

Allergan plc  
Form 10-K  
February 15, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2018

OR

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

For the transition period from            to

Commission	Exact name of registrant as specified in its charter,	State of incorporation	I.R.S. Employer
File Number 001-36867	principal office and address and telephone number Allergan plc  Clonshaugh Business and Technology Park  Coolock, Dublin, D17 E400, Ireland  (862) 261-7000	or organization Ireland	Identification No. 98-1114402
001-36887	Warner Chilcott Limited  Canon's Court  22 Victoria Street  Hamilton HM 12	Bermuda	98-0496358

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Bermuda

(441) 295-2244

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

Title of Each Class	Name of Each Exchange on Which Registered
Allergan plc Ordinary Shares, \$0.0001 par value	New York Stock Exchange

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Allergan plc	Yes	No
Warner Chilcott Limited	Yes	No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Allergan plc	Yes	No
Warner Chilcott Limited	Yes	No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days:

Allergan plc	Yes	No
Warner Chilcott Limited	Yes	No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Allergan plc	Yes	No
Warner Chilcott Limited	Yes	No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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Allergan plc  
Warner Chilcott Limited

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

Allergan plc	Large accelerated filer	Accelerated filer
	Non-accelerated filer	Smaller reporting company
	Emerging growth company	
Warner Chilcott Limited	Large accelerated filer	Accelerated filer
	Non-accelerated filer	Smaller reporting company
	Emerging growth company	

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Allergan plc	Yes	No
Warner Chilcott Limited	Yes	No

The aggregate market value of the voting and non-voting stock held by non-affiliates of Allergan plc as of June 30, 2018, based upon the last sale price reported for such date on the New York Stock Exchange, was \$56.5 billion. The calculation of the aggregate market value of voting and non-voting stock excludes Class A ordinary shares of Allergan plc held by executive officers, directors, and stockholders that the registrant concluded were affiliates of Allergan plc on that date.

Number of shares of Allergan plc’s Ordinary Shares outstanding on February 8, 2019: 332,614,474

This Annual Report on Form 10-K is a combined report being filed separately by two different registrants: Allergan plc and Warner Chilcott Limited. Warner Chilcott Limited is an indirect wholly owned subsidiary of Allergan plc. The information in this Annual Report on Form 10-K is equally applicable to Allergan plc and Warner Chilcott Limited, except where otherwise indicated. Warner Chilcott Limited meets the conditions set forth in General Instruction H(1)(a) and (b) of Form 10-K and, to the extent applicable, is therefore filing this form with a reduced disclosure format.

### DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K (“Annual Report”) is incorporated by reference from the Allergan plc proxy statement to be filed pursuant to Regulation 14A with respect to the Registrant’s Annual General Meeting of Shareholders to be held on May 1, 2019.



ALLERGAN PLC

WARNER CHILCOTT LIMITED

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## PART I

### ITEM 1. BUSINESS

#### Explanatory Note

This Annual Report on Form 10-K is a combined annual report being filed separately by two registrants: Allergan plc and its indirect wholly-owned subsidiary, Warner Chilcott Limited. Each registrant hereto is filing on its own behalf all the information contained in this annual report that relates to such registrant. Each registrant hereto is not filing any information that does not relate to such registrant, and therefore makes no representations as to any such information.

#### Company History

Allergan plc was incorporated in Ireland on May 16, 2013 as a private limited company and re-registered effective September 20, 2013 as a public limited company. Except where otherwise indicated, and excluding certain insignificant cash and non-cash transactions at the Allergan plc level, the consolidated financial statements and disclosures are for two separate registrants, Allergan plc and Warner Chilcott Limited. The results of Warner Chilcott Limited are consolidated into the results of Allergan plc. Due to the de minimis activity between Allergan plc and Warner Chilcott Limited, references throughout this document relate to both Allergan plc and Warner Chilcott Limited. Refer to “Note 3 —Reconciliation of Warner Chilcott Limited results to Allergan plc results” in the accompanying “Notes to the Consolidated Financial Statements” in this document for a summary of the details on the differences between Allergan plc and Warner Chilcott Limited.

Allergan plc ordinary shares are traded on the NYSE under the ticker symbol “AGN.” Pursuant to Rule 12g-3(c) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), Allergan plc’s ordinary shares are deemed to be registered under Section 12(b) of the Exchange Act, and Allergan plc is subject to the informational requirements of the Exchange Act, and the rules and regulations promulgated thereunder.

In August 2016 we completed the divestiture of our global generics business and certain other assets to Teva Pharmaceutical Industries Ltd. (“Teva”) (the “Teva Transaction”) for \$33.3 billion in cash, net of cash acquired by Teva, which included estimated working capital and other contractual adjustments, and 100.3 million unregistered Teva ordinary shares (or American Depositary Shares with respect thereto). As part of the Teva Transaction, Teva acquired our global generics business, including the United States (“U.S.”) and international generic commercial units, our third-party supplier Medis, our global generic manufacturing operations, our global generic research and development (“R&D”) unit, our international over-the-counter (“OTC”) commercial unit (excluding OTC eye care products) and certain established international brands.

In October 2016, the Company completed the divestiture of the Anda Distribution business to Teva for \$500.0 million. The Anda Distribution business distributed generic, branded, specialty and OTC pharmaceutical products from more than 300 manufacturers to retail independent and chain pharmacies, nursing homes, mail order pharmacies, hospitals, clinics and physician offices across the U.S.

As a result of the Teva Transaction and the divestiture of the Company’s Anda Distribution business, and in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) No. 2014-08 “Presentation of Financial Statements (Topic 205) and Property, Plant and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity,” the financial results of the businesses held for sale were reclassified to discontinued operations for all periods presented in our consolidated financial statements. The results of our discontinued operations include the results of our generic

product development, manufacturing and distribution of off-patent pharmaceutical products, certain established international brands marketed similarly to generic products and out-licensed generic pharmaceutical products primarily in Europe through our Medis third-party business through August 2016, as well as our Anda Distribution business through October 2016.

References throughout to “we,” “our,” “us,” the “Company” or “Allergan” refer to financial information and transactions of Watson Pharmaceuticals, Inc. prior to January 23, 2013, Allergan Finance, LLC from January 23, 2013 until October 1, 2013 and Allergan plc and Warner Chilcott Limited subsequent to October 1, 2013.

References throughout to “Ordinary Shares” refer to Allergan plc’s ordinary shares, par value \$0.0001 per share.

This discussion contains forward-looking statements that are subject to known and unknown risks, uncertainties and other factors that may cause our actual results to differ materially from those expressed or implied by such forward-looking statements. These risks, uncertainties and other factors include, among others, those identified under “Risk Factors” in this Annual Report and in other reports we have filed with the U.S. Securities and Exchange Commission (“SEC”).



## Business Overview

Allergan plc is a global pharmaceutical leader. Allergan is focused on developing, manufacturing and commercializing branded pharmaceutical, device, biologic, surgical and regenerative medicine products for patients around the world. Allergan markets a portfolio of leading brands and best-in-class products primarily focused on four key therapeutic areas including medical aesthetics, eye care, central nervous system and gastroenterology. Allergan is an industry leader in Open Science, a model of research and development, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. The Company has operations in more than 100 countries. Warner Chilcott Limited is an indirect wholly-owned subsidiary of Allergan plc and has the same principal business activities.

Allergan plc's principal executive offices are located at Clonshaugh Business and Technology Park, Coolock, Dublin, Ireland and our administrative headquarters are located at 5 Giralda Farms, Madison, NJ 07940. Our Internet website address is [www.allergan.com](http://www.allergan.com). We do not intend this website address to be an active link or to otherwise incorporate by reference the contents of the website into this report. Our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and all amendments thereto, are available free of charge on our Internet website. These reports are posted on our website as soon as reasonably practicable after such reports are electronically filed with the SEC. The public may read and copy any materials that we file with the SEC electronically through the SEC website ([www.sec.gov](http://www.sec.gov)). The information contained on the SEC's website is not incorporated by reference into this Form 10-K and should not be considered to be part of this Form 10-K. Within the Investors section of our website, we provide information concerning corporate governance, including our Corporate Governance Guidelines, Board Committee Charters and Composition, Code of Conduct and other information. Refer to "ITEM 1A. RISK FACTORS-CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS" in this document.

## Business Development

### 2018 Significant Business Developments

The following are the significant transactions that were completed or announced in the year ended December 31, 2018.

#### Licenses and Asset Acquisitions

##### Bonti, Inc.

On October 24, 2018, the Company acquired Bonti, Inc. ("Bonti"), a privately held clinical-stage biotechnology company focused on the development and commercialization of novel, fast-acting neurotoxin programs for aesthetic and therapeutic applications, for \$195.0 million upfront plus contingent consideration of up to \$90.0 million which may be recorded if the corresponding events become probable. The transaction was accounted for as an asset acquisition as the purchase primarily related to one asset. The aggregate upfront expense of \$196.6 million was recorded as a component of R&D expense in the year ended December 31, 2018.

##### Elastagen Pty Ltd

On April 6, 2018, the Company completed the acquisition of Elastagen Pty Ltd, a clinical stage medical company developing medical and cosmetic treatments including recombinant human tropoelastin, the precursor of elastin, which will be combined with Allergan's existing fillers product lines. The transaction was accounted for as an asset acquisition as the purchase primarily related to one asset. The aggregate upfront expense of \$96.1 million was recorded as a component of R&D expense during the year ended December 31, 2018. Under the terms of the

agreement, Elastagen Pty Ltd is eligible to receive additional contingent consideration of up to \$165.0 million which may be recorded if the corresponding events become probable.

Repros Therapeutics, Inc.

On January 31, 2018, the Company completed the acquisition of Repros Therapeutics, Inc., which was accounted for as an asset acquisition as the purchase primarily related to one asset. The aggregate upfront expense of \$33.2 million was recorded as a component of R&D expense during the year ended December 31, 2018.

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## Divestitures

### Anti-Infectives Business Classified as Held for Sale

As of December 31, 2018, Allergan concluded that its Anti-Infectives business met the criteria for held for sale based on management's intent and ability to divest the business within the next twelve months. As a result of this decision, Allergan impaired the business assets by \$771.7 million, including goodwill of \$622.0 million, based on the expected aggregate fair value to be received of approximately \$885.0 million. Upon the sale of the business, Allergan would only recognize the upfront proceeds received in exchange for the assets disposed, which may result in further potential write downs as of the date of sale. If contingent consideration is part of the aggregate fair value received, the Company would recognize any future benefits in "other income / (expense)" as the contingent portion of the divestiture is earned.

### Aclaris Therapeutics, Inc.

On November 30, 2018, the Company divested Rhofade® to Aclaris Therapeutics, Inc. Under the terms of the agreement, the purchase price included an upfront cash payment, a potential development milestone payment for an additional dermatology product, and tiered payments based on annual net sales of Rhofade®, which have a fair value estimated to be \$50.3 million. As a result of this transaction, the Company recorded a net loss of \$266.2 million which is included as a component of "Asset sales and impairments, net".

### Almirall, S.A.

On September 20, 2018, the Company completed the sale of five medical dermatology products (Aczone®, Tazorac®, Azelex®, Cordran® Tape and Seysara™) in the U.S. to Almirall, S.A. Allergan concluded that these assets constituted a business. As part of the sale, the Company received cash consideration of \$550.0 million and is eligible to receive a contingent payment of up to an additional \$100.0 million in the event that net sales of the divested products in a specified calendar year exceed a sales target, to which no fair value has been ascribed. As a result of this transaction, the Company recorded a net gain of \$129.6 million included as a component of "other income / (expense), net".

## 2017 Significant Business Developments

The following are the significant transactions that were completed or announced in the year ended December 31, 2017.

### Acquisitions

#### Keller Medical, Inc.

On June 23, 2017, the Company acquired Keller Medical, Inc. ("Keller"), a privately held medical device company and developer of the Keller Funnel® (the "Keller Acquisition"). The Keller Acquisition combined the Keller Funnel® with the Company's leading breast implants business.

#### Zeltiq® Aesthetics, Inc.

On April 28, 2017, the Company acquired Zeltiq<sup>®</sup> Aesthetics, Inc. (“Zeltiq”) for an acquisition accounting purchase price of \$2,405.4 million (the “Zeltiq Acquisition”). Zeltiq was focused on developing and commercializing products utilizing its proprietary controlled-cooling technology platform (Coolsculpting<sup>®</sup>). The Zeltiq Acquisition combined Zeltiq’s body contouring business with the Company’s leading portfolio of medical aesthetics.

#### LifeCell Corporation

On February 1, 2017, the Company acquired LifeCell Corporation (“LifeCell”), a regenerative medicine company, for an acquisition accounting price of \$2,883.1 million (the “LifeCell Acquisition”). The LifeCell Acquisition combined LifeCell's novel, regenerative medicines business, including its high-quality and durable portfolio of dermal matrix products, with the Company’s leading portfolio of medical aesthetic products, breast implants and tissue expanders. The LifeCell Acquisition expanded the Company’s medical aesthetics portfolio by adding Allodern<sup>®</sup> and Strattice<sup>®</sup>.

Licenses and Other Transactions Accounted for as Asset Acquisitions

Lyndra, Inc.

On July 31, 2017, the Company entered into a collaboration, option and license agreement with Lyndra, Inc. (“Lyndra”) to develop orally administered ultra-long-acting (once-weekly) products for the treatment of Alzheimer’s disease and an additional, unspecified indication. The total upfront payment of \$15.0 million was included as a component of R&D expense in the year ended December 31, 2017. The Company concluded based on the stage of development of the assets, the lack of acquired employees and manufacturing, as well as the lack of certain other inputs and processes, that the transaction did not qualify as a business. The future option exercise payments, if any, and any future success based milestones relating to the licensed products of up to \$85.0 million will be recorded if the corresponding events become probable.

Editas Medicine, Inc.

On March 14, 2017, the Company entered into a strategic alliance and option agreement with Editas Medicine, Inc. (“Editas”) for access to early stage, first-in-class eye care programs. Pursuant to the agreement, Allergan made an upfront payment of \$90.0 million for the right to license up to five of Editas’ gene-editing programs in eye care, including its lead program for Leber Congenital Amaurosis (“LCA”). Under the terms of the agreement, if an option is exercised, Editas is eligible to receive contingent research and development and commercial milestones plus royalties based on net sales. The Company concluded based on the stage of development of the assets, the lack of acquired employees and manufacturing, as well as the lack of certain other inputs and processes, that the transaction did not qualify as a business. The total upfront payment of \$90.0 million was included as a component of R&D expense in the year ended December 31, 2017. The future option exercise payments, if any, and any future success based milestones relating to the licensed products will be recorded if the corresponding events become probable.

In the year ended December 31, 2018, the Company exercised a \$15.0 million option to develop and commercialize EDIT-101 globally for the treatment of LCA10 which was included as a component of R&D expense. Additionally, Editas has exercised its option to co-develop and share equally in the profits and losses from EDIT-101 in the United States. Editas received an additional \$25.0 million milestone, which was included as a component as R&D expense in the year ended December 31, 2018, as the Food and Drug Administration (“FDA”) accepted the Investigational New Drug Application (“IND”) for EDIT-101.

Assembly Biosciences, Inc.

On January 9, 2017, the Company entered into a licensing agreement with Assembly Biosciences, Inc. (“Assembly”) for the worldwide rights to Assembly’s microbiome gastrointestinal development programs. Under the terms of the agreement, the Company made an upfront payment to Assembly of \$50.0 million for the exclusive, worldwide rights to develop and commercialize certain development compounds. Additionally, Assembly will be eligible to receive success-based development and commercial milestone payments plus royalties based on net sales. The Company and Assembly will generally share development costs through proof-of-concept (“POC”) studies, and Allergan will assume all post-POC development costs. The Company concluded based on the stage of development of the assets, the lack of acquired employees and manufacturing, as well as the lack of certain other inputs and processes, that the transaction did not qualify as a business. The total upfront payment of \$50.0 million was included as a component of R&D expense in the year ended December 31, 2017 and the future success based milestone payments of up to \$2,771.0 million, including amounts for additional development programs not committed to as of December 31, 2017, will be recorded if the corresponding events become probable.

Lysosomal Therapeutics, Inc.

On January 9, 2017, the Company entered into a definitive agreement for the option to acquire Lysosomal Therapeutics, Inc. (“LTI”). LTI is focused on innovative small-molecule research and development in the field of neurodegeneration, yielding new treatment options for patients with severe neurological diseases. Under the agreement, Allergan acquired an option right directly from LTI shareholders to acquire LTI for \$150.0 million plus future milestone payments following completion of a Phase Ib trial for LTI-291 as well as an upfront research and development payment. The Company concluded based on the stage of development of the assets, the lack of acquired employees and manufacturing, as well as the lack of certain other inputs and processes, that the transaction did not qualify as a business. The aggregate upfront payment of \$145.0 million was recorded as a component of R&D expense in the year ended December 31, 2017. The Company did not exercise its option and on January 2, 2019, the option agreement with LTI was terminated.

## Other Transactions

### Saint Regis Mohawk Tribe

On September 8, 2017, the Company entered into an agreement with the Saint Regis Mohawk Tribe, under which the Saint Regis Mohawk Tribe obtained the rights to Orange Book-listed patents covering Restasis® (Cyclosporine Ophthalmic Emulsion) 0.05%, and the Company was granted exclusive licenses under the patents related to the product. Pursuant to the agreement, the Company paid the Saint Regis Mohawk Tribe an upfront payment of \$13.8 million, which was recorded as a component of cost of sales in the year ended December 31, 2017. Additionally, the Saint Regis Mohawk Tribe will be eligible to receive up to \$15.0 million in annual royalties starting in 2018, during the period that certain patent claims remain in effect.

## 2016 Significant Business Developments

The following are the significant transactions that were completed in the year ended December 31, 2016.

### Acquisitions

#### Tobira Therapeutics, Inc.

On November 1, 2016, the Company acquired Tobira Therapeutics, Inc. (“Tobira”), a clinical-stage biopharmaceutical company focused on developing and commercializing therapies for non-alcoholic steatohepatitis (“NASH”) and other liver diseases for an acquisition accounting purchase price of \$570.1 million, plus contingent consideration of up to \$49.84 per share in contingent value rights (“CVR”), or up to \$1,101.3 million, that may be payable based on the successful completion of certain development, regulatory and commercial milestones (the “Tobira Acquisition”), of which \$303.1 million was paid in the year ended December 31, 2017 for the initiation of Phase III clinical trials. The CVR had an acquisition date fair value of \$479.0 million. The Tobira Acquisition added Cenicriviroc, a differentiated, complementary development program for the treatment of the multi-factorial elements of NASH, including inflammation, metabolic syndromes and fibrosis, to Allergan's global gastroenterology R&D pipeline.

#### Vitae Pharmaceuticals, Inc.

On October 25, 2016, the Company acquired Vitae Pharmaceuticals, Inc. (“Vitae”), a clinical-stage biotechnology company, for an acquisition accounting purchase price of \$621.4 million (the “Vitae Acquisition”). At the time of the transaction, the Vitae Acquisition was anticipated to expand Allergan's dermatology product pipeline with the addition of a Phase II orally active ROR $\gamma$ t (retinoic acid receptor-related orphan receptor gamma) inhibitor for the potential treatment of psoriasis and other autoimmune disorders, and a Phase II atopic dermatitis drug candidate. In the year ended December 31, 2018, the Company recorded In-process Research and Development (“IPR&D”) impairments of \$562.0 million relating to the acquired assets.

#### ForSight VISION5, Inc.

On September 23, 2016, the Company acquired ForSight VISION5, Inc. (“ForSight”), a privately held, clinical-stage biotechnology company focused on eye care, in an all cash transaction of approximately \$95.0 million (the “ForSight Acquisition”). Under the terms of the ForSight Acquisition, the Company acquired ForSight for an acquisition

accounting purchase price of \$74.5 million plus the payment of outstanding indebtedness of \$14.8 million and other miscellaneous charges. ForSight shareholders are eligible to receive contingent consideration of up to \$125.0 million, which had an initial estimated fair value of \$79.8 million, relating to commercialization milestones. The Company acquired ForSight for its lead development program, a peri-ocular ring designed for extended drug delivery and reducing elevated intraocular pressure (“IOP”) in glaucoma patients.

#### Licenses and Asset Acquisitions

##### Motus Therapeutics, Inc.

On December 15, 2016, the Company acquired Motus Therapeutics, Inc. (“Motus”) for an upfront payment of approximately \$200.0 million (the “Motus Transaction”). Motus has the worldwide rights to RM-131 (relamorelin), a peptide ghrelin agonist being developed for the treatment of diabetic gastroparesis. Under the terms of the Motus Transaction, Motus shareholders are eligible to receive contingent consideration in connection with the commercial launch of the product. The Company concluded based on the stage of development of the assets, the lack of acquired employees as well as certain other inputs and processes that the transaction did not qualify as a business. The total upfront net payment of \$199.5 million was included as a component of R&D expense in the year ended December 31, 2016 and the future milestone will be recorded if the corresponding event becomes probable.



#### Chase Pharmaceuticals Corporation

On November 22, 2016, the Company acquired Chase Pharmaceuticals Corporation (“Chase”), a clinical-stage biopharmaceutical company focused on the development of improved treatments for neurodegenerative disorders including Alzheimer's disease, for an upfront payment of approximately \$125.0 million plus potential regulatory and commercial milestones of up to \$875.0 million related to Chase's lead compound, CPC-201, and certain backup compounds (the “Chase Transaction”). The Company concluded based on the stage of development of the assets, the lack of acquired employees as well as certain other inputs and processes that the Chase Transaction did not qualify as a business. The total upfront net payment of \$122.9 million was expensed as a component of R&D expense in the year ended December 31, 2016 and the future milestones will be recorded if the corresponding events become probable. In the year ended December 31, 2018, milestone payments of \$75.0 million were included as a component of R&D expense.

#### AstraZeneca plc License

On October 2, 2016, the Company entered into a licensing agreement with MedImmune, AstraZeneca plc's (“AstraZeneca”) global biologics research and development arm, for the global rights to brazikumab (the “AstraZeneca Transaction”). Brazikumab is an anti-IL-23 monoclonal antibody that as of the acquisition date was in Phase IIb clinical development for the treatment of patients with moderate-to-severe Crohn's disease and was Phase II ready for ulcerative colitis and other conditions treated with anti-IL-23 monoclonal antibodies. Under the terms of the AstraZeneca Transaction, AstraZeneca received \$250.0 million for the exclusive, worldwide license to develop and commercialize brazikumab and can receive contingent consideration of up to \$1.27 billion (as of the time of the transaction), as well as tiered royalties on sales of the product. The Company concluded based on the stage of development of the assets, the lack of acquired employees and manufacturing as well as certain other inputs and processes that the transaction did not qualify as a business. The total upfront payment of \$250.0 million was included as a component of R&D expense in the year ended December 31, 2016 and the future milestones will be recorded if the corresponding events become probable. In the year ended December 31, 2018, milestones of \$90.0 million, related to the probable initiation of clinical studies, were expensed as a component of R&D expense.

#### RetroSense Therapeutics, LLC

On September 6, 2016, the Company acquired certain assets of RetroSense Therapeutics, LLC (“RetroSense”), a private, clinical-stage biotechnology company focused on novel gene therapy approaches to restore vision in patients suffering from blindness (the “RetroSense Transaction”). Under the terms of the RetroSense Transaction, RetroSense received approximately \$60.0 million upfront, and is eligible to receive up to \$495.0 million in contingent regulatory and commercialization milestone payments related to its lead development program, RST-001, a novel gene therapy for the treatment of retinitis pigmentosa. The Company concluded based on the stage of development of the assets, the lack of acquired employees as well as certain other inputs and processes that the RetroSense Transaction did not qualify as a business. The total upfront net payment of \$59.7 million was included as a component of R&D expense in the year ended December 31, 2016 and the future milestones will be recorded if the corresponding events become probable.

#### Akarna Therapeutics, Ltd.

On August 26, 2016, the Company acquired Akarna Therapeutics, Ltd. (“Akarna”), a biopharmaceutical company developing novel small molecule therapeutics that target inflammatory and fibrotic diseases (the “Akarna Transaction”). Under the terms of the Akarna Transaction, Akarna shareholders received approximately \$50.0 million upfront and were eligible to receive contingent development and commercialization milestones of up to \$1,015.0 million. The Company concluded based on the stage of development of the assets as well as a lack of certain other inputs and

processes that the Akarna Transaction did not qualify as a business. The total upfront net payment of \$48.2 million was included as a component of R&D expense in the year ended December 31, 2016 and the future milestones will be recorded if the corresponding events become probable. In the year ended December 31, 2017, a milestone of \$39.6 million, related to the initiation of a clinical study, was included as a component of R&D expense.

Topokine Therapeutics, Inc.

On April 21, 2016, the Company acquired Topokine Therapeutics, Inc. (“Topokine”), a privately held, clinical-stage biotechnology company focused on development stage topical medicines for fat reduction (the “Topokine Transaction”). Under the terms of the Topokine Transaction, Topokine shareholders received an upfront payment of \$85.8 million and are eligible to receive contingent development and commercialization milestones of up to \$260.0 million for XAF5, a first-in-class topical agent in development for the treatment of steatoblepharon, also known as undereye bags. The Company concluded based on the stage of development of the assets, the lack of acquired employees as well as certain other inputs and processes that the Topokine Transaction did not qualify as a business. The total upfront net payment of approximately \$85.0 million was included as a component of R&D expense in the year ended December 31, 2016 and the future milestones will be recorded if the corresponding events become probable.

#### Heptares Therapeutics, Ltd.

On April 6, 2016, the Company entered into an agreement with Heptares Therapeutics, Ltd. (“Heptares”), under which the Company licensed exclusive global rights to a portfolio of novel subtype-selective muscarinic receptor agonists in development for the treatment of major neurological disorders, including Alzheimer's disease (the “Heptares Transaction”). Under the terms of the Heptares Transaction, Heptares received an upfront payment of \$125.0 million and is eligible to receive contingent milestone payments of up to approximately \$665.0 million upon successful Phase I, II and III clinical development and launch of the first three licensed compounds for multiple indications and up to approximately \$2.575 billion associated with achieving certain annual sales thresholds during the several years following launch. In addition, Heptares was eligible to receive contingent tiered royalties on net sales of all products resulting from the partnership. The Company concluded based on the stage of development of the assets, the lack of acquired employees as well as certain other inputs and processes that the Heptares Transaction did not qualify as a business. The total upfront payment of \$125.0 million was included as a component of R&D expense in the year ended December 31, 2016 and the future milestones will be recorded if the events become probable. In the year ended December 31, 2017, a milestone of \$15.0 million, related to the initiation of a clinical study, was included as a component of R&D expense.

#### Anterios, Inc.

On January 6, 2016, the Company acquired Anterios, Inc. (“Anterios”), a clinical stage biopharmaceutical company developing a next generation delivery system and botulinum toxin-based prescription products (the “Anterios Transaction”). Under the terms of the Anterios Transaction, Anterios shareholders received an upfront net payment of approximately \$90.0 million and are eligible to receive contingent development and commercialization milestone payments up to \$387.5 million related to an investigational topical formulation of botulinum toxin type A in development for the potential treatment of hyperhidrosis, acne, and crow’s feet lines and the related NDS™, Anterios' proprietary platform delivery technology that enables local, targeted delivery of neurotoxins through the skin without the need for injections. The Company concluded based on the stage of development of the assets, the lack of acquired employees as well as certain other inputs and processes that the Anterios Transaction did not qualify as a business. The total upfront net payment of \$89.2 million was included as a component of R&D expense in the year ended December 31, 2016 and the future milestones will be recorded if the corresponding events become probable.

