the Board of Directors.

Section 5.11 Checks; Drafts; Evidences of Indebtedness. From time to time, the Board of Directors shall determine the method, and designate (or authorize officers of the Corporation to designate) the person or persons who shall have authority, to sign or endorse all checks, drafts, other orders for payment of money and notes, bonds, debentures or other evidences of indebtedness that are issued in the name of or payable by the Corporation, and only the persons so authorized shall sign or endorse such instruments.

Section 5.12 Corporate Contracts and Instruments; How Executed. Except as otherwise provided in these Bylaws, the Board of Directors may determine the method, and designate (or authorize officers of the Corporation to designate) the person or persons who shall have authority to enter into any contract or execute any instrument in the name of and on behalf of the Corporation. Such authority may be general or confined to specific instances. Unless so authorized, or within the power incident to a person's office or other position with the Corporation, no person shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

Section 5.13 General Power of Officers. Unless otherwise determined by the Board of Directors or otherwise provided by law or these Bylaws, contracts, evidences of indebtedness and other instruments or documents of the Corporation may be executed, signed or endorsed: (i) by the Chief Executive Officer; or (ii) by the Chief Financial Officer, Treasurer, Secretary or Controller, in each case only with regard to such instruments or documents that pertain to or relate to such person's duties or business functions.

Section 5.14 Action with Respect to Securities of Other Corporations or Entities. The Chief Executive Officer or any other officer of the Corporation authorized by the Board of Directors or the Chief Executive Officer is authorized to vote, represent, and exercise on behalf of the Corporation all rights incident to any and all shares or other equity interests of any other corporation or entity or corporations or entities, standing in the name of the Corporation. The authority herein granted may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by the person having such authority.

Section 5.15 Delegation. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officers or agents, notwithstanding the foregoing provisions of this Article V.

ARTICLE VI
INDEMNIFICATION AND ADVANCEMENT OF EXPENSES

Section 6.1 Right to Indemnification.

(a) Each person who was or is a party or is threatened to be made a party to, or was or is otherwise involved in, any action, suit, arbitration, alternative dispute resolution mechanism, investigation, inquiry, judicial, administrative or legislative hearing, or any other threatened, pending or completed proceeding, whether brought by or in the right of the Corporation or otherwise, including any and all appeals, whether of a civil, criminal, administrative, legislative, investigative or other nature (hereinafter a "proceeding"), by reason of the fact that he or she is or was a director or an officer of the Corporation or while a director or officer of the Corporation is or was serving at the request of the Corporation as a director, officer, employee, agent or trustee of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan (hereinafter an "indemnitee"), or by reason of anything done or not done by him or her in any such capacity, shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended, against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes, penalties and amounts paid in settlement by or on behalf of the indemnitee) actually and reasonably incurred by such indemnitee in connection therewith, all on the terms and conditions set forth in these Bylaws. Notwithstanding anything in this Article VI to the contrary: (i) except as otherwise required by law or by Section 6.3, no indemnification shall be paid to any such indemnitee with respect to any proceeding brought by or in the right of the Corporation against the indemnitee that is authorized or ratified by the Board of Directors of the Corporation, unless the Board of Directors otherwise determines that indemnification is appropriate; and (ii) except as otherwise required by law or provided in Section 6.4 with respect to suits to enforce rights under this Article VI, the Corporation shall indemnify any such indemnitee in connection with a proceeding, or part thereof, voluntarily initiated by such indemnitee (including claims and counterclaims, whether such counterclaims are asserted by such indemnitee, or the Corporation in a proceeding initiated by such indemnitee) only if such proceeding, or part thereof, was authorized or ratified by the Board of Directors or the Board of Directors otherwise determines that indemnification is appropriate.

(b) To receive indemnification under this Article VI, an indemnitee shall submit a written request to the Secretary of the Corporation. Such request shall include documentation or information that is necessary to determine the entitlement of the indemnitee to indemnification and that is reasonably available to the indemnitee. Upon receipt by the Secretary of the Corporation of such a written request, unless indemnification is required by Section 6.3,

the entitlement of the indemnitee to indemnification shall be determined by the following person or persons who shall be empowered to make such determination, as selected by the Board of Directors (except with respect to clause (v) of this Section 6.1(b)): (i) the Board of Directors by a majority vote of the directors who are not parties to such proceeding, whether or not such majority constitutes a quorum; (ii) a committee of such directors designated by a majority vote of such directors, whether or not such majority constitutes a quorum; (iii) if there are no such directors, or if such directors so direct, by independent legal counsel (as defined below) selected by the Corporation in a written opinion to the Board of Directors, a copy of which shall be delivered to the indemnitee; (iv) the stockholders of the Corporation; or (v) in the event that a change of control (as defined below) has occurred, by independent legal counsel (to be mutually agreed upon by the Corporation and the indemnitee, with such agreement not to be unreasonably withheld) in a written opinion to the Board of Directors, a copy of which shall be delivered to the indemnitee. The determination of entitlement to indemnification shall be made and, unless a contrary determination is made, such indemnification shall be paid in full by the Corporation not later than 60 days after receipt by the Secretary of the Corporation of a written request for indemnification. For purposes of this Section 6.1(b), (A) "independent counsel" shall mean a law firm or a member of a law firm that neither is presently nor in the past five years has been retained to represent the Corporation or the indemnitee in any matter material to either such party or any other party to the proceeding giving rise to a request for indemnification hereunder; provided that the term "independent counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Corporation or the indemnitee in an action to determine the indemnitee's right to indemnification under these Bylaws; and (B) a "change of control" will be deemed to have occurred if, with respect to any particular 24-month period, the individuals who, at the beginning of such 24-month period, constituted the Board of Directors (the "incumbent board"), cease for any reason to constitute at least a majority of the Board of Directors; provided, however, that any individual becoming a director subsequent to the beginning of such 24-month period whose election, or nomination for election by the stockholders of the Corporation, was approved by a vote of at least a majority of the directors then comprising the incumbent board shall be considered as though such individual were a member of the incumbent board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a person other than the Board of Directors. For the avoidance of doubt, a "change of control" for purposes of this Article VI shall not include the "spin-off," "distribution" or the "separation" (in each case, as defined in the registration statement on Form 10 filed by the Corporation) relating to Merck & Co., Inc. and the Corporation or the actions or transactions contemplated to effect any of them.

Section 6.2 Right to Advancement of Expenses.

(a) In addition to the right to indemnification conferred in Section 6.1, an indemnitee shall, to the fullest extent permitted by law, also have the right to be paid by the Corporation the expenses (including attorneys' fees) incurred in defending any proceeding in advance of its final disposition (hereinafter an "advancement of expenses"), other than a proceeding brought by or in the right of the Corporation against the indemnitee that is authorized or ratified by the Board of Directors; provided, however, that an advancement of expenses shall

be made only upon delivery to the Corporation of an undertaking (hereinafter an "undertaking"), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision of a court of competent jurisdiction from which there is no further right to appeal (hereinafter a "final adjudication") that such indemnitee is not entitled to be indemnified for such expenses under this Article VI or otherwise.

(b) To receive an advancement of expenses under this Section 6.2, an indemnitee shall submit a written request to the Secretary of the Corporation. Such request shall reasonably evidence the expenses incurred by the indemnitee and shall include or be accompanied by the undertaking required by Section 6.2(a). Each such advancement of expenses shall be made within 20 days after the receipt by the Secretary of the Corporation of a written request for advancement of expenses.

Section 6.3 Indemnification for Successful Defense. To the extent that an indemnitee has been successful on the merits or otherwise in defense of any proceeding (or in defense of any claim, issue or matter therein), such indemnitee shall be indemnified under this Section 6.3 against expenses (including attorneys' fees) actually and reasonably incurred in connection with such defense. Indemnification under this Section 6.3 shall not be subject to satisfaction of a standard of conduct, and the Corporation may not assert the failure to satisfy a standard of conduct as a basis to deny indemnification or recover amounts advanced, including in a suit brought pursuant to Section 6.4 (notwithstanding anything to the contrary therein); provided, however, that, any indemnitee who is not a current or former director or officer (as such term is defined in the final sentence of Section 145(c)(1) of the DGCL) shall be entitled to indemnification under Section 6.1 and this Section 6.3 only if such indemnitee has satisfied the standard of conduct required for indemnification under Section 145(a) or Section 145(b) of the DGCL.

Section 6.4 Right of Indemnitee to Bring Suit. In the event that a determination is made that the indemnitee is not entitled to indemnification or if payment is not timely made following a determination of entitlement to indemnification pursuant to Section 6.1(b), if a request for indemnification under Section 6.3 is not paid in full by the Corporation within 60 days after a written request has been received by the Secretary of the Corporation, or if an advancement of expenses is not timely made under Section 6.2(b), the indemnitee may at any time thereafter bring suit against the Corporation in a court of competent jurisdiction in the State of Delaware seeking an adjudication of entitlement to such indemnification or advancement of expenses. If successful in whole or in part in any such suit, or in a suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the indemnitee shall be entitled to be paid also the expense of prosecuting or defending such suit to the fullest extent permitted by law. In any suit brought by the indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the indemnitee to enforce a right to an advancement of expenses) it shall be a defense that the indemnitee has not met any applicable standard of conduct for indemnification set forth in Section 145(a) or Section 145(b) of the DGCL. Further, in any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that the indemnitee has not met any applicable standard of conduct for indemnification set forth in Section 145(a) or Section 145(b) of the DGCL. Neither the failure of the Corporation (including its directors who are not parties to such action, a

committee of such directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the indemnitee is proper in the circumstances because the indemnitee has met the applicable standard of conduct set forth in the DGCL, nor an actual determination by the Corporation (including its directors who are not parties to such action, a committee of such directors, independent legal counsel or its stockholders) that the indemnitee has not met such applicable standard of conduct, shall create a presumption that the indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the indemnitee, be a defense to such suit. In any suit brought by the indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the burden of proving that the indemnitee is not entitled to be indemnified, or to such advancement of expenses, under applicable law, this Article VI or otherwise shall be on the Corporation.

Section 6.5 Non-Exclusivity of Rights. The rights to indemnification and to the advancement of expenses conferred in this Article VI shall not be exclusive of any other right which any person may have or hereafter acquire under any law, agreement, vote of stockholders or disinterested directors, provisions of an entity's organizational documents (including the Corporation's), or otherwise.

Section 6.6 Insurance. The Corporation may maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise against any expense, liability or loss, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

Section 6.7 Indemnification of Employees and Agents of the Corporation. The Corporation may, to the extent and in the manner permitted by law, and to the extent authorized from time to time, grant rights to indemnification and to the advancement of expenses to any employee or agent of the Corporation.

