Allergan plc Form 10-K February 26, 2016

**UNITED STATES** 

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended December 31, 2015

OR

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

For the transition period from to

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

Hamilton HM 12

Bermuda

(441) 295-2244

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

Name of Each Exchange on Which

Title of Each Class Registered

Allergan plc Ordinary Shares, \$0.0001 par value

Allergan plc 5.500% Mandatory Convertible Preferred Shares, Series A, par

New York Stock Exchange

New York Stock Exchange

Allergan plc 5.500% Mandatory Convertible Preferred Shares, Series A, par value of \$0.0001

New York Stock Exchange

Actavis Funding SCS \$500,000,000 Floating Rate Notes due 2016\*

\*Notes issued by Actavis Funding SCS and guaranteed by Warner Chilcott Limited

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 x No o Warner Chilcott Limited Yes x 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 x Warner Chilcott Limited Yes No x

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 x No "Warner Chilcott Limited Yes x No "

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).

Allergan plc Yes x No "Warner Chilcott Limited Yes x 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.

Allergan plc "Warner Chilcott Limited x

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

Allergan plc	Large accelerated filer	x Accelerated filer	O
	Non-accelerated filer (Do not check if a smaller reporting	oSmaller reporting	O
	company)	company	
Warner Chilcott Li	mitedLarge accelerated filer	o Accelerated filer	o
	Non-accelerated filer (Do not check if a smaller reporting	x Smaller reporting	o
	company)	company	

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

Allergan plc Yes "No x Warner Chilcott Limited Yes "No x

The aggregate market value of the voting and non-voting stock held by non-affiliates of Allergan plc as of June 30, 2015, based upon the last sale price reported for such date on the New York Stock Exchange, was \$119.0 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 15, 2016: 394,687,384

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'				
Annual Meeting of Shareholders to be held on or about May 5, 2016.	.10			

# ALLERGAN PLC

# WARNER CHILCOTT LIMITED

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# 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 (formerly known as Actavis 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. It was established for the purpose of facilitating the business combination between Actavis, Inc. and Warner Chilcott plc ("Warner Chilcott"). On October 1, 2013, pursuant to the transaction agreement dated May 19, 2013 among Actavis, Inc., Warner Chilcott, Allergan plc, Actavis Ireland Holding Limited, Actavis W.C. Holding LLC (now known as Actavis W.C. Holding Inc.) and Actavis W.C. Holding 2 LLC (now known as Actavis W.C. Holding 2 Inc.) ("MergerSub"), (i) the Company acquired Warner Chilcott (the "Warner Chilcott Acquisition") pursuant to a scheme of arrangement under Section 201, and a capital reduction under Sections 72 and 74, of the Irish Companies Act of 1963 where each Warner Chilcott ordinary share was converted into 0.160 of an Allergan plc ordinary share (the "Company Ordinary Shares"), or \$5,833.9 million in equity consideration, and (ii) MergerSub merged with and into Actavis, Inc., with Actavis, Inc. as the surviving corporation in the merger (the "Merger" and, together with the Warner Chilcott Acquisition, the "Transactions"). Following the consummation of the Transactions, Actavis, Inc. and Warner Chilcott became wholly-owned subsidiaries of Allergan plc. Each of Actavis, Inc.'s common shares was converted into one Company Ordinary Share. Effective October 1, 2013, through a series of related-party transactions, Allergan plc contributed its indirect subsidiaries, including Actavis, Inc., to Warner Chilcott Limited.

On March 17, 2015, the Company acquired Allergan, Inc. ("Legacy Allergan") for approximately \$77.0 billion including outstanding indebtedness assumed of \$2.2 billion, cash consideration of \$40.1 billion and equity consideration of \$34.7 billion, which includes outstanding equity awards (the "Allergan Acquisition"). Under the terms of the agreement, Legacy Allergan shareholders received 111.2 million of the Company's ordinary shares, 7.0 million of the Company's non-qualified stock options and 0.5 million of the Company's share units. The addition of Legacy Allergan's therapeutic franchises in ophthalmology, neurosciences and medical aesthetics/dermatology/plastic surgery complements the Company's existing central nervous system, gastroenterology, women's health and urology franchises. The combined company benefits from Legacy Allergan's global brand equity and consumer awareness of key products, including Botox® and Restasis®. The transaction expanded our presence and market and product reach across many international markets, with strengthened commercial positions across Canada, Europe, Southeast Asia and other high-value growth markets, including China, India, the Middle East and Latin America.