#### Business Description

The Company markets brand pharmaceutical products and medical devices, including aesthetic products, under brand names through programs that are designed to generate physician and consumer loyalty.

As a result of the differences between the types of products we market and/or distribute, we operate and manage our business in three distinct operating segments: US Specialized Therapeutics, US General Medicine and International. The operating segments are organized as follows:

- The US Specialized Therapeutics segment includes sales and expenses relating to branded products within the U.S., including Medical Aesthetics, Medical Dermatology through September 20, 2018, Eye Care and Neuroscience and Urology therapeutic products.
- The US General Medicine segment includes sales and expenses relating to branded products within the U.S. that do not fall into the US Specialized Therapeutics business units, including Central Nervous System, Gastrointestinal, Women’s Health, Anti-Infectives and Diversified Brands.
  - The International segment includes sales and expenses relating to products sold outside the U.S.

#### Business Strategy

We apply four key strategies to achieve growth for our US Specialized Therapeutics, US General Medicine and International businesses: (i) internal development of differentiated and high-demand products, (ii) investing behind key marketed brands, (iii) establishment of strategic alliances and collaborations and (iv) acquisition of products and companies that complement our current business.

Based upon business conditions, our financial strength and other factors, we regularly reexamine our business strategies and may change them at any time. Refer to “ITEM 1A. RISK FACTORS —Risks Related to Our Business” in this document.

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As of December 31, 2018, our portfolio of products within the US Specialized Therapeutics, US General Medicine and International segments include the following products with sales in excess of \$200.0 million:

Product	Therapeutic Area	Active Ingredient	Therapeutic Classification
Alloderm®	Medical Aesthetics	Tissue	Skin graft
Alphagan®/Combigan®	Eye Care	Brimonidine tartrate	Selective alpha <sub>2</sub> agonist
Botox® Cosmetics	Facial Aesthetics	Onabotulinumtoxin A	Acetylcholine release inhibitor
Botox® Therapeutics	Neuroscience and Urology	Botulinum toxin	Musculoskeletal agent
Breast Implants	Plastic Surgery	Silicone	Reconstructive plastic surgery
Bystolic®/Byvalson®	Diversified Brands	Nebivolol	Hypertension
Carafate®/Sulcrate®	Gastrointestinal	Sucralfate	Ulcerative colitis
Coolsculpting®	Medical Aesthetics	Medical device	Body contouring
Juvederm® Collection	Facial Aesthetics	Hyaluronic acid	Fillers
Linzess®/Constella®	Gastrointestinal	Linaclotide	Irritable bowel syndrome
Lo Loestrin®	Women's Health	Ethinyl estradiol and norethindrone	Oral contraceptive
Lumigan®/Ganfort®	Eye Care	Bimatoprost	Prostaglandin analogue
Ozurdex®	Eye Care	Dexamethasone	Intravitreal eye implant
Restasis®	Eye Care	Cyclosporine	Topical immunomodulator
Viibryd®/Fetzima®	Central Nervous System	Vilazodone HCl/Levomilnacipran	Major depressive disorders
Vraylar®	Central Nervous System	Cariprazine HCl	Schizophrenia, bipolar mania
Zenpep®	Gastrointestinal	Pancrelipase	Exocrine pancreatic insufficiency

Our portfolio of products also includes eye drops including Optive and Refresh with net sales in excess of \$200.0 million in 2018.

#### Businesses

Our US Specialized Therapeutics business offers certain of our branded products within the U.S., including Medical Aesthetics, Medical Dermatology through September 20, 2018, Eye Care and Neuroscience and Urology therapeutic products.

Our US General Medicine business is focused on newly developed pharmaceutical products, which are normally patented or have market exclusivity. These patented and off-patent trademarked products are branded pharmaceutical products, and as a result of patents or other market exclusivity are generally offered by a single provider when first introduced to the market. We market a number of branded products to physicians, hospitals, and other customers that we serve as well as the end patient.

Our International segment offers a wide array of branded products, including aesthetics products, outside of the United States.

Net revenues in our segments, including % of total net revenues, consisted of the following for the years ended December 31, 2018, 2017 and 2016 (\$ in millions):

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	Year Ended December 31, 2018		Year Ended December 31, 2017		Year Ended December 31, 2016	
	Net Revenue	% of Total Net Revenue	Net Revenue	% of Total Net Revenue	Net Revenue	% of Total Net Revenue
US Specialized Therapeutics	\$6,920.3	43.8 %	\$6,803.6	42.7 %	\$5,811.7	39.9 %
US General Medicine	5,322.9	33.7 %	5,796.2	36.4 %	5,923.9	40.6 %
International	3,504.7	22.2 %	3,319.5	20.8 %	2,881.3	19.8 %
Other	39.5	0.3 %	21.4	0.1 %	(46.3 )	(0.3 )%
Total	\$15,787.4	100.0 %	\$15,940.7	100.0 %	\$14,570.6	100.0 %

Included in segment revenues are product sales that were sold through the Anda Distribution business once the Anda Distribution business had sold the product to a third-party customer. These sales are included in segment results and are reclassified into revenues from discontinued operations through a reduction of Corporate revenues which eliminates the sales made by the Anda Distribution business through October 3, 2016 from results of continuing operations.

## Business Strategies

Our US Specialized Therapeutics business is focused on maintaining a leading position in the therapeutic areas in which we participate within the U.S. market. Our sales and marketing efforts focus on targeted activities, including direct-to-consumer advertising to increase consumer awareness of our products and also to engage specialty physicians and surgeons through our sales professionals and other programs to ensure they are fully informed about our product offerings. For reimbursed products, we also contract with payors to ensure that our products are widely available to patients.

In our US General Medicine business, we market our branded products through our active sales professionals in the United States. Our sales and marketing efforts focus on both general practitioners and specialty physicians who specialize in the diagnosis and treatment of particular medical conditions. We also conduct targeted activities, including direct-to-consumer advertising to increase consumer awareness of our products. We believe that our current sales force structure gives us a competitive advantage in launching and promoting products due to our ability to reach a larger target audience of both general practitioners and specialists. For reimbursed products, we also contract with payors to ensure that our products are widely available to patients.

Our International business is focused on maintaining a leading position by offering a consistent and reliable supply of quality branded and aesthetic products in key markets. We have maintained an ongoing effort to enhance efficiencies and reduce costs in our manufacturing operations.

## Research and Development

We devote significant resources to the R&D of branded products, biosimilars and proprietary drug delivery technologies. R&D activities are expensed as incurred and consist of self-funded R&D costs, the costs associated with work performed under collaborative R&D agreements, regulatory fees, and acquisition and license related milestone payments, if any.

Our R&D strategy focuses on the following product development areas:

- the application of proprietary drug-delivery technology for new product development in specialty areas;
- the acquisition of mid-to-late development-stage brand drugs;
- early stage collaboration arrangements; and
- the development of sustained-release, semi-solid, liquid, oral transmucosal, transdermal, gel, injectable, and other drug delivery technologies and the application of these technologies to proprietary drug forms.

As of December 31, 2018, we are developing a number of products, some of which utilize novel drug delivery systems, through a combination of internal and collaborative programs including but not limited to the following:

Product	Therapeutic Area	Indication	Expected	
			Year	Phase
Cariprazine	Central Nervous System	Bipolar Depression	2019	Review
Abicipar	Eye Care	Age Related Macular Degeneration	2020	III

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Bimatoprost SR	Eye Care	Glaucoma	2020	III
Ubrogepant	Central Nervous System	Acute Migraine	2020	III
Atogepant	Central Nervous System	Prophylaxis Migraine	2021	III
Presbyol	Eye Care	Presbyopia	2021	III
Rapastinel	Central Nervous System	Depression	2021	III
Cenicriviroc	Gastrointestinal	NASH	2022	III
Relamorelin	Gastrointestinal	Gastroparesis	2023	III
Abicipar	Eye Care	Diabetic Macular Edema	2023	II
Brimonidine DDS	Eye Care	Geographic Atrophy	2023	II
Brazikumab	Gastrointestinal	Crohn's Disease	2024	II
Botox	Medical Aesthetics	Platysma/Masseter	2025/2023	II
Brazikumab	Gastrointestinal	Ulcerative Colitis	2025	II

We also have a number of products in development as part of our life-cycle management strategy for our existing product portfolio.



As of December 31, 2018, we conducted the majority of our branded drug delivery R&D activities in Irvine, California. We are presently developing a number of products through a combination of internal and collaborative programs.

#### Financial Information About Segments and Geographic Areas

The Company evaluates segment performance for its three operating segments based on segment contribution. Segment contribution for our segments represents net revenues less cost of sales (defined below), selling and marketing expenses, and select general and administrative expenses. Included in segment revenues for 2016 are product sales that were sold through our former Anda Distribution business once the Anda Distribution business had sold the product to a third-party customer. These sales are included in segment results and are reclassified into revenues from discontinued operations through a reduction of Corporate revenues which eliminates the sales made by our former Anda Distribution business through October 3, 2016 from results of continuing operations. Cost of sales for these products in discontinued operations is equal to our average third-party cost of sales for third party branded products distributed by our former Anda Distribution business. The Company does not evaluate the following items at the segment level:

- Revenues and operating expenses within cost of sales, selling and marketing expenses, and general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, divestitures, acquisitions, certain milestones and other shared costs.
- General and administrative expenses that result from shared infrastructure, including certain expenses located within the United States.
- Other select revenues and operating expenses including R&D expenses, amortization, IPR&D impairments, goodwill impairments and asset sales and impairments, net as not all such information has been accounted for at the segment level, or such information has not been used by all segments.
- Total assets including capital expenditures.

The Company defines segment net revenues as product sales and other revenue derived from our products or licensing agreements.

Cost of sales within segment contribution includes standard production and packaging costs for the products we manufacture, third-party acquisition costs for products manufactured by others, profit-sharing or royalty payments for products sold pursuant to licensing agreements and finished goods inventory reserve charges. Cost of sales within segment contribution excludes non-standard production costs, such as non-finished goods inventory obsolescence charges, manufacturing variances and excess capacity utilization charges, where applicable. Cost of sales does not include amortization or impairment costs for acquired product rights or other acquired intangibles.

Selling and marketing expenses consist mainly of personnel-related costs, product promotion costs, distribution costs, professional service costs, insurance, depreciation and travel costs.

General and administrative expenses consist mainly of personnel-related costs, facilities costs, transaction costs, insurance, depreciation, litigation costs and professional services costs which are general in nature and attributable to the segment.

#### Customers

In US Specialized Therapeutics, US General Medicine and International operations, we sell our brand and aesthetic products primarily to drug wholesalers, retailers and distributors, including national retail drug and food store chains,

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hospitals, clinics, mail order retailers, government agencies and managed healthcare providers such as health maintenance organizations and other institutions. Certain medical aesthetic products and devices are also sold directly to physicians.

Sales to certain of our customers within the U.S. and Canada accounted for 10% or more of our annual revenues during the past three years. The following table illustrates customers and the respective percentage of revenues which they comprised in each of the last three years:

Customer	2018	2017	2016
McKesson Corporation	25 %	23 %	23 %
Cardinal Health, Inc.	23 %	19 %	18 %
AmerisourceBergen Corporation	22 %	19 %	18 %

Our significant customers comprise a large part of the distribution network for pharmaceutical products in North America. As a result, a small number of large wholesaler distributors control a significant share of the market for our products. No other countries outside the U.S. and Canada had 10% or more of global sales.

The loss of any of these customers could have a material adverse effect on our business, results of operations, financial condition and cash flows.

## Competition

The pharmaceutical industry is highly competitive. In our US Specialized Therapeutics, US General Medicine and International businesses, we compete with different companies to develop competitive products, in certain product categories, and within each applicable product category, upon dosage strengths and drug delivery systems. Our competitors include the major brand name manufacturers of pharmaceutical products. In addition to product development, other competitive factors in the pharmaceutical industry include product quality, price, reputation, service and access to proprietary and technical information. It is possible that developments by others will make our products or technologies noncompetitive or obsolete.

Competing in the brand and aesthetic product business requires us to identify and successfully bring to market new products embodying technological innovations. Successful marketing of brand and aesthetic products depends primarily on the ability to communicate the effectiveness, safety and value of these products to healthcare professionals in private practice and group practices and to receive formulary status from managed care organizations. We anticipate that our brand and aesthetic product offerings will support our existing areas of therapeutic focus. Based upon business conditions and other factors, we regularly reevaluate our business strategies and may from time to time reallocate our resources from one therapeutic area to another, withdraw from a therapeutic area or add an additional therapeutic area in order to maximize our overall growth opportunities.

Many of our competitors, except for those in the Medical Aesthetics business, have been in business for a longer period of time, have a greater number of products on the market and have greater financial and other resources than we do. When we directly compete with these companies for certain contracted business or for the same markets and/or products, their financial strength could prevent us from capturing a meaningful share of those markets.

## Social Contract

In September 2016, we introduced our Social Contract with Patients, in which we pledged to invest in new and innovative treatments, make our treatments accessible and affordable to patients, provide enhanced patient assistance programs (including in some cases free medicine) to eligible patients and maintain safety reporting and quality standards. Additionally, in our Social Contract with Patients, we committed to limit price increases. If we increase prices on our products, we will limit increases to once per year, and only increase the list price of a product by single-digit percentages. Our expectation is that net price increases, which are price increases after discounts and rebates, would be in the low to mid- single digit range.

For the full-year 2018, our net price on U.S. products decreased by an average 0.1 percent, and list price increases averaged 6.4 percent. The difference between the net price decreases and the list price increases is due to higher rebates and discounts.

## Manufacturing, Suppliers and Materials

As of December 31, 2018, we manufactured certain of our own finished products at our plants. We also have development and manufacturing capabilities for raw material and active pharmaceutical ingredients (“API”) and intermediate ingredients to support our R&D internal product development efforts in our Campbell, California, Irvine, California and Liverpool, United Kingdom locations.

We have major manufacturing sites in:

Location	State / Country
Branchburg	New Jersey / USA
Campbell	California / USA
Cincinnati	Ohio / USA
Clonshaugh	Ireland
Dublin	California / USA
Galway	Ireland
Guarulhos	Brazil
Heredia	Costa Rica
Houston	Texas / USA
Liege	Belgium
Pringy	France
Waco	Texas / USA
Westport	Ireland

Our manufacturing operations are subject to extensive regulatory oversight and could be interrupted at any time. Refer to Legal Matters in “NOTE 25 — Commitments and Contingencies” in the accompanying “Notes to the Consolidated Financial Statements” in this document.

While we manufacture certain of our own finished products at our plants, we are dependent on third parties for the supply of many of our finished products. In addition, we are dependent on third parties for the supply of the raw materials necessary to develop and manufacture our commercialized products, including the API and inactive pharmaceutical ingredients used in many of these products. We are required to identify the supplier(s) of all the raw materials for our products in the drug applications that we file with the FDA in the U.S. and other regulatory authorities outside the U.S. If raw materials for a particular product become unavailable from an approved supplier specified in a drug application, we would be required to qualify a substitute supplier with the FDA and with other regulatory authorities outside the U.S., which could interrupt manufacturing of the affected product. To the extent practicable, we attempt to identify more than one supplier in each drug application. However, some raw materials are available only from a single source and, in many of our drug applications, only one supplier of raw materials has been identified, even in instances where multiple sources exist.

Furthermore, we obtain a significant portion of our raw materials from foreign suppliers. Arrangements with international raw material suppliers are subject to, among other things, FDA regulation, customs clearance, various import duties, foreign currency risk and other government clearances. Acts of governments outside the U.S. may affect the price or availability of raw materials needed for the development or manufacture of our products. In addition, any changes in patent laws in jurisdictions outside the U.S. may make it increasingly difficult to obtain raw materials for R&D prior to the expiration of the applicable U.S. or foreign patents. Refer to “ITEM 1A. RISK

FACTORS — Risks Related to Our Business — If we are unable to obtain sufficient supplies of raw materials, our ability to deliver our products to the market may be impeded.” and — “The supply of APIs into Europe may be negatively affected by regulations promulgated by the European Union.” in this document.

#### Patents and Proprietary Rights

We believe patent protection of our proprietary products is important to our products. Our success with our branded products will depend, in part, on our ability to obtain, and successfully defend if challenged, patent or other proprietary protection for such products. We currently have a number of U.S. and foreign patents issued or pending. However, the issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. Accordingly, our patents may not prevent other companies from developing similar or functionally equivalent products or from successfully challenging the validity of our patents. If our patent applications are not allowed or, even if allowed, if such patents are circumvented or not upheld in a court of law or in administrative proceedings, including oppositions, re-examinations or inter partes review (“IPR”), our ability to competitively market our patented products and technologies may be significantly reduced. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by competitors, in which case our ability to

commercially market these products may be diminished. For example, in October 2017, the U.S. District Court for the Eastern District of Texas issued an adverse trial decision finding that the four asserted patents covering our Restasis® (Cyclosporine Ophthalmic Emulsion) 0.05% product are invalid, and on November 13, 2018, the United States Court of Appeals for the Federal Circuit affirmed that ruling. From time to time, we may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market our products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially market such products may be inhibited or prevented. In addition, patents covering, for example, Actonel® (certain indications), Androderm®, Carafate®, Minastrin®, Estrace® Cream, Namenda XR®, Femhrt®, INFed®, Namenda® (IR), Pylera® and Rapaflo® products have expired and we have no further patent protection on these products. Generic versions of our Minastrin® product entered the market during 2017 pursuant to settlement agreements previously entered into. Generic versions of our Estrace® product entered the market in January 2018, generic versions of our Namenda XR® product entered the market in March 2018, and generic versions of our Rapaflo® product entered the market in December 2018.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, through confidentiality agreements with our partners, customers, employees and consultants. It is possible that these agreements will be breached or will not be enforceable in every instance, and we will not have adequate remedies for any such breach. It is also possible that our trade secrets will otherwise become known or independently developed by competitors.

We may find it necessary to initiate litigation to enforce our patent and trademark rights, to protect our trade secrets or know-how or to determine the scope and validity of the proprietary rights of others. Litigation concerning patents, trademarks, copyrights and proprietary technologies can often be protracted and expensive and, as with litigation generally, the outcome is inherently uncertain.

Litigation alleging infringement of patents, trademarks, copyrights or other intellectual property rights may be costly and time consuming. Refer to “ITEM 1A. RISK FACTORS — Risks Related to Our Business — Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products.” and Legal Matters in “NOTE 25 — Commitments and Contingencies” in the accompanying “Notes to the Consolidated Financial Statements” in this document.

## Government Regulation and Regulatory Matters

The following discussion focuses on key markets to the Company’s overall business.

### United States

All U.S. pharmaceutical manufacturers, including Allergan, are subject to extensive, complex and evolving regulation by the federal government, principally the FDA, and to a lesser extent, by the U.S. Drug Enforcement Administration (“DEA”), Occupational Safety and Health Administration and state government agencies, as well as by various regulatory agencies in foreign countries where our products or product candidates are being manufactured and/or marketed. The Federal Food, Drug, and Cosmetic Act (“FFDCA”), the Controlled Substances Act and other federal statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. In our international markets, the approval, manufacture and sale of pharmaceutical products is similar to that of the United States with some variations dependent upon local market dynamics.

### Specialty Pharmaceuticals

In the United States, FDA approval is required before any dosage form of any new drug, including an off-patent equivalent of a previously approved drug, can be marketed. The process for obtaining governmental approval to

manufacture and market pharmaceutical products is rigorous, time-consuming and costly, and the extent to which it may be affected by legislative and regulatory developments cannot be predicted. We are dependent on receiving FDA and other governmental approvals prior to manufacturing, marketing and shipping new products. Refer to “ITEM 1A. RISK FACTORS — Risks Related to Our Business — If we are unable to successfully develop or commercialize new products, our operating results will suffer.” and “— Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.” in this document.

All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. We file a New Drug Application (“NDA”) when we seek approval for drugs with active ingredients and/or with dosage strengths, dosage forms, delivery systems or pharmacokinetic profiles that have not been previously approved by the FDA. Generally, NDAs are filed for new chemical entities or for a new dosage form of previously approved drugs.

For innovative or non-generic new drugs, an FDA-approved NDA is required before the drug may be marketed in the United States. The NDA must contain data to demonstrate that the drug is safe and effective for its intended uses and that it will be manufactured to appropriate quality standards. In order to demonstrate safety and effectiveness, an NDA generally must include or reference pre-clinical studies and clinical data from controlled trials in humans. For a new chemical entity, this generally means that lengthy, uncertain and rigorous pre-clinical and clinical testing must be conducted. For compounds that have a record of prior or current use, it may be possible to utilize existing data or medical literature and limited new testing to support an NDA. Any pre-clinical testing that we wish to rely upon for FDA action must comply with the FDA's good laboratory practice and other requirements. Clinical testing in human subjects must be conducted in accordance with the FDA's good clinical practice and other requirements. In order to initiate a clinical trial, the sponsor must submit an IND to the FDA or meet one of the narrow exemptions that exist from the IND requirement.

The FDA has the authority to either approve or not approve NDAs, and if an application is not approved, additional data (clinical, non-clinical, manufacturing or quality data, among other types of data) is generally required. In addition, the FDA may approve an NDA subject to post-approval studies or monitoring requirements, or require that other risk management measures be utilized when the product is commercialized. There are also requirements to conduct pediatric trials for all new NDAs and supplements to NDAs for pharmaceutical products that may be used in the pediatric patient population, unless a waiver or deferral applies.

Once approved, the NDA is subject to life-cycle management regulations (for example, annual reports) in order to maintain product registrations. A Supplemental New Drug Application ("sNDA") is required for changes that require FDA evaluation and/or approval prior to implementation, including the transfer of certain products from one manufacturing site to another, a change in API supplier, or a new indication or dosage form. In addition, a change in the manufacturing site for certain products may only be approved once new bioequivalency studies are conducted or other requirements are satisfied. In addition, the FDA may require post-marketing studies.

To obtain FDA approval of NDAs and sNDAs, our manufacturing procedures and operations must conform to FDA quality system and control requirements generally referred to as current Good Manufacturing Practices ("cGMP"), as defined in Title 21 of the U.S. Code of Federal Regulations, and cGMP must be adhered to throughout the life cycle of a product, as these regulations encompass all aspects of the production process from receipt and qualification of components to distribution procedures for finished products. cGMP standards are evolving standards; thus, we must continue to expend substantial time, money and effort in all production and quality control areas to maintain compliance with these standards. The evolving and complex nature of regulatory requirements, the broad authority and discretion of the FDA, and the generally high level of regulatory oversight results in the continuing possibility that we may be adversely affected by regulatory actions despite our efforts to maintain compliance with regulatory requirements.

We are subject to the periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA, the DEA and other health authorities, which conduct periodic inspections to assess compliance with applicable regulations. In addition, in connection with its review of our applications for new products, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes comply with cGMP and other FDA regulations. Among other things, the FDA may withhold approval of NDAs, sNDAs, or other product applications of a facility if deficiencies are found at that facility. Vendors that supply finished products or components to us that we use to manufacture, package and label products are subject to similar regulation and periodic inspections.

Following such inspections, the FDA may issue notices on Form 483 and Warning Letters that may require us to modify certain activities identified during the inspection. A Form 483 notice may be issued at the conclusion of an FDA inspection and lists issues the FDA investigators believe may violate cGMP or other FDA regulations. FDA



guidelines specify that a Warning Letter be issued only for violations of “regulatory significance” for which the failure to adequately and promptly address the correction to the satisfaction of the FDA may be expected to result in an enforcement action.

Additionally, FDA reviews promotional and marketing materials for compliance with the FDCA and FDA regulations. FDA may issue letters or take other enforcement action if FDA believes promotional and marketing materials do not comply with the law and regulations.

Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA’s review of NDAs or sNDAs or other product application enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on our business. Refer to “ITEM 1A. RISK FACTORS — Risks Related to Our Business — Extensive industry

regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.” in this document. The FDA can also significantly delay the approval of any pending NDA or other regulatory submissions under the Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Policy Act.

#### Medical Devices

Medical devices are subject to regulation by the FDA, state agencies and foreign government health. FDA regulations, as well as various U.S. federal and state laws, govern the development, clinical testing, manufacturing, labeling, record keeping and marketing of medical device products agencies in the United States. Our medical device product candidates, including our breast implants, must undergo rigorous clinical testing and an extensive government regulatory clearance or approval process prior to sale in the United States and other countries. The lengthy process of clinical development and submissions for clearance or approval, and the continuing need for compliance with applicable laws and regulations, require the expenditure of substantial resources. Regulatory clearance or approval, when and if obtained, may be limited in scope, and may significantly limit the indicated uses for which a product may be marketed. Cleared or approved products and their manufacturers are subject to ongoing review, and discovery of previously unknown problems with products may result in restrictions on their manufacture, sale, and/or use or require their withdrawal from the market.

Our medical device products are subject to extensive regulation by the FDA in the United States. Unless an exemption applies, each medical device we market in the United States must have a 510(k) clearance or a Premarket Approval Application (“PMA”) in accordance with the FFDCA and its implementing regulations. The FDA classifies medical devices into one of three classes, depending on the degree of risk associated with each medical device and the extent of controls that are needed to ensure safety and effectiveness. Devices deemed to pose a lower risk are placed in either Class I or Class II, and devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or a device deemed to be not substantially equivalent to a previously cleared 510(k) device, are placed in Class III. In general, a Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a PMA, and any changes to the device subsequent to initial FDA approval must also be reviewed and approved by the FDA. The majority of our medical device products, including our breast implants, are regulated as Class III medical devices. A Class III device may have significant additional obligations imposed in its conditions of approval, and the time in which it takes to obtain approval can be long. Compliance with regulatory requirements is assured through periodic, unannounced facility inspections by the FDA and other regulatory authorities, and these inspections may include the manufacturing facilities of our subcontractors or other third-party manufacturers. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning letters or untitled letters; fines, injunctions and civil penalties; recall or seizure of our products; operating restrictions, partial suspension or total shutdown of production; refusing our request for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMA approvals that are already granted; and criminal prosecution.

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k) premarket notification. Clinical trials generally require submission of an application for an investigational device exemption (“IDE”), which must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. A study sponsor must obtain approval for its IDE from the FDA, and it must also obtain approval of its study from the Institutional Review Board (“IRB”) overseeing the trial. The results of clinical testing may not be sufficient to obtain approval of the investigational device.

Once a device is approved, the manufacture and distribution of the device remains subject to continuing regulation by the FDA, including Quality System Regulation requirements, which involve design, testing, control, documentation

and other quality assurance procedures during the manufacturing process. Medical device manufacturers and their subcontractors are required to register their establishments and list their manufactured devices with the FDA and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with regulatory requirements. Manufacturers must also report to the FDA if their devices may have caused or contributed to a death or serious injury or malfunctioned in a way that could likely cause or contribute to a death or serious injury, or if the manufacturer conducts a field correction or product recall or removal to reduce a risk to health posed by a device or to remedy a violation of the FDCA that may present a health risk. Further, the FDA continues to regulate device labeling, and prohibits the promotion of products for unapproved or “off-label” uses along with other labeling restrictions. If a manufacturer or distributor fails to comply with any of these regulatory requirements, or if safety concerns with a device arise, the FDA may take legal or regulatory action, including civil or criminal penalties, suspension, withdrawal or delay in the issuance of clearances or approvals, or seizure or recall of products, any one or more of which could have a material adverse effect upon us.