Section 6.8 Nature of Rights. The rights conferred upon indemnitees in this Article VI shall be contract rights and such rights shall continue as to an indemnitee who has ceased to be a director or officer and shall inure to the benefit of the indemnitee's heirs, executors and administrators. Any amendment, alteration or repeal of this Article VI that adversely affects any right of an indemnitee or its successors shall be prospective only and shall not limit or eliminate any such right with respect to any proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment, alteration or repeal.

Section 6.9 Settlement of Claims. Notwithstanding anything in this Article VI to the contrary, the Corporation shall not be liable to indemnify any indemnitee under this Article VI for any amounts paid in settlement of any proceeding effected without the Corporation's written consent, which consent shall not be unreasonably withheld.

Section 6.10 Subrogation. In the event of payment under this Article VI, the Corporation shall be subrogated to the extent of such payment to all of the rights of recovery of the indemnitee (excluding insurance obtained on the indemnitee's own behalf), and the indemnitee shall execute all papers required and shall do everything that may be necessary to secure such rights, including the execution of such documents necessary to enable the Corporation effectively to bring suit to enforce such rights.

Section 6.11 Severability. If any provision or provisions of this Article VI shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law: (a) the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Article VI (including, without limitation, all portions of any paragraph of this Article VI containing any such provision held to be invalid, illegal or unenforceable, that are not by themselves invalid, illegal or unenforceable) and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby; and (b) to the fullest extent possible, the provisions of this Article VI (including, without limitation, all portions of any paragraph of this Article VI containing any such provision held to be invalid, illegal or unenforceable, that are not themselves invalid, illegal or unenforceable) shall be construed so as to give effect to the intent of the parties that the Corporation provide protection to the indemnitee to the fullest extent set forth in this Article VI.

ARTICLE VII
CAPITAL STOCK

Section 7.1 Certificates of Stock. The shares of the Corporation shall be represented by certificates; provided, however, that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Corporation. Every holder of stock represented by certificates shall be entitled to have a certificate signed by or in the name of the Corporation by any two authorized officers of the Corporation, including, without limitation, the Chief Executive Officer, the Chief Financial Officer, the Treasurer, an Assistant Treasurer, the Secretary of the Corporation or an Assistant Secretary, certifying the number of shares owned by such holder in the Corporation. Any or all such signatures may be facsimiles. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue.

Section 7.2 Special Designation on Certificates. If the Corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock; provided, however, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock

or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the registered owner thereof shall be given a notice, in writing or by electronic transmission, containing the information required to be set forth or stated on certificates pursuant to this Section 7.2 or Sections 151, 156, 202(a) or 218(a) of the DGCL or with respect to this Section 7.2 and Section 151 of the DGCL a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.

Section 7.3 Transfers of Stock. Transfers of shares of stock of the Corporation shall be made only on the books of the Corporation upon authorization by the registered holder thereof or by such holder's attorney thereunto authorized by a power of attorney duly executed and filed with the Secretary of the Corporation or a transfer agent for such stock, and if such shares are represented by a certificate, upon surrender of the certificate or certificates for such shares properly endorsed or accompanied by a duly executed stock transfer power and the payment of any taxes thereon; provided, however, that the Corporation shall be entitled to recognize and enforce any lawful restriction on transfer.

Section 7.4 Lost Certificates. The Corporation may issue a new share certificate or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate or the owner's legal representative to give the Corporation a bond (or other adequate security) sufficient to indemnify it against any claim that may be made against it (including any expense or liability) on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares. The Board of Directors may adopt such other provisions and restrictions with reference to lost certificates, not inconsistent with applicable law, as it shall in its discretion deem appropriate.

Section 7.5 Registered Stockholders. The Corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise required by law.

Section 7.6 Record Date for Determining Stockholders.

(a) In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjourned meeting, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall, unless otherwise required by law, not be more than 60 nor less than 10 days before the date of such meeting. If the Board of Directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board of Directors determines, at the

time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at the close of business (as defined in Section 2.10(c)(ii) above) on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjourned meeting; provided, however, that the Board of Directors may fix a new record date for the determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

(b) In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than 60 days prior to such action. If no such record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

Section 7.7 Regulations. To the extent permitted by applicable law, the Board of Directors may make such additional rules and regulations as it may deem expedient concerning the issue, transfer and registration of shares of stock of the Corporation.

Section 7.8 Waiver of Notice. Whenever notice is required to be given under any provision of the DGCL or the Certificate of Incorporation or these Bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders, the Board of Directors or a committee of the Board of Directors need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the Certificate of Incorporation or these Bylaws.

ARTICLE VIII
GENERAL MATTERS

Section 8.1 Fiscal Year. The fiscal year of the Corporation shall begin on the first day of January of each year and end on the last day of December of the same year, or shall extend for such other 12 consecutive months as the Board of Directors may designate.

Section 8.2 Corporate Seal. The Board of Directors may provide a suitable seal, containing the name of the Corporation, which seal shall be in the charge of the Secretary of the Corporation. If and when so directed by the Board of Directors or a committee thereof, duplicates of the seal may be kept and used by the Secretary, Treasurer or by an Assistant Secretary or Assistant Treasurer.

Section 8.3 Reliance Upon Books, Reports and Records. Each director and each member of any committee designated by the Board of Directors shall, in the performance of his or her duties, be fully protected in relying in good faith upon the books of account or other records of the Corporation and upon such information, opinions, reports or statements presented to the Corporation by any of its officers or employees, or committees of the Board of Directors so designated, or by any other person as to matters which such director or committee member reasonably believes are within such other person's professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation.

Section 8.4 Subject to Law and Certificate of Incorporation. All powers, duties and responsibilities provided for in these Bylaws, whether or not explicitly so qualified, are qualified by the Certificate of Incorporation (including any Preferred Stock Designation) and applicable law.

Section 8.5 Electronic Signatures, etc. Except as otherwise required by the Certificate of Incorporation (including as otherwise required by any Preferred Stock Designation) or these Bylaws (including, without limitation, as otherwise required by Section 2.15), any document, including, without limitation, any consent, agreement, certificate or instrument, required by the DGCL, the Certificate of Incorporation (including any Preferred Stock Designation) or these Bylaws to be executed by any officer, director, stockholder, employee or agent of the Corporation may be executed using a facsimile or other form of electronic signature to the fullest extent permitted by applicable law. All other contracts, agreements, certificates or instruments to be executed on behalf of the Corporation may be executed using a facsimile or other form of electronic signature to the fullest extent permitted by applicable law. The terms "electronic mail," "electronic mail address," "electronic signature" and "electronic transmission" as used herein shall have the meanings ascribed thereto in the DGCL.

ARTICLE IX
FORUM FOR ADJUDICATION OF DISPUTES

Section 9.1 Forum. Unless the Corporation, in writing, selects or consents to the selection of an alternative forum: (a) the sole and exclusive forum for any complaint asserting any internal corporate claims (as defined below), to the fullest extent permitted by law, and subject to applicable jurisdictional requirements, shall be the Court of Chancery of the State of Delaware (the "Court of Chancery") (or, if the Court of Chancery does not have, or declines to accept, jurisdiction, another state court or a federal court located within the State of Delaware); and (b) the sole and exclusive forum for any complaint asserting a cause of action arising under the Securities Act, to the fullest extent permitted by law, shall be the federal district courts of the United States of America. For purposes of this Article IX, "internal corporate claims" means claims, including claims in the right of the Corporation that are based upon a violation of a duty by a current or former director, officer, employee or stockholder in such capacity, or as to which the DGCL confers jurisdiction upon the Court of Chancery. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article IX.

Section 9.2 Enforceability. If any provision of this Article IX shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provision in any other circumstance and of the remaining provisions of this Article IX (including, without limitation, each portion of any sentence of this Article IX containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities or circumstances shall not in any way be affected or impaired thereby.

ARTICLE X
AMENDMENTS

Section 10.1 Amendments. In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors is expressly authorized to adopt, amend or repeal these Bylaws. Except as otherwise provided in the Certificate of Incorporation (including the terms of any Preferred Stock Designation) or these Bylaws, and in addition to any other vote required by law, the affirmative vote of the holders of at least a majority of the voting power of the stock outstanding and entitled to vote thereon, voting together as a single class, shall be required for the stockholders to adopt, amend or repeal any provision of these Bylaws.

The foregoing Amended and Restated Bylaws were adopted by the Board of Directors on _____, 2021, effective as of _____, 2021.

Exhibit 10.12

EXECUTION VERSION

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

SPECIFIED TECHNOLOGY LICENSE AGREEMENT
(NEXPLANON ROD TECHNOLOGY)

This Specified Technology License Agreement (this "**Agreement**"), dated as of October 28, 2020 (the "**Effective Date**") is entered into by and between MERCK SHARP & DOHME B.V., a private company with limited liability incorporated under the laws of the Netherlands ("**Licensee**"), and MSD RT B.V., a private company with limited liability incorporated under the laws of the Netherlands ("**Licensor**" and together with Licensee, each a "**Party**" and collectively, the "**Parties**").

RECITALS

WHEREAS, Merck & Co., Inc. ("**Merck Parent**"), an Affiliate of Licensor, has announced that it will be entering into a separation transaction (the "**Separation**", and the separation and distribution agreement pursuant to which the Separation will be effected, the "**Separation Agreement**", and the date of consummation of the Separation, the "**Separation Date**") pursuant to which, among other things, Merck Parent will transfer to a newly formed independent entity ("**Organon**") certain assets and liabilities as will be more particularly described in the Separation Agreement; and

WHEREAS, in connection with, and in anticipation of, the Separation, Licensor has agreed to grant Licensee a license to use the Licensed Technology in connection with the Permitted Product that is being transferred to Organon as part of the Separation, in accordance with the terms, and subject to the conditions, set forth in this Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Parties hereby agree as follows:

1. Definitions. For the purpose of this Agreement, the following capitalized terms have the following respective meanings:

1.1 "**Affiliate**" means any Person which, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with a Party, for so long as such Person controls, is controlled by or is under common control with a Party, and regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date. For purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person means (i) direct or indirect ownership of more than fifty percent (50%) of the voting securities or other voting interest of any Person (including attribution from related parties), or (ii) the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such

Person, whether through ownership of voting securities, by contract, as a general partner, as a manager, or otherwise. Notwithstanding the foregoing, the Parties agree that from and after the Separation Date, neither Organon nor any of its post-Separation subsidiaries (including Licensee) shall be deemed to be an Affiliate of Merck Parent or any of its post-Separation subsidiaries (including Licensor), and neither Merck Parent nor any of its post-Separation subsidiaries (including Licensor) shall be deemed to be an Affiliate of Organon or any of its post-Separation subsidiaries (including Licensee).