In connection with the Allergan Acquisition, the Company changed its name from Actavis plc to Allergan plc. Actavis plc's ordinary shares were traded on the NYSE under the symbol "ACT" until the opening of trading on June 15, 2015, at which time Actavis plc changed its corporate name to "Allergan plc" and changed its ticker symbol to "AGN." Pursuant to Rule 12g-3(c) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), Allergan plc is the successor issuer to Actavis plc's ordinary shares and Actavis plc's mandatory convertible preferred shares, both of which 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.

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, Actavis, Inc. 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 Actavis, Inc.'s Class A common shares, par value \$0.0033 per share, prior to the consummation of the Transactions and to Allergan plc's ordinary shares, par value \$0.0001 per share, since the consummation of the Transactions.

On July 26, 2015, Allergan plc entered into a master purchase agreement (the "Teva Agreement"), under which Teva Pharmaceutical Industries Ltd. ("Teva") agreed to acquire the Company's global generic pharmaceuticals business and certain other assets (the "Teva Transaction"). Under the Teva Agreement, upon the closing of the Teva Transaction, we will receive \$33.75 billion in cash and 100.3 million Teva ordinary shares (or American Depository Shares with respect thereto), which approximates \$6.75 billion in Teva stock using the then-current stock price at the time the Teva Transaction was announced, in exchange for which Teva will acquire 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 R&D unit, our international over-the-counter (OTC) commercial unit (excluding OTC eye care products) and some established international brands. We continue to work toward

satisfying all conditions in order to close by the end of the first quarter of 2016; however, it is possible that closing could slip beyond the end of the first quarter. As a result of the transaction, and in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") number 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 Company is accounting for the assets and liabilities to be divested as held for sale. Further, the financial results of the business held for sale have been reclassified to discontinued operations for all periods presented in our consolidated financial statements.

On November 23, 2015, the Company announced that it entered into a definitive merger agreement (the "Pfizer Agreement") under which Pfizer Inc. ("Pfizer"), a global innovative biopharmaceutical company, and Allergan plc will merge in a stock and cash transaction (the "Pfizer Transaction"), which attributes a \$160.0 billion enterprise valuation using the then-current stock price at the time the Pfizer Transaction was announced. Company shareholders will receive 11.3 shares of the combined company ordinary shares for each of their existing Allergan shares and Pfizer stockholders will receive in respect of each share of Pfizer common stock held by them, at their election and subject to certain proration procedures described in the Pfizer Agreement, either one share of the combined company or an amount in cash equal to the volume weighted average price per share of Pfizer common stock on the New York Stock Exchange ("NYSE") on the trading day immediately preceding the date of the consummation of the Pfizer Transaction. The Pfizer Transaction is anticipated to close in the second half of 2016.

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 deminimis 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.

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 specialty pharmaceutical company engaged in the development, manufacturing, marketing, and distribution of brand name pharmaceutical products ("brand", "branded" or "specialty brand"), medical aesthetics, biosimilar and over-the-counter ("OTC") pharmaceutical products. 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. As a result of the Allergan Acquisition which closed on March 17, 2015, the Company expanded its franchises to include ophthalmology, neurosciences and medical aesthetics/dermatology/plastic surgery, which complements the Company's existing central nervous system, gastroenterology, women's health and urology franchises. The combined company benefits significantly from Legacy Allergan's global brand equity and consumer awareness of key products, including Botox® and Restasis®. The Allergan Acquisition expanded our presence and market and product reach across many international markets, with strengthened commercial positions across Canada, Europe, Southeast Asia and other high-value growth markets, including China, India, the Middle East and Latin America.

The results of our discontinued operations includes the results of our generic product development, manufacturing and distribution of off-patent pharmaceutical products, established international brands marketed similar to generic

products and out-licensed generic pharmaceutical products primarily in Europe through our Medis third-party business.

Allergan plc's principal executive offices are located at Clonshaugh Business and Technology Park, Coolock, Dublin, Ireland and our administrative headquarters are located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Our Internet website address is 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 at the SEC's Public Reference Room at 100 F Street, NE, Washington DC 20549 or electronically through the SEC website (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. Information may be obtained regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. 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** 

2015 Significant Business Developments

The following are the material transactions that were completed in the year ended December 31, 2015.