#### Other Regulatory Requirements Applicable to Our Business

The FDA imposes a number of complex regulatory requirements on entities that advertise and promote pharmaceutical products and medical devices, including, but not limited to, standards and regulations for direct-to-consumer advertising, “off-label” promotion, industry-sponsored scientific and educational activities, and promotional activities including internet marketing. Pharmaceutical

products and medical devices can only be marketed for indications approved or cleared by the FDA. Failure to comply with these regulations can result in penalties, the issuance of warning letters directing a company to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and federal and state civil and criminal investigations and prosecutions.

U.S. government reimbursement programs include Medicare, Medicaid, TriCare, and State Pharmaceutical Assistance Programs established according to statute, government regulations and policy. Federal law requires all pharmaceutical manufacturers, as a condition of having their products receive federal reimbursement under Medicaid and Medicare Part B, to pay rebates to state Medicaid programs on units of their pharmaceuticals that are dispensed to Medicaid beneficiaries. With enactment of the Patient Protection and Affordable Care Act (“ACA”), as amended, manufacturer rebate liability for brand drugs increased from 15.1% to 23.1% of the Average Manufacturer Price, or the difference between the Average Manufacturer Price and the drug’s Best Price (i.e., the lowest net sales price to a non-government customer during a specified period), whichever is greater. In some states, supplemental rebates are required as a condition of including the manufacturer’s drug on a state’s Preferred Drug List, which if agreed upon would generally permit access to a manufacturer’s product without utilization management (e.g., step therapy).

The ACA prescribed that the coverage gap phase of the Medicare Part D benefit be closed such that, by 2020, beneficiaries will pay co-insurance of 25% (or co-payment equivalents) of the cost of prescription drugs dispensed to them under their applicable Medicare Part D plans, until they reach the catastrophic phase of the Medicare Part D benefit. As such, the coverage gap or “donut hole” will be effectively closed beginning in the 2020 plan year. The cost of closing the donut hole is being borne in part by brand drug companies as well as Medicare Part D plan sponsors and the federal government. Beginning in 2011, brand drug manufacturers were required to provide a 50% discount on their drugs while beneficiaries are in the coverage gap; the Bipartisan Budget Act of 2018, however, increased this discount to 70% beginning in 2019. Additionally, beginning in 2013, the government and Medicare Part D plan sponsors began providing additional subsidies for brand name drugs bought by seniors who enter the coverage gap. The government/sponsor share originally was designed to provide a 25% discount in the cost of drugs by 2020, however the Bipartisan Budget Act of 2018 revised this percentage down to 5%. Consequently, the combined industry discounts and government subsidies still will add up to 75% of brand name drug costs by 2020, however pharmaceutical manufacturers are required to extend far greater discounts under this coverage gap program than originally was contemplated.

On January 21, 2016, the Centers for Medicare and Medicaid Services (“CMS”) issued a final rule on the calculation of AMP, Best Price, and the Unit Rebate Amount for the Medicaid Drug Rebate Program; the final rule took effect in April 2016 (for most provisions). Allergan has implemented required changes to its Medicaid rebate calculations and policies, effective for its Q2 2016 calculations and pricing submissions. Notably, however, the Medicaid Drug Rebate Program requires compliance with complex statutory pricing formulas and requirements, and manufacturers frequently are required to adopt “reasonable assumptions,” as permitted by CMS guidance, where the regulations are silent or unclear. Any changes in existing CMS guidance could affect our compliance efforts, existing reasonable assumptions, and rebate liability. We are also required to discount products to authorized users of the Federal Supply Schedule, under which additional laws and requirements apply.

The ACA also expanded the government’s 340B drug discount program by adding new categories of covered entity types that are qualified to participate in the program and benefit from its deeply discounted drug pricing. The ACA also obligated the Health Resources and Services Administration (HRSA), which administers the 340B program, to update the Pharmaceutical Pricing Agreement, which each manufacturer must sign to participate in the 340B program, to require each manufacturer to offer the 340B price to covered entities if the manufacturer makes its drugs available to any other purchaser at any price, and to report statutory ceiling prices for its drugs to the government. HRSA issued this update in late 2016 and the Company subsequently signed and executed an amendment to our agreement. In addition, on January 5, 2017, HRSA finalized regulations that, among other things, implement rules regarding civil

monetary penalties for knowing and intentional overcharges of 340B covered entities by pharmaceutical manufacturers; these rules became effective on January 1, 2019.

In connection with the commercialization of our products, we often are required to negotiate and enter into discount and rebate agreements for our products with government and private health insurers, including Health Maintenance Organizations (“HMOs”) and Managed Care Organizations (“MCOs”). These discount and rebate agreements commonly are required to ensure the accessibility of our drugs to beneficiaries of the individual health insurance plans, whether sponsored by the government or a commercial entity. Indeed, the sale of our existing and any future products largely is dependent on the extent to which our products are covered by health insurance. Any changes to product coverage requirements, including pursuant to federal law or regulation, or government or private drug cost containment measures could have an adverse effect on our business operations.

Additionally, we may in the future -- as we have in the past -- receive requests for information, sometimes in the form of civil investigative demands or subpoenas, from the U.S. Federal Trade Commission (“FTC”) and the European Commission - Competition. Any adverse outcome of these types of investigations or actions could have a material adverse effect on our business, results of operations, financial condition and cash flows. Refer to “ITEM 1A. RISK FACTORS — Risks Related to Our Business—Federal regulation of arrangements between manufacturers of branded and generic products could adversely affect our business.” Also refer to

Legal Matters in “NOTE 25 — Commitments and Contingencies” in the accompanying “Notes to the Consolidated Financial Statements” in this document.

As part of the Medicare Prescription Drug and Modernization Act of 2003 (“MMA”), companies are required to file with the FTC and the Department of Justice certain types of agreements entered into between brand and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of brand drugs. This requirement could affect the manner in which drug manufacturers resolve intellectual property litigation and other disputes with competitor pharmaceutical companies and could result generally in an increase in private-party litigation against pharmaceutical companies. The impact of this requirement, and the potential private-party lawsuits associated with arrangements between brand name and generic drug manufacturers, is uncertain and could adversely affect our business. For example, beginning in April 2013, private parties have filed lawsuits against us alleging that a settlement of a patent litigation between a subsidiary of the Company and potential generic competitor that had filed an Abbreviated New Drug Application (“ANDA”) for a generic version of Loestrin<sup>®</sup> is unlawful. Those lawsuits, as well as additional suits challenging the validity of our settlements related to Asacol<sup>®</sup> and Namenda<sup>®</sup> remain pending. Refer to Legal Matters in “NOTE 25 — Commitments and Contingencies” in the accompanying “Notes to the Consolidated Financial Statements” in this document.

Federal, state, local and foreign laws of general applicability, such as laws regulating working conditions, also govern us. In addition, we are subject, as are all manufacturers generally, to numerous and increasingly stringent federal, state and local environmental laws and regulations concerning, among other things, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances and the discharge of pollutants into the air and water. Environmental permits and controls are required for some of our operations, and these permits are subject to modification, renewal and revocation by the issuing authorities. Our environmental capital expenditures and costs for environmental compliance may increase in the future as a result of changes in environmental laws and regulations or increased manufacturing activities at any of our facilities. We could be adversely affected by any failure to comply with environmental laws, including the costs of undertaking a clean-up at a site to which our wastes were transported.

#### European Union

We encounter similar regulatory and legislative issues in most other countries, including countries that are members of the European Union (the “EU”). Pharmaceutical manufacturers are regulated in the EU by the European Medicines Agency (the “EMA”) and national health authorities. All manufacturers are required to submit medicinal products, including generic versions of previously approved products and new strengths, dosages and formulations of previously approved products, to the EMA and its member states for review and marketing authorization before such products are placed on the market in the EU.

Marketing authorizations are granted to applicants after the relevant health authority issues a positive assessment of quality, safety and efficacy of the product. In order to receive such assessment, applicants must submit applications, which must contain the results of pre-clinical tests, pharmaceutical tests, and clinical trials with respect to originator products. All of these tests or trials must be conducted in accordance within European regulations and must allow the reviewing body to evaluate the quality, safety and efficacy of the medicinal product.

In addition to obtaining marketing authorization for each product, all member states require that a manufacturer’s facilities obtain approval from the national authority. The EU has a code of good manufacturing practices that each manufacturer must follow and comply with. Regulatory authorities in the EU may conduct inspections of the manufacturing facilities to review procedures, operating systems and personnel qualifications. Refer to “ITEM 1A. — RISK FACTORS — Risks Related to Our Business — The supply of APIs into Europe may be negatively affected by regulations promulgated by the European Union.” in this document.

In the EU, member states regulate the pricing of pharmaceutical products, and in some cases, the formulation and dosing of products. This regulation is handled by individual member state national health services. These individual regulatory bodies can result in considerable price differences and product availability among member states. The implementation of tendering systems for the pricing of pharmaceuticals in several countries generally impacts drug pricing; generally “tendering” refers to a system that requires bids to be submitted to the relevant national health services organizations by competing manufacturers to be the exclusive, or one of a few, supplier(s) of a product for such tender.

Further, faced with major budget constraints, many European countries have resorted to price cuts or claim-back schemes that affect both innovative and generic pharmaceuticals. Refer to “ITEM 1A. RISK FACTORS — Risks Related to Our Business—Global economic conditions could harm us.” in this document.

Medical device products that are marketed in the European Union must comply with the requirements of the Medical Device Directive (the “MDD”), as implemented in the national legislation of the European Union member states. The MDD, as implemented,

provides for a regulatory regime with respect to the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices to ensure that medical devices marketed in the European Union are safe and effective for their intended uses. Medical devices that comply with the MDD, as implemented, are entitled to bear a Conformité Européenne (“CE”) marking evidencing such compliance and may be marketed in the European Union. Failure to comply with these domestic and international regulatory requirements could affect our ability to market and sell our products in these countries. For example, following the non-renewal of our textured breast implant CE Mark licenses in Europe pending the request for additional information by LNE-GMED, the notified body responsible for certification of our breast implants, Allergan suspended sales of textured breast implants in Europe and withdrew the remaining textured breast implants then on the market in Europe in the fourth quarter of 2018.

#### Canada

In Canada, pharmaceutical manufacturers are regulated by the Therapeutic Products Directorate (the “TPD”) which derives its authority from the Canadian federal government under the Food and Drugs Act and the Controlled Drug and Substances Act. The TPD evaluates and monitors the safety, effectiveness and quality of pharmaceutical products. Products are officially approved for marketing in Canada following receipt of a market authorization, or “Notice of Compliance” (a “NOC”), which is subject to the Food and Drug Regulations. Issuance of a NOC for generic drug products is also subject to the Patented Medicines (Notice of Compliance) Regulations (the “NOC Regulations”) under the Patent Act.

The NOC Regulations allow branded drug marketers to list patents that contain a claim for a medicinal ingredient, a claim for the formulation containing the medicinal ingredient, a claim for the dosage form, or a claim for the use of the medicinal ingredient in their branded drug on a patent register maintained by the TPD. In its abbreviated new drug submission, a generic applicant must address each patent listed against the reference product by making at least one statutory allowed allegation (for example, alleging that the patent is invalid or would not be infringed). If the generic applicant alleges invalidity or non-infringement, it must provide the branded manufacturer with an explanation of its allegations. Upon receipt of the explanation, the branded manufacturer may commence an action against the generic applicant in the Federal Court of Canada for a declaration that the making, constructing, using or selling of the generic applicant’s drug would infringe any patent that is subject of an allegation. The NOC Regulations prohibits the Minister of Health from issuing an NOC to the generic applicant that is a party to the action, for a 24-month period from the day on which the action is brought, until the action is determined by the court. The branded manufacturer who brought the action, may also renounce application of the 24-month period but this could allow for early market entry, subject to data protection and the generic applicant’s willingness to launch at risk.

Facilities, procedures, operations and/or testing of products are subject to periodic inspection by Health Canada and the Health Products and Food Branch Inspectorate. In addition, Health Canada conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems are in compliance with the good manufacturing practices in Canada, Drug Establishment Licensing requirements and other provisions of the NOC Regulations. Competitors are subject to similar regulations and inspections.

Each Canadian province and territory also provides a comprehensive public drug program, which controls drug pricing and reimbursement and is responsible for ensuring eligible patients receive drugs through public funding. The provinces and territories in Canada operate drug benefit programs through which eligible recipients receive drugs through public funding; these drugs are listed on provincial or territorial Drug Benefit Formularies (“Formularies”). Eligible recipients include seniors, persons on social assistance, low-income earners, and those with certain specified conditions or diseases. Formulary listings are also used by private payors to reimburse generic products. To be listed in a Formulary, drug products must have been issued a NOC and must comply with each jurisdiction’s individual review process. Currently, Canada’s provinces and territories are looking at national competitive bidding processes/tendering of drugs, which may affect the sustainability of the industry and the supply of pharmaceuticals.



Finally, Canada has reached a trade agreement with the European Union (the “Comprehensive Economic and Trade Agreement”) in which it has implemented a form of patent term extensions and certain procedural amendments to the NOC Regulations. Canada is further involved in trade negotiations with ten Pacific countries (the “Comprehensive and Progressive Agreement for Trans-Pacific Partnership”), which could lead to further changes to Canada’s intellectual property framework and affect our business.

#### Environmental Matters

We are subject to federal, state, and local environmental laws and regulations in the United States and abroad. Our environment, health and safety group monitors our operations around the world, providing us with an overview of regulatory requirements and overseeing the implementation of our standards for compliance. We believe that our operations comply in all material respects with applicable environmental laws and regulations in each jurisdiction where we have a business presence, and we periodically audit our manufacturing and R&D facilities for compliance with all federal, state and local environmental laws and regulations. Although we continue to make capital expenditures for environmental protection, we do not anticipate any significant expenditure in order to

comply with such laws and regulations that would have a material impact on our earnings or competitive position. We are not aware of any pending litigation or significant financial obligations arising from current or past environmental practices that are likely to have a material adverse effect on our financial position. We cannot assure, however, that environmental problems relating to facilities owned or operated by us will not develop in the future, and we cannot predict whether any such problems, if they were to develop, could require significant expenditures on our part.

Climate change presents risks to our operations, including the potential for additional regulatory requirements and associated costs, and the potential for more frequent and severe weather events and water availability challenges that may impact our facilities and those of our suppliers. These potential risks are integrated into the Company's business planning including investment in reducing energy, water use and greenhouse gas emissions. We cannot provide assurance that physical risks to our facilities and supply chain due to climate change will not occur in the future; however we do not believe these risks are material to our business at this time.

In addition, we are unable to predict what legislation or regulations may be adopted or enacted in the future with respect to environmental protection and waste disposal. Refer to "ITEM 1A. RISK FACTORS — Risks Related to Our Business — Our business will continue to expose us to risks of environmental liabilities." in this document.

#### Seasonality

Consistent with the United States pharmaceutical industry, our business experiences seasonality, with the first quarter of each year typically being the lowest revenue quarter for our products. In addition, our aesthetics products, including our Botox<sup>®</sup> cosmetic indications, have tended to be marginally higher during the second and fourth quarters, presumably in advance of the summer vacation and holiday seasons. Fluctuations of our sales are also impacted by the effect of promotional activity, which cause non-seasonal variability in sales trends.

#### Backlog

As a result of the extent of our supply chain, backlog of orders is not material to our business.

#### Employees

As of December 31, 2018, we had approximately 16,900 employees. Of our employees, approximately 2,150 were engaged to support R&D functions, 4,900 supported Cost of Goods Sold functions, 8,450 supported sales, marketing and distribution functions, and 1,400 supported administrative functions.

## ITEM 1A. RISK FACTORS

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Any statements made in this report that are not statements of historical fact or that refer to estimated or anticipated future events are forward looking statements, as contemplated in the Private Securities Litigation Reform Act of 1995. We have based our forward looking statements on management's beliefs and assumptions based on information available to our management at the time these statements are made. Such forward looking statements reflect our current perspective of our business, future performance, existing trends and information as of the date of this filing. These include, but are not limited to, our beliefs about future revenue and expense levels and growth rates, prospects related to our strategic initiatives and business strategies, including the integration of, and synergies associated with, strategic acquisitions, express or implied assumptions about government regulatory action or inaction, anticipated product approvals and launches, business initiatives and product development activities, assessments related to clinical trial results, product performance and competitive environment, and anticipated financial performance.

Without limiting the generality of the foregoing, words such as "may," "will," "expect," "believe," "anticipate," "plan," "intend," "could," "would," "should," "estimate," "continue," or "pursue," or the negative or other variations thereof or comparable terminology, are intended to identify forward looking statements. The statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. We caution the reader that these statements are based on certain assumptions, risks and uncertainties, many of which are beyond our control.

In addition, certain important factors may affect our actual operating results and could cause such results to differ materially from those expressed or implied by forward looking statements. We believe the risks and uncertainties discussed under the section entitled "Risks Related to Our Business," and other risks and uncertainties detailed herein and from time to time in our SEC filings, may cause our actual results to vary materially from those anticipated in any forward looking statement.

We operate in a rapidly changing environment that involves a number of risks and uncertainties, some of which are beyond our control. The following discussion highlights some of these risks and speaks as of the date of this document, including the assets held for sale. These and other risks could have a material adverse effect on our business, results of operations, financial condition and cash flows.

#### Risks Related to Our Business

Global economic conditions could harm us.

While global economic conditions have been fairly stable as a whole in recent years, continued concerns about the systemic impact of potential geopolitical issues and economic policy uncertainty, particularly in areas in which we operate, could potentially cause economic and market instability in the future and could adversely affect the Company's business, including the Company's financial performance.

Challenging economic conditions could result in tighter credit conditions. The cost and availability of credit may be adversely affected by illiquid credit markets and wider credit spreads, which could adversely affect the ability of third-party distributors, partners, manufacturers and suppliers to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations, and which could adversely affect the liquidity and financial conditions of our customers.

Global efforts towards health care cost containment continue to exert pressure on product pricing and market access. In many international markets, government-mandated pricing actions have reduced prices of patented drugs. Some countries may be subject to periods of financial instability or may have reduced resources to spend on healthcare or may be or will be in the future subject to economic sanctions, and our business in these countries may be disproportionately affected by these changes. In addition, the currencies of some countries may depreciate against the U.S. Dollar substantially and if the Company is unable to offset the impact of such depreciation, then the Company's financial performance within such countries could be adversely affected.

If we are unable to successfully develop or commercialize new products, our operating results will suffer.

Our future results of operations depend to a significant extent upon our ability to successfully develop and commercialize new products in a timely manner. There are numerous difficulties in developing and commercializing new products, including:

- developing, testing and manufacturing products in compliance with regulatory standards in a timely manner;
- receiving requisite regulatory approvals for such products in a timely manner, or at all;
- the availability, on commercially reasonable terms, of raw materials, including API and other key ingredients;

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- preclusion from commercialization by the proprietary rights of others;
- developing products that are economical to manufacture and commercialize;
- time consuming and costly nature of developing and commercializing new products;
- costly legal actions brought by our competitors that may delay or prevent the development and commercialization of new products;
- delays as a result of limited resources at the FDA or other regulatory agencies;
- changing review and approval policies and standards at the FDA and other regulatory agencies; and
- completion of numerous other regulatory approvals in international markets.

As a result of these and other difficulties, products currently in development by us may or may not receive timely regulatory approvals necessary for marketing by us or other third party partners, or approvals at all. In addition, there are uncertainties, high costs and lengthy time frames associated with R&D of our proprietary products and the market acceptance of such products is inherently unproven. Our operating results and financial condition may fluctuate as the amount we spend to research and develop, promote, acquire or license new products, technologies and businesses changes. If any of our products are not approved in a timely manner or, when approved, cannot be successfully manufactured or commercialized in a timely manner, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing products will be recouped, even if we are successful in commercializing those products. Refer to “Our expenditures may not result in commercially successful products.”

Our expenditures may not result in commercially successful products.

Developing and commercializing branded pharmaceutical products is generally more costly than developing and commercializing generic products. In order to grow and achieve success in our business, we must continually identify, develop, acquire and license new products that we can ultimately market. In the future, we anticipate continuing and increasing our product development expenditures. There are many difficulties and uncertainties inherent in pharmaceutical research and development, and there is a high rate of failure inherent in new drug discovery and development. Failure can occur at any point in the process, including late in the process after substantial investment. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals and payer reimbursement, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Products that do reach the market may ultimately be subject to recalls or other suspensions in sales. Delays and uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity. Because there is a high rate of failure inherent in the research and development process of new products, there is a significant risk that funds invested by the Company in research and development will not generate financial returns. The Company cannot be certain when or whether any of its products currently under development will be approved or launched or whether, once launched, such products will be commercially successful.

We may be required to spend several years and incur substantial expense in completing certain clinical trials. The length of time, number of trial sites and patients required for clinical trials vary substantially, and we may have difficulty finding a sufficient number of sites and subjects to participate in our trials. Delays in planned clinical trials can result in increased development costs, delays in regulatory approvals and delays in product candidates reaching the market. We rely on independent third party clinical investigators to recruit subjects and conduct clinical trials in accordance with applicable study protocols and laws and regulations. If regulatory authorities determine that we have not complied with regulations in the R&D of a product candidate, they may refuse to accept trial data from the site and/or not approve the product candidate, and we would not be able to market and sell that product. If we are not able to market and sell our products after significant expenditures to develop and test them, our business and results of operations could be materially and adversely affected.

We currently have products in various stages of development, including new medical aesthetics, eye care, GI and CNS products, among others. Such clinical trials are costly and may not result in successful outcomes. The results of preclinical studies and early clinical studies may not be predictive of the results of later stage clinical studies. Product candidates that have shown promising results in early stage clinical studies may still suffer significant setbacks in subsequent clinical studies. There is a high rate of failure for products proceeding through clinical studies, and product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical studies. Clinical studies may not proceed as planned or be completed on schedule, if at all. The rate of completion of clinical trials is significantly dependent upon a number of factors, including the rate of patient enrollment. We may not be able to attract a sufficient number of sites or enroll a sufficient number of patients in a timely manner in order to complete clinical trials. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and our data may not provide adequate efficacy and safety information to obtain

regulatory approval of our candidates. We cannot be sure that our business expenditures, including but not limited to our expenditures related to internally developed products, products acquired in past acquisitions, or products of our third party partners, among others, will result in the successful discovery, development or launch of branded products that will prove to be commercially successful or will improve the long term profitability of our business. If such business expenditures do not result in successful discovery, development or launch of commercially successful branded products our results of operations and financial condition could be materially adversely affected.

If any of our major products become subject to problems, our business could be adversely affected.

We recorded direct product revenues of more than \$500 million for the following pharmaceutical products: Botox<sup>®</sup>, the Juvederm Collection, Linzess<sup>®</sup>/Constella<sup>®</sup>, Lumigan<sup>®</sup>/Ganfort<sup>®</sup>, Bystolic<sup>®</sup>/Byvalson<sup>®</sup>, Alphagan<sup>®</sup>/Combigan<sup>®</sup>, Lo Loestrin<sup>®</sup> and Restasis<sup>®</sup>. Those products and revenues accounted for 57.9% of our total revenues in 2018. These products, as well as our other major products, may become subject to problems such as loss of patent protection (if applicable), changes in prescription growth rates, material product liability litigation, unexpected side effects, regulatory proceedings, publicity affecting doctor or patient confidence, pressure from existing or new competitive products or changes in labeling, our results of operations and financial condition could be materially adversely affected. For example, in October 2017, the U.S. District Court for the Eastern District of Texas issued an adverse trial decision finding that the four asserted patents covering Restasis<sup>®</sup> (Cyclosporine Ophthalmic Emulsion) 0.05% are invalid and on November 13, 2018, the United States Court of Appeals for the Federal Circuit affirmed that ruling.

If generic products that compete with any of our branded pharmaceutical products are approved and sold, sales of our products will be adversely affected.

Generic equivalents for branded pharmaceutical products are typically sold at lower prices than the branded products. The regulatory approval process in the United States and European Union exempts generic products from costly and time-consuming clinical trials to demonstrate their safety and efficacy and rely instead on the safety and efficacy of prior products, manufacturers of generic products can invest far less in research and development. After the introduction of a competing generic product, a significant percentage of the prescriptions previously written for the branded product are often written for the generic version. In addition, legislation enacted in most U.S. states and Canadian provinces allows or, in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded product, in the absence of specific instructions from the prescribing physician. Pursuant to the provisions of the Hatch Waxman Act, manufacturers of branded products often bring lawsuits to enforce their patent rights against generic products seeking approval prior to the expiration of branded products' patents, but it is possible for generic manufacturers to offer generic products while such litigation is pending. Refer to "If we are unable to adequately protect our technology or enforce our patents, our business could suffer." As a result, branded products typically experience a significant loss in revenues following the introduction of a competing generic product, even if subject to an existing patent. Our branded pharmaceutical products are or may become subject to competition from generic equivalents because there is no proprietary protection for some of the branded pharmaceutical products we sell, because our patent protection expires or because our patent protection is not sufficiently broad or enforceable. In addition, we may not be successful in our efforts to extend the proprietary protection afforded our branded products through the development and commercialization of proprietary product improvements.

During the next few years, additional products of ours, including some of our large revenue drivers, like Bystolic<sup>®</sup>, Delzicol<sup>®</sup>, Gelnique<sup>®</sup>, Saphris<sup>®</sup> and Viibryd<sup>®</sup>, will lose patent protection and/or likely become subject to generic or other competition. Generic versions of our Canasa<sup>®</sup> product entered the market in December 2018 pursuant to an agreement previously entered into and generic versions of our Rapaflo<sup>®</sup> product entered the market in December 2018 upon patent expiration. Some of our products may also become subject to generic competition prior to the expiration of patent protection in the event a generic competitor elects to launch its generic equivalent product "at risk." For

example, before the Court of Appeals for the Federal Circuit has reviewed Allergan's appeal of a district court judgment of patent invalidity, Sandoz launched "at risk" a generic version of Latisse<sup>®</sup> in December 2016. Competition from generic equivalents could result in a material impairment of our intangible assets or the acceleration of amortization on our non-impaired intangible assets and may have a material adverse impact on our revenues, financial condition, results of operations and cash flows.

The pharmaceutical industry is highly competitive and our future revenue growth and profitability are dependent on our timely development and launches of new products ahead of our competitors.

We face strong competition across our business. The intensely competitive environment of the pharmaceutical industry requires an ongoing, extensive search for technological innovations and the ability to market and price products effectively, including the ability to communicate the effectiveness, safety and value of branded products to healthcare professionals in private practice, group practices and Managed Care Organizations. Our competitors vary depending upon product categories, and within each product category, upon dosage strengths and drug delivery systems. Based on total assets, annual revenues, and market capitalization, we are smaller than certain of our national and international competitors in the brand and distribution product arenas. Furthermore, recent



trends in this industry are toward further market consolidation of large drug companies into a smaller number of very large entities, further concentrating financial, technical and market strength and increasing competitive pressure in the industry. If we directly compete with them for the same markets and/or products, their financial strength could prevent us from capturing a profitable share of those markets. It is possible that developments by our competitors will make our products or technologies noncompetitive or obsolete. In addition, competitive forces may result in changes to the mix of products that we sell during a given time period or lower demand for our products than expected.