1.2 "**Agreement**" has the meaning set forth in the Preamble.

1.3 "**Applicable Law**" means applicable laws, rules, regulations, guidelines or other requirements of a Governmental Authority that may be in effect from time to time.

1.4 "**Confidential Information**" means all confidential information and data relating to a Party (including information regarding such Party's and its Affiliates' business, employees, development plans, programs, documentation, techniques, trade secrets, systems, and know-how) disclosed or provided by or on behalf of such Party to the other Party pursuant to, or in connection with, this Agreement. "Confidential Information" does not include any information or data: (i) rightfully previously known by a Party hereto, or acquired from a Third Party without a continuing restriction on use (for clarity, excluding any such information or data possessed by Licensor (or its Affiliate) prior to the Separation and assigned to Organon as part of the Separation, which shall be considered Confidential Information of Licensee for purposes of this clause (i), as applicable); (ii) which is or becomes publicly known without breach of this Agreement; or (iii) which is independently developed without violating any obligations under this Agreement and without reference to the Confidential Information of the other Party. Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

1.5 "**Control**", "**Controls**" or "**Controlled by**" means, with respect to any patents or Know-How, as applicable, the ownership of such patents or Know-How by Licensor (or its Affiliates), with the ability of Licensor (or its Affiliate) to grant a license of such patents or Know-How to Licensee as provided for herein without violating any Applicable Law or the terms of any agreement or other arrangement with any Third Party existing as of the Effective Date.

1.6 "**Device**" means a device used for subdermal implantation of the Permitted Product in humans claimed in the Licensed Patents.

1.7 "**Effective Date**" has the meaning set forth in the Preamble.

1.8 "**Field**" means (i) with respect to the Permitted Product, the use of the Permitted Product as a pharmaceutical product in humans solely as a contraceptive implant, and for no other uses, and (ii) with respect to the Device, the use of the Device (a) to implant the Permitted Product within the scope of the foregoing clause (i) or (b) to implant a placebo of the Permitted Product within the scope of the foregoing clause (i), and for no other uses.

1.9 "**Force Majeure Event**" has the meaning set forth in Section 9.2.

1.10 "**Governmental Authority**" means any United States (federal, state or local), or any other foreign, government or political subdivision thereof, or any multinational governmental organization or authority, or any authority, agency or commission, in each case, entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.11 "**Know-How**" means any and all proprietary and confidential information, data (including pre-clinical, clinical and regulatory data, post-approval data and data contained within any regulatory filings), processes, methods, techniques, trade secrets, chemistry manufacturing & controls (CMC), quality procedures, pharmacovigilance procedures, manufacturing procedures or other know-how, whether patentable or unpatentable.

1.12 "**Licensed Know-How**" means that Know-How specifically related to the technology claimed in the Licensed Patents and that (i) is Controlled by Licensor (or its Affiliate) as of the Effective Date and (ii) immediately prior to the Effective Date, was actually used by Licensor (or any of its Affiliates) for the manufacture or commercialization of the Permitted Product or Device, as applicable, in the Field; provided that, for clarity, "Licensed Know-How" shall exclude any Know-How to which Licensee (or its Affiliates) obtains ownership rights in connection with the Separation.

1.13 "**Licensed Patents**" means (i) those patents that are set forth on Schedule 1.13, and (ii) all renewals, extensions, reissues, reexaminations, divisionals, continuations, continuations-in-part, and foreign counterparts of any of the foregoing patents in clause (i), in each case of clause (i) and (ii), that are Controlled by Licensor or its Affiliates.

1.14 "**Licensed Technology**" means, collectively, the Licensed Patents and Licensed Know-How.

1.15 "**Licensee**" has the meaning set forth in the Preamble.

1.16 "**Licensor**" has the meaning set forth in the Preamble.

1.17 "**Licensor Indemnitees**" has the meaning set forth in Section 6.1.

1.18 "**Merck Parent**" has the meaning set forth in the Recitals.

1.19 "**Organon**" has the meaning set forth in the Recitals.

1.20 "**Party**" or "**Parties**" has the meaning set forth in the Preamble.

1.21 "**Permitted Product**" means any subdermally-implanted human pharmaceutical product that contains synthetic progestin etonogestrel as the sole active pharmaceutical ingredient (but excluding, for clarity, fixed dose combinations with any other active pharmaceutical ingredient).

1.22 "**Person**" means any individual, corporation, general or limited partnership, trust, joint venture, unincorporated organization, limited liability entity or other entity, or Governmental Authority, including any successor or permitted assignee, by merger or otherwise, of any of the foregoing.

1.23 "**Separation**" has the meaning set forth in the Recitals.

1.24 "**Separation Agreement**" has the meaning set forth in the Recitals.

1.25 "**Separation Date**" has the meaning set forth in the Recitals.

1.26 "**Sublicensee**" has the meaning set forth in Section 2.2.

1.27 "**Term**" has the meaning set forth in Section 8.1.

1.28 "**Territory**" means worldwide.

1.29 "**Third Party**" means any Person other than Licensor or Licensee or any of their respective Affiliates.

1.30 "**Third Party Claim**" means any and all suits, claims, actions, proceedings or demands brought by a Third Party against Licensor (or other Licensor Indemnitees, as applicable).

1.31 "**Third Party Damages**" means all losses, costs, claims, damages, judgments, liabilities and expenses payable to a Third Party by Licensor (or other Licensor Indemnitees, as applicable) under a Third Party Claim (including reasonable attorneys' fees and other reasonable out-of-pocket costs of litigation in connection therewith).

1.32 "**Transaction Documents**" means the Separation Agreement and any other agreements entered into between Merck Parent (or any of its Affiliates) and Organon (or any of its Affiliates) in connection with the Separation.

2. License Grant.

2.1 License Grants. Subject to the terms of this Agreement, Licensor hereby grants to Licensee an exclusive (including as to Licensor and its Affiliates, except to the extent necessary for Licensor or its Affiliates to perform their obligations or exercise their rights under the Transaction Documents), sublicensable (in accordance with Section 2.2), fully paid-up, royalty-free license during the Term under the Licensed Technology to make, have made, use, offer to sell, sell and import (i) the Permitted Product solely for use in the Field in the Territory and (ii) the Device solely for use in the Field in the Territory.

2.2 Sublicenses. Licensee may sublicense the license rights it receives under Section 2.1 to any Person (each such sublicense recipient, a "**Sublicensee**"), on condition that each Sublicensee agrees in writing to be bound by terms of use and obligations with respect to the Licensed Technology that are no less restrictive than those set forth in this Agreement. Licensee is liable to Licensor for the failure of any Sublicensee to comply with the terms of use and obligations with respect to the Licensed Technology as set forth herein to the same extent that Licensee would have been had Licensee failed to comply with this Agreement. If Licensor or Licensee determine that any Sublicensee is using any Licensed Technology outside the scope of the license hereunder, Licensee shall cooperate with Licensor to terminate and prevent such unauthorized activities.

2.3 Recordation of License. As between Licensor and Licensee, Licensee is responsible, in its sole discretion, for recording this Agreement with any applicable Governmental Authority and for all associated recordation fees and related costs and expenses. Upon Licensee's request and at Licensee's expense, Licensor shall provide Licensee with reasonable assistance in connection with such recording activities.

2.4 Reservation of Rights. Licensee agrees that it does not acquire any ownership or other proprietary interest in any Licensed Technology, regardless of its embodiment or use in the Permitted Product or Device, except for the licenses as expressly set forth in Section 2.1. Except as expressly set forth in Section 2.1, nothing in this Agreement grants to Licensee, by implication, estoppel or otherwise, and Licensee does not acquire pursuant to this Agreement, any right, interest or license in or to any intellectual property of Licensor or any of its Affiliates. Licensor reserves all rights in and to the Licensed Technology not expressly granted to Licensee in Section 2.1, including (i) all rights under the Licensed Technology outside the Field, (ii) all rights under the Licensed Technology for use with any products (including, for clarity, any fixed dose combination products) other than the Permitted Product in the Field and (iii) all rights under the Licensed Technology for use with any other devices (including for clarity, use of the Device in connection with any products other than the Permitted Product in the Field) other than the Device in the Field. Licensee further acknowledges that the rights granted hereunder with respect to the Licensed Technology are subject to any rights of Third Parties that exist as of the Effective Date.

2.5 Disclosure of Licensed Know-How. Notwithstanding anything to the contrary herein, Licensor shall have no obligation to disclose to Licensee any Licensed Know-How.

2.6 Compliance with Applicable Laws. Licensee shall observe and comply with, and give all notices required by, Applicable Law in connection with its activities under this Agreement, including the exercise of the rights and licenses granted to it hereunder. Licensee shall promptly notify Licensor if it becomes aware of any noncompliance with Applicable Law in connection with its activities under this Agreement, and shall take all appropriate action necessary to ensure compliance with Applicable Law in connection with its activities under this Agreement.

2.7 Licensee's Affiliates. Licensee shall ensure that Licensee's Affiliates comply with all provisions of this Agreement applicable to Licensee. Licensee is liable to Licensor and, as between the Parties, to all other Persons, for the failure of Licensee's Affiliates to comply with this Agreement to the same extent that Licensee would have been had Licensee failed to comply.

3. Prosecution, Maintenance, Enforcement and Defense.

3.1 Prosecution and Maintenance of Licensed Patents. Licensor shall have the first right (but not the obligation), in its discretion, to prosecute and maintain in the Territory the Licensed Patents licensed to Licensee under this Agreement. Licensor shall give notice to Licensee of the revocation or invalidation of any Licensed Patents licensed to Licensee for which Licensor is responsible for prosecution and maintenance.

3.1.1 Option of Licensee to Prosecute and Maintain Licensed Patents. Licensor shall give notice to Licensee of any desire to cease prosecution and/or maintenance of Licensed Patents on a country-by-country basis in the Territory and, in such cases, shall permit Licensee, in its sole discretion, to continue prosecution or maintenance of such Licensed Patents at its own expense and in the name of Licensor. If Licensee elects to continue prosecution or maintenance, Licensor shall execute such documents and perform such acts at Licensee's expense as may be reasonably necessary for Licensee to perform such prosecution or maintenance.