Acquisitions

AqueSys

On October 16, 2015, the Company acquired AqueSys, Inc. ("AqueSys"), a private, clinical-stage medical device company focused on developing ocular implants that reduce intraocular pressure ("IOP") associated with glaucoma, in an all-cash transaction. Under the terms of the agreement, the Company acquired AqueSys for an acquisition accounting purchase price of \$298.9 million, including \$193.5 million for the estimated fair value of contingent consideration relating to the regulatory approval and commercialization milestone payments. The Company acquired AqueSys for the lead development program, including XEN45, a soft shunt that is implanted in the sub conjunctival space in the eye through a minimally invasive procedure with a single use, pre-loaded proprietary injector (the "AqueSys Acquisition").

### Northwood Medical Innovation

On October 1, 2015, the Company acquired Northwood Medical Innovation Ltd., developer of innovative implant technology, earFold<sup>TM</sup>, which is being accounted for as a business acquisition. earFold<sup>TM</sup> is a medical device for the correction of prominent ears, with or without asymmetry, in patients aged 7 years and older. earFold<sup>TM</sup> received a Conformité Européene ("CE") mark in April 2015, and has been made available by Northwood Medical Innovation Ltd to trained and accredited plastic surgeons, otolaryngologists (Ear, Nose and Throat) and maxillo-facial surgeons, primarily in the United Kingdom ("UK"). The Company acquired Northwood Medical Innovation Ltd. for acquisition accounting purchase price consideration of \$25.5 million (the "Northwood Acquisition"), including \$15.0 million of contingent consideration.

# Kythera

On October 1, 2015, the Company acquired Kythera Biopharmaceuticals ("Kythera"), for \$75 per share, or an acquisition accounting purchase price of \$2,089.5 million (the "Kythera Acquisition"). Kythera was focused on the discovery, development and commercialization of novel prescription aesthetic products. Kythera's lead product, Kybella® injection, is the first and only United States Food and Drug Administration ("FDA") approved, non-surgical treatment for moderate to severe submental fullness, commonly referred to as double chin.

# Oculeve

On August 10, 2015, the Company acquired Oculeve, Inc. ("Oculeve"), a development-stage medical device company focused on developing novel treatments for dry eye disease. Under the terms of the agreement, Allergan acquired Oculeve for an acquisition accounting purchase price of \$134.5 million (the "Oculeve Acquisition"), including \$90.0 million for the estimated fair value of contingent consideration of which the Company may owe up to \$300.0 million in future payments. The Company acquired Oculeve and its lead product candidate OD-01, an intranasal neurostimulation device, as well as other dry eye products in development.

# Auden Mckenzie

On May 29, 2015 the Company acquired Auden Mckenzie Holdings Limited ("Auden"), a company specializing in the development, licensing and marketing of niche generic medicines and proprietary brands in the United Kingdom ("UK") and across Europe for approximately 323.7 million British Pounds, or \$495.9 million (the "Auden Acquisition"). The assets and liabilities acquired, as well as the results of operations for the acquired Auden business are part of the assets being divested in the Teva Transaction and are included as a component of income from discontinued operations. In addition the acquired financial position is included in assets and liabilities held for sale.

# Allergan

On March 17, 2015, the Company completed the Allergan Acquisition. The addition of Legacy Allergan's therapeutic franchises in ophthalmology, neurosciences and medical aesthetics/dermatology/plastic surgery complements the Company's existing central nervous system, gastroenterology, women's health and urology franchises. The combined company benefited from Legacy Allergan's global brand equity and consumer awareness of key products, including Botox® and Restasis®. The transaction also expanded our presence and market and product reach across many international markets, with strengthened commercial positions across Canada, Europe, Southeast Asia and other high-value growth markets, including China, India, the Middle East and Latin America.

# Licenses and Asset Acquisitions

# Mimetogen

On November 4, 2015, the Company entered into an exclusive licensing agreement with Mimetogen Pharmaceuticals ("Mimetogen"), a clinical stage biotechnology company, to develop and commercialize tavilermide (MIM-D3), a topical formulation of a novel small molecule TrkA agonist for the treatment of dry eye disease, in exchange for an upfront payment of \$50.0 million to Mimetogen, which is included as a component of research and development ("R&D") expenses in the year ended December 31, 2015. Mimetogen will be entitled to receive potential milestones based on achieving regulatory approval and predefined labeling of the product. In addition, Mimetogen is entitled to receive one-time annual sales based milestone payments based on multiple pre-defined annual net sales thresholds which may or may not be achieved, and tiered royalties based on net sales to third parties of the licensed products (the "Mimetogen Transaction"). 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.