Some of our competitors have technical, competitive or other advantages over us for the development of technologies and processes. These advantages may make it difficult for us to compete with them to successfully discover, develop and market new products and for our current products to compete with new products that these competitors may bring to market. As a result, our products may compete against products that have lower prices, equivalent or superior performance, a better safety profile, are easier to administer, achieve earlier entry into the market or that are otherwise competitive with our products. For example, in the past few years, a number of other companies have started to develop, have successfully developed and/or are currently marketing products that are being positioned as competitors to Botox<sup>®</sup>. While we believe that Botox<sup>®</sup> is a product that is superior to and can be differentiated from its competitors, any commercial success of other toxin products could have an adverse impact on our revenues or results of operations.

If we are unable to adequately protect our technology or enforce our patents, our business could suffer.

Our success with the branded products that we develop will depend, in part, on our ability to obtain patent protection for these products. We currently have a number of U.S. and foreign patents issued and pending. However, issuance of a patent is not conclusive evidence of its validity or enforceability. We cannot be sure that we will receive patents for any of our pending patent applications or any patent applications we may file in the future, or that our issued patents will be upheld if challenged. If our current and future patent applications are not approved or, if approved, our patents are not upheld in a court of law if challenged, it may reduce our ability to competitively utilize our patented products. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by our competitors, in which case our ability to commercially market these products may be diminished. Patent disputes may be lengthy and a potential violator of our patents may bring a potentially infringing product to market during the dispute, subjecting us to competition and damages due to infringement of the competitor product. Further, patents covering Androderm<sup>®</sup>, Carafate<sup>®</sup>, Estrace<sup>®</sup> Cream, Femhr<sup>®</sup>, INFed<sup>®</sup>, Namenda<sup>®</sup> (IR), Pylera<sup>®</sup>, and Rapaflo<sup>®</sup> products have expired and we have no further patent protection on these products. As a result, generic versions of our Estrace<sup>®</sup> Cream product and Namenda XR<sup>®</sup> entered the market in January and March 2018, respectively, and generic versions of our Rapaflo<sup>®</sup> product entered the market in December 2018. During the next few years, additional products will lose patent protection and/or likely become subject to generic or other competition, including Bystolic<sup>®</sup>, Delzicol<sup>®</sup>, Gelnique<sup>®</sup>, Saphris<sup>®</sup> and Viibryd<sup>®</sup>. Therefore, it is possible that a competitor may launch a generic version of any of these products at any time, which would result in a significant decline in that product's revenue and profit.

Generic versions of our Minastrin<sup>®</sup> product which entered the market during March 2017 pursuant to settlement agreements previously entered into; and generic versions of our Canasa<sup>®</sup> product entered the market in December 2018 pursuant to a settlement agreement previously entered into. Some of our products, e.g., Combigan<sup>®</sup>, may also become subject to generic competition prior to the expiration of patent protection in the event a generic competitor is not enjoined and elects to launch its generic equivalent product "at risk."

Generic competitors to our branded products may also challenge the validity or enforceability of the patents protecting our products or otherwise seek to circumvent them. Forest also recently brought actions against certain manufacturers of generic drugs for infringement of several patents covering our Byvalson<sup>®</sup>, Canasa<sup>®</sup>, Delzicol<sup>®</sup>, Linzess<sup>®</sup>, Fetzima<sup>®</sup>, Namenda XR<sup>®</sup>, Namzaric<sup>®</sup>, Saphris<sup>®</sup>, Savella<sup>®</sup>, Teflaro<sup>®</sup> and Viibryd<sup>®</sup> products. Allergan recently brought actions

against manufacturers of generic drugs in the United States for infringement of several patents covering our Combigan<sup>®</sup>, Lastacaft<sup>®</sup>, Latisse<sup>®</sup>, and Restasis<sup>®</sup> products. While we intend to vigorously defend these and other patents and pursue our legal rights, we can offer no assurance as to when the pending or any future litigation will be decided, whether such lawsuits will be successful or that a generic equivalent of one or more of our products will not be approved and enter the market. In addition, patents covering our branded pharmaceutical products may be challenged in proceedings other than court proceedings, including IPR at the U.S. Patent Office. In 2011, Congress amended the patent laws and created a new way to challenge the validity of patents: the inter partes review. IPR proceedings take place in the U.S. Patent Office and have both advantages and disadvantages when compared to district court proceedings. Although IPR proceedings are limited to certain types of invalidity challenges, the U.S. Patent Office applies different standards that make it easier for challengers to invalidate patents. Moreover, IPR proceedings generally take no more than 18 months, which means it is much faster than challenging a patent's validity in a district court proceeding. In addition, an IPR challenge can be mounted even after a patent has been upheld in court.

In addition to patent protection, our business relies on our protection of other intellectual property rights, trade secrets, and other proprietary technologies. We rely on trademark, copyright, trade secret protection, and confidentiality and/or license agreements with

our employees, customers, partners and others to protect our proprietary rights. The protection of our proprietary technology may require the expenditure of significant financial and managerial resources. For example, in April 2017, Allergan brought an action for unfair competition, false advertising, dilution, conspiracy and infringement of Allergan's JUVÉDERM trademarks in the U.S. District Court for the Central District of California against Dermavita Limited Partnership, Dima Corp. S.A. and KBC Media Relations LLC. However, we may not be able to discover or determine the extent of any unauthorized use of our proprietary rights, and we may not be able to prevent third parties from misappropriating or infringing upon our proprietary rights.

We rely on certain information, processes, and know how that are not protected by patents or other intellectual property rights. We seek to protect this information through trade secret or confidentiality agreements, as well as through other measures. These measures may not provide adequate protection for our unpatented technology.

If we are unable to adequately protect our technology, trade secrets or proprietary know how, or enforce our intellectual property rights, our results of operations, financial condition and cash flows could suffer.

The Company may not be able to identify, acquire or license products or proprietary technologies, and could lose rights to intellectual property after such intellectual property has been licensed.

Like other pharmaceutical companies, in order to remain competitive, the Company must continue to launch new products. Expected declines in sales of products after the loss of market exclusivity mean that the Company's future success is dependent on its pipeline of new products, including new products that, as part of its open science model, the Company obtains through acquisitions, licenses or collaborations. To accomplish this, the Company commits substantial effort, funds and other resources to the identification, acquisition or licensing of new products. The Company may face competition from other companies in pursuing acquisitions, licenses or collaborations or may not be able to enter into such transactions on commercially reasonable terms. Our ability to complete such transactions may also be limited by applicable antitrust and trade regulation or other laws and regulations in the United States and foreign jurisdictions in which we or the operations or assets we seek to acquire carry on business. Additionally, because we license significant intellectual property with respect to certain of our products, including Namzaric®, Linzess®, Teflaro® and Viibryd®, any loss or suspension of our rights to licensed intellectual property could materially adversely affect our business, financial condition, cash flows and results of operations. Failure to successfully identify, acquire or license new products or maintain licenses to products or proprietary technologies once acquired would have a material adverse effect on the Company's business, results of operations, cash flow, financial position and prospects.

Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products.

The manufacture, use and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity, enforceability and infringement of patents or proprietary rights of third parties. We may have to defend ourselves against charges that we violated patents or proprietary rights of third parties. This is especially true in the case of new branded products where a competitor has obtained patents for similar products. Litigation may be costly, unpredictable, time consuming, often involves complex legal, scientific and factual questions, and could divert the attention of our management and technical personnel. In addition, if it is determined that we infringe the rights of others, we could lose our right to develop, manufacture or market products, product launches could be delayed or we could be required to pay monetary damages or royalties to license proprietary rights from third parties. Furthermore, we cannot be certain that the necessary licenses would be available to us on commercially reasonable terms, or at all. As a result, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could result in substantial monetary damage awards and could prevent us from manufacturing and selling a number of our products,

which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Certain aspects of our operations are highly dependent upon third party service providers.

We rely on suppliers, vendors and other third party service providers to research, develop, manufacture, commercialize, promote and sell our products. Reliance on third party manufacturers reduces our oversight and control of the manufacturing process. Some of these third party providers are subject to legal and regulatory requirements, privacy and security risks, and market risks of their own. The failure of a critical third party service provider to meet its obligations could have a material adverse impact on our operations and results. If any third party service providers have violated or are alleged to have violated any laws or regulations during the performance of their obligations to us, it is possible that we could suffer financial and reputation harm or other negative outcomes, including possible legal consequences.

If we are unable to obtain sufficient supplies of raw materials, our ability to deliver our products to the market may be impeded.

We are required to identify the supplier(s) of all the raw materials for our products in our applications with the FDA and regulatory agencies outside the United States. To the extent practicable, we attempt to identify more than one API supplier in each drug application. However, many raw materials, including API, are available only from a single source and, in many of our drug applications, only one supplier of raw materials has been identified, even in instances where multiple sources exist. Some of these products have historically or may in the future account for a significant portion of our revenues, such as Botox<sup>®</sup>, our Juvederm<sup>®</sup> dermal filler family of products, Linzess<sup>®</sup> and Bystolic<sup>®</sup>. Any failure by us to forecast demand for, or to maintain an adequate supply of, the raw materials could result in an interruption in the supply of certain products and a decline in sales of that product. In addition, if our suppliers are unable to meet our manufacturing requirements, we may not be able to produce a sufficient amount of product in a timely manner, which could cause a decline in our sales. From time to time, certain of our suppliers have experienced regulatory or supply related difficulties that have inhibited their ability to deliver raw materials to us, causing supply delays or interruptions. The availability and prices of raw materials and supplies are subject to volatility and are influenced by worldwide economic conditions, speculative action, world supply and demand balances, inventory levels, availability of substitute materials, currency exchange rates, anticipated or perceived shortages, product contamination, among other factors. To the extent any difficulties experienced by our suppliers cannot be resolved or extensions of our key supply agreements cannot be negotiated within a reasonable time and on commercially reasonable terms, or if raw materials for a particular product become unavailable from an approved supplier and we are required to qualify a new supplier with the FDA or other regulatory agency, or if we are unable to do so, our profit margins and market share for the affected product could decrease or be eliminated, as well as delay our development and sales and marketing efforts. Such outcomes could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Although we are developing and executing a global risk management framework designed to identify, prioritize, mitigate and continuously monitor potential risks to raw material suppliers, including mitigation strategies such as holding safety stock of raw materials and developing additional sources for sole- or single- sourced raw materials, there is no guarantee that these strategies will be successful and will be able to mitigate any material adverse effect on our business, results of operations, financial condition and cash flows.

In addition, our manufacturing sites outside of the United States and our arrangements with foreign suppliers are subject to certain additional risks, including the availability of government clearances, export duties, political instability, war, acts of terrorism, currency fluctuations and restrictions on the transfer of funds. Arrangements with international raw material suppliers are subject to, among other things, FDA and foreign regulatory body regulation, customs clearances, various import duties and other government clearances, as well as potential shipping delays due to inclement weather, political instability, strikes or other matters outside of our control. Acts of governments outside the U.S. may affect the price or availability of raw materials needed for the development or manufacture of our products. In addition, changes in patent laws in jurisdictions outside the U.S. may make it increasingly difficult to obtain raw materials for R&D prior to the expiration of the applicable U.S. or foreign patents.

Disruption in global trade could prevent us from getting our product to market.

Allergan relies on global trade channels to supply product to the United States and other countries around the world. For example, manufacturing of Botox<sup>®</sup>, Bystolic<sup>®</sup> and Linzess<sup>®</sup> is exclusively performed in Ireland, and manufacturing of our Juvederm<sup>®</sup> dermal filler family of products is exclusively performed in France. Global trade is subject to certain additional risks, including the availability of government clearances, export duties, political instability, war, acts of terrorism, currency fluctuations and restrictions on the transfer of funds. For example, we obtain a significant portion of our raw materials from suppliers that are not in the same country as the manufacturing

plant that uses them. Arrangements with international raw material suppliers are subject to, among other things, FDA and other regulatory body regulation, customs clearances, various import duties and other government clearances, as well as potential shipping delays due to inclement weather, political instability, strikes or other matters outside of our control. Acts of governments may affect the price or availability of raw materials needed for the development or manufacture of our products. In addition, recent changes in patent laws in jurisdictions outside the U.S. may make it increasingly difficult to obtain raw materials for R&D prior to the expiration of the applicable U.S. or foreign patents.

The design, development, manufacture and sale of our products involves the risk of product liability and other claims by consumers and other third parties, and insurance against such potential claims is expensive and may be difficult to obtain.

The design, development, manufacture and sale of our products involves an inherent risk of product liability claims and the associated adverse publicity. For example, the Company is subject to more than 100 legal actions asserting product liability claims relating to the use of Celexa® or Lexapro®. These cases include claims that Celexa® or Lexapro® caused various birth defects. While we believe there is no merit to these cases, litigation is inherently subject to uncertainties and we may be required to expend substantial amounts in the defense or resolution of certain of these matters. In addition, consumer groups and certain plaintiffs have alleged that certain uses of Botox®, including “off-label” uses, have caused patient injuries and death and have further failed to

adequately warn patients of the risks relating to Botox® use. From time to time reports related to the quality and safety of breast implant devices are published, including reports that have suggested a possible association between anaplastic large cell lymphoma and breast implants, and such reports may lead to actions being taken by regulatory authorities, such as the National Agency for the Safety of Medicines and Health Products in France. We regularly monitor the use of our products for trends or increases in reports of adverse events or product complaints, and regularly report such matters to the FDA and other regulatory authorities as applicable. In some, but not all cases, an increase in adverse event reports may be an indication that there has been a change in a product's specifications or efficacy. Such changes could lead to a recall of the product in question or, in some cases, increases in product liability claims related to the product in question. If the coverage limits for product liability insurance policies are not adequate or if certain of our products are excluded from coverage, a claim brought against us, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows. We also rely on self insurance to cover product liability claims, and these claims may exceed amounts we have reserved under our self insurance program.

We are also subject to a variety of other types of claims, proceedings, investigations and litigation initiated by government agencies or third parties. These include compliance matters, product regulation or safety, taxes, employee benefit plans, employment discrimination, health and safety, environmental, antitrust, customs, import/export, government contract compliance, financial controls or reporting, intellectual property, allegations of misrepresentation, false claims or false statements, commercial claims, claims regarding promotion of our products and services, shareholder derivative suits or other similar matters. In addition, government investigations related to the use of products, but not the efficacy themselves, may cause reputational harm to the Company. Negative publicity, whether accurate or inaccurate, about the efficacy, safety or side effects of our products or product categories, whether involving us or a competitor, could materially reduce market acceptance to our products, cause consumers to seek alternatives to our products, result in product withdrawals and cause our stock price to decline. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact. Any such claims, proceedings, investigations or litigation, regardless of the merits, might result in substantial costs, restrictions on product use or sales, or otherwise injure our business.

Our business could suffer as a result of manufacturing difficulties or delays.

The manufacture of our products and product candidates requires precise manufacturing process controls, API that conforms to very tight tolerances for specific characteristics and equipment that operates consistently within narrow performance ranges. Manufacturing complexity, testing requirements, and safety processes combine to increase the overall difficulty of manufacturing these products and resolving manufacturing problems that we may encounter.

Our manufacturing and other processes utilize sophisticated equipment, which sometimes require a significant amount of time to obtain and install. Our business could suffer if certain manufacturing or other equipment, or a portion or all of our facilities were to become inoperable for a period of time. This could occur for various reasons, including catastrophic events such as earthquake, monsoon, hurricane or explosion, unexpected equipment failures or delays in obtaining spare parts, contamination by microorganisms or viruses, labor disputes or shortages, contractual disputes with our suppliers and contract manufacturers, as well as construction delays or defects and other events, both within and outside of our control. Certain products, including Botox®, our Juvederm® dermal filler family of products, Linzess® and Bystolic®, are each manufactured at only one of the Allergan facilities. Additionally, we expect to continue to rely on our third-party manufacturing partners, such as Teva for Lo Loestrin® and Patheon for Viberzi®, that utilize single manufacturing facilities. Therefore, a significant disruptive event at certain manufacturing facilities or sites could materially and adversely affect our business and results of operations, as noted with our supply interruption with Ozurdex® in 2018. In the event of a disruption, we may need to build or locate replacement facilities as well as seek and obtain the necessary regulatory approvals for these facilities. Our inability to timely manufacture any of our significant products could have a material adverse effect on our results of operations, financial condition

and cash flows.

Manufacturing processes at Allergan-owned facilities and those of our third-party contract manufacturers must undergo a potentially lengthy regulatory approval process by the FDA and/or equivalent agencies in other countries. It can take longer than five years to build, validate and license a new manufacturing plant and it can take longer than three years to qualify and license a new contract manufacturer. If regulatory authorities determine that we or our third party contract manufacturers or certain of our third party service providers have violated regulations or if they restrict, suspend or revoke our prior approvals, they could prohibit us from manufacturing our products or conducting clinical trials or selling our marketed products until we or the affected third party contract manufacturers or third party service providers comply, or indefinitely. Because our third-party contract manufacturers and certain of our third-party service providers are subject to the FDA and foreign regulatory authorities, alternative qualified third-party contract manufacturers and third-party service providers may not be available on a timely basis or at all. Although we have launched a global manufacturing business continuity program to reduce the potential for manufacturing difficulties or delays and reduce the severity of a disruptive event, under which program manufacturing sites identify and develop temporary workarounds for manufacturing processes that may be disrupted with the aim of reducing the risk and severity of a disruptive event, there is no guarantee that this program will be successful, and if we or our third party contract manufacturers or third party service providers cease or interrupt production or if



our third party contract manufacturers and third party service providers fail to supply materials, products or services to us, we may experience delayed shipments, supply constraints, stock outs and/or recalls of our products.

Our business could suffer as a result of failure of our R&D program or the failure of our product pipeline to produce successful products.

The discovery and development of safe, effective new products, as well as the development of additional uses for existing products, are necessary for the continued strength of our businesses. Our product lines must be replenished over time in order to offset revenue losses when products lose their market exclusivity, as well as to provide for earnings growth. Our growth potential depends in large part on our ability to identify and develop new products or new indications for existing products that address unmet medical needs and receive reimbursement from payers, either through internal R&D or through collaborations, acquisitions, joint ventures or licensing or other arrangements with third parties. However, balancing current growth, investment for future growth and the delivery of shareholder return remains a major challenge. The average costs of product development continue to rise, as do the regulatory requirements in many therapeutic areas, which may affect the number of candidates funded as well as the sustainability of the R&D portfolio. Our ongoing investments in new product introductions and in R&D for new products and existing product extensions could exceed corresponding sales growth.

Additionally, our R&D investment plans and resources may not be correctly matched between science and markets, and failure to invest in the right technology platforms, therapeutic segments, product classes, geographic markets and/or in-licensing and out-licensing opportunities in order to deliver a robust pipeline could adversely impact the productivity of our pipeline. Further, even if the areas with the greatest market attractiveness are identified, the science may not work for any given program despite the significant investment required for R&D, and the commercial potential of the product may not be as competitive as expected because of the highly dynamic market environment and the hurdles in terms of access and reimbursement.

We are subject to U.S. federal and state healthcare fraud and abuse and health information privacy and security laws, and the failure to comply with such laws may adversely affect our business.

In the United States, many of our products are reimbursed under federal and state health care programs such as Medicaid, Medicare, TriCare, and/or state pharmaceutical assistance programs, and as a result, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to: (i) the U.S. Anti Kickback Statute, which applies to our marketing and research practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; (ii) federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third party payers that are false or fraudulent; (iii) the U.S. Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), which among other things created federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters, and HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information and places restrictions on the use of such information for marketing communications; (iv) the U.S. Physician Payments Sunshine Act, which among other things, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under a federal healthcare program to report annually information related to "payments or

other transfers of value” made to physicians and teaching hospitals, and ownership and investment interests held by certain healthcare professionals and their immediate family members and similar state laws; (v) the government pricing rules applicable to the Medicaid, Medicare Part B, 340B Drug Pricing Program, the U.S. Department of Veterans Affairs program, the TriCare program, and state price reporting laws; and (vi) state and foreign law equivalents of each of the above U.S. laws, such as anti kickback and false claims laws which may apply to items or services reimbursed by any third party payer, including commercial insurers, and state (e.g., the California Consumer Privacy Act of 2018 or “CCPA”) and foreign laws (e.g., the EU General Data Protection Regulation or “GDPR”) governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Violations of the fraud and abuse and privacy laws may result in severe penalties against Allergan and/or its responsible employees, including jail sentences, large fines, and the exclusion of our products from reimbursement under federal and state programs. Defense of litigation claims and government investigations can be costly, time consuming, and distract management, and it is possible that Allergan could incur judgments or enter into settlements that would require us to change the way we operate our business. We are committed to conducting the sales and marketing of our products in compliance with the healthcare fraud and abuse and privacy laws, but certain applicable laws may impose liability even in the absence of specific intent to defraud or misuse health information. Furthermore, should there be ambiguity, a governmental authority may take

a position contrary to a position we have taken, or should an employee violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions.

Any adverse outcome in these types of actions, or the imposition of penalties or sanctions for failing to comply with the fraud and abuse and privacy laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Some of the statutes and regulations that govern our activities, such as federal and state anti kickback and false claims and privacy laws, are broad in scope, and while exemptions and safe harbors protecting certain common activities exist, they are often narrowly drawn. While we manage our business activities to comply with these statutory provisions, due to their breadth, complexity and, in certain cases, uncertainty of application, it is possible that our activities could be subject to challenge by various government agencies. In particular, the FDA, the U.S. Department of Justice and other agencies are engaged in enforcement activities with respect to the sales, marketing, research and similar activities of pharmaceutical companies, and many pharmaceutical companies have been subject to government investigations related to these practices. A determination that we are in violation of these and/or other government regulations and legal requirements may result in civil damages and penalties, criminal fines and prosecution, administrative remedies, the recall of products, the total or partial suspension of manufacture and/or distribution, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions.

Allergan is also currently responding to subpoenas seeking information relating to its sales and marketing activities, including payments to people who are in a position to recommend drugs and “off label” promotion and the Company is defending litigations based on similar allegations. Refer to Legal Matters in “NOTE 25 — Commitments and Contingencies” in the accompanying “Notes to the Consolidated Financial Statements” for more information. We cannot predict or determine the impact of these inquiries on our future financial condition or results of operations. These investigations and any other threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could be used productively on other aspects of our business.

Additionally, the Company has been named as a defendant in over 1,000 matters relating to the promotion and sale of prescription opioid pain relievers and additional suits may be filed. Refer to Legal Matters in “NOTE 25 — Commitments and Contingencies” in the accompanying “Notes to the Consolidated Financial Statements” for more information. We cannot predict or determine the impact of these suits on our future financial condition or results of operations. These suits and any other threatened or actual suits could also generate adverse publicity and require that we devote substantial resources that could be used productively on other aspects of our business.

Any of these types of investigations, suits, or enforcement actions could affect our ability to commercially distribute our products and could materially and adversely affect our business, financial condition, results of operations and cash flows.

Changes in privacy and data protection laws and regulations, particularly in Europe and California, or any failure to comply with such laws and regulations, could adversely affect our business and financial results.

We are subject to a variety of continuously evolving and developing laws and regulations globally regarding privacy, data protection, and data security, including those related to the collection, storage, handling, use, disclosure, transfer, and security of personal data. Significant uncertainty exists as privacy and data protection laws may be interpreted and applied differently from country to country and may create inconsistent or conflicting requirements. These laws apply to our uses of personal data, transfers of information among our affiliates, as well as to transactions we enter into with third party vendors. For example, the European Union adopted the GDPR, which became effective in May 2018, and California has enacted the CCPA, a broad state privacy law, that mandates compliance by 2020. Both the GDPR and the CCPA require companies to satisfy requirements regarding the handling of personal and sensitive data, including

its use, protection and the ability of persons whose data is stored to access and/or delete some types of data about themselves. Failure to comply with these laws could have a material adverse impact on our financial results. Additionally, complying with the enhanced obligations imposed by the GDPR and CCPA may result in significant costs to our business and require us to revise certain of our business practices. In addition, legislators and regulators globally are proposing new and more robust cybersecurity rules in light of the recent broad-based cyberattacks at a number of companies.

These and similar initiatives around the world could increase the cost of developing, implementing or securing our servers and require us to allocate more resources to improved technologies, adding to our IT and compliance costs. In addition, enforcement actions and investigations by regulatory authorities related to data security incidents and privacy violations continue to increase. The enactment of more restrictive laws, rules, regulations, or future enforcement actions or investigations could impact us through increased costs or restrictions on our business, and noncompliance could result in regulatory penalties and significant legal liability.

Extensive industry regulation has had, and will continue to have, a significant impact on our business, especially our product development, manufacturing and distribution capabilities.

All pharmaceutical companies, including Allergan, are subject to extensive, complex, costly and evolving government regulation. For the U.S., this is principally administered by the FDA, but is also administered by the DEA and state government agencies, as well as by varying regulatory agencies in foreign countries where products or product candidates are being manufactured and/or marketed. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal statutes and regulations, and similar foreign statutes and regulations, govern or influence the development, testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale, distribution and import/ export of our drugs and medical devices. Foreign regulatory authorities impose similar requirements focused on drug safety and effectiveness. Obtaining and maintaining regulatory approval has been and will continue to be increasingly difficult, time consuming and costly. In addition, changes in applicable federal, state and foreign laws and regulations or the implementation of new laws and regulations could affect our ability to obtain or maintain approval of our products and could have a material adverse effect on the Company's business. There is currently the potential for regulatory changes adverse to our business due to recent uncertainty related to the direction of U.S. regulatory policy related to the pharmaceutical industry.

Once regulatory approval has been obtained, agencies continue to have substantial authority to require additional testing, perform inspections, change product labeling based on post-marketing safety information or mandate withdrawals of our products. Failure to comply with applicable regulatory requirements may subject us to administrative or judicially imposed sanctions. These sanctions may include, among others, untitled letters, warning letters, fines, civil penalties, criminal penalties, injunctions, debarment, product seizure or detention, product recalls and total or partial suspension of production, sale and promotion. In addition, we may voluntarily elect to recall or restrict the use of a product. Any recall or restriction could divert managerial and financial resources and might harm our reputation.

Under these statutes and regulations, we are subject to periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA and similar ex U.S. authorities, the DEA and other authorities, which conduct periodic inspections to confirm that we are in compliance with all applicable requirements. In addition, the FDA and foreign regulatory agencies conduct pre approval and post approval reviews and plant inspections to determine whether our systems and processes are in compliance with cGMP, quality systems regulations and other applicable regulations. Following such inspections, the FDA or other agency may issue observations, notices, citations and/or warning letters that could cause us to modify certain activities identified during the inspection. FDA guidelines specify that a warning letter is issued only for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. We are also required to report adverse events associated with our products to the FDA and other regulatory authorities. Unexpected or serious health or safety concerns could result in product liability claims, labeling changes, recalls, market withdrawals or other regulatory actions, including withdrawal of product approvals. Adverse events and safety concerns can arise as our product candidates are evaluated in clinical trials or as our marketed products are used in clinical practice. We are required to communicate to regulatory agencies adverse events reported to us regarding our products.