3.1.2 Patent Term Extension. The Parties shall cooperate fully with each other to provide necessary information and assistance, as the other Party may reasonably request, in obtaining patent term extension or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Licensed Patents; provided that Licensor shall have the final decision making authority with respect thereto.

3.1.3 Other Cooperation. The Parties agree to reasonably cooperate and provide any relevant information that either may reasonably request for the prosecution and maintenance of Licensed Patents.

3.1.4 Prosecution and Maintenance Expenses. With respect to all prosecution and maintenance activities under this Section 3.1, the prosecuting Party shall be responsible for payment of all costs and expenses related to such activities.

3.2 Enforcement and Defense.

3.2.1 Licensed Patents.

(i) The Parties shall give notice to each other of any (a) infringement of Licensed Patents by a Third Party (including any certification regarding the Licensed Patents pursuant to 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV), or its successor provisions or any similar provisions in a country in the Territory other than the United States), or (b) assertion by a Third Party that any Licensed Patent is invalid or unenforceable. Subject to Sections 3.2.1(ii) and 3.2.1(iii), Licensee and Licensor shall thereafter consult and reasonably cooperate to determine a course of action, including the commencement of legal action by either or both Licensee and Licensor to terminate any infringement of Licensed Patents or defend the claim of invalidity or unenforceability.

(ii) Licensor (or its designee), upon notice to Licensee, shall [* * *] initiate and prosecute such legal action [* * *]. Licensee shall reasonably cooperate with Licensor in connection therewith, including joining the action to the extent necessary.

(iii) If the infringement by a Third Party is in the Field, then Licensor shall inform Licensee if [* * *] Licensee shall thereafter have the right in the Field to either initiate and prosecute such action against the Third Party or to control the defense of such declaratory judgment action in the name of Licensee and, if necessary, Licensor, in each case, as reasonably agreed to by the Parties; [* * *]. Each Party shall have the right to be represented by counsel of its own choice and at its own expense.

[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

(iv) For any action to terminate any infringement of Licensed Patents in the Field, in the event that a Party is unable to initiate or prosecute such action solely in its own name, the other Party will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for the Party to initiate litigation to prosecute and maintain such action under this Section 3.2.1. In connection with any such action or potential action, Licensee and Licensor will reasonably cooperate and will provide each other with any relevant information that either may reasonably request. Each Party shall keep the other informed of developments in any such action or proceeding.

(v) Any recovery obtained by either or both Licensee and Licensor in connection with or as a result of any action contemplated by this Section 3.2.1, whether by settlement or otherwise, shall be shared in order as follows:

i. [* * *];

ii. [* * *]; and

iii. [* * *].

3.2.2 Licensed Know-How. The Parties shall give notice to each other of any misappropriation or misuse of Licensed Know-How by a Third Party that may come to its attention. [* * *]. To the extent that any claim of misappropriation or misuse of Licensed Know-How by a Third Party may be applicable both inside and outside of the Field, the following shall apply:

(i) Licensee and Licensor shall consult and reasonably cooperate to determine a course of action, including the commencement of legal action by either or both Licensee and Licensor to terminate any such misappropriation or misuse of Licensed Know-How; [* * *].

(ii) Any recovery obtained by either or both Licensee and Licensor in connection with or as a result of any proceeding for misappropriation or misuse of Licensed Know-How against a Third Party both inside and outside of the Field , whether by settlement or otherwise, shall be shared in order as follows:

i. [* * *];

ii. [* * *]; and

iii. [* * *].

3.3 Patenting Restriction. [* * *]. In the event that, after the Effective Date, Licensor files for and obtains a patent claiming Licensed Know-How and Licensor Controls such patent, then such a patent will become a Licensed Patent under this Agreement, and Licensor hereby grants a license under such Licensed Patent pursuant to Section 2.1.

[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

4. General Representations and Warranties. Each Party represents and warrants to the other Party, as of the Effective Date, that (i) it is a corporation duly organized and validly existing and in good standing under the laws of its jurisdiction of organization, (ii) it is qualified or licensed to do business and in good standing in every jurisdiction where such qualification or licensing is required, (iii) it has the corporate power and authority to execute, deliver and perform its obligations under this Agreement, and the execution, delivery and performance of this Agreement by it has been duly authorized by all necessary corporate action, (iv) this Agreement has been duly executed and delivered by it, and (v) this Agreement constitutes the valid and binding obligations of it, enforceable against it in accordance with its terms except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting creditor's rights generally, or general principles of equity.

5. Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT, ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED. FOR THE AVOIDANCE OF DOUBT, NOTHING CONTAINED IN THIS ARTICLE 5 SHALL OPERATE TO LIMIT OR INVALIDATE ANY REPRESENTATION OR WARRANTY CONTAINED IN THE SEPARATION AGREEMENT. LICENSOR DISCLAIMS ALL RESPONSIBILITY OR LIABILITY UNDER THIS AGREEMENT FOR CLAIMS BY THIRD PARTIES AFTER THE EFFECTIVE DATE ARISING OUT OF OR RELATING TO THE USE OF ANY LICENSED TECHNOLOGY BY LICENSEE, ITS AFFILIATES OR ITS SUBLICENSEES.

6. Indemnification; Damages.

6.1 Indemnification. In addition to any other available remedies, Licensee hereby agrees to indemnify, defend and hold harmless Licensor and its Affiliates, and their respective officers, directors, employees, shareholders, members, partners, agents, representatives, successors and assigns (collectively, "**Licensor Indemnitees**") from and against all Third Party Damages based on a Third Party Claim, imposed on, incurred by or asserted against the Licensor Indemnitees arising out of or relating to (i) Licensee's (or any of its Affiliate's or Sublicensee's) failure to comply with any of its obligations under this Agreement, (ii) the exercise by Licensee (or any of its Affiliates or Sublicensees) of any of the licenses granted to Licensee hereunder or (iii) any enforcement action by Licensee (or any of its Affiliates) pursuant to Section 3.2.1 or 3.2.2 that is either brought in the name or Licensor (or any of its Affiliates) or joined by Licensor (or any of its Affiliates).

6.2 Procedure. Licensor will notify Licensee of any demand by Licensor for indemnification from Licensee that is based on any Third Party Claim and provide Licensee with copies of any papers served on Licensor relating to that Third Party Claim, but Licensor's failure to provide or delay in providing that notice or those copies will not release Licensee from its obligations under Section 6.1, except to the extent that the failure or delay materially prejudices Licensee. Subject to Article 3, Licensee has the exclusive right to conduct the defense of any such Third Party Claim and any negotiations for its settlement, except that (i) Licensee may not enter into any compromise or settlement unless Licensor consents to such compromise or settlement,

which consent shall not be unreasonably withheld or delayed, and which consent shall be deemed given with respect to any compromise or settlement relating solely to the payment of money damages if such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Licensor Indemnitees of a release from all liability in respect of such claim, (ii) Licensor may participate at its expense in Licensee's defense of or settlement negotiations for any Third Party Claim with counsel of Licensor's own selection, and (iii) Licensor may, at its option and Licensee's expense, and on prior written notice to the Licensee, conduct the defense of and any settlement negotiations for any Third Party Claim in place of Licensee if Licensee fails to promptly defend the Third Party Claim as required in this Article 6. At Licensor's request and Licensee's expense, and in addition to Licensee's other obligations under this Agreement, Licensee shall assist Licensor with the defense of any Third Party Claim for which Licensor conducts the defense under this Article 6.

6.3 Damages. EXCEPT WITH RESPECT TO A BREACH OF A PARTY'S CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 7, IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES OR ITS OR THEIR RESPECTIVE OFFICERS, DIRECTORS, EMPLOYEES OR AGENTS BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES OR ITS OR THEIR RESPECTIVE OFFICERS, DIRECTORS, EMPLOYEES OR AGENTS FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES OR INDIRECT OR CONSEQUENTIAL LOSSES, OR FOR ANY LOSS OF REVENUES OR LOST PROFITS (WHETHER DIRECT OR INDIRECT), IN EACH CASE OF ANY KIND, NATURE OR DESCRIPTION WHATSOEVER SUFFERED OR INCURRED BY SUCH PARTY ARISING UNDER OR IN CONNECTION WITH THIS AGREEMENT OR AS A RESULT OF ANY ACTIVITIES HEREUNDER, REGARDLESS OF WHETHER ARISING FROM BREACH OF CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY IS ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE OR IF SUCH LOSS OR DAMAGE COULD HAVE BEEN REASONABLY FORESEEN. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 6.3 IS INTENDED TO OR SHALL LIMIT OR RESTRICT (I) THE INDEMNIFICATION RIGHTS OF LICENSOR OR OBLIGATIONS OF LICENSEE WITH RESPECT TO ANY THIRD PARTY CLAIMS UNDER SECTION 6.1 OR (II) LOSSES OR DAMAGES THAT MAY BE SOUGHT BY LICENSOR (OR ITS AFFILIATES) DUE TO EXERCISE OF THE LICENSES UNDER SECTION 2.1 BY LICENSEE (OR ANY OF ITS AFFILIATES OR SUBLICENSEES) OUTSIDE THE SCOPE OF THE LICENSE GRANT IN BREACH OF SECTION 2.1.

6.4 Equitable Relief. Licensee acknowledges that (i) the Licensed Technology and Confidential Information are valuable to Licensor, (ii) any breach of this Agreement by Licensee may cause Licensor irreparable injury, and (iii) the remedies at law for a breach of this Agreement may be inadequate and the resulting damages may not readily be measured in monetary terms. Without limiting any of Licensor's other rights and remedies, and notwithstanding anything in this Agreement to the contrary, in the event of any breach or threatened breach of this Agreement by Licensee, Licensor may obtain and will be entitled to any injunctive or other equitable relief that a court of competent jurisdiction deems proper (including an order restraining any threatened or future breach), on use of affidavit evidence or otherwise, and without furnishing proof of actual damages or posting a bond or other surety.

6.5 Treatment. Any [* * *] made by a Party under this Agreement shall be reported for U.S. federal income tax purposes [* * *].

7. Confidentiality.

7.1 Disclosure of Confidential Information. Each Party hereto: (i) will retain in strict confidence the terms and conditions of this Agreement (including the nature of the services provided) and the Confidential Information of the other Party; and (ii) will not disclose the terms and conditions of this Agreement or the Confidential Information of the other Party to any other Third Party, unless otherwise required by Applicable Law or judicial or administrative process (in which case the provisions of Section 7.2.2 shall apply), without the other Party's prior written consent. Notwithstanding the foregoing, each Party (and its respective Affiliates) shall be permitted to disclose any terms of this Agreement to the extent required in connection with its filings with the Securities and Exchange Commission or in compliance with the rules of any securities exchange or listing requirements.

7.2 Permitted Disclosures.

7.2.1 Notwithstanding Section 7.1, each Party shall be permitted to disclose Confidential Information of the other Party, if such Confidential Information:

(i) is disclosed by Licensee (or its Affiliates) to a Governmental Authority in order to maintain or obtain regulatory approvals for Permitted Products (including the use of the Device in connection therewith) in the Field, but such disclosure may be only to the extent reasonably necessary to obtain such approvals;

(ii) is disclosed by the receiving Party (or its Affiliates) to agent(s), consultant(s), and/or other Third Parties who are performing obligations of the receiving Party or exercising rights granted to the receiving Party under this Agreement on the condition that such Third Parties agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement;

(iii) is deemed necessary by counsel to the receiving Party to be disclosed to such Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party, on the condition that such attorneys, independent accountants and financial advisors agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; or

(iv) is disclosed in connection with a merger or acquisition of a given Party (or its Affiliate) or a divestiture of a portion of such Party's business related to this Agreement, such Party shall have the further right to disclose the material financial terms of this Agreement to Third Parties involved in such merger or acquisition provided that such Third Parties agrees to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement.

[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

7.2.2 In addition, if a Party is required by judicial or administrative process or Applicable Law to disclose Confidential Information that is subject to the non-disclosure provisions of Section 7.1, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process or as required by Applicable Law shall remain otherwise subject to the confidentiality and non-use provisions of Section 7.1, and the Party disclosing Confidential Information pursuant to law or court order or as required by Applicable Law shall take all steps reasonably necessary, including obtaining an order of confidentiality, to ensure the continued confidential treatment of such Confidential Information.

7.3 Return of Confidential Information. Upon expiration or termination of this Agreement, the receiving Party shall immediately either return to the disclosing Party, or destroy, all Confidential Information of the disclosing Party, in accordance with the instructions of the disclosing Party, including all notes, summaries, and translations that have been made regarding such Confidential Information, and all copies of the foregoing. In the event destruction is requested by the disclosing Party, the receiving Party shall certify such destruction in writing. Notwithstanding the foregoing, the receiving Party may retain a copy for purposes of exercising any licenses under this Agreement that survive the termination or expiration of this Agreement, and may archive one (1) copy of Confidential Information for purposes of demonstrating its compliance with this Agreement, subject to confidentiality requirements of this Agreement.

7.4 Publicity. Except as otherwise required by Applicable Laws or by judicial or administrative process (or as otherwise agreed to by the other Party in writing), each Party agrees not to: [* * *] of the other Party without the prior written consent of such other Party, which consent may be withheld at such other Party's discretion; provided, that in the event Applicable Laws or judicial or administrative process requires such disclosure, use or reference, such Party shall promptly notify the other Party and allow such other Party a reasonable time and opportunity to oppose such process before making such disclosure, use or reference.

8. Term.

8.1 Term. This Agreement is effective as of the Effective Date and shall continue (i) with respect to the Licensed Know-How in perpetuity, and (ii) with respect to the Licensed Patents, until the last to expire patent contained in the Licensed Patents, in each case of (i)-(ii) unless this Agreement is terminated in accordance with Sections 8.2 or 8.3 or the Parties otherwise agree in writing to terminate this Agreement (the period in which this Agreement is in effect, the "**Term**").

8.2 Termination for Breach. If Licensee materially breaches this Agreement, Licensor may give written notice to Licensee, specifying the nature of the material breach and, if such material breach is not remedied within thirty (30) calendar days of receipt of such notice (provided, however, that the cure period shall be suspended during any time that Licensee seeks resolution of a dispute as to whether an alleged material breach occurred pursuant to any dispute resolution mechanisms under this Agreement), then Licensor shall have the right, in its sole discretion, to immediately terminate this Agreement upon written notice to Licensee.

[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

8.3 Termination for Bankruptcy. This Agreement may be terminated by written notice given by Licensor upon the occurrence of any of the following with respect to the Licensee: (i) Licensee becomes insolvent, or (ii) voluntary or involuntary proceedings by or against Licensee are instituted in bankruptcy or under any insolvency law, which proceedings, if involuntary, shall not have been dismissed within ninety (90) days after the date of filing, or (iii) a receiver or custodian is appointed for Licensee, or proceedings are instituted by or against Licensee for corporate reorganization or the dissolution of Licensee, which proceedings, if involuntary, shall not have been dismissed within ninety (90) days after the date of filing, or (iv) Licensee makes an assignment of substantially all of its assets for the benefit of its creditors, or substantially all of the assets of Licensee are seized or attached and not released within ninety (90) days thereafter.

8.4 Effects of Expiration or Termination.

8.4.1 The expiration or termination of this Agreement shall not affect the rights and obligations of the Parties accruing prior to such expiration or termination. Subject to the foregoing, all rights and licenses granted hereunder (and all sublicenses of such rights and licenses) shall terminate upon termination of this Agreement, including that (i) Licensee promptly shall cease using the Licensed Technology and (ii) all rights granted by Licensee to Sublicensees to use the Licensed Technology shall automatically terminate. Notwithstanding the foregoing, the following sections survive expiration or termination of this Agreement: Section 2.4, Article 5, Article 6, Article 7 (for a period of ten (10) years after the expiration or termination of this Agreement), Article 9 and this Section 8.4.

8.4.2 In the event that this Agreement is terminated due to the rejection of this Agreement by or on behalf of Licensor due to a bankruptcy or other insolvency event (an "**Insolvency Event**") of Licensor, all licenses and rights to licenses granted under or pursuant to this Agreement by Licensor to Licensee are and shall otherwise be deemed to be licenses of rights to "intellectual property" (including for purposes of 365(n) of the United States Bankruptcy Code). The Parties agree that Licensee, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under any applicable insolvency statute, and that upon commencement of an Insolvency Event by or against Licensor, Licensee shall be entitled to a complete duplicate of or complete access to (as Licensee deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to Licensee (a) upon any such commencement of a bankruptcy proceeding, at the written request therefor by Licensee, unless Licensor elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, upon the rejection of this Agreement by or on behalf of Licensor, then at the written request of Licensee therefore. The provisions of this Section 8.4.2 shall be (i) without prejudice to any rights Licensee may have arising under any applicable insolvency statute or other Applicable Law and (ii) effective only to the extent permitted by Applicable Law.

9. Miscellaneous.

9.1 Independent Contractor.

9.1.1 In the performance of Licensor's obligations under this Agreement, Licensor shall at all times act as and be deemed an independent contractor. Nothing in this Agreement shall be construed to render Licensor or any of its employees, agents, or officers, as an employee, joint venture, agent, or partner of Licensee. Licensor is not authorized to assume or create any obligations or responsibilities, express or implied, on behalf of or in the name of Licensee. It is understood that the employees, methods, facilities, and equipment of Licensor shall at all times be under Licensor's exclusive direction and control.

9.1.2 In the performance of Licensee's obligations under this Agreement, Licensee shall at all times act as and be deemed an independent contractor. Nothing in this Agreement shall be construed to render Licensee or any of its employees, agents, or officers, as an employee, joint venture, agent, or partner of Licensor. Licensee is not authorized to assume or create any obligations or responsibilities, express or implied, on behalf of or in the name of Licensor. It is understood that the employees, methods, facilities, and equipment of Licensee shall at all times be under Licensee's exclusive direction and control.

9.2 Force Majeure. No Party shall be liable for a failure or delay in performing any of its obligations under this Agreement (except for the payment of money) if, but only to the extent that, such failure or delay is due to causes beyond the reasonable control of the affected Party, including: (i) acts of God; (ii) fire or explosion (except to the extent caused by the negligence or willful misconduct of the affected Party); (iii) unusually severe weather; (iv) war, invasion, riot or other civil unrest; (v) governmental laws, orders, restrictions, actions, embargoes, or blockages; (vi) national or regional emergency; (vii) injunctions, strikes, lockouts, labor trouble, or other industrial disturbances; and (viii) shortage of supply of non-commodity materials on a global basis (each, a "**Force Majeure Event**"); provided that the Party affected shall promptly notify the other of the Force Majeure Event and shall exert reasonable efforts to eliminate, cure, or overcome any such causes and to resume performance of its obligations as soon as practicable.

9.3 Governing Law; Jurisdiction.

9.3.1 This Agreement shall be construed and governed under and in accordance with the laws of the State of New York, without giving effect to the principle of conflict of laws thereof.

9.3.2 The Parties agree that any action, suit or proceeding to enforce the rights of either Party under this Agreement or otherwise arising out of this Agreement shall be brought in the state or federal courts located in the State of New York, having jurisdiction over the subject matter and the Parties (in each case, except to the extent that an alternate method of resolution is specified in other sections of this Agreement).

9.3.3 Subject to Section 9.3.2, in any action, suit or proceeding to enforce the rights of either Party under this Agreement or otherwise arising out of this Agreement, each Party, by execution and delivery of this Agreement, expressly and irrevocably consents to the service of any complaint, summons, notice or other process relating to any such action, suit or proceeding by delivery thereof to it by hand or by any other manner provided for in Section 9.7. IN ADDITION, EACH PARTY HEREBY EXPRESSLY AND IRREVOCABLY WAIVES ANY CLAIM OR DEFENSE IN ANY SUCH PROCEEDING BASED ON ANY ALLEGED LACK OF PERSONAL JURISDICTION, IMPROPER VENUE, FORUM NON CONVENIENS OR ANY SIMILAR DOCTRINE OR THEORY. EACH PARTY HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

9.4 No Waiver. Any Party's failure to enforce any of the terms or conditions herein or to exercise any right or privilege pursuant hereto, or any Party's waiver of any breach under this Agreement, shall not be construed to be a waiver of any other terms, conditions, or privileges, whether of a similar or different type.

9.5 Assignment.

9.5.1 This Agreement may not be assigned, in whole or in part, whether by operation of law or otherwise (however structured), without the prior written consent of the other Party; provided, however, that

(i) a Party shall have the right, without the prior consent of the other Party, to assign this Agreement, in whole or in part to any Affiliate of such Party; and

(ii) a Party shall have the right, without the prior consent of the other Party, to assign this Agreement, in whole, to any Third Party in connection with a sale of all or substantially all of the assets of such Party to which this Agreement relates whether by merger, sale of stock, sale of assets or other similar transaction (including by operation of Applicable Law), in each case upon prior written notice to the other Party.