We cannot assure that the FDA inspections at any of our manufacturing sites will not result in inspectional observations at such sites, that approval or clearance of any of the pending or subsequently submitted NDAs or supplements to such applications, 510(k)s or PMAs by Allergan plc or our subsidiaries will be granted or that the FDA will not seek to impose additional sanctions against Allergan plc or any of its subsidiaries. The range of possible sanctions includes, among others, FDA issuance of product recalls or seizures, fines, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions, and civil or criminal prosecution. Any such sanctions, if imposed, could have a material adverse effect on our business, operating results, financial condition and cash flows. Under certain circumstances, the FDA also has the

authority to revoke previously granted product approvals. Similar sanctions as detailed above may be available to the FDA under a consent decree, depending upon the actual terms of such decree. Although we have instituted internal compliance programs, if these programs do not meet regulatory agency standards or if compliance is deemed deficient in any significant way, it could materially harm our business. Certain of our vendors are subject to similar regulation and periodic inspections and may be operating under consent decrees.

In order to market our products in the United States and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements required for approval as well as maintaining registrations post-approval in every country where our products are approved. The process for obtaining governmental clearance or approval to manufacture and market pharmaceutical products and medical devices is rigorous, time consuming, uncertain and costly, and we cannot predict the extent to which we may be affected by legislative and regulatory requirement changes. We are dependent on receiving FDA and other governmental or third party approvals prior to manufacturing, marketing and distributing our products. There is always the chance that we will not obtain FDA or other necessary approvals, or that the rate, timing and cost of obtaining such approvals, will adversely affect our product introduction plans or impact operations. Additionally, any regulatory approvals we receive may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval may require costly additional studies and additional safety surveillance of the product. We may only market or promote our products for their approved

indications, and our labeling, promotional activities and advertising are subject to extensive regulation and oversight. We carry inventories of certain product(s) in anticipation of launch, and if such product(s) are not subsequently launched, we may be required to write off the related inventory.

Our customers are subject to various regulatory requirements, including requirements of the DEA, FDA, state boards of pharmacy and city and county health regulators, among others. These include licensing, registration, recordkeeping, security and reporting requirements. Additionally, although physicians may prescribe FDA approved products for an “off label” indication, we are permitted to market our products only for the indications for which they have been approved. Some of our products are prescribed “off label” and the FDA, the U.S. Department of Justice, the U.S. Attorney or other regulatory authorities could take enforcement actions if they conclude that we or our distributors have engaged in “off label” marketing. In addition, historically a number of states and the federal government have enforced licensing and anti-counterfeit drug pedigree laws which require the tracking of all transactions involving prescription drugs beginning with the manufacturer, through the supply chain, and down to the pharmacy or other health care provider dispensing or administering prescription drug products. Therefore, manufacturers and wholesale distributors have been required to maintain records documenting the chain of custody on distribution of prescription drugs. On November 27, 2013, the federal government enacted the Drug Quality and Security Act (“DQSA”) amending federal requirements in regard to the licensing and tracking of prescription drugs. Certain provisions in the law related to licensing and tracking and tracing specifically preempted prior state laws related to drug pedigrees that are inconsistent, more stringent, or in addition to the federal law. Specifically, Title II of the DQSA, also known as the Drug Supply Chain Security Act (“DSCSA”), provides for creation of an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. These amendments include requirements on licensing, tracking and tracing and other operations applicable to manufacturers and wholesale distributors of prescription drug products. The full requirements of the DSCSA are being phased in over a ten-year period; however, in January 2015, specific product tracing requirements for manufacturers, wholesalers, repackagers and dispensers (e.g., pharmacies) of prescription drugs became effective. Also, as of January 2015, the DSCSA required manufacturers and wholesale distributors to implement systems to identify potential “suspect” or “illegitimate” product, and take appropriate action. The DSCSA also addresses product tracing using unique product identifiers on packaging, which requirement became effective for drug manufacturers on November 27, 2017. FDA began enforcement of the law requiring product identifiers on November 27, 2018, for products packaged after that date after having exercised a year of enforcement discretion. The DSCSA also sets forth requirements for the interoperable, electronic tracing of products, which are intended to take effect ten years after enactment of the DSCSA, or in 2023.

In addition to government agencies that promulgate regulations and guidelines directly applicable to us, other professional societies, practice management groups, insurance carriers, physicians, private health or science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to healthcare providers, administrators and payers, and patient communities. For example, the treatment practices of physicians that currently prescribe our products may change. Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies, as well as reimbursement of our products by government and private payers. Any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could materially and adversely affect our product sales, business and operating results.

The supply of APIs into Europe may be negatively affected by regulations promulgated by the European Union.

All APIs imported into the EU must be certified as complying with the good manufacturing practice standards established by the EU, as stipulated by the International Conference for Harmonization. These regulations place the certification requirement on the regulatory bodies of the exporting countries. Accordingly, the national regulatory authorities of each exporting country must: (i) ensure that all manufacturing plants within their borders that export

API into the EU comply with EU manufacturing standards and; (ii) for each API exported, present a written document confirming that the exporting plant conforms to EU manufacturing standards. The imposition of this responsibility on the governments of the nations exporting API may cause a shortage of API necessary to manufacture our products, as certain governments may not be willing or able to comply with the regulation in a timely fashion, or at all. A shortage in API may cause us to have to cease manufacture of certain products, or to incur costs and delays to qualify other suppliers to substitute for those API manufacturers unable to export. This could adversely affect the Company and could have a material adverse effect on our business, results of operations, financial condition and cash flow.

Federal regulation of arrangements between manufacturers of branded and generic products could adversely affect our business.

As part of the Medicare Prescription Drug and Modernization Act of 2003, companies are required to file with the FTC and the Department of Justice certain types of agreements entered into between branded and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of branded drugs. This requirement, as well as legislation pending in the U.S. Congress related to settlements between brand and generic drug manufacturers, could affect the manner in which brand drug manufacturers resolve intellectual property litigation and other disputes with generic pharmaceutical companies and could result generally in an increase or lengthening of litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities. The impact of this requirement, the pending legislation and the potential private party



lawsuits associated with arrangements between brand and generic drug manufacturers, is uncertain and could adversely affect our business. For example, in April 2013, class actions were filed against certain subsidiaries of the Company alleging that certain 2009 patent lawsuit settlements with Watson Laboratories, Inc. and Lupin Pharmaceuticals, Inc. related to Loestrin<sup>®</sup> 24 Fe (norethindrone acetate/ethinyl estradiol tablets and ferrous fumarate tablets, “Loestrin<sup>®</sup> 24”) are unlawful. The complaints generally allege that Watson and Lupin improperly delayed launching generic versions of Loestrin<sup>®</sup> 24 in exchange for substantial payments from Warner Chilcott plc in violation of federal and state antitrust and consumer protection laws. Similar lawsuits have been filed against the Company challenging the lawfulness of patent litigation settlements related to Asacol<sup>®</sup> and Namenda<sup>®</sup>. We have also received requests for information and Statements of Objection in connection with investigations into settlements and other arrangements between competing pharmaceutical companies by the Federal Trade Commission and the European Competition Commission. For example, in May 2014, Forest received a Civil Investigatory Demand from the FTC requesting information about Forest’s agreements with ANDA filers for Bystoli<sup>®</sup>. Any adverse outcome of these actions or investigations, or actions or investigations related to other settlements we have entered into, could have a material adverse effect on our business, results of operations, financial condition and cash flows. Refer to Legal Matters in “NOTE 25 — Commitments and Contingencies” in the accompanying “Notes to the Consolidated Financial Statements.”

Healthcare reform and a reduction in the coverage and reimbursement levels by governmental authorities, HMOs, MCOs or other third party payers may adversely affect our business.

Demand for our products depends in part on the extent to which coverage and reimbursement is available from third party payers, such as the Medicare and Medicaid programs and private payors. In order to commercialize our products, we have obtained from government authorities and private health insurers and other organizations, such as HMOs and MCOs, recognition for coverage and reimbursement at varying levels for the cost of certain of our products and related treatments. Third party payers and government entities increasingly continue to challenge the prices of pharmaceutical products. Further, the trend toward managed healthcare in the U.S., the growth of organizations such as HMOs and MCOs, and legislative and regulatory proposals to reform healthcare and government insurance programs create uncertainties regarding the future levels of coverage and reimbursement for pharmaceutical products. For example, the Trump Administration recently proposed a rule that would redefine the way Medicare Part B providers are paid for physician-administered drugs (to be based, in part, on international reference pricing). Such cost containment measures and healthcare reform could reduce reimbursement of our pharmaceutical products, resulting in lower prices and a reduction in the product demand. This could affect our ability to sell our products and could have a material adverse effect on our business, results of operations, financial condition and cash flows.

There have been changes in reimbursement for pharmaceuticals under various government programs, including Medicaid, and there is uncertainty surrounding implementation of legislation and regulatory changes relating to reimbursement for pharmaceuticals under Medicaid and other government programs such as Medicare and TriCare. Reimbursement changes under such government programs may impact demand for our products and may negatively affect the price. In addition, any reimbursement granted may not be maintained or limits on reimbursement available from third-party payers may reduce demand for, or negatively affect the price of, those products. Additionally, various legislative and regulatory initiatives in states, including proposed modifications to reimbursements and rebates, price transparency laws, product pedigree and tracking, pharmaceutical waste “take back” initiatives, restrictions on co-pay assistance programs and therapeutic category generic substitution carve out legislation may also have a negative impact on the Company. We maintain a full-time government affairs department in Washington, D.C., which is responsible for coordinating state and federal legislative activities, and places a major emphasis in terms of management time and resources to ensure a fair and balanced legislative and regulatory arena.

Although the ACA reforms have significantly impacted our business, in the coming years, it is likely that additional changes will be made to governmental healthcare and insurance reimbursement programs. On January 20, 2017, President Donald Trump signed an executive order, which stated that it is the policy of his Administration to seek the prompt repeal of the ACA and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the ACA to the maximum extent permitted by law. In addition, a federal court in Texas ruled in December 2018 that the ACA is unconstitutional. That decision currently is being appealed and may result in an opinion by appellate courts, including potentially the Supreme Court of the United States, on the constitutionality of the ACA as revised. We cannot predict the ultimate content, timing, or effect of any such reform activities, litigation, or court decisions on our business. Additionally, the pricing and reimbursement of pharmaceutical products continues to receive significant attention from U.S. policymakers, the Trump Administration, and others. For example, on January 31, 2019, the Department of Health and Human Services issued a proposed rule that removes from existing anti-kickback statute safe harbor protection certain reductions in price paid by pharmaceutical manufacturers to Medicare Part D plan sponsors, Medicaid MCOs, and those entities' pharmacy benefit managers ("PBMs") and adds two new safe harbors that protect certain point-of-sale price reductions by pharmaceutical manufacturers as well as certain service fee payments from pharmaceutical manufacturer to PBMs. At this time, we cannot predict the impact of this increased scrutiny on the pricing or reimbursement of our products or pharmaceutical products generally.

Sales of our products may continue to be adversely affected by the continuing consolidation of our distribution network and the concentration of our customer base.

Our principal customers are wholesale drug distributors and major retail drug store chains. These customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network is continuing to undergo significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drug store chains. As a result, a small number of large wholesale distributors and large chain drug stores control a significant share of the market. We expect that consolidation of drug wholesalers and retailers will increase pricing and other competitive pressures on drug manufacturers, including the Company.

The loss of any of these customers could have a material adverse effect on our business, results of operations, financial condition and cash flows. In addition, none of our customers are party to any long term supply agreements with us, and thus are able to change suppliers freely should they wish to do so.

Developments after a product reaches the market may adversely affect sales of our products.

Even after regulatory approval, certain developments may decrease demand for our products, including the following:

- the re review of products that are already marketed;
- new scientific information and evolution of scientific theories;
- the recall or loss of marketing approval of products that are already marketed;
- changing standards from government, regulatory or supervisory authorities or public expectations regarding safety, efficacy or labeling changes; and
- greater scrutiny in advertising and promotion.

In the past, clinical trials, government, regulatory or other supervisory review and/or post marketing surveillance of certain marketed drugs of the Company and of competitors within the industry have raised concerns that have led to recalls, withdrawals or adverse labeling of marketed products, including the recent recall of our Ozurdex® product. 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 its distribution or applying for labeling changes.

In addition, certain health authorities, regulators and agencies have increased their focus on safety when assessing the balance of benefits and risks of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products and are re reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the U.S., on advertising, and promotion (in particular, direct to consumer advertising) and pricing of pharmaceutical products. Certain regulatory changes or decisions could make it more difficult for us to sell our products and could have a material adverse effect on our business, results of operations, financial condition and cash flows.

If we do not successfully integrate newly acquired businesses into our business operations, our business could be adversely affected.

We will need to successfully integrate the operations of acquired businesses with our business operations. As a result of recent and future or pending acquisitions, we have undergone substantial changes in a short period of time and our business has changed and broadened in size and the scope of products we offer. Integrating the operations of multiple new businesses with that of our own is a complex, costly and time consuming process, which requires significant

management attention and resources to integrate the business practice and operations. The integration process may disrupt the businesses and, if implemented ineffectively, would preclude realization of the full benefits expected by us. Our failure to meet the challenges involved in integrating the businesses in order to realize the anticipated benefits of the acquisitions could cause an interruption of, or a loss of momentum in, our activities and could adversely affect our results of operations. Prior to each acquisition, the acquired business operated independently, with its own business, corporate culture, locations, employees and systems. There may be substantial difficulties, costs and delays involved in any integration of other businesses with that of our own.

These may include:

- distracting management from day to day operations;
- potential incompatibility of corporate cultures;
- an inability to achieve synergies as planned;
- risks associated with the assumption of contingent or other liabilities of acquisition targets;
- adverse effects on existing business relationships with suppliers or customers;
- inheriting and uncovering previously unknown issues, problems and costs from the acquired company;
- delays between our expenditures to acquire new products, technologies or businesses and the generation of revenues from those acquired products, technologies or businesses;
- realization of assets and settlement of liabilities at amounts equal to estimated fair value as of the acquisition date of any acquisition or disposition;
- revenue recognition related to licensing agreements and/or strategic collaborations;
- loss of key employees of the acquired business, including because such employees have become employed by our competitors;
- overlap between our products or customers and the companies that we acquire that may create conflicts in relationships or other commitments detrimental to the integrated businesses;
- costs and delays in implementing common systems and procedures (including technology, compliance programs, financial systems, distribution and general business operations, among others); and
- increased difficulties in managing our business due to the addition of international locations.

These risks may be heightened in cases where the majority of the former businesses' operations, employees and customers are located outside of the United States. Any one or all of these factors may increase operating costs or lower anticipated financial performance. Many of these factors are also outside of our control. In addition, dispositions of certain key products, technologies and other rights may affect our business operations.

In addition, even if the operations of the businesses are integrated successfully, we may not realize the full benefits of the acquisitions, including the synergies, cost savings or sales or growth opportunities that we expect. These benefits may not be achieved within the anticipated time frames, or at all. Additional unanticipated costs may be incurred in the integration of the businesses. All of these factors could cause a reduction to our earnings, decrease or delay the expected accretive effect of the transactions, and negatively impact the price of our ordinary shares.

The failure to integrate the business operations of the acquired businesses successfully would have a material adverse effect on our business, financial condition and results of operations.

If we are unsuccessful in our joint ventures and other collaborations, our operating results could suffer.

We have made substantial investments in joint ventures and other collaborations, including our collaborations for Linzess<sup>®</sup> and LCA10, and may use these and other methods to develop or commercialize products in the future. These arrangements typically involve other pharmaceutical companies as partners that may be competitors of ours in certain markets. In many instances, we will not control these joint ventures or collaborations or the commercial exploitation of the licensed products, and cannot assure you that these ventures will be profitable. Joint venture or collaboration agreements may place limitations or restrictions on marketing our products. Any such marketing restrictions could affect future revenues and have a material adverse effect on our operations. Our results of operations may suffer if existing joint venture or collaboration partners withdraw, or if these products are not timely developed, approved or successfully commercialized and we cannot guarantee the successful outcome of such efforts, nor that they will result in any intellectual property rights or products that inure to our benefit.

We have incurred significant transaction, integration and restructuring costs in connection with recent transactions, including our acquisitions of Zeltiq, LifeCell, and the sale of our generics business and certain other assets to Teva.

We have incurred significant transaction costs related to our acquisitions such as Zeltiq, LifeCell, and the sale of our generics business and certain other assets to Teva and may continue to incur significant transaction costs related to past acquisitions. In

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addition, we may incur integration costs and restructuring costs as we integrate new businesses. While Allergan has assumed that a certain level of transaction and coordination expenses will be incurred, there are a number of factors beyond Allergan's control that could affect the total amount or the timing of these transaction and coordination expenses. Many of the expenses that will be incurred, by their nature, are difficult to estimate accurately. Although we expect that the realization of benefits and efficiencies related to the integration of the businesses may offset these transaction costs, integration costs and restructuring costs over time, no assurances can be made that this net benefit will be achieved in the near term, or at all. The failure to realize the expected benefits and efficiencies related to the integration of the businesses could adversely affect our financial condition and results of operations.

In addition, as a result of acquiring businesses, technologies or products, or entering into other significant transactions, we may experience significant charges to earnings for merger and related expenses. These costs may include substantial fees for investment bankers, attorneys, accountants, advisors, consultants and severance and other closure costs associated with regulator mandated divestitures and the elimination of duplicate or discontinued products, operations and facilities. Charges that we may incur in connection with acquisitions could adversely affect our results of operations for particular quarterly or annual periods.

Our operating results and financial condition may fluctuate.

Our operating results and financial condition may fluctuate from quarter to quarter and year to year for a number of reasons. As a result, we believe that period to period comparisons of our results of operations are not necessarily meaningful, and these comparisons should not be relied upon as an indication of future performance. Our operating results and financial condition are also subject to fluctuation from all of the risks described throughout this section. These fluctuations may adversely affect our results of operations and financial conditions.

Our debt and other financial obligations could impair our financial condition and our ability to fulfill our debt obligations. Any refinancing of this debt could be at significantly higher interest rates.

Our indebtedness and other financial obligations could:

- impair our ability to obtain financing or additional debt in the future for working capital, capital expenditures, acquisitions or general corporate purposes;
  - impair our ability to access capital and credit markets on terms that are favorable to us;
  - have a material adverse effect on us if we fail to comply with financial and affirmative and restrictive covenants in our debt agreements and an event of default occurs as a result of a failure that is not cured or waived;
  - require us to dedicate a substantial portion of our cash flow for interest payments on our indebtedness and other financial obligations, thereby reducing the availability of our cash flow to fund working capital and capital expenditures;
  - limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; and
  - place us at a competitive disadvantage compared to our competitors that have proportionally less debt.
- Additionally, certain of our financing agreements may contain cross default or other similar provisions whereby a default under one financing agreement could result in a default under our other financing agreements.

If we are unable to meet our debt service obligations and other financial obligations such as planned dividends, we could be forced to restructure or refinance our indebtedness and other financial transactions, seek additional equity capital or sell our assets. We might then be unable to obtain such financing or capital or sell our assets on satisfactory terms, if at all. Any refinancing of our indebtedness could be at significantly higher interest rates, and/or incur significant transaction fees. Refer to "NOTE 17 — Long-Term Debt and Capital Leases" for a detailed discussion of our outstanding indebtedness.

Significant balances of intangible assets, including product rights and goodwill acquired, are subject to impairment testing and may result in impairment charges, which will adversely affect our results of operations and financial condition.

A significant amount of our total assets is related to acquired intangibles and goodwill. As of December 31, 2018, the carrying value of our product rights and other intangible assets was \$43,695.4 million and the carrying value of our goodwill was \$45,913.3 million.

Our product rights are stated at cost, less accumulated amortization. We determine original fair value and amortization periods for product rights based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired products. Such factors include the product's position in its life cycle, the existence or absence of like products in the market, various other competitive and regulatory issues and contractual terms. Significant adverse changes to any of these factors require us to perform an impairment test on the affected asset and, if evidence of impairment exists, require us to take an impairment charge with respect to the



asset. For assets that are not impaired, we may adjust the remaining useful lives. Such a charge could have a material adverse effect on our results of operations and financial condition.

Our other significant intangible assets include acquired core technology and customer relationships, which are intangible assets with definite lives, and our acquired IPR&D intangible products, acquired in recent business acquisitions, which are intangible assets with indefinite lives.

Our acquired core technology and customer relationship intangible assets are stated at cost, less accumulated amortization. We determined the original fair value of our other intangible assets by performing a discounted cash flow analysis, which is based on our assessment of various factors. Such factors include existing operating margins, the number of existing and potential competitors, product pricing patterns, product market share analysis, product approval and launch dates, the effects of competition, customer attrition rates, consolidation within the industry and generic product lifecycle estimates. Our other intangible assets with definite lives are tested for impairment when there are significant changes to any of these factors. If evidence of impairment exists, we are required to take an impairment charge with respect to the impaired asset. Such a charge could have a material adverse effect on our results of operations and financial condition.

Goodwill and our IPR&D intangible assets are tested for impairment annually, or when events occur or circumstances change that could potentially reduce the fair value of the reporting unit or intangible asset. Impairment testing compares the fair value of the reporting unit or intangible asset to its carrying amount. A goodwill or IPR&D impairment, if any, would be recorded in operating income and could have a material adverse effect on our results of operations and financial condition. For example, Allergan recorded a \$2,841.1 million goodwill impairment relating to its General Medicine Reporting Unit in the twelve months ended December 31, 2018.

We may need to raise additional funds in the future which may not be available on acceptable terms or at all.

We may consider issuing additional debt or equity securities in the future to fund potential acquisitions or investments, to refinance existing debt, or for general corporate purposes. If we issue equity, convertible preferred equity or convertible debt securities to raise additional funds, our existing shareholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing shareholders. If we incur additional debt, it may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest expenses and potentially lowering our credit ratings. We may not be able to market such issuances on favorable terms, or at all, in which case, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements.

The loss of our key personnel could cause our business to suffer.

The success of our present and future operations will depend, to a significant extent, upon the experience, abilities and continued services of key personnel. For example, although we have other senior management personnel, a significant loss of the services of Brent Saunders, our Chief Executive Officer, or other senior executive officers without having or hiring a suitable successor, could cause our business to suffer. We cannot assure you that we will be able to attract and retain key personnel. We have entered into employment agreements with certain of our senior executive officers but such agreements do not guarantee that our senior executive officers will remain employed by us for a significant period of time, or at all. We do not carry key employee life insurance on any of our officers.

Substantial amounts of our information concerning our products, customers, employees and ongoing business are stored digitally and are subject to threats of theft, exposure, tampering, or other intrusions.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent upon information technology systems, devices, infrastructure and data. This digital information includes, but is not limited to, confidential and proprietary information as well as personal information regarding our customers and employees. We also rely to a large extent upon sophisticated information technology systems to operate our businesses. Data maintained in digital form is subject to the risk of intrusion, exposure, tampering and theft. Cyber-attacks are increasing in frequency, sophistication and intensity. Such attacks are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation-states and others. Cyber attacks could include the deployment of harmful malware, denial of service attacks, worms, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for the processing, transmission and storage of digital information. However, the development and maintenance of these systems is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly more sophisticated. While we continue to build and improve our systems and infrastructure and

believe we have taken appropriate security measures to reduce these risks to our information technology systems, devices, infrastructure and data, the possibility of a future data compromise cannot be eliminated entirely, and risks associated with intrusion, exposure, tampering, and theft remain. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. Data privacy or security breaches by employees or others may pose a risk that data, including intellectual property or personal information, may be exposed to unauthorized individuals or to the public. In addition, we also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information, because we provide confidential, proprietary and personal information to third parties when it is necessary to pursue our business objectives. While we obtain assurances that these third parties will protect this information and, where appropriate, monitor the protections employed by these third parties, there is a risk the confidentiality of data held by third parties may be compromised. If our data systems are compromised, our business operations may be impaired, we may lose profitable opportunities, or the value of those opportunities may be diminished, and we may lose revenue because of unlicensed use of our intellectual property. If personal information of our customers or employees is misappropriated, our reputation with our customers and employees may be injured resulting in loss of business and/or morale, and we may incur costs to remediate possible injury to our customers and employees or be required to pay fines or take other action with respect to judicial or regulatory actions arising out of such incidents.

Our business will continue to expose us to risks of environmental liabilities.

Our product and API development programs, manufacturing processes and distribution logistics involve the controlled use of hazardous materials, chemicals and toxic compounds in our owned and leased facilities. As a result, we are subject to numerous and increasingly stringent federal, state and local environmental laws and regulations concerning, among other things, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous materials and the discharge of pollutants into the air and water. Our programs and processes expose us to risks that an accidental contamination could result in (i) our noncompliance with such environmental laws and regulations and (ii) regulatory enforcement actions or claims for personal injury and property damage against us. If an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. The substantial unexpected costs we may incur could have a material and adverse effect on our business, results of operations, financial condition, and cash flows. In addition, environmental permits and controls are required for some of our operations, and these permits are subject to modification, renewal and revocation by the issuing authorities. Any modification, revocation or non-renewal of our environmental permits could have a material adverse effect on our ongoing operations, business and financial condition. Our environmental capital expenditures and costs for environmental compliance may increase in the future as a result of changes in environmental laws and regulations or increased development or manufacturing activities at any of our facilities.

Our foreign operations may become less attractive if political and diplomatic relations between the United States and any country where we conduct business operations deteriorates.

The relationship between the United States and the foreign countries where we conduct business operations may weaken over time. Changes in the state of the relations between any such country and the United States are difficult to predict and could adversely affect our future operations. This could lead to a decline in our profitability. Any meaningful deterioration of the political, economic and diplomatic relations between the United States and the relevant country could have a material adverse effect on our operations.

Our global operations expose us to risks and challenges associated with conducting business internationally.

We operate on a global basis with offices or activities in Europe, Africa, Asia, South America, Australia and North America. We face several risks inherent in conducting business internationally, including compliance with international and U.S. laws and regulations that apply to our international operations. These laws and regulations include data privacy requirements, including GDPR; advertising and promotion laws both for pharmaceutical and medical device products; labor relations laws; tax laws; competition regulations; import and trade restrictions; economic sanctions; export requirements; U.S. laws such as the Foreign Corrupt Practices Act; the UK Bribery Act 2010; and other local laws that prohibit corrupt payments to governmental officials or certain payments or remunerations to customers. Given the high level of complexity of these laws there is a risk that some provisions may be breached by us, for example through fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements, or otherwise. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, our business and our operating results. Our success

depends, in part, on our ability to anticipate these risks and manage these challenges. Further, certain of our employees, including employees located in certain jurisdictions in Canada, Europe and Asia, are represented by collective bargaining or other labor agreements or arrangements that provide bargaining or other rights to employees. Such employment rights require us to expend greater time and expense in making changes to employees' terms of employment or carrying out staff reductions. In addition, any national or other labor disputes in these regions could result in a work stoppage or strike by our employees that could delay or interrupt our ability to supply products and conduct operations. Due to the nature of these collective bargaining agreements, we will have no control over such work stoppages or strikes by such employees, and a strike may occur even if the employees do not have any grievances against us. Any interruption in manufacturing or operations could interfere with our business and could have a material adverse effect on our revenues.