9.5.2 Any permitted assignee shall assume all obligations of its assignor under this Agreement; provided, however, that in the event of an assignment to an Affiliate (but excluding any assignment by Merck Sharp & Dohme B.V. to its Affiliate N.V. Organon), the assignor Party shall remain as principal obligor for all or any obligations and liabilities assigned to such Affiliate under the terms of this Agreement. No assignment shall relieve any Party of responsibility for the performance of any accrued obligation which such Party has hereunder as of the time of such assignment. Any other attempted assignment of this Agreement in violation of this Section 9.5 shall be null and void.

9.5.3 The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties hereto and their respective successors and permitted assigns.

9.6 Severability. If any provision of this Agreement is found invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall continue in full force and effect. The Parties shall negotiate in good faith to substitute a valid, legal, and enforceable provision that reflects the intent of such invalid or unenforceable provision.

9.7 Notices.

9.7.1 The term "notice" as used throughout this Agreement, shall mean written notice, except where specifically provided herein to the contrary. Notice shall be delivered by (i) certified mail, return receipt requested (or the equivalent); (ii) hand delivery with receipt acknowledged; or (iii) overnight courier service that provides a delivery receipt. Notices shall be delivered to the following addresses or to such other address or person as a Party may specify by notice given in accordance with this Section 9.7.1.

If to Licensor:

MSD RT B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands
With a copy to:

Merck Sharp & Dohme Corp.
One Merck Drive
Whitehouse Station, NJ, 08889
Attention: Office of Secretary

If to Licensee:

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

With a copy to:

Organon LLC
2000 Galloping Hill Road
Kenilworth, NJ 07033-1310
Attention: Office of Secretary

9.7.2 Notice given in accordance with Section 9.7.1 shall be deemed delivered when received, or upon refusal of receipt.

9.8 Cumulative Remedies. Except as otherwise expressly set forth herein, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy available under the terms of this Agreement or otherwise available at law or in equity.

9.9 Entire Agreement/Amendments; Conflicts.

9.9.1 This Agreement, together with all attachments hereto, the Separation Agreement (once entered into) and the other Transaction Documents, constitutes the entire agreement between the Parties hereto and shall supersede and take the place of any and all agreements, documents, minutes of meetings, or letters concerning the subject matter hereof that may, prior to the Effective Date, be in existence. This Agreement may only be amended by a statement in writing to that effect signed by duly authorized representatives of Licensee and Licensor.

9.9.2 In the event of any conflict or inconsistency between the terms of the Separation Agreement (or any other Transaction Documents) and the terms of this Agreement, the terms of this Agreement shall govern with respect to the subject matter hereof.

9.10 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall for all purposes be deemed an original and all of which together shall constitute one and the same instrument. In addition, this Agreement may be executed by facsimile or "PDF" and such facsimile or "PDF" signature shall be deemed to be an original.

9.11 Headings. The headings assigned to the Articles and Sections of this Agreement are for convenience only and shall not limit the scope and applicability of the Articles and Sections.

9.12 Further Assurances. Each Party agrees to execute such further papers, agreements, documents, instruments and the like as may be necessary or desirable to effect the purpose of this Agreement and to carry out its provisions.

9.13 English Language. If there exist versions of this Agreement, or any Schedules or attachments, or any amendments hereto or thereto, in any language other than English, the binding version of all of the foregoing shall be the English version, except as otherwise required by Applicable Law. All notices and other written documentation provided by a Party to the other Party under this Agreement shall be in English, unless otherwise agreed to by the Parties.

9.14 Third Party Beneficiaries. Nothing in this Agreement, express or implied, is intended to confer upon any Third Party, any rights, remedies, obligations or liabilities.

9.15 Interpretation. In this Agreement, unless otherwise specified, (i) "includes" and "including" and words of similar import shall mean includes and including without limitation; (ii) words denoting any gender shall include all genders; (iii) words denoting the singular shall include the plural and vice versa; (iv) the Exhibits, Schedules, Addenda and other attachments form part of the operative provision of this Agreement and references to this Agreement shall, unless the context otherwise requires, include references to the Exhibits, Schedules, Addenda and attachments; (v) the word "or" is disjunctive but not necessarily exclusive; (vi) references to "Articles", "Sections" and "subsections" in this Agreement shall be to Articles, Sections and subsections respectively, of this Agreement unless otherwise specifically provided; and (vii) references to any Articles or Sections include Sections and subsections that are part of the reference Article or Section (*e.g.*, a section numbered "Section 2.2(a)" would be part of "Section 2.2", and references to "Article 2" or "Section 2.2" would refer to material contained in the subsection described as "Section 2.2(a)"). Words and abbreviations that have known or technical trade meanings are used in this Agreement in accordance with such recognized meanings.

[remainder of page intentionally left blank]

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be duly executed and delivered in its name and on its behalf, all as of the day and year first above written.

LICENSEE:

MERCK SHARP & DOHME B.V.

By: /s/ Ben Paul Lucas
Name: Ben Paul Lucas
Title: Managing Director

LICENSOR:

MSD RT B.V.

By: /s/ Marieke Poulie
Name: Marieke Poulie
Title: Director

[Signature Page to Specified Technology License Agreement (Nexplanon Rod Technology)]

Schedule 1.13

[* * *]

[* * *]=[CONFIDENTIAL PORTION HAS BEEN OMITTED BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.]

Exhibit 99.1

, 2021

Dear Merck Shareholder:

On , 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 of a share of Organon common stock for every Merck share of common stock held on , 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 , 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.

, 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 our people 10,000 strong, are looking forward to building a strong company that benefits you and our other stakeholders.

Sincerely,

Kevin Ali

Chief Executive Officer
Organon & Co.

Table of Contents

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 , 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 , 2021, the record date for the distribution, you will receive 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 , 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 your shares of Organon common stock.

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 , 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 , 2021. This information statement will be mailed to Merck's shareholders who previously elected to receive a paper copy of Merck's materials.

Presentation of Information

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 , 2021, each share of Merck common stock that you held at the close of business on such date will entitle you to receive 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 , 2021.
When will the distribution occur?	It is expected that all of the shares of Organon common stock will be distributed by Merck on , 2021 to holders of shares of Merck common stock at the close of business on , 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 your shares of Organon common stock. 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. For any shares of Merck common stock that are held in your Merck dividend reinvestment account as of the close of business on the record date, you will receive shares of Organon common stock in a new Organon dividend reinvestment program account that will be created for you. Organon will not issue any physical stock certificates to any shareholders, even if requested.

If I am enrolled in the Merck dividend reinvestment program, will I automatically be enrolled in the Organon dividend reinvestment program?

Yes. If you elected to have your Merck cash dividends applied toward the purchase of additional shares of Merck common stock, the shares of Organon common stock you receive in the distribution will be automatically enrolled in the Organon dividend reinvestment program sponsored by Equiniti Trust Company, unless you notify Equiniti Trust Company Services that you do not want to reinvest Organon cash dividends in additional shares of Organon common stock. For contact information for Equiniti Trust Company, see "Description of Capital Stock—Transfer Agent and Registrar."

How many shares of Organon common stock will I receive in the distribution?

You will receive of a share of Organon common stock for each share of Merck common stock held as of the close of business on , 2021, the record date. Based on approximately shares of Merck common stock outstanding as of , 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 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 $ 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 , 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 , 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.

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 551-430-6000

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.

Key Products

Women's Health	Biosimilars	Established Brands
Nexplanon (etonogestrel implant) 68mg Radiopaque	RENFLEXIS infliximab	ARCOXIA (etoricoxib, MSD)
NUVARING (etonogestrel/ethinyl estradiol vaginal ring)	BRENZYS etanercept	Zetia (ezetimibe) 10 mg Tablets
Follistim AQ Cartridge (follitropin beta injection) 300 IU, 600 IU, 900 IU For use only with Follistim Pen	Ontruzant trastuzumab	SINGULAIR (MONTELUKAST SODIUM)
elonva corifollitropin alfa	Aybintio bevacizumab	Propecia (finasteride)
		COZAAR losartan
		HYZAAR

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, 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 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.
- ***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.** 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. We may not be successful in implementing our acquisition strategy and fail to achieve growth and value creation. 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 $ 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.

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 , 2021, the Merck Board of Directors approved the distribution of all of Organon's issued and outstanding shares of common stock on the basis of a share of Organon common stock for each share of Merck common stock held as of the close of business on , 2021, the record date.

On , 2021, the distribution date, each Merck shareholder will receive 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 agreement" or 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 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 $ 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 , 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, Jersey City, New Jersey 07302. Organon's telephone number is 551-430-6000.

Organon will also 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, 2020	As of December 31, 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	3,434	3,378	3,955
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
	1,804	1,833	1,356
Less: accumulated depreciation	820	835	676
	984	998	680
Goodwill	4,603	4,603	4,603
Other Intangibles, Net	503	503	569
Other Assets	892	438	741
	$ 10,416	$ 9,920	$10,548
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	1,201	2,484	1,341
Deferred Income Taxes	121	128	139
Related Party Loans Payable	—	—	70
Other Noncurrent Liabilities	9,952	1,822	1,963
Organon & Co. Equity			
Accumulated deficit	(254)	—	—
Net investment from Parent	—	6,108	7,949
Accumulated other comprehensive loss	(604)	(622)	(914)
Total equity	(858)	5,486	7,035
	$ 10,416	$ 9,920	$10,548

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 Person 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.

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. We may not be successful in implementing our acquisition strategy and fail to achieve growth and value creation. 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.

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;
- 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 Person 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 agreement could adversely affect us.

The separation 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

agreement, see "Certain Relationships and Related Person 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 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 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 agreement or any ancillary agreement. Our indemnity obligations to Merck under the circumstances set forth in the separation 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 Person 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. 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;
- issuing equity securities beyond certain thresholds;
- repurchasing our capital stock;
- ceasing to actively conduct our business; 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 such tax liabilities as a result of such actions, even if we did not participate in or otherwise facilitate such actions.

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 $ 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 Person 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 Internal Revenue 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;

- 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

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. We currently expect that we will pay regular cash dividends following the distribution. 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 more detail 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited annual combined financial statements and the related notes included elsewhere in this information statement.

($ in millions)	Historical	Pro Forma
Assets:		
Cash and cash equivalents	$ 70	$
Liabilities:		
144A Senior Notes	$ —	$
Credit Agreement	—	
Shareholders' Equity:		
Net investment from Parent	6,108	
Accumulated other comprehensive loss	(622)	
Total Capitalization	$ 5,486	$

Unaudited Pro Forma Financial Information

On , 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 as of the record date.

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 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 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

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

	Year ended December 31, 2020						
		Transaction Accounting Adjustments					
($ in millions except per share data)	**Historical**	**Business Retained by Merck[a]**	**Other Adjustments**		**Autonomous Entity Adjustments**		**Pro Forma**
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	(i)	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	(b),(o)	22	(l)	436
	5,416	(1,636)	384		628		4,792
Income from Continuing Operations Before Taxes	2,680	72	(384)		(553)		1,815
Taxes on Income	520	(24)	(81)	(e)	(100)	(e)	315
Net Income from Continuing Operations	$ 2,160	$ 96	$ (303)		$ (453)		$1,500
Basic Earnings per Common Share from Continuing Operations						(f)	
Diluted Earnings per Common Share from Continuing Operations						(g)	
Weighted-average common shares outstanding							
Basic						(f)	
Diluted						(g)	

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)	Historical	Transaction Accounting Adjustments: Business Retained by Merck[a]	Transaction Accounting Adjustments: Other Adjustments		Autonomous Entity Adjustments		Pro Forma
	As of December 31, 2020						
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)	282	(b),(e),(i),(o)	249	(k),(n)	892
	$ 9,920	$ (576)	$ 824		$ 248		$ 10,416
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)	9,556	(b),(i)	(1,343)	(k),(n)	9,952
Organon Equity							
Net investment from Parent	6,108	(572)	(5,536)	(j)	—		—
Common stock, $0.01 par value, shares authorized; shares issued and outstanding on a pro forma basis	—	—	—	(j)	—		—
Accumulated deficit	—	—	(1,988)	(j)	1,734	(k)	(254)
Accumulated other comprehensive loss	(622)	18	—		—		(604)
Total equity	5,486	(554)	(7,524)		1,734		(858)
	$ 9,920	$ (576)	$ 824		$ 248		$ 10,416

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 approximately $9.5 billion of borrowings expected to be incurred in connection with the separation and offset by anticipated debt issuance costs of $121 million. Organon plans to distribute approximately $9.0 billion of the proceeds to Merck in connection with the separation. The pro forma condensed combined statement of income reflects estimated interest expense of $386 million related to the $9.5 billion of long-term debt that Organon expects to incur in connection with the separation and amortization of deferred issuance costs. Based on Organon's currently expected debt rating, the interest rate on the debt is expected to be approximately 3.8%. Interest expense was calculated assuming constant debt levels throughout the periods. Interest expense may be higher or lower if Organon's actual interest rate or credit ratings change or if Organon prepays its debt with excess cash. 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 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 intercompany arrangements between Organon and Merck in place prior to December 31, 2020. The net adjustment to Sales of $75 million is required to reflect the total sales that Organon will record for product manufactured and sold to Merck at the price expected to be provided for in the manufacturing and supply agreements to be entered into in conjunction with the Separation. The Cost of sales adjustment of $76 million is required to reflect total costs expected to be incurred to manufacture certain products for Merck. The Cost of sales adjustment also includes adjustment of $17 million to reflect approximate cost of products sold by Merck to Organon at the supply price. 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 share of Organon common stock for each share of Merck common stock outstanding. The assumed number of outstanding shares of common stock is based on the number of Merck common shares of outstanding as of .

(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.

(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 outstanding as of and an assumed pro-rata distribution ratio of 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 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;
- 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:

($ in millions)	**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	$2,395
Restructuring costs	3
Organon formation costs	238
Pro Forma Adjusted EBITDA	$2,636

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

($ in millions)	**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	2,141
Pro Forma Taxes on income	315
Estimated tax benefit on above items	55
Pro Forma Adjusted taxes on income	370
Pro Forma Adjusted Net Income	$1,771

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	10,416	9,920	10,548	10,494
Total equity	(858)	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

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 , 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 Person 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. 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
Clarinex	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
Diprospan	—	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.*

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-bwwd) 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

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)	2020	% Change	% Change Excluding Foreign Exchange	2019	% Change	% Change Excluding Foreign Exchange	2018
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.

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.

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)
	$5,416	(9)%	$5,975	(15)%	$7,048

* *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.

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.

Segment Profits

$ in millions	Organon Products	Merck Retained Products	Total	Organon Products	Merck Retained Products	Total	Organon Products	Merck 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	$ 2,752	$ (72)	$2,680	$ 3,696	$ (141)	$3,555	$ 2,865	$ (136)	$2,729

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	$2,827	$3,896	$4,387
Restructuring costs (excluding depreciation costs above)	73	101	121
Organon formation costs	126	—	—
Gain on settlement of certain patent litigation	—	—	(115)
Adjusted EBITDA	$3,026	$3,997	$4,393
Less: Merck Retained Products Adjusted EBITDA(1)	(54)	(110)	(121)
Organon Products Adjusted EBITDA	$3,080	$4,107	$4,514

(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.*

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	$2,482	$3,352	$3,670

(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.

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:

	Payments Due by Period				
($ in millions)	Total	2021	2022 — 2023	2024 — 2025	Thereafter
Purchase obligations(1)	$ 954	$170	$308	$260	$ 216
Leases(2)	79	22	35	19	3
	$1,033	$192	$343	$279	$ 219

(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 Tax Cuts and Jobs Act of 2017 (the "TCJA") are not reflected in the table above as this liability is expected to 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	$ 343	$ 365

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

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
Nexplanon (etonogestrel implant) 68mg Radiopaque	RENFLEXIS infliximab	ARCOXIA (etoricoxib, MSD)
NUVARING (etonogestrel/ethinyl estradiol vaginal ring)	BRENZYS etanercept	Zetia (ezetimibe) 10 mg Tablets
Follistim AQ Cartridge (follitropin beta injection) 300 IU, 600 IU, 900 IU For use only with Follistim Pen	Ontruzant trastuzumab	SINGULAIR (MONTELUKAST SODIUM)
elonva corifollitropin alfa	Aybintio bevacizumab	Propecia (finasteride)
		COZAAR losartan
		HYZAAR

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, 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 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.
- ***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 ("OBGYN"), 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:

Our Biosimilar	Biologic Product	Global Sales of Biologic Product[1]	Launch of Our Biosimilar
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.

Hadlima (SB5)

Hadlima (adalimumab-bwwd) 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, Diprospan (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.

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 lawsuits. 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. 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.

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.

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 can 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 re-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 chance 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 March 1, 2021, regarding individuals who are expected to serve as our executive officers and/or directors following the distribution.

Name	Age	Position
Kevin Ali	60	Chief Executive Officer and Director Nominee
Matthew Walsh	54	Chief Financial Officer
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
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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, 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.

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.

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 TB Alliance. 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

As mentioned above, upon the completion of this distribution, we expect our Board of Directors to consist of at least ten 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 person 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.

Governance Committee

The responsibilities of our Governance Committee (the "Governance Committee") will be more fully described in our Governance Committee charter, and we anticipate that they will include, among others, the following duties:

- engaging in succession planning for the Board of Directors;

- 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 Governance 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 Governance 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 Governance 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

After the initial constitution of our Board of Directors, we intend to establish a Governance Committee which will develop criteria for filling vacant Board of Director positions.

Effective as of the date of our separation, the Governance 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 Governance 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."

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. Aaron Falcione	Chief Human Resources Officer
4. Susanne Fiedler	Chief Commercial Officer
5. Sandra Milligan	Head of Research & Development
6. Joseph T. Morrissey, Jr.	Head of Manufacturing
7. Vittorio Nisita	Head of Global Business Services
8. Geralyn S. Ritter	Head of External Affairs and ESG
9. Rachel Stahler	Chief Information Officer
10. 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. 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 will also receive a target long-term incentive equity award with a grant date value of approximately $8,000,000. Please see the section titled "Certain Relationships and Related Party Transactions" for additional detail on the adjustment of this long-term incentive equity award in connection with the legal separation of Organon from Merck.

Offer Letter with Chief Financial Officer

In March of 2020, MSD 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 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 MSD 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 MSD 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 (iii) 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 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.

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 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; (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 organization document; 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 Organon 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.

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 (including applying truncated performance periods to certain performance metrics for PSUs granted in 2019 and 2020) 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 PSU awards with a 2020-2022 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 non-qualified deferred compensation plan distributions from Merck (that are not conditioned on future services) of $ in 2019 and $ in 2020 and is expected to receive $ of such distributions in 2021.

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 (1) each person who Organon believes will be a beneficial owner of 5% or more of Organon's outstanding common stock, (2) each expected director and named executive officer and (3) 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 , 2021 unless Merck indicates some other basis for the share amounts, and assume a distribution ratio of shares 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, Jersey City, New Jersey 07302.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership of Organon's Common Stock	Percent of Class
The Vanguard Group 100 Vanguard Blvd. Malvern, PA 19355		%
BlackRock, Inc. 55 East 52nd Street New York, NY 10055		%

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 , 2021, the Merck Board of Directors approved the distribution of all of Organon's issued and outstanding shares of common stock on the basis of of a share of Organon common stock for each share of Merck common stock held as of the close of business on , 2021, the record date.

On , 2021, the distribution date, each Merck shareholder will receive 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 , 2021, the distribution date, to all holders of outstanding shares of Merck common stock as of the close of business on , 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.

For any shares of Merck common stock that are held in a shareholder's Merck dividend reinvestment account as of the close of business on the record date, such shareholder will receive shares of Organon common stock in a new Organon dividend reinvestment program account that will be created for such shareholder.

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 , 2021, the record date, you will receive 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 , 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 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 Person 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 own 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 $ 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 , 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.

144A Senior Notes Issuances

Effective upon the spin-off, we expect that Organon and a wholly-owned subsidiary of Organon will co-issue senior notes with a total aggregate principal amount of approximately $ to "qualified institutional buyers" (as defined in Rule 144A ("Rule 144A")) under the Securities Act in reliance on Rule 144A or another available exemption from registration under the Securities Act, of which approximately $ will be paid to Merck as a distribution. 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.

Credit Agreement

We expect to cause a direct, wholly-owned subsidiary of Organon to enter into a credit agreement providing for a credit facility in an aggregate principal amount of up to $. At this time, we do not know the expected terms of this facility.

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 shares of common stock, par value $0.01 per share and 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, Organon expects that approximately shares of its common stock will be issued and outstanding 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 ratable 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 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.

Index to Financial Statements

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.