In addition to the foregoing, engaging in international business inherently involves a number of other difficulties and risks, including:

- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability or sanctions in areas in which we operate;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- regulations related to customs and import/export matters (including sanctions);
- tax issues, such as tax law changes and variations in tax laws;
- challenges in collecting accounts receivable from customers in the jurisdictions in which we operate;
- complying with laws, rules and regulations relating to the manufacturing, marketing, distribution and sale of pharmaceutical products in the jurisdictions in which we do or will operate;
- operating under regulations in jurisdictions related to obtaining eligibility for government or private payor reimbursement for our products at the wholesale/retail level;
- competition from local, regional and international competitors;
- difficulties and costs of staffing and managing foreign operations, including cultural and language differences and additional employment regulations, union workforce negotiations and potential disputes in the jurisdictions in which we operate;
- difficulties associated with compliance with a variety of laws and regulations governing international trade, including the Foreign Corrupt Practices Act;
- difficulties protecting or procuring intellectual property rights;
- illegal diversions of our products and/or counterfeiting of our products; and
- fluctuations in foreign currency exchange rates.

These factors or any combination of these factors could have a material adverse effect on our results of operations and financial condition.

The U.S. government shutdown and lapse in appropriations could adversely affect our business.

The U.S. federal government began a partial government shut down due to a lapse in appropriations on December 22, 2018, which continued until January 25, 2019. If there is a future lapse in appropriation or similar government shutdown the FDA may be unable to accept new regulatory submissions, including NDAs. Delay in submissions of NDAs and other regulatory submissions to the FDA could delay approvals of our products and adversely affect our business.

The United Kingdom's impending departure from the European Union could adversely affect our business and financial results.

The United Kingdom held a referendum on June 23, 2016 in which a majority of voters voted to exit the European Union (“Brexit”) and on March 29, 2017, the United Kingdom submitted a formal notification of its intention to withdraw from the European Union pursuant to Article 50 of the Treaty of Lisbon. The United Kingdom has a period of a maximum of two years from the date of its formal notification (such period ending on March 29, 2019, unless an extension is agreed) to negotiate the terms of its withdrawal from, and future relationship with, the European Union, including the terms of trade between the United Kingdom and the European Union and potentially other countries. If no formal withdrawal agreement is reached between the United Kingdom and the European

Union, then it is expected the United Kingdom's membership of the European Union will automatically terminate two years after the submission of the notification of the United Kingdom's intention to withdraw from the European Union, unless all remaining member states unanimously consent to an extension of this period. Discussions between the United Kingdom and the European Union focused on finalizing withdrawal issues and transition agreements are ongoing. However, limited progress to date in these negotiations and ongoing uncertainty within the UK Government and Parliament increases the possibility of the United Kingdom leaving the European Union on March 29, 2019 without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption. The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to European Union markets either during a transitional period or more permanently. Brexit could adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets, including volatility in the value of the euro. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws to replace or replicate. Any of these effects of Brexit, and others we cannot anticipate, could negatively affect our business and financial results.

Our ordinary share dividend policy is subject to change and could adversely affect the price of our ordinary shares.

Our ordinary share dividend policy is based upon our Board of Directors' current assessment of our business and the environment in which we operate. That assessment could change based on competitive or commercial developments (which could, for example, increase our need for capital expenditures), new growth opportunities, the terms of future debt instruments, legal risks, changes in Irish corporate or tax or federal tax law and challenges to our business model. Our Board of Directors may, in its discretion, amend or repeal our dividend policy to decrease the level of dividends on our ordinary shares or entirely discontinue the payment of dividends on our ordinary shares. The reduction or elimination of our cash dividend could adversely affect the market price of our ordinary shares.

Our share repurchase program may not enhance shareholder value.

Repurchases by the Company of our ordinary shares reduce the number of outstanding shares of our ordinary shares. There can be no assurance that any share repurchases will enhance shareholder value because the market price of our ordinary shares may decline below the levels at which we repurchased ordinary shares. Although the Company's repurchases of its shares are intended to enhance long-term shareholder value, short-term stock price fluctuations could reduce the effectiveness of these repurchases.

We have exposure to tax liabilities.

As a multinational corporation, we are subject to income taxes as well as non income based taxes in various jurisdictions. Significant judgment is required in determining our worldwide provision for income taxes and other tax liabilities. We are subject to costs and other potential outcomes from tax audits. The Company believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued.

Changes in tax laws or tax rulings in the U.S. and abroad could have a significant adverse impact on our effective tax rate.

On December 22, 2017, the Tax Cuts and Jobs Act (“TCJA”), was enacted into law by President Trump. The TCJA makes significant changes to the U.S. taxation of our domestic and international operations. The TCJA contains a number of provisions that may adversely impact our effective tax rate or operating cash flows going forward, including:

- The limitation on the amount of interest expense deduction available to our U.S. subsidiaries to the extent we are unable to absorb any unused interest deductions over time;
- The “Base Erosion Anti-Abuse Tax,” which requires our U.S. subsidiaries to make an alternative determination of taxable income without regard to tax deductions for certain payments to affiliates.

Many countries in Europe where we conduct business have proposed or recently enacted changes to existing tax laws in order to limit base erosion and profit shifting. These changes could impact our effective tax rate or future tax obligations. The European Commission has conducted investigations in multiple countries focusing on whether local country tax rulings or tax legislation provides preferential tax treatment that violates European Union state aid rules. If the Company’s effective tax rates were to increase, or if the ultimate determination of the Company’s taxes owed is for an amount in excess of amounts previously accrued, the Company’s operating results, cash flows and financial condition could be adversely affected.



We would be adversely affected if, either based on current law or in the event of a change in law, the Internal Revenue Service (“IRS”) did not agree that Allergan is a foreign corporation for U.S. federal tax purposes. In addition, future changes to international tax laws not specifically related to inversions could adversely affect us.

Allergan believes that, under current law, it is treated as a foreign corporation for U.S. federal tax purposes because it is an Irish incorporated entity. However, the IRS may assert that Allergan should be treated as a U.S. corporation for U.S. federal tax purposes pursuant to Section 7874 of the U.S. Internal Revenue Code. Under Section 7874, a corporation created or organized outside the United States (i.e., a foreign corporation) will be treated as a U.S. corporation for U.S. federal tax purposes when (i) the foreign corporation directly or indirectly acquires substantially all of the assets held directly or indirectly by a U.S. corporation (including the indirect acquisition of assets of the U.S. corporation by acquiring all the outstanding shares of the U.S. corporation), (ii) the shareholders of the acquired U.S. corporation hold at least 80% (by either vote or value) of the shares of the foreign acquiring corporation after the acquisition by reason of holding shares in the U.S. acquired corporation (including the receipt of the foreign corporation’s shares in exchange for the U.S. corporation’s shares) and (iii) the foreign corporation’s “expanded affiliated group” does not have substantial business activities in the foreign corporation’s country of organization or incorporation relative to such expanded affiliated group’s worldwide activities. For purposes of Section 7874, multiple acquisitions of U.S. corporations by a foreign corporation, if treated as part of a plan or series of related transactions, may be treated as a single acquisition. If multiple acquisitions of U.S. corporations are treated as a single acquisition, all shareholders of the acquired U.S. corporations would be aggregated for purposes of the test set forth above concerning such shareholders holding at least 80% (by either vote or value) of the shares of the foreign acquiring corporation after the acquisitions by reason of holding shares in the acquired U.S. corporations.

Allergan believes that the test set forth above to treat Allergan as a foreign corporation was satisfied in connection with the Warner Chilcott Acquisition, the Forest Acquisition and the Allergan Acquisition. However, the law and Treasury regulations promulgated under Section 7874 are somewhat unclear, and thus it cannot be assured that the IRS will agree that the ownership requirements to treat Allergan as a foreign corporation were met in the Warner Chilcott Acquisition, the Forest Acquisition and/or the Allergan Acquisition, and the IRS may assert that, even though the Allergan Acquisition is a separate transaction from the Warner Chilcott Acquisition and the Forest Acquisition, the Allergan Acquisition should be integrated with the Warner Chilcott Acquisition and the Forest Acquisition as a single transaction. In the event the IRS were to prevail with such assertion, Allergan would be treated as a U.S. corporation for U.S. federal tax purposes and significant adverse tax consequences would result for Allergan.

Even if Allergan is respected as a foreign corporation for U.S. federal tax purposes, Allergan might be adversely impacted by recent proposals that have aimed to make other changes in the taxation of multinational corporations. For example, the Organization for Economic Cooperation and Development has created an agreed set of international rules for fighting base erosion and profit shifting. As a result, the tax laws in the United States, Ireland and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect Allergan and its affiliates (including Allergan Inc. (“Legacy Allergan”) and its affiliates).

Foreign currency fluctuations could adversely affect our business and financial results.

We do business and generate sales in numerous countries outside the United States. The Company has also entered and will from time to time enter into acquisition, licensing, borrowing, hedging or other financial transactions that may give rise to currency and interest rate exposure. As such, foreign currency fluctuations may affect the costs that we incur in such international operations. Some of our operating expenses are incurred in non U.S. dollar currencies. The appreciation of non U.S. dollar currencies in those countries where we have operations against the U.S. dollar could increase our costs and could harm our results of operations and financial condition.

A failure of our internal control over financial reporting could materially impact our business or share price.

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. An internal control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all internal control systems, internal control over financial reporting may not prevent or detect misstatements. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud, and could expose us to litigation or adversely affect the market price of the Allergan plc Ordinary Shares.

For example, in the year ended December 31, 2016, management concluded that there was a material weakness in internal controls over financial reporting as it did not maintain effective controls to appropriately assess the tax implications of certain transactions between our subsidiaries. This control deficiency did not result in a material misstatement of our current or prior period

consolidated financial statements. However, this control deficiency could have resulted in a misstatement to the income tax accounts and disclosures, which would have resulted in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. Accordingly, management previously concluded that this control deficiency constituted a material weakness, which has since been remediated. See Item 9A—CONTROLS AND PROCEDURES.

We are incorporated in Ireland, and Irish law differs from the laws in effect in the United States and may afford less protection to, or otherwise adversely affect, our shareholders.

Our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction of the United States. As an Irish company, we are governed by the Irish Companies Act 2014 (the “Companies Act”). The Companies Act and other relevant aspects of Irish law differ in some material respects from laws generally applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, mergers, amalgamations and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. For example, under Irish law, the duties of directors and officers of a company are generally owed to the company only. As a result, shareholders of Irish companies do not have the right to bring an action against the directors or officers of a company, except in limited circumstances. In addition, depending on the circumstances, you may be subject to different or additional tax consequences under Irish law as a result of your acquisition, ownership and/or disposition of our ordinary shares, including, but not limited to, Irish stamp duty, dividend withholding tax and capital acquisitions tax.

As a result of different shareholder voting requirements in Ireland relative to laws in effect in certain states in the United States, we may have less flexibility with respect to certain aspects of capital management than companies organized in the United States.

Under Irish law, our authorized share capital can be increased by an ordinary resolution of our shareholders and the directors may issue new ordinary or preferred shares up to a maximum amount equal to the authorized but unissued share capital, without shareholder approval, once authorized to do so by our articles of association or by an ordinary resolution of our shareholders. Additionally, subject to specified exceptions, Irish law grants statutory preemption rights to existing shareholders where shares are being issued for cash consideration but allows shareholders to disapply such statutory preemption rights either in our articles of association or by way of special resolution. Such disapplication can either be generally applicable or be in respect of a particular allotment of shares. Accordingly, our articles of association contain, as permitted by Irish company law, provisions authorizing the board to issue new shares, and to disapply statutory preemption rights. The authorization of the directors to issue shares and the disapplication of statutory preemption rights is subject to approval by our shareholders annually, and we cannot provide any assurance that these authorizations will always be approved, which could limit our ability to issue equity and thereby adversely affect the holders of our securities.

We are an Irish company and it may be difficult for you to enforce judgments against us or certain of our officers and directors.

We are incorporated in Ireland and a substantial portion of our assets are located in jurisdictions outside the United States. In addition, some of our officers and directors reside outside the United States, and some or all of their respective assets are or may be located in jurisdictions outside of the United States. Therefore, it may be difficult for investors to effect service of process against us or such officers or directors or to enforce against us or them judgments of U.S. courts predicated upon civil liability provisions of the U.S. federal securities laws.

There is no treaty between Ireland and the United States providing for the reciprocal enforcement of foreign judgments. The following requirements must be met before the foreign judgment will be recognized and deemed

enforceable in Ireland:

- the judgment must be for a definite monetary sum;
- the judgment must be final and conclusive and the decree final and unalterable in the court which pronounces it; and
- the judgment must be provided by a court of competent jurisdiction.

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An Irish court will also refuse to recognize or enforce a foreign judgment obtained by fraud, or if to enforce the judgment would violate Irish public policy or breach natural or constitutional justice. Further, an Irish court may not recognize or enforce a judgment that is irreconcilable with an earlier judgment, and may stay recognition and enforcement proceedings, if concurrent proceedings are in being elsewhere. Further, as a matter of public policy, an Irish Court will not recognize or enforce foreign revenue, penal or other public laws, either directly or through the recognition and enforcement of a foreign judgment. Judgments of U.S. courts of liabilities predicated upon U.S. federal securities laws may not be recognized or enforced by Irish courts if deemed to be contrary to public policy in Ireland.

A transfer of our ordinary shares, other than by means of the transfer of book entry interests in the Depository Trust Company (“DTC”), may be subject to Irish stamp duty, as may a transfer of preference shares.

Transfers of our ordinary shares effected by means of the transfer of book entry interests in DTC will not be subject to Irish stamp duty. However, if you hold your ordinary shares directly rather than beneficially through DTC, any transfer of your ordinary shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. Transfers of preference shares, including our mandatory convertible preferred shares, may also be subject to Irish stamp duty at the same rate. The potential for stamp duty could adversely affect the price of your shares.

In certain limited circumstances, dividends we pay may be subject to Irish dividend withholding tax.

In certain limited circumstances, dividend withholding tax (currently at a rate of 20%) may arise in respect of any dividends paid on our ordinary shares. A number of exemptions from dividend withholding tax exist such that shareholders resident in the U.S. and shareholders resident in certain countries may be entitled to exemptions from dividend withholding tax.

Shareholders resident in the U.S. that hold their shares through DTC will not be subject to dividend withholding tax provided the addresses of the beneficial owners of such shares in the records of the brokers holding such shares are recorded as being in the U.S. (and such brokers have further transmitted the relevant information to a qualifying intermediary appointed by us). U.S. resident shareholders in Allergan that hold their shares outside of DTC and shareholders resident in certain other countries (irrespective of whether they hold their shares through DTC or outside DTC) will not be subject to dividend withholding tax provided the beneficial owners of such shares have furnished completed and valid dividend withholding tax forms or an IRS Form 6166, as appropriate, to our transfer agent or their brokers (and such brokers have further transmitted the relevant information to our transfer agent). However, other shareholders may be subject to dividend withholding tax, which could adversely affect the price of your shares.

Dividends received by Irish residents and certain other shareholders may be subject to Irish income tax.

Shareholders entitled to an exemption from Irish dividend withholding tax on dividends received from us will not be subject to Irish income tax in respect of those dividends, unless they have some connection with Ireland other than their shareholding in us (for example, they are resident in Ireland). Shareholders who are not resident nor ordinarily resident in Ireland but who are not entitled to an exemption from Irish dividend withholding tax will generally have no further liability to Irish income tax on those dividends which suffer dividend withholding tax.

Allergan’s Ordinary Shares received by means of a gift or inheritance could be subject to Irish capital acquisitions tax.

Irish capital acquisitions tax (“CAT”) could apply to a gift or inheritance of ordinary shares, irrespective of the place of residence, ordinary residence or domicile of the parties. This is because Company Ordinary Shares are regarded as property situated in Ireland. The person who receives the gift or inheritance has primary liability for CAT. Gifts and inheritances passing between spouses are exempt from CAT. Children have a tax-free threshold of €320,000 in respect of taxable gifts or inheritances received from their parents. Certain other tax-free thresholds may also apply.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

There are no unresolved staff comments.

**ITEM 2. PROPERTIES**

We conduct our operations using a combination of owned and leased properties.

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Our owned and leased properties consist of facilities used for R&D, manufacturing, distribution (including warehousing and storage), sales and marketing and administrative functions and relate to our US Specialized Therapeutics, US General Medicine and International segments. The following table provides a summary of locations for our significant owned and leased properties as of December 31, 2018:

Location	Primary Use	Leased / Owned
Austin, TX, USA	Administration	Leased
Branchburg, NJ, USA	Manufacturing	Leased
Bridgewater, NJ, USA	R&D	Leased
Campbell, CA, USA	Manufacturing	Owned
Cincinnati, OH, USA	Manufacturing	Owned
Clonsaugh, Ireland	Manufacturing	Owned
Dublin, CA, USA	Manufacturing	Leased
Galway, Ireland	Manufacturing	Leased
Guarulhos, Brazil	Manufacturing	Owned
Heredia, Costa Rica	Manufacturing	Owned
Houston, TX, USA	Manufacturing	Owned
Irvine, CA, USA	R&D	Owned
Liege, Belgium	Manufacturing	Leased
Liverpool, United Kingdom	R&D	Leased
Madison, NJ, USA	Administration	Leased
Marlow, UK	Administration	Leased
Pleasanton, CA, USA	Administration	Leased
Pringy, France	Manufacturing	Owned
Sunrise, FL, USA	R&D	Leased
Waco, TX, USA	Manufacturing	Owned
Westport, Ireland	Manufacturing	Owned

Our leased properties are subject to various lease terms and expirations.

We believe that we have sufficient facilities to conduct our operations during 2019. However, we continue to evaluate the purchase or lease of additional properties, or the consolidation of existing properties, as our business requires.

### ITEM 3. LEGAL PROCEEDINGS

For information regarding legal proceedings, refer to Legal Matters in “NOTE 25 — Commitments and Contingencies” in the accompanying “Notes to the Consolidated Financial Statements” in this Annual Report.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.





## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

## Market for Registrant's Common Equity

Allergan plc Ordinary Shares are traded on the New York Stock Exchange under the symbol "AGN." The following table sets forth the quarterly high and low closing share trading price information for the periods indicated:

Year Ended December 31, 2018	High	Low
First	\$188.15	\$144.02
Second	\$175.19	\$143.80
Third	\$192.51	\$167.21
Fourth	\$193.46	\$129.82

  

Year Ended December 31, 2017	High	Low
First	\$249.32	\$210.80
Second	\$248.91	\$218.73
Third	\$256.15	\$202.66
Fourth	\$210.98	\$163.58

As of February 8, 2019, there were approximately 3,176 registered holders of Allergan plc's Ordinary Shares.

We have paid cash dividends on ordinary shares quarterly beginning with the 2017 fiscal year.

The Company paid a quarterly dividend on shares of its mandatory convertible preferred shares, which were converted to ordinary shares on March 1, 2018.

Warner Chilcott Limited is a wholly-owned subsidiary of Allergan and has no publicly traded equity securities.

## Issuer Purchases of Equity Securities

During the quarter ended December 31, 2018, we repurchased 32,168 of Allergan plc's Ordinary Shares to satisfy tax withholding obligations in connection with the vesting of restricted stock issued to employees and directors. On July 26, 2018, the Company's Board of Directors approved a \$2.0 billion share repurchase program, of which we repurchased \$1,200.2 million of our Ordinary Shares in the year ended December 31, 2018.

On January 29, 2019, the Company announced that its Board of Directors approved a separate \$2.0 billion share repurchase program.

Period	Total Number of Shares Purchased	Total Number of Shares Purchased to Satisfy Tax Withholdings	Average Price Paid per Share	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Share Repurchase Program (\$ in millions)		
				Total Number of Shares Purchased as Part of Repurchase Program	Average Price Paid per Share as Part of Repurchase Program	Total Dollar Value of Shares that May Yet Be Purchased Under the Share Repurchase Program (\$ in millions)
October 1 - 31, 2018	399,200	3,249	\$179.91	395,951	\$ 159.40	\$ 1,486.9
November 1 - 30, 2018	3,301,163	2,303	\$162.78	3,298,860	\$ 162.82	\$ 949.8
December 1 - 31, 2018	1,154,562	26,616	\$134.05	1,127,946	\$ 132.99	\$ 799.8
October 1 - December 31, 2018	4,854,925	32,168	\$140.74	4,822,757	\$ 155.56	

## Securities Authorized for Issuance Under Equity Compensation Plans

For information regarding securities authorized for issuance under equity compensation plans, refer to “ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS” and “NOTE 20 — Shareholders’ Equity” in the accompanying “Notes to the Consolidated Financial Statements” in this Annual Report.

## Performance Graph

The information in this section of the Annual Report pertaining to Allergan plc’s performance relative to our peers is being furnished but not filed with the SEC, and as such, the information is neither subject to Regulation 14A or 14C or to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended.

Notwithstanding anything to the contrary set forth in our previous filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, which might incorporate future filings made by us under those statutes, the following graph will not be deemed incorporated by reference into any future filings made by us under those statutes.

The following graph compares the cumulative 5-year total return of holders of Allergan plc’s Ordinary Shares (formerly Class A common shares of Actavis plc) with the cumulative total returns of the S&P 500 index and the Dow Jones U.S. Pharmaceuticals index. The graph tracks the performance of a \$100 investment in our Ordinary Shares and in each of the indexes (with reinvestment of all dividends, if any) on December 31, 2013 with relative performance tracked through December 31, 2018.

	12/13	12/14	12/15	12/16	12/17	12/18
Allergan plc	\$100.00	\$153.22	\$186.01	\$125.01	\$98.65	\$82.00
S&P 500	\$100.00	\$113.69	\$115.26	\$129.05	\$157.22	\$150.33
Dow Jones US Pharmaceuticals	\$100.00	\$121.41	\$128.94	\$126.14	\$141.33	\$153.17

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

## ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth our selected historical consolidated financial data. The selected consolidated financial data as of December 31, 2018 and 2017 and for the years ended December 31, 2018, 2017, and 2016 presented in this table have been derived from our audited consolidated financial statements and related notes included elsewhere in this Annual Report. The selected consolidated financial data as of December 31, 2016, 2015, and 2014 and for the years ended December 31, 2015 and 2014 presented in this table are derived from our audited consolidated financial statements and related notes which are not included in this Annual Report.

The selected consolidated financial data set forth below should be read in conjunction with, and is qualified by reference to, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the Notes to the Consolidated Financial Statements included elsewhere in this Annual Report and in our previously filed Annual Reports on Form 10-K, as amended by Form 8-K, where applicable.

## ALLERGAN PLC

## FINANCIAL HIGHLIGHTS

(\$ in millions, except per share amounts)

	Years Ended December 31,				
	2018 <sup>(1)(2)(3)</sup>	2017 <sup>(4)(5)(6)(7)</sup>	2016 <sup>(10)(11)(12)</sup>	2015 <sup>(11)(12)(14)</sup>	2014 <sup>(11)(12)(15)</sup>
<b>Operating Highlights:</b>					
Net revenues	\$ 15,787.4	\$ 15,940.7	\$ 14,570.6	\$ 12,688.1	\$ 4,676.5
Net (loss) from continuing operations, net of tax	(5,086.2 )	(3,716.0 )	(935.0 )	(2,941.6 )	(2,484.6 )
Net (loss) / income attributable to ordinary shareholders	(5,142.8 )	(4,403.9 )	14,695.0	3,683.2	(1,630.5 )
Basic (loss) / earnings per share from continuing operations	\$(15.26 )	\$(11.99 )	\$(3.17 )	\$(8.64 )	\$(11.31 )
Diluted (loss) / earnings per share from continuing operations	\$(15.26 )	\$(11.99 )	\$(3.17 )	\$(8.64 )	\$(11.31 )
Basic (loss) / earnings per share	\$(15.26 )	\$(13.19 )	\$ 38.18	\$ 10.01	\$(7.42 )
Diluted (loss) / earnings per share	\$(15.26 )	\$(13.19 )	\$ 38.18	\$ 10.01	\$(7.42 )
<b>Weighted average ordinary shares outstanding:</b>					
Basic	337.0	333.8	384.9	367.8	219.7
Diluted	337.0	333.8	384.9	367.8	219.7

	At December 31,				
	2018 <sup>(1)(2)(3)</sup>	2017 <sup>(4)(5)(6)(7)</sup>	2016 <sup>(8)(9)(10)(11)(12)</sup>	2015 <sup>(11)(12)(13)(14)</sup>	2014 <sup>(11)(12)(15)</sup>
<b>Balance Sheet Highlights:</b>					
Total assets	\$ 101,787.6	\$ 118,341.9	\$ 128,986.3	\$ 135,583.3	\$ 52,758.0
Total debt and capital leases	23,797.7	30,075.3	32,768.7	42,530.4	15,531.1
Total equity	65,131.0	73,837.1	76,200.5	76,589.3	28,335.5

<sup>(1)</sup>In the year ended December 31, 2018, the Company recorded impairment charges relating to its General Medicine Reporting Unit goodwill of \$2.8 billion, an impairment of \$771.7 million as a result of holding its Anti-Infectives business for sale, currently marketed intangibles assets of \$1,831.4 million, including its Kybella®/Belkyra® asset

of \$1,643.8 million and IPR&D assets of \$804.6 million, including \$522.0 million relating to RORyt.

- (2) On September 20, 2018, the Company completed the sale of five medical dermatology products in the U.S. to Almirall, S.A. As part of the sale, the Company received cash consideration of \$550.0 million and recorded a net gain of \$129.6 million included as a component of “other income / (expense), net”.
- (3) In the year ended December 31, 2018, the Company repurchased \$2.74 billion or 16,772,162 shares as a result of the Company’s share repurchase programs.
- (4) On April 28, 2017, Allergan plc completed the Zeltiq Acquisition for \$2.4 billion through which it acquired Zeltiq’s body contouring business.
- (5) On February 1, 2017, Allergan plc completed the LifeCell Acquisition for \$2.9 billion through which it acquired LifeCell’s regenerative medicines business.
- (6) In the year ended December 31, 2017, the Company recognized intangible impairments including, but not limited to, \$3,230.0 million related to Restasis<sup>®</sup>, \$170.0 million related to Dry Eye IPR&D assets, and \$646.0 million related to Aczone<sup>®</sup>.

- (7) In the year ended December 31, 2017, the Company retired 6,822,394 shares as a result of the Company's share buyback programs.
- (8) On November 1, 2016, Allergan plc completed the Tobira Acquisition. The acquisition increased the Company's intangible assets with the addition of Cenicriviroc.
- (9) On October 25, 2016, Allergan plc completed the Vitae Acquisition. The acquisition increased the Company's intangible assets with the addition of RORyt.
- (10) In the year ended December 31, 2016, the Company retired 61,620,459 shares as a result of the Company's \$15.0 billion share buyback programs.
- (11) On October 3, 2016, we completed the divestiture of the Anda Distribution business to Teva for \$0.5 billion.
- (12) On August 2, 2016, Teva acquired our global generics business for \$38.3 billion of cash and Teva shares.
- (13) On October 1, 2015, Allergan plc completed the acquisition of Kythera Biopharmaceuticals, Inc. The acquisition increased the Company's intangible assets with the addition of Kybella® / Belkyra®.
- (14) On March 17, 2015, Allergan plc completed the acquisition of Allergan, Inc. ("Legacy Allergan") for approximately \$77.0 billion (the "Allergan Acquisition").
- (15) On July 1, 2014, the Company completed the acquisition of Forest Laboratories, Inc. for \$30.9 billion including outstanding indebtedness assumed of \$3.3 billion, equity consideration of \$20.6 billion, and cash consideration of \$7.1 billion (the "Forest Acquisition").