Combined Statement of Income
Organon & Co.
Years Ended December 31
($ in millions)

	2020	2019	2018
Sales *(1)*	**$ 8,096**	$ 9,530	$ 9,777
Costs, Expenses and Other			
Cost of sales *(2)*	**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

(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)

	2020	2019	2018
Net Income	**$2,160**	$3,218	$2,153
Other Comprehensive Loss, Net of Taxes:			
Benefit plan net loss and prior service cost, net of amortization	**(143)**	(60)	(59)
Cumulative translation adjustment	**(30)**	54	(125)
	(173)	(6)	(184)
Comprehensive Income	**$1,987**	$3,212	$1,969

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

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	**3,378**	3,955
Property, Plant and Equipment (at cost)		
Land	**15**	7
Buildings	**653**	382
Machinery, equipment and office furnishings	**803**	824
Construction in progress	**362**	143
	1,833	1,356
Less: accumulated depreciation	**835**	676
	998	680
Goodwill	**4,603**	4,603
Other Intangibles, Net	**503**	569
Other Assets	**438**	741
	$9,920	$10,548
Liabilities and Equity		
Current Liabilities		
Trade accounts payable	**$ 294**	$ 258
Accrued and other current liabilities	**752**	807
Due to related party	**1,150**	34
Income taxes payable	**288**	242
Total current liabilities	**2,484**	1,341
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	**5,486**	7,035
	$9,920	$10,548

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	$ 8,941	$ (724)	$8,217
Net income	2,153	—	2,153
Adoption of new accounting standard (see Note 3)	329	—	329
Other comprehensive loss, net of taxes	—	(184)	(184)
Net transfers to Parent	(4,167)	—	(4,167)
Balance December 31, 2018	7,256	(908)	6,348
Net income	3,218	—	3,218
Other comprehensive loss, net of taxes	—	(6)	(6)
Net transfers to Parent	(2,525)	—	(2,525)
Balance December 31, 2019	7,949	(914)	7,035
Net income	**2,160**	**—**	**2,160**
Other comprehensive loss, net of taxes	**—**	**(173)**	**(173)**
Net transfers to Parent	**(4,001)**	**465**	**(3,536)**
Balance December 31, 2020	**$ 6,108**	**$ (622)**	**$ 5,486**

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

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	**2,187**	2,767	3,687
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	**(258)**	(102)	(69)
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	**(2,175)**	(2,621)	(4,164)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	**(3)**	31	19
Net (Decrease) Increase in Cash and Cash Equivalents	**(249)**	75	(527)
Cash and Cash Equivalents at Beginning of Year	**319**	244	771
Cash and Cash Equivalents at End of Year	**$ 70**	$ 319	$ 244

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.

(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.

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

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).

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:

Years Ended December 31	**2020**	**2019**	**2018**
Sales	**$330**	$252	$ 64
Cost of sales	**208**	152	40
Selling, general and administrative	**87**	91	47

December 31	**2020**	**2019**
Receivables from Samsung included in *Other current assets*	**$ 52**	$ 86
Payables to Samsung included in *Trade Accounts Payable*	**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:

	Separation Costs	Accelerated Depreciation	Other	Total
Year Ended December 31, 2020				
Cost of sales	**$ —**	**$ —**	**$ 3**	**$ 3**
Restructuring costs	**33**	**—**	**37**	**70**
	$ 33	**$ —**	**$ 40**	**$ 73**
Year Ended December 31, 2019				
Cost of sales	$ —	$ 7	$—	$ 7
Restructuring costs	87	—	14	101
	$ 87	$ 7	$ 14	$108
Year Ended December 31, 2018				
Cost of sales	$ —	$ 5	$ 2	$ 7
Restructuring costs	86	—	33	119
	$ 86	$ 5	$ 35	$126

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:

	2020	2019
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)
	$1,098	$1,164
Recognized as:		
Inventories	**$ 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:

	2020			2019		
	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
	$ 24,360	**$ 23,857**	**$ 503**	$ 24,335	$ 23,766	$ 569

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

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:

December 31	**2020**	2019
Assets		
Other Assets	**$ 91**	$ 82
Liabilities		
Accrued and other current liabilities	**20**	14
Other Noncurrent Liabilities	**71**	68
	$ 91	$ 82
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
	$ 91

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

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:

Years Ended December 31	**2020**	2019	2018
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.

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:

Years Ended December 31	**2020**	2019	2018
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	**$ (9)**	$ (31)	$ (27)

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:

	2020	2019
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**	$2,746
Funded status December 31	**$ (55)**	$ 118
Recognized as:		
Other assets	**$ —**	$ 177
Other Noncurrent Liabilities	**(55)**	(59)

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.

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
Investment funds								
Developed markets equities	**—**	**198**	**—**	**198**	—	1,332	—	1,332
Government and agency obligations	**—**	**198**	**—**	**198**	—	1,018	—	1,018
Emerging markets equities	**—**	**—**	**—**	**—**	—	96	—	96
Fixed income securities								
Government and agency obligations	**—**	**5**	**—**	**5**	—	—	—	—
Other investments								
Insurance contracts	**—**	**34**	**—**	**34**	—	32	382	414
Other	**—**	**1**	**—**	**1**	—	—	—	—
Plan assets at fair value	**$ —**	**$ 436**	**$ —**	**$436**	$ 4	$2,478	$ 382	$2,864

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 Insurance Contracts	2019 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	**$ —**	$ 382

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.

Years Ended December 31	**2020**	2019	2018
Net loss arising during the period	**$(186)**	$ (75)	$ (96)
Prior service cost arising during the period	**(1)**	—	(7)
	$(187)	$ (75)	$(103)
Net loss amortization included in benefit cost	**$ 18**	$ 9	$ 15
Prior service credit amortization included in benefit cost	**(3)**	(2)	(3)
	$ 15	$ 7	$ 12

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:

December 31	**2020**	2019	2018
Net periodic benefit cost			
Discount rate	**1.75%**	2.51%	2.36%
Expected rate of return on plan assets	**4.35%**	4.95%	5.40%
Salary growth rate	**2.22%**	3.14%	3.13%
Benefit obligation			
Discount rate	**0.93%**	1.63%	2.39%
Salary growth rate	**2.68%**	3.03%	3.13%

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:

Years Ended December 31	**2020**	2019	2018
Interest income	**$(16)**	$(19)	$ (21)
Interest expense	**6**	6	6
Exchange losses	**70**	64	60
Net periodic defined benefit plan credit other than service cost	**(45)**	(59)	(57)
Cost reimbursements and fees to (from) Merck affiliates	**22**	19	(26)
Other, net	**(8)**	(12)	(104)
	$ 29	$ (1)	$(142)

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
	$ 520	**19.4%**	337	9.5%	576	21.1%

(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:

Years Ended December 31	**2020**	2019	2018
Domestic	**$ 528**	$ 516	$ 414
Foreign	**2,152**	3,039	2,315
	$ 2,680	$ 3,555	$ 2,729

Taxes on income consisted of:

Years Ended December 31	**2020**	2019	2018
Current provision			
Federal	**$ 101**	$(164)	$ 152
Foreign	**412**	480	395
State	**1**	(45)	(8)
	$514	$271	$539
Deferred provision			
Federal	**$ 9**	$ 3	$ (44)
Foreign	**(4)**	44	65
State	**1**	19	16
	$ 6	$ 66	$ 37
	$ 520	$ 337	$ 576

Deferred income taxes at December 31 consisted of:

	2020		2019	
	Assets	**Liabilities**	Assets	Liabilities
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	**$ 126**	**$ 89**	$ 122	$ 64
Net deferred income taxes	**$ 37**		$ 58	
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:

	2020	2019	2018
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	**$219**	$ 213	$619

(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.

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									
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
Clarinex	**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
Diprospan	**—**	**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 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.

Combined sales by geographic area where derived are as follows:

Years Ended December 31	**Organon Products**	**Merck Retained Products**	**Total**	Organon Products	Merck Retained Products	Total	Organon Products	Merck Retained Products	Total
	2020			2019			2018		
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)
	$ 6,532	**$ 1,564**	**$8,096**	$ 7,777	$ 1,753	$9,530	$ 8,292	$ 1,485	$9,777

Income Before Taxes by segment is as follows:

Years Ended December 31	**Organon Products**	**Merck Retained Products**	**Total**	Organon Products	Merck Retained Products	Total	Organon Products	Merck Retained Products	Total
	2020			2019			2018		
Sales	**$ 6,532**	**$ 1,564**	**$8,096**	$ 7,777	$ 1,753	$9,530	$ 8,292	$ 1,485	$9,777
Costs, Expenses and Other									
Cost of sales	**2,119**	**1,228**	**3,347**	2,274	1,347	3,621	3,541	1,152	4,693
Selling, general and administrative	**1,356**	**310**	**1,666**	1,443	479	1,922	1,567	446	2,013
Research and development	**210**	**94**	**304**	220	112	332	262	103	365
Restructuring costs	**60**	**10**	**70**	78	23	101	108	11	119
Other (income) expense, net	**35**	**(6)**	**29**	66	(67)	(1)	(51)	(91)	(142)
Income (Loss) Before Taxes	**$ 2,752**	**$ (72)**	**$2,680**	$ 3,696	$ (141)	$3,555	$ 2,865	$ (136)	$2,729

Interest income, interest expense and depreciation and amortization by segment is as follows:

Years Ended December 31	**Organon Products**	**Merck Retained Products**	**Total**	Organon Products	Merck Retained Products	Total	Organon Products	Merck 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:

December 31	**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:

Years Ended December 31	**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

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:

Years Ended December 31	**2020**	2019	2018
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:

December 31	**2020**	**2019**
Trade receivables, net	**$—**	$ 32
Less: Short term borrowings, net	**—**	(19)
Due from related party	**$—**	$ 13

December 31	**2020**	2019
Short term borrowings, net	**$1,266**	$—
Short term loans and notes payable, net	**25**	34
Less: Trade receivables, net	**(141)**	—
Due to related party	**$1,150**	$ 34

December 31	**2020**	2019
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:

Years Ended December 31	**2020**	2019	2018
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	**3,340**	2,577	4,223
Share-based compensation expense	**(54)**	(52)	(56)
Net assets distributed to Merck affiliates	**250**	—	—
Derecognition of amounts recognized in *Accumulated other comprehensive loss* related to employee benefit plan transfers to Merck affiliates	**465**	—	—
Net transfers to Parent as reflected in the Combined Statement of Equity	**$ 4,001**	$ 2,525	$ 4,167

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. Additionally, the Company has evaluated transactions that occurred through March 17, 2021, the date these financial statements were available for issuance, for the purposes of unrecognized subsequent events.