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion contains forward-looking statements that are subject to known and unknown risks, uncertainties and other factors that may cause actual results to differ materially from those expressed or implied by such forward-looking statements. We discuss such risks, uncertainties and other factors throughout this report and specifically under the caption "Cautionary Note Regarding Forward-Looking Statements" under "ITEM 1A. RISK FACTORS" in this document. In addition, the following discussion of financial condition and results of operations should be read in conjunction with the Consolidated Financial Statements and Notes thereto included elsewhere in this document.

The results of Warner Chilcott Limited are consolidated into the results of Allergan plc. Due to the de minimis activity between Allergan plc and Warner Chilcott Limited, references throughout this section relate to both Allergan plc and Warner Chilcott Limited.

### EXECUTIVE SUMMARY

#### Overview

Allergan plc is a global pharmaceutical leader. Allergan is focused on developing, manufacturing and commercializing branded pharmaceutical, device, biologic, surgical and regenerative medicine products for patients around the world. Allergan markets a portfolio of leading brands and best-in-class products primarily focused on four key therapeutic areas including medical aesthetics, eye care, central nervous system and gastroenterology. Allergan is an industry leader in Open Science, a model of research and development, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. The Company has operations in more than 100 countries. Warner Chilcott Limited is an indirect wholly-owned subsidiary of Allergan plc and has the same principal business activities.

#### Discontinued Operations

On August 2, 2016 we completed the Teva Transaction for \$38.3 billion of cash and Teva shares. On October 3, 2016, the Company completed the divestiture of the Anda Distribution business to Teva for \$500.0 million. The Company recognized a combined gain on the sale of the Anda Distribution business and the Teva Transaction of \$15,932.2 million in the year ended December 31, 2016.

In October 2016, pursuant to our agreement with Teva, Teva provided the Company with its proposed estimated adjustment to the closing date working capital balance. The Company disagreed with Teva's proposed adjustment, and, pursuant to our agreement with Teva, each of the Company's and Teva's proposed adjustments were submitted to arbitration (the "Working Capital Arbitration") to determine the working capital amount in accordance with GAAP as applied by the Company consistent with past practice. On January 31, 2018, Allergan plc and Teva entered into an agreement pursuant to which the Company made a one-time payment of \$700.0 million to Teva. As a result, the Company recorded a pre-tax charge of \$466.0 million as a component of other (expense) / income, net from discontinued operations relating to the settlement in the year ended December 31, 2017. The one-time payment of \$700.0 million, which represents a refund of purchase price, is shown in the Consolidated Statement of Cash Flows as both a cash outflow in investing activities of \$466.0 million and a cash outflow in financing cash flows of \$234.0 million for the portion of the payment which was outstanding greater than one year in the year ended December 31, 2018.

As a result of the Teva Transaction and the divestiture of the Company's Anda Distribution business, and in accordance with FASB ASU No. 2014-08 "Presentation of Financial Statements (Topic 205) and Property, Plant and



Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity”, the financial results of the businesses held for sale were reclassified to discontinued operations for all periods presented in our consolidated financial statements. The results of our discontinued operations include the results of our generic product development, manufacturing and distribution of off-patent pharmaceutical products, certain established international brands marketed similarly to generic products and out-licensed generic pharmaceutical products primarily in Europe through our Medis third-party business through August 2, 2016, as well as our Anda Distribution business through October 3, 2016.

## Significant Business Developments

Refer to the Business Development section in ITEM 1. BUSINESS for the significant transactions that were completed or announced in the years ended December 31, 2018, 2017 and 2016.

## Segments

The Company's businesses are organized into the following segments: US Specialized Therapeutics, US General Medicine and International. In addition, certain revenues and shared costs, and the results of corporate initiatives, are managed outside of the three segments.

The operating segments are organized as follows:

- The US Specialized Therapeutics segment includes sales and expenses relating to branded products within the U.S., including Medical Aesthetics, Medical Dermatology through September 20, 2018, Eye Care, and Neuroscience and Urology therapeutic products.
- The US General Medicine segment includes sales and expenses relating to branded products within the U.S. that do not fall into the US Specialized Therapeutics business units, including Central Nervous System, Gastrointestinal, Women's Health, Anti-Infectives and Diversified Brands.
  - The International segment includes sales and expenses relating to products sold outside the U.S.

The Company evaluates segment performance based on segment contribution. Segment contribution for our segments represents net revenues less cost of sales (defined below), selling and marketing expenses, and select general and administrative expenses. Included in segment revenues for 2016 are product sales that were sold through our former Anda Distribution business once the Anda Distribution business had sold the product to a third-party customer. These sales are included in segment results and are reclassified into revenues from discontinued operations through a reduction of Corporate revenues which eliminates the sales made by our former Anda Distribution business through October 3, 2016 from results of continuing operations. Cost of sales for these products in discontinued operations is equal to our average third-party cost of sales for third party branded products distributed by our former Anda Distribution business. The Company does not evaluate the following items at the segment level:

- Revenues and operating expenses within cost of sales, selling and marketing expenses, and general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, divestitures, acquisitions, certain milestones and other shared costs.
- General and administrative expenses that result from shared infrastructure, including certain expenses located within the United States.
- Other select revenues and operating expenses including R&D expenses, amortization, IPR&D impairments, goodwill impairments and asset sales and impairments, net as not all such information has been accounted for at the segment level, or such information has not been used by all segments.
- Total assets including capital expenditures.

The Company defines segment net revenues as product sales and other revenue derived from our products or licensing agreements.

Cost of sales within segment contribution includes standard production and packaging costs for the products we manufacture, third party acquisition costs for products manufactured by others, profit-sharing or royalty payments for products sold pursuant to licensing agreements and finished goods inventory reserve charges. Cost of sales within segment contribution excludes non-standard production costs, such as non-finished goods inventory obsolescence charges, manufacturing variances and excess capacity utilization charges, where applicable. Cost of sales does not include amortization or impairment costs for acquired product rights or other acquired intangibles.

Selling and marketing expenses consist mainly of personnel-related costs, product promotion costs, distribution costs, professional service costs, insurance, depreciation and travel costs.

General and administrative expenses consist mainly of personnel-related costs, facilities costs, transaction costs, insurance, depreciation, litigation costs and professional services costs which are general in nature and attributable to the segment.

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## Operating Results for the Years Ended December 31, 2018, 2017 and 2016

Results of operations, including segment net revenues, segment operating expenses and segment contribution consisted of the following for the years ended December 31, 2018, 2017 and 2016 (\$ in millions):

	Year Ended December 31, 2018			
	US			
	Specialized Therapeutics	US General Medicine	International	Total
Net revenues	\$6,920.3	\$ 5,322.9	\$ 3,504.7	\$15,747.9
Operating expenses:				
Cost of sales <sup>(1)</sup>	565.2	799.1	537.1	1,901.4
Selling and marketing	1,348.3	924.6	928.7	3,201.6
General and administrative	205.3	156.4	141.7	503.4
Segment contribution	\$4,801.5	\$ 3,442.8	\$ 1,897.2	\$10,141.5
Contribution margin	69.4	% 64.7	% 54.1	% 64.4
Corporate <sup>(2)</sup>				1,067.3
Research and development				2,266.2
Amortization				6,552.3
Goodwill impairments				2,841.1
In-process research and development impairments				804.6
Asset sales and impairments, net				2,857.6
Operating (loss)				\$(6,247.6)
Operating margin				(39.7)%

(1) Excludes amortization and impairment of acquired intangibles including products rights, as well as indirect cost of sales not attributable to segment results.

(2) Corporate includes net revenues of \$39.5 million.

	Year Ended December 31, 2017			
	US			
	Specialized Therapeutics	US General Medicine	International	Total
Net revenues	\$6,803.6	\$ 5,796.2	\$ 3,319.5	\$15,919.3
Operating expenses:				
Cost of sales <sup>(1)</sup>	495.4	843.9	478.7	1,818.0
Selling and marketing	1,369.5	1,084.1	913.8	3,367.4
General and administrative	208.2	177.3	120.6	506.1
Segment contribution	\$4,730.5	\$ 3,690.9	\$ 1,806.4	\$10,227.8
Contribution margin	69.5	% 63.7	% 54.4	% 64.2
Corporate <sup>(2)</sup>				1,471.8
Research and development				2,100.1
Amortization				7,197.1
In-process research and development impairments				1,452.3

Asset sales and impairments, net	3,927.7
Operating (loss)	\$(5,921.2 )
Operating margin	(37.2 )%

(1) Excludes amortization and impairment of acquired intangibles including products rights, as well as indirect cost of sales not attributable to segment results.

(2) Corporate includes net revenues of \$21.4 million.

	Year Ended December 31, 2016			
	US			
	Specialized Therapeutics	US General Medicine	International	Total
Net revenues	\$5,811.7	\$ 5,923.9	\$ 2,881.3	\$14,616.9
Operating expenses:				
Cost of sales <sup>(1)</sup>	290.9	879.8	418.2	1,588.9
Selling and marketing	1,137.0	1,185.7	788.2	3,110.9
General and administrative	174.2	174.9	117.2	466.3
Segment contribution	\$4,209.6	\$ 3,683.5	\$ 1,557.7	\$9,450.8
Contribution margin	72.4 %	62.2 %	54.1 %	64.7 %
Corporate <sup>(2)</sup>				1,481.3
Research and development				2,575.7
Amortization				6,470.4
In-process research and development impairments				743.9
Asset sales and impairments, net				5.0
Operating (loss)				\$(1,825.5 )
Operating margin				(12.5 )%

<sup>(1)</sup> Excludes amortization and impairment of acquired intangibles including products rights, as well as indirect cost of sales not attributable to segment results.

<sup>(2)</sup> Corporate includes net revenues of \$(46.3) million, which includes a reduction of \$(80.0) million for revenues that were included in the segment results and reclassified into revenues from discontinued operations as a reduction of Corporate revenues for sales through our former Anda Distribution business.

No country outside of the United States represents ten percent or more of net revenues. The US Specialized Therapeutics and US General Medicine segments are comprised solely of sales within the United States.

## US Specialized Therapeutics Segment

The following table presents top product sales and net contribution for the US Specialized Therapeutics segment for the years ended December 31, 2018, 2017 and 2016 (\$ in millions):

	Years Ended December 31,			2018 vs 2017		2017 vs 2016	
	2018	2017	2016 <sup>(1)</sup>	\$	%	\$	%
Total Eye Care	\$2,235.7	\$2,460.2	\$2,437.7	\$(224.5)	(9.1)%	\$22.5	0.9%
Restasis <sup>®</sup>	1,197.0	1,412.3	1,419.5	(215.3)	(15.2)%	(7.2)	(0.5)%
Alphagan <sup>®</sup> /Combigan <sup>®</sup>	375.4	377.3	376.6	(1.9)	(0.5)%	0.7	0.2%
Lumigan <sup>®</sup> /Ganfort <sup>®</sup>	291.8	317.5	326.4	(25.7)	(8.1)%	(8.9)	(2.7)%
Eye Drops	202.7	199.5	186.5	3.2	1.6%	13.0	7.0%
Ozurdex <sup>®</sup>	111.0	98.4	84.4	12.6	12.8%	14.0	16.6%
Other Eye Care	57.8	55.2	44.3	2.6	4.7%	10.9	24.6%
Total Medical Aesthetics	2,774.6	2,449.2	1,622.9	325.4	13.3%	826.3	50.9%
Facial Aesthetics	1,487.3	1,362.8	1,226.3	124.5	9.1%	136.5	11.1%
Botox <sup>®</sup> Cosmetics	907.3	812.2	729.2	95.1	11.7%	83.0	11.4%
Juvederm <sup>®</sup> Collection	548.2	501.1	446.9	47.1	9.4%	54.2	12.1%
Kybella <sup>®</sup>	31.8	49.5	50.2	(17.7)	(35.8)%	(0.7)	(1.4)%
Plastic Surgery	263.0	242.6	210.4	20.4	8.4%	32.2	15.3%
Breast Implants	263.0	242.6	206.0	20.4	8.4%	36.6	17.8%
Other Plastic Surgery	-	-	4.4	-	n.a.	(4.4)	(100.0)%
Regenerative Medicine	523.9	433.9	-	90.0	20.7%	433.9	n.a.
Alloderm <sup>®</sup>	407.3	321.2	-	86.1	26.8%	321.2	n.a.
Other Regenerative Medicine	116.6	112.7	-	3.9	3.5%	112.7	n.a.
Body Contouring	361.6	256.7	-	104.9	40.9%	256.7	n.a.
Coolsculpting <sup>®</sup> Consumables	235.3	150.1	-	85.2	56.8%	150.1	n.a.
Coolsculpting <sup>®</sup> Systems & Add On							
Applicators	126.3	106.6	-	19.7	18.5%	106.6	n.a.
Skin Care <sup>(5)</sup>	138.8	153.2	186.2	(14.4)	(9.4)%	(33.0)	(17.7)%
Total Medical Dermatology	115.5	273.6	331.3	(158.1)	(57.8)%	(57.7)	(17.4)%
Aczone <sup>®</sup>	55.1	166.3	217.3	(111.2)	(66.9)%	(51.0)	(23.5)%
Tazorac <sup>®</sup>	25.4	65.4	95.5	(40.0)	(61.2)%	(30.1)	(31.5)%
Other Medical Dermatology	35.0	41.9	18.5	(6.9)	(16.5)%	23.4	n.m.
Total Neuroscience and Urology	1,720.4	1,550.3	1,371.5	170.1	11.0%	178.8	13.0%
Botox <sup>®</sup> Therapeutics <sup>(4)</sup>	1,638.5	1,442.2	1,254.0	196.3	13.6%	188.2	15.0%
Rapaflo <sup>®</sup>	81.9	108.1	116.6	(26.2)	(24.2)%	(8.5)	(7.3)%
Other Neuroscience and Urology	-	-	0.9	-	n.a.	(0.9)	(100.0)%
Other revenues	74.1	70.3	48.3	3.8	5.4%	22.0	45.5%
Net revenues	\$6,920.3	\$6,803.6	\$5,811.7	\$116.7	1.7%	\$991.9	17.1%
Operating expenses:							
Cost of sales <sup>(2)</sup>	565.2	495.4	290.9	69.8	14.1%	204.5	70.3%
Selling and marketing	1,348.3	1,369.5	1,137.0	(21.2)	(1.5)%	232.5	20.4%
General and administrative	205.3	208.2	174.2	(2.9)	(1.4)%	34.0	19.5%

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Segment contribution	\$4,801.5	\$4,730.5	\$4,209.6	\$71.0	1.5	%	\$520.9	12.4	%	
Segment margin	69.4	%	69.5	%	72.4	%	(0.1)	)%	(2.9)	)%
Segment gross margin <sup>(3)</sup>	91.8	%	92.7	%	95.0	%	(0.9)	)%	(2.3)	)%

(1) Includes revenues earned that were distributed through our former Anda Distribution business to third party customers.

(2) Excludes amortization and impairment of acquired intangibles including product rights, as well as indirect cost of sales not attributable to segment results.

(3) Defined as net revenues less segment related cost of sales as a percentage of net revenues.

(4) Includes Botox<sup>®</sup> Hyperhidrosis of \$67.2 million and \$65.2 million which was previously disclosed under Medical Dermatology in the years ended December 31, 2017 and 2016, respectively.

(5) Includes SkinMedica<sup>®</sup> and Latisse<sup>®</sup>.



The Zeltiq Acquisition and LifeCell Acquisition contributed the following to the segment in the years ended December 31, 2018 and 2017 (\$ in millions):

	Year Ended December 31, 2018			Year Ended December 31, 2017		
	LifeCell	Zeltiq	Combined	LifeCell	Zeltiq	Combined
Net revenues	\$526.1	\$361.7	\$ 887.8	\$436.0	\$256.8	\$ 692.8
Operating expenses:						
Cost of sales	112.6	101.0	213.6	107.5	70.7	178.2
Selling and marketing	112.3	159.7	272.0	97.8	96.1	193.9
General and administrative	10.6	7.2	17.8	11.4	10.7	22.1

## Net Revenues

### Years Ended December 31, 2018 and 2017

The increase in net revenues in the year ended December 31, 2018 was primarily driven by the Zeltiq Acquisition and the LifeCell Acquisition and growth in Botox<sup>®</sup> Therapeutics and Botox<sup>®</sup> Cosmetics, partially offset by decreases in Restasis<sup>®</sup> and the divestiture of our Medical Dermatology business. Botox<sup>®</sup> Therapeutics and Botox<sup>®</sup> Cosmetics increased versus the prior year period primarily driven by demand growth. The decline in Restasis<sup>®</sup> revenues was due to both price declines and volume declines as a result of changes in promotional efforts ahead of an anticipated launch of a generic. As a result of the U.S. District Court for the Eastern District of Texas issuing an adverse trial decision finding that the four asserted patents covering Restasis<sup>®</sup> (Cyclosporine Ophthalmic Emulsion) 0.05% are invalid, there is a potential risk for future declines in Restasis<sup>®</sup> revenues. The decline in Aczone<sup>®</sup> revenues prior to divestiture was due to genericization of the branded acne market, increased discounts to maintain formulary access and a generic launch of Aczone 5%.

### Years Ended December 31, 2017 and 2016

The increase in net revenues in the year ended December 31, 2017 was primarily driven by growth in Botox<sup>®</sup> Therapeutics, Facial Aesthetics and the LifeCell Acquisition and Zeltiq Acquisition. Botox<sup>®</sup> Therapeutics increased versus the prior year period driven by demand growth. The increase in Facial Aesthetics revenues was driven, in part, by Botox<sup>®</sup> Cosmetics primarily due to demand growth. Also contributing was an increase in Juvederm<sup>®</sup> Collection revenues primarily due to demand and an increase in market share, offset, in part, by an increase in discounts. The decline in Aczone revenues was due to genericization of the branded acne market.

## Cost of Sales

### Years Ended December 31, 2018 and 2017

The decrease in segment gross margin was due in part to the Zeltiq Acquisition and the LifeCell Acquisition. Excluding Zeltiq Acquisition and the LifeCell Acquisition in both periods, segment gross margin decreased to 94.2% in the year ended December 31, 2018 versus 94.8% in the prior year period primarily due to product mix, including a decline in Restasis<sup>®</sup> sales.

Years Ended December 31, 2017 and 2016

The decrease in segment gross margin was primarily the result of the LifeCell Acquisition and the Zeltiq Acquisition, which contributed lower margin products to the segment. Excluding the LifeCell Acquisition and the Zeltiq Acquisition, segment gross margin was 94.8% in the year ended December 31, 2017, in line with 95.0% in the prior year period.

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## Selling and Marketing Expenses

Years Ended December 31, 2018 and 2017

The decrease in selling and marketing expenses in the year ended December 31, 2018 was primarily related to lower headcount in the Eye Care and Medical Dermatology field forces due to the Company's restructuring initiatives, lower promotional costs and a decrease in the charge for the non-tax deductible Branded Prescription Drug Fee, offset in part by the impact of the Zeltiq Acquisition and the LifeCell Acquisition.

Years Ended December 31, 2017 and 2016

The increase in selling and marketing expenses was primarily related to increased costs from the LifeCell Acquisition and the Zeltiq Acquisition of \$193.9 million as well as increased promotional costs for Rhofade<sup>®</sup> and Xen.

## General and Administrative Expenses

Years Ended December 31, 2018 and 2017

General and administrative expenses remained stable period over period.

Years Ended December 31, 2017 and 2016

The increase in general and administrative expenses was primarily due to the LifeCell Acquisition and Zeltiq Acquisition and additional bad debt write-offs of \$7.9 million.

## US General Medicine Segment

The following table presents top product sales and net contribution for the US General Medicine segment for the years ended December 31, 2018, 2017 and 2016 (\$ in millions):

	Years Ended December 31,			2018 vs 2017		2017 vs 2016			
	2018	2017	2016 <sup>(1)</sup>	\$	%	\$	%		
Total Central Nervous System (CNS)	\$1,156.0	\$1,359.9	\$1,303.6	\$(203.9)	(15.0)%	\$56.3	4.3	%	
Vraylar <sup>®</sup>	487.1	287.8	94.3	199.3	69.2%	193.5	n.m.		
Viibryd <sup>®</sup> /Fetzima <sup>®</sup>	342.4	333.2	342.3	9.2	2.8%	(9.1)	(2.7)	%	
Saphris <sup>®</sup>	139.7	155.2	166.8	(15.5)	(10.0)%	(11.6)	(7.0)	%	
Namzaric <sup>®</sup>	115.8	130.8	57.5	(15.0)	(11.5)%	73.3	n.m.		
Namenda <sup>®</sup> (4)	71.0	452.9	642.7	(381.9)	(84.3)%	(189.8)	(29.5)	%	
Total Gastrointestinal (GI)	1,723.7	1,695.0	1,721.0	28.7	1.7%	(26.0)	(1.5)	%	
Linzess <sup>®</sup>	761.1	701.1	625.6	60.0	8.6%	75.5	12.1	%	
Zenpep <sup>®</sup>	237.3	212.3	200.7	25.0	11.8%	11.6	5.8	%	
Carafate <sup>®</sup> /Sulcrate <sup>®</sup>	217.8	235.8	229.0	(18.0)	(7.6)%	6.8	3.0	%	
Viberzi <sup>®</sup>	176.5	156.6	93.3	19.9	12.7%	63.3	67.8	%	
Canasa <sup>®</sup> /Salofalk <sup>®</sup>	169.2	162.7	178.7	6.5	4.0%	(16.0)	(9.0)	%	
Asacol <sup>®</sup> /Delzicol <sup>®</sup>	130.8	195.5	360.8	(64.7)	(33.1)%	(165.3)	(45.8)	%	
Other GI	31.0	31.0	32.9	-	0.0%	(1.9)	(5.8)	%	
Total Women's Health	786.8	1,044.2	1,179.6	(257.4)	(24.7)%	(135.4)	(11.5)	%	
Lo Loestrin <sup>®</sup>	527.7	459.3	403.5	68.4	14.9%	55.8	13.8	%	
Liletta <sup>®</sup>	50.9	37.6	23.3	13.3	35.4%	14.3	61.4	%	
Estrace <sup>®</sup> Cream	49.0	366.6	379.4	(317.6)	(86.6)%	(12.8)	(3.4)	%	
Minastrin <sup>®</sup> 24	9.5	61.4	325.9	(51.9)	(84.5)%	(264.5)	(81.2)	%	
Other Women's Health	149.7	119.3	47.5	30.4	25.5%	71.8	n.m.		
Total Anti-Infectives	304.4	257.3	225.1	47.1	18.3%	32.2	14.3	%	
Teflaro <sup>®</sup>	128.0	121.9	133.6	6.1	5.0%	(11.7)	(8.8)	%	
Avycaz <sup>®</sup>	94.6	61.2	36.1	33.4	54.6%	25.1	69.5	%	
Dalvance <sup>®</sup>	56.1	53.9	39.3	2.2	4.1%	14.6	37.2	%	
Other Anti-Infectives	25.7	20.3	16.1	5.4	26.6%	4.2	26.1	%	
Diversified Brands	1,156.0	1,242.6	1,366.6	(86.6)	(7.0)%	(124.0)	(9.1)	%	
Bystolic <sup>®</sup> / Byvalson <sup>®</sup>	583.8	612.2	638.8	(28.4)	(4.6)%	(26.6)	(4.2)	%	
Armour Thyroid	198.8	169.1	166.5	29.7	17.6%	2.6	1.6	%	
Savella <sup>®</sup>	85.0	98.2	103.2	(13.2)	(13.4)%	(5.0)	(4.8)	%	
Other Diversified Brands <sup>(5)(6)(7)</sup>	288.4	363.1	458.1	(74.7)	(20.6)%	(95.0)	(20.7)	%	
Other revenues	196.0	197.2	128.0	(1.2)	(0.6)%	69.2	54.1	%	
Net revenues	\$5,322.9	\$5,796.2	\$5,923.9	\$(473.3)	(8.2)%	\$(127.7)	(2.2)	%	
Operating expenses:									
Cost of sales <sup>(2)</sup>	799.1	843.9	879.8	(44.8)	(5.3)%	(35.9)	(4.1)	%	
Selling and marketing	924.6	1,084.1	1,185.7	(159.5)	(14.7)%	(101.6)	(8.6)	%	
General and administrative	156.4	177.3	174.9	(20.9)	(11.8)%	2.4	1.4	%	
Segment contribution	\$3,442.8	\$3,690.9	\$3,683.5	\$(248.1)	(6.7)%	\$7.4	0.2	%	
Segment margin	64.7%	63.7%	62.2%		1.0%		1.5%		

Segment gross margin <sup>(3)</sup>	85.0	%	85.4	%	85.1	%	(0.4	)%	0.3	%
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(1) Includes revenues earned that were distributed through our former Anda Distribution business to third party customers.

(2) Excludes amortization and impairment of acquired intangibles including product rights, as well as indirect cost of sales not attributable to segment results.

(3) Defined as net revenues less segment related cost of sales as a percentage of net revenues.

(4) Includes Namenda XR<sup>®</sup> and Namenda<sup>®</sup> IR.

(5) Includes Lexapro<sup>®</sup> sales of \$51.8 million and \$66.6 million which were previously disclosed separately in the years ended December 31, 2017 and December 31, 2016, respectively.

(6) Includes PacPharma sales of \$14.0 million and \$52.0 million which were previously disclosed separately in the years ended December 31, 2017 and December 31, 2016, respectively.

(7) Includes Enablex<sup>®</sup> sales of \$3.6 million and \$17.1 million which were previously disclosed separately in the years ended December 31, 2017 and December 31, 2016, respectively.

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## Net Revenues

### Years Ended December 31, 2018 and 2017

The decrease in net revenues in the year ended December 31, 2018 was primarily due to a decline in products that lost exclusivity, including Namenda XR<sup>®</sup>, Estrace<sup>®</sup> Cream, and Minastrin<sup>®</sup> 24, as well as a decline in Other Diversified Brands, offset, in part, by growth in Vraylar<sup>®</sup>, Lo Loestrin<sup>®</sup> and Linzess<sup>®</sup>. CNS revenues declined primarily due to the decline in Namenda XR<sup>®</sup> as a result of loss of exclusivity, offset, in part, by strong demand growth for Vraylar<sup>®</sup>. Women's Health revenues declined primarily due to the loss of exclusivity on Estrace<sup>®</sup> Cream and Minastrin<sup>®</sup> 24, offset, in part, by growth for Lo Loestrin<sup>®</sup> driven by higher average selling prices and increased demand. GI revenues increased primarily due to growth for Linzess<sup>®</sup> resulting from increased demand which more than offset negative pricing pressure on the product. GI was negatively affected by the generic impact on Asacol<sup>®</sup>.

### Years Ended December 31, 2017 and 2016

The decrease in net revenues in the year ended December 31, 2017 was primarily due to a decline in Diversified Brand revenues, Women's Health revenues, and Gastrointestinal revenues versus the prior year period, offset, in part, by increases in Other Revenues and CNS revenues.

Diversified Brand revenues decreased due to a decline in Other Diversified Brands and Bystolic<sup>®</sup> / Byvalson<sup>®</sup>. Bystolic<sup>®</sup> / Byvalson<sup>®</sup> revenues declined as a result of decreased demand offset in part by higher average selling prices. Other Diversified Brands declined due to demand declines and the impact of loss of exclusivity on certain products including Enablex<sup>®</sup> as well as a decline in PacPharma revenues as the Company out licensed these product rights. Included within "Other Revenues" for the year ended December 31, 2017 was an increase in royalty revenues related to these products of \$30.3 million.

Women's Health revenues declined primarily due to the loss of exclusivity on Minastrin<sup>®</sup> 24. Offsetting this decline, in part, were an increase in Taytulla<sup>®</sup> revenues of \$72.4 million and increased sales of Lo Loestrin<sup>®</sup> due primarily to strong demand growth and higher average selling prices.

Declines within our Gastrointestinal franchise were primarily driven by a reduction in demand for Asacol<sup>®</sup> HD following the launch of an authorized generic in August 2016. Offsetting this decline, in part, was an increase in royalty revenue of \$34.8 million relating to our authorized generic version of Asacol<sup>®</sup> HD, which was included within "Other Revenues". Further offsetting this decline was growth in Linzess<sup>®</sup> and newly launched Viberzi<sup>®</sup>. Linzess<sup>®</sup> revenues increased primarily due to strong demand growth.

The increase in Central Nervous System revenues was driven by the launch of Vraylar<sup>®</sup> and Namzaric<sup>®</sup> offset, in part, by the continued decline in Namenda<sup>®</sup> due to decreased demand and conversion to Namzaric<sup>®</sup>.

## Cost of Sales

### Years Ended December 31, 2018 and 2017

The decrease in cost of sales in the year ended December 31, 2018 was primarily due to lower product sales and product mix in addition to the favorable impact of a \$29.9 million Linzess<sup>®</sup> profit share true-up. Segment gross margin was 85.0% in the year ended December 31, 2018 compared to 85.4% in the prior year period as a result of product mix including the impact of generics on sales of Estrace<sup>®</sup> Cream.



Years Ended December 31, 2017 and 2016

The decrease in cost of sales was the result of lower product revenues and the impact of reacquiring rights on select licensed products in the year ended December 31, 2017 offset, in part, by unfavorable product mix. As a result of the reacquired rights, the Company is no longer obligated to pay royalties on the specific products, which increases the segment gross margin. In the year ended December 31, 2016, royalties incurred relating to the reacquired product rights were \$71.3 million.

Selling and Marketing Expenses

Years Ended December 31, 2018 and 2017

The decrease in selling and marketing expenses in the year ended December 31, 2018 was related to headcount reductions from the Company's restructuring initiatives, lower promotional costs, and a decrease in the charge for the non-tax deductible Branded Prescription Drug Fee.

Years Ended December 31, 2017 and 2016

The decrease in selling and marketing expenses related to headcount reductions and lower promotional costs.

General and Administrative Expenses

Years Ended December 31, 2018 and 2017

General and administrative expenses in the year ended December 31, 2018 decreased period-over-period due to cost savings initiatives.

Years Ended December 31, 2017 and 2016

General and administrative expenses were in line period-over-period.



## International Segment

The following tables present top product sales and net contribution for the International segment for the years ended December 31, 2018, 2017 and 2016 (\$ in millions):

	Years Ended December 31,		Change		Operational		Operational		Operational	
	2018	2017	Change	Change <sup>(3)</sup>	Change	Change	Change <sup>(3)</sup>	Change	Change	
			\$	\$	\$	%	%	%	%	
			Overall	Change <sup>(3)</sup>	Currency	Overall	Change <sup>(3)</sup>	Currency	Overall	
Total Eye Care	\$1,294.6	\$1,282.1	\$12.5	\$19.4	\$(6.9)	1.0%	1.5%	0.5%	(0.5)%	
Lumigan®/Ganfort®	392.6	371.5	21.1	15.2	5.9	5.7%	4.1%	1.6%	1.6%	
Eye Drops <sup>(4)</sup>	279.7	281.0	(1.3)	3.7	(5.0)	(0.5)%	1.3%	(1.8)%	(1.8)%	
Ozurdex®	187.7	213.4	(25.7)	(32.2)	6.5	(12.0)%	(15.0)%	3.0%	3.0%	
Alphagan®/Combigan®	176.0	175.1	0.9	5.8	(4.9)	0.5%	3.3%	(2.8)%	(2.8)%	
Restasis®	64.5	61.3	3.2	5.9	(2.7)	5.2%	9.6%	(4.4)%	(4.4)%	
Other Eye Care	194.1	179.8	14.3	21.0	(6.7)	8.0%	11.7%	(3.7)%	(3.7)%	
Total Medical Aesthetics	1,533.3	1,366.6	166.7	185.6	(18.9)	12.2%	13.6%	(1.4)%	(1.4)%	
Facial Aesthetics	1,262.3	1,104.5	157.8	178.0	(20.2)	14.3%	16.1%	(1.8)%	(1.8)%	
Botox® Cosmetics	641.2	557.0	84.2	96.6	(12.4)	15.1%	17.3%	(2.2)%	(2.2)%	
Juvederm® Collection	614.8	540.7	74.1	81.9	(7.8)	13.7%	15.1%	(1.4)%	(1.4)%	
Belkyra® (Kybella®)	6.3	6.8	(0.5)	(0.5)	(0.0)	(7.4)%	(7.4)%	0.0%	0.0%	
Plastic Surgery	131.5	158.6	(27.1)	(28.7)	1.6	(17.1)%	(18.1)%	1.0%	1.0%	
Breast Implants	130.1	156.9	(26.8)	(28.5)	1.7	(17.1)%	(18.2)%	1.1%	1.1%	
Other Plastic Surgery	1.4	1.7	(0.3)	(0.2)	(0.1)	(17.6)%	(11.7)%	(5.9)%	(5.9)%	
Regenerative Medicine	16.8	16.5	0.3	(0.1)	0.4	1.8%	(0.6)%	2.4%	2.4%	
Alloderm®	8.0	7.5	0.5	0.4	0.1	6.7%	5.4%	1.3%	1.3%	
Other Regenerative Medicine	8.8	9.0	(0.2)	(0.5)	0.3	(2.2)%	(5.5)%	3.3%	3.3%	
Body Contouring	107.5	73.7	33.8	35.0	(1.2)	45.9%	47.5%	(1.6)%	(1.6)%	
Coolsculpting®			22.6	23.1	(0.5)	54.3%	55.5%	(1.2)%	(1.2)%	
Consumables	64.2	41.6								
Coolsculpting® Systems & Add On			11.2	11.9	(0.7)	34.9%	37.1%	(2.2)%	(2.2)%	
Applicators	43.3	32.1								
Skin Care	15.2	13.3	1.9	1.4	0.5	14.3%	10.5%	3.8%	3.8%	
Botox® Therapeutics and Other	611.5	587.4	24.1	22.7	1.4	4.1%	3.9%	0.2%	0.2%	
Botox® Therapeutics	390.4	357.5	32.9	34.9	(2.0)	9.2%	9.8%	(0.6)%	(0.6)%	
Asacol®/Delzicol®	45.7	50.2	(4.5)	(5.9)	1.4	(9.0)%	(11.8)%	2.8%	2.8%	
Constella®	24.1	21.9	2.2	1.8	0.4	10.0%	8.2%	1.8%	1.8%	
Other Products	151.3	157.8	(6.5)	(8.1)	1.6	(4.1)%	(5.1)%	1.0%	1.0%	
Other revenues	65.3	83.4	(18.1)	(18.5)	0.4	(21.7)%	(22.2)%	0.5%	0.5%	

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Net revenues	\$3,504.7	\$3,319.5	\$185.2	\$209.2	\$(24.0)	5.6	%	6.3	%	(0.7)	%
Operating expenses:											
Cost of sales <sup>(1)</sup>	537.1	478.7	58.4	66.2	(7.8)	12.2	%	13.8	%	(1.6)	%
Selling and marketing	928.7	913.8	14.9	14.9	0.0	1.6	%	1.6	%	0.0	%
General and administrative	141.7	120.6	21.1	25.6	(4.5)	17.5	%	21.2	%	(3.7)	%
Segment contribution	\$1,897.2	\$1,806.4	\$90.8	\$102.5	\$(11.7)	5.0	%	5.6	%	(0.6)	%
Segment margin	54.1	%	54.4	%				(0.3)	%		
Segment gross margin <sup>(2)</sup>	84.7	%	85.6	%				(0.9)	%		

(1) Excludes amortization and impairment of acquired intangibles including product rights, as well as indirect cost of sales not attributable to segment results.

(2) Defined as net revenues less segment related cost of sales as a percentage of net revenues.

(3) Defined as overall change excluding foreign exchange impact.

(4) Includes Optive® sales of \$114.1 million which were previously disclosed separately in the year ended December 31, 2017.

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	Years Ended December 31,		Change							
	2017	2016	Change	Change <sup>(3)</sup>	\$	%	\$	%	%	%
			Overall	Operational	Currency	Overall	Operational	Currency	Overall	Currency
			Change	Change <sup>(3)</sup>	Change	Change	Change <sup>(3)</sup>	Change	Change <sup>(3)</sup>	Change
Total Eye Care	\$1,282.1	\$1,219.4	\$62.7	\$48.0	\$14.7	5.1 %	3.9 %	1.2 %		
Lumigan®/Ganfort®	371.5	361.7	9.8	4.9	4.9	2.7 %	1.3 %	1.4 %		
Eye Drops <sup>(4)</sup>	281.0	276.2	4.8	1.1	3.7	1.7 %	0.4 %	1.3 %		
Ozurdex®	213.4	179.0	34.4	32.4	2.0	19.2 %	18.1 %	1.1 %		
Alphagan®/Combigan®	175.1	169.3	5.8	4.0	1.8	3.4 %	2.3 %	1.1 %		
Restasis®	61.3	68.0	(6.7 )	(5.9 )	(0.8 )	(9.9 )%	(8.7 )%	(1.2 )%		
Other Eye Care	179.8	165.2	14.6	11.5	3.1	8.8 %	6.9 %	1.9 %		
Total Medical Aesthetics	1,366.6	1,064.6	302.0	301.3	0.7	28.4 %	28.3 %	0.1 %		
Facial Aesthetics	1,104.5	902.7	201.80	202.1	(0.3 )	22.4 %	22.4 %	(0.0 )%		
Botox® Cosmetics	557.0	480.0	77.0	83.5	(6.5 )	16.0 %	17.4 %	(1.4 )%		
Juvederm® Collection	540.7	420.4	120.3	114.2	6.1	28.6 %	27.1 %	1.5 %		
Belkyra® (Kybella®)	6.8	2.3	4.5	4.4	0.1	n.m.	n.m.	4.3 %		
Plastic Surgery	158.6	150.7	7.90	7.3	0.6	5.2 %	4.8 %	0.4 %		
Breast Implants	156.9	149.9	7.0	6.4	0.6	4.7 %	4.3 %	0.4 %		
Other Plastic Surgery	1.7	0.8	0.9	0.9	-	n.m.	n.m.	0.0 %		
Regenerative Medicine	16.5	-	16.5	16.5	-	n.a.	n.a.	n.a.		
Alloderm®	7.5	-	7.5	7.5	-	n.a.	n.a.	n.a.		
Other Regenerative Medicine	9.0	-	9.0	9.0	-	n.a.	n.a.	n.a.		
Body Contouring	73.7	-	73.7	73.7	-	n.a.	n.a.	n.a.		
Coolsculpting® Consumables	41.6	-	41.6	41.6	-	n.a.	n.a.	n.a.		
Coolsculpting® Systems & Add On			32.1	32.1	-	n.a.	n.a.	n.a.		
Applicators	32.1	-								
Skin Care	13.3	11.2	2.1	1.7	0.4	18.8 %	15.2 %	3.6 %		
Botox® Therapeutics and Other	587.4	537.3	50.1	43.6	6.5	9.3 %	8.1 %	1.2 %		
Botox® Therapeutics	357.5	323.0	34.5	30.1	4.4	10.7 %	9.3 %	1.4 %		
Asacol®/Delzicol®	50.2	53.7	(3.5 )	(2.3 )	(1.2 )	(6.5 )%	(4.3 )%	(2.2 )%		
Constella®	21.9	17.3	4.6	4.5	0.1	26.6 %	26.0 %	0.6 %		
Other Products	157.8	143.3	14.5	11.3	3.2	10.1 %	7.9 %	2.2 %		
Other revenues	83.4	60.0	23.4	22.4	1.0	39.0 %	37.3 %	1.7 %		
Net revenues	\$3,319.5	\$2,881.3	\$438.2	\$415.3	\$22.9	15.2 %	14.4 %	0.8 %		
Operating expenses:										
Cost of sales <sup>(1)</sup>	478.7	418.2	60.5	55.4	5.1	14.5 %	13.3 %	1.2 %		
Selling and marketing	913.8	788.2	125.6	114.7	10.9	15.9 %	14.5 %	1.4 %		
General and administrative	120.6	117.2	3.4	2.3	1.1	2.9 %	2.0 %	0.9 %		

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Segment contribution	\$1,806.4		\$1,557.7		\$248.7	\$242.9	\$5.8	16.0 %	15.6 %	0.4 %
Segment margin	54.4	%	54.1	%				0.3 %		
Segment gross margin <sup>(2)</sup>	85.6	%	85.5	%				0.1 %		

(1) Excludes amortization and impairment of acquired intangibles including product rights, as well as indirect cost of sales not attributable to segment results.

(2) Defined as net revenues less segment related cost of sales as a percentage of net revenues.

(3) Defined as overall change excluding foreign exchange impact.

(4) Includes Optive® sales of \$114.1 million and \$101.9 million which were previously disclosed separately in the years ended December 31, 2017 and December 31, 2016, respectively.

The following tables present our revenue disaggregated by geography for our International segment (\$ in millions):

	Years Ended December 31,					
			\$	\$	%	%
			Overall	Operational	Overall	Operational
	2018	2017	Change	Change	Change	Change
Europe	\$1,482.6	\$1,439.2	\$43.4	\$22.1	3.0 %	1.5 %
Asia Pacific, Middle East and Africa	1,089.9	929.9	160.0	156.0	17.2 %	16.8 %
Latin America and Canada	862.4	863.3	(0.9 )	48.9	(0.1 )%	5.7 %
Other*	69.8	87.1	(17.3 )	(17.8 )	(19.9 )%	(20.4 )%
<b>Total International</b>	<b>\$3,504.7</b>	<b>\$3,319.5</b>	<b>\$185.2</b>	<b>\$209.2</b>	<b>5.6 %</b>	<b>6.3 %</b>

\*Includes royalty and other revenue

	Years Ended December 31,					
			\$	\$	%	%
			Overall	Operational	Overall	Operational
	2017	2016	Change	Change	Change	Change
Europe	\$1,439.2	\$1,322.8	\$116.4	\$115.5	8.8 %	8.7 %
Asia Pacific, Middle East and Africa	929.9	776.1	153.8	153.0	19.8 %	19.7 %
Latin America and Canada	863.3	722.3	141.0	119.8	19.5 %	16.6 %
Other*	87.1	60.1	27.0	27.0	44.9 %	44.9 %
<b>Total International</b>	<b>\$3,319.5</b>	<b>\$2,881.3</b>	<b>\$438.2</b>	<b>\$415.3</b>	<b>15.2 %</b>	<b>14.4 %</b>

\*Includes royalty and other revenue

The Zeltiq Acquisition contributed the following to the segment in the years ended December 31, 2018 and 2017 (\$ in millions):

	For the Years Ended December 31,	
	2018	2017
Net revenues	\$107.5	\$73.7
Operating expenses:		
Cost of sales	39.2	25.6
Selling and marketing	54.0	39.0
General and administrative	3.5	-

Net Revenues

Years Ended December 31, 2018 and 2017

The increase in net revenues in the year ended December 31, 2018 was primarily due to the operational growth of total Facial Aesthetics and Botox<sup>®</sup> Therapeutics, as well as the Zeltiq Acquisition. Within Facial Aesthetics, the increase in sales of Botox<sup>®</sup> Cosmetics was driven primarily by demand growth and higher average prices. The increase in sales of Botox<sup>®</sup> Therapeutics was driven primarily by demand growth. Juvederm<sup>®</sup> Collection revenues increased versus the prior year period, primarily resulting from demand growth. Within total Eye Care, Ozurdex<sup>®</sup> decreased versus the prior year period, primarily driven by the third quarter product recall and the temporary period of not shipping product. Plastic Surgery decreased versus the prior year period, primarily driven by a fourth quarter suspension of sales and withdrawal of the remaining textured breast implants from the market in Europe. This suspension and withdrawal followed the non-renewal of our textured breast implant CE Mark licenses in Europe pending a request for additional information by LNE-GMED, the notified body responsible for certification of our breast implants. Sales returns reserves recorded for the recalls totaled \$56.7 million in the year ended December 31, 2018.

Years Ended December 31, 2017 and 2016

The increase in net revenues in the year ended December 31, 2017 was primarily due to the operational growth of total Facial Aesthetics, Eye Care and Botox<sup>®</sup> Therapeutics, as well as the acquisition of Zeltiq, which contributed \$73.7 million of net revenues during the year ended December 31, 2017. Within Total Eye Care, Ozurdex<sup>®</sup> increased primarily due to demand growth. Within Facial Aesthetics, Juvederm<sup>®</sup> Collection revenues increased primarily resulting from demand growth. Botox<sup>®</sup> Cosmetics sales grew due to demand growth. Botox<sup>®</sup> Therapeutics sales also grew due to demand growth. International operational growth came from all regions primarily driven by Facial Aesthetics.

Cost of Sales

Years Ended December 31, 2018 and 2017

The increase in cost of sales in the year ended December 31, 2018 was primarily due to the increase in net revenues and the Zeltiq Acquisition and the LifeCell Acquisition. Excluding the Zeltiq Acquisition and the LifeCell Acquisition in both periods, segment gross margin was 85.5% in the year ended December 31, 2018 compared to 86.1% in the prior year period.

Years Ended December 31, 2017 and 2016

The increase in cost of sales was primarily due to the increase in net revenues. Segment gross margins of 85.6% for the year ended December 31, 2017 remained consistent with the prior year.

Selling and Marketing Expenses

Years Ended December 31, 2018 and 2017

The increase in selling and marketing expenses in the year ended December 31, 2018 was due in part to the Zeltiq Acquisition as well as increased promotional spending in Medical Aesthetics.

Years Ended December 31, 2017 and 2016

The increase in selling and marketing expenses related to the addition of Zeltiq, which contributed spending of \$39.0 million, as well as increased promotional spending associated with Ozurdex<sup>®</sup>, Botox<sup>®</sup> Cosmetics and the Juvederm<sup>®</sup> Collection and recent product launches.

General and Administrative Expenses

Years Ended December 31, 2018 and 2017

General and administrative expenses increased due in part to \$12.4 million of contract tender costs associated with the Ozurdex and textured breast implants recalls.

Years Ended December 31, 2018 and 2017

General and administrative expenses were in line period-over-period.

Corporate

Corporate represents the results of corporate initiatives as well as the impact of select revenues and shared costs. The following represents the Corporate amounts for the years ended December 31, 2018, 2017 and 2016 (\$ in millions):

Year Ended December 31, 2018						
Integration	Non-Acquisition	Fair Value		Effect of Purchase		Revenues and
Divestiture	Restructuring	Adjustments	Accounting	Other	Shared Costs	Total

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Net revenues	\$-	\$ -	\$ -	\$ -	\$-	\$ 39.5	\$39.5
Operating expenses:							
Cost of sales <sup>(1)</sup>	1.3	33.7	(111.7 )	2.1	(0.1 )	364.7	290.0
Selling and marketing	1.5	38.8	-	8.6	-	0.1	49.0
General and administrative	50.9	5.4	-	2.9	58.8	649.8	767.8
Contribution	\$(53.7)	\$( 77.9	) \$ 111.7	\$ (13.6	) \$(58.7)	\$ (975.1	) \$(1,067.3)

<sup>(1)</sup> Excludes amortization and impairment of acquired intangibles including product rights.

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	Year Ended December 31, 2017						Revenues and Shared Costs	Total
	Integration / Divestiture	Related Restructuring	Fair Value Adjustments	Effect of Purchase Accounting	Other			
Net revenues	\$-	\$ -	\$ -	\$ -	\$-	\$ 21.4	\$21.4	
Operating expenses:								
Cost of sales <sup>(1)</sup>	8.0	61.5	(183.2 )	136.3	12.5	314.9	350.0	
Selling and marketing	29.5	80.8	-	33.1	0.5	3.5	147.4	
General and administrative	138.8	32.8	-	49.0	97.4	677.8	995.8	
Contribution	\$(176.3)	\$(175.1 )	\$ 183.2	\$(218.4 )	\$(110.4)	\$(974.8 )	\$(1,471.8)	

<sup>(1)</sup> Excludes amortization and impairment of acquired intangibles including product rights.

	Year Ended December 31, 2016						Revenues and Shared Costs	Total
	Integration / Divestiture	Fair Value Adjustments	Effect of Purchase Accounting	Reclassification of Sales Distributed Through And to Discontinued Operations	Other			
Net revenues	\$-	\$ -	\$ -	\$(80.0 )	\$-	\$ 33.7	\$(46.3 )	
Operating expenses:								
Cost of sales <sup>(1)</sup>	23.0	(17.4 )	50.5	(78.2 )	-	294.0	271.9	
Selling and marketing	82.5	-	65.4	-	-	7.6	155.5	
General and administrative	269.6	24.3	80.5	-	136.3	496.9	1,007.6	
Contribution	\$(375.1)	\$(6.9 )	\$(196.4 )	\$(1.8 )	\$(136.3)	\$(764.8 )	\$(1,481.3)	

<sup>(1)</sup> Excludes amortization and impairment of acquired intangibles including product rights.

## Integration

Years Ended December 31, 2018, 2017 and 2016

In the years ended December 31, 2018 and 2017, integration and restructuring charges included costs related to the integration of LifeCell and Zeltiq. In the year ended December 31, 2016, integration and restructuring charges primarily related to the integration of the Legacy Allergan business as well as charges incurred with the terminated

merger with Pfizer, Inc. of \$124.9 million.

#### Non-Acquisition Related Restructuring

##### Years Ended December 31, 2018 and 2017

In the years ended December 31, 2018 and 2017, the Company incurred charges related to the restructuring of its internal infrastructure. In the year ended December 31, 2018, the restructuring programs included charges associated with scaling our manufacturing plants and changes in the international commercial promotional focus in certain markets which include an anticipated reduction of approximately 200 sales representatives internationally. In the year ended December 31, 2017, restructuring programs included a mid-year commercial initiative as well as a December 2017 program. As part of these initiatives, the Company reduced its employee headcount within selling and marketing by approximately 350 as of December 31, 2017. A reduction of approximately 900 employees within cost of sales, selling and marketing and general and administrative was reserved for in the year ended December 31, 2017.

## Fair Value Adjustments

Years Ended December 31, 2018 and 2017

Fair value adjustments primarily relate to changes in estimated contingent liabilities for future amounts to be paid based on achievement of sales levels for the respective products.

In the year ended December 31, 2018, the income in cost of sales primarily reflects the reduction of the contingent liability for True Tear<sup>®</sup> when the product did not achieve a milestone event, as well as a corresponding decrease in commercial forecasts. The income recorded in the year ended December 31, 2017 primarily related to reduced or delayed revenue forecasts for select products including Rhofade<sup>®</sup> and Liletta<sup>®</sup>.

## Effect of Purchase Accounting

Years Ended December 31, 2018, 2017 and 2016

The Company incurred charges related to the purchase accounting impact on share-based compensation related to the Zeltiq Acquisition in the years ended December 31, 2018 and 2017, and the Allergan Acquisition and the Forest Acquisition in the years ended December 31, 2018, 2017 and 2016, which increased cost of sales, selling and marketing and general and administrative expenses. A cash stock-based compensation charge of \$31.5 million associated with the Zeltiq Acquisition was also included in the year ended December 31, 2017.

In the year ended December 31, 2017, the Company incurred purchase accounting effects of \$131.7 million in cost of sales related to the fair value inventory step-up from the LifeCell Acquisition and the Zeltiq Acquisition as products were sold to the Company's third-party customers. In the year ended December 31, 2016, the Company incurred similar purchase accounting effects in cost of sales totaling \$42.4 million related to the fair value inventory step-up from the Allergan Acquisition and the Forest Acquisition.

## Other

Years Ended December 31, 2018, 2017 and 2016

In the years ended December 31, 2018, 2017 and 2016, general and administrative costs included legal settlement charges of \$56.8 million, \$96.5 million and \$117.3 million, respectively.

## Revenues and Shared Costs

Years Ended December 31, 2018, 2017 and 2016

Shared costs primarily include above site and unallocated costs associated with running our global manufacturing facilities and corporate general and administrative expenses.

In the year ended December 31, 2018, the Company recorded milestone revenue related to an on-going intellectual property agreement of \$25.0 million.

In the year ended December 31, 2018, the increase in cost of goods sold within revenues and shared costs was primarily due to unfavorable inventory variances due to third-party manufacturing delays, an increase in compensation costs and \$15.8 million of inventory write-offs associated with the Ozurdex<sup>®</sup> and textured breast implants product recalls versus the prior year.

In the years ended December 31, 2018 and 2017, the Company incurred transactional foreign exchange losses of \$28.8 million and \$97.5 million, respectively, compared with transactional foreign exchange gains of \$52.8 million, excluding mark-to-market unrealized losses for foreign currency option contracts, in the year ended December 31, 2016.

#### Research and Development Expenses

R&D expenses consist predominantly of personnel-related costs, active pharmaceutical ingredient costs, contract research, license and milestone fees, biostudy and facilities costs associated with product development.

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R&D expenses consisted of the following in the years ended December 31, 2018, 2017 and 2016 (\$ in millions):

	Years Ended December 31,			2018 vs 2017		2017 vs 2016	
	2018	2017	2016	\$	%	\$	%
Ongoing operating expenses	\$1,574.5	\$1,598.8	\$1,433.8	\$(24.3)	(1.5)%	\$165.0	11.5%
Milestone expenses and upfront license payments	678.9	391.8	1,134.7	287.1	73.3%	(742.9)	(65.5)%
Acquisition accounting fair market value adjustment							
to share-based compensation	4.8	18.3	53.8	(13.5)	(73.8)%	(35.5)	(66.0)%
Acquisition, integration, and restructuring charges	2.9	41.2	24.5	(38.3)	(93.0)%	16.7	68.2%
Contingent consideration adjustments, net	5.1	50.0	(71.1)	(44.9)	(89.8)%	121.1	(170.3)%
Total R&D Expenses	\$2,266.2	\$2,100.1	\$2,575.7	\$166.1	7.9%	\$(475.6)	(18.5)%