# Almirall

On October 27, 2015, the Company and Ironwood Pharmaceuticals, Inc. announced that Allergan has acquired rights to Constella® (linaclotide) in the European Union, Switzerland, Turkey and the Commonwealth of Independent States from Almirall, S.A. and has also reacquired rights to Linzess® (linaclotide) in Mexico from Almirall for &60.0 million. The consideration was accounted for as an asset acquisition and included as a component of intangible assets. The Company concluded based on the lack of acquired employees and the lack of certain other inputs and processes that the transaction did not qualify as a business.

#### Naurex

On August 28, 2015, the Company acquired certain products in early stage development of Naurex, Inc. ("Naurex") in an all-cash transaction of \$571.7 million (the "Naurex Transaction"), plus future contingent payments up to \$1,150.0 million, which was accounted for as an asset acquisition. The Company recognized the upfront consideration of \$571.7 million as a component of R&D expenses in the year ended December 31, 2015. 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 Naurex Transaction expands our pipeline with Naurex's two leading product candidates GLYX-13 and NRX-1074, two compounds that utilize NMDA modulation as a potential new approach to the treatment of Major Depressive Disorder ("MDD"), a disease that can lead to suicidality among the most severe patients.

# Migraine License

On August 17, 2015, the Company entered into an agreement with Merck & Co. ("Merck") under which the Company acquired the exclusive worldwide rights to Merck's early development stage investigational small molecule oral calcitonin gene-related peptide receptor antagonists, which are being developed for the treatment and prevention of migraines (the "Merck Transaction"). The transaction is being accounted for as an asset acquisition. The Company acquired these rights for an upfront charge of \$250.0 million which was recognized as a component of R&D expenses in the year ended December 31, 2015. 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 Company paid \$125.0 million in the year ended December 31, 2015 and the remaining \$125.0 million is payable on April 30, 2016. Additionally, Merck is owed contingent payments based on commercial and development milestones of up to \$965.0 million as well as royalties.

#### **Divestitures**

# Respiratory Business

As part of the Forest Acquisition (defined below), we acquired certain assets that comprised Legacy Forest's branded respiratory business in the U.S. and Canada (the "Respiratory Business"). During the year ended December 31, 2014, we held for sale respiratory assets of \$734.0 million, including allocated goodwill to this unit of \$309.1 million. On March 2, 2015, the Company sold the Respiratory Business to AstraZeneca plc ("AstraZeneca") for consideration of \$600.0 million upon closing, additional funds to be received for the sale of certain of our inventory to AstraZeneca and low single-digit royalties above a certain revenue threshold. AstraZeneca also paid Allergan an additional \$100.0 million and Allergan has agreed to a number of contractual consents and approvals, including certain amendments to the ongoing collaboration agreements between AstraZeneca and Allergan (the "Respiratory Sale"). As a result of the final terms of the agreement, in the year ended December 31, 2015, the Company recognized an incremental charge in cost of sales (including the acquisition accounting fair value mark-up of inventory) relating to inventory that will not be sold to AstraZeneca of \$35.3 million. The Company recognized a loss in other (expense) income, net for the sale of the business of \$5.3 million in the year ended December 31, 2015.

#### Pharmatech

As part of the Forest Acquisition, the Company acquired certain manufacturing plants and contract manufacturing agreements within the business known as Aptalis Pharmaceutical Technologies ("Pharmatech"). In accordance with acquisition accounting, the assets were fair valued on July 1, 2014 as assets held in use, including market participant synergies anticipated under the concept of "highest and best use." During the fourth quarter of 2014, the decision was made to hold these assets for sale as one complete unit, without integrating the unit and realizing anticipated synergies. During the year ended December 31, 2014, the Company recognized an impairment on assets held for sale of \$189.9 million (the "Pharmatech Transaction") which included a portion of goodwill allocated to this business unit. In the year ended 2015, the Company completed the divestiture of the Pharmatech business and there was no material impact to the Company's results of operations.

### 2014 Significant Business Developments

The following are the material transactions that were completed in the year ended December 31, 2014.

# Acquisitions

#### **Durata Therapeutics**

On November 17, 2014, we completed our tender offer to purchase all of the outstanding shares of Durata Therapeutics, Inc. ("Durata"), an innovative pharmaceutical company focused on the development and commercialization of novel therapeutics for patients with infectious diseases and acute illnesses (the "Durata Acquisition"). Allergan purchased all outstanding shares of Durata, which were valued at approximately \$724.5 million, including the assumption of debt, as well as one contingent value right ("CVR") per share, entitling the holder to receive additional cash payments of up to \$5.00 per CVR if certain regulatory or commercial milestones related to Durata's lead product Dalvanc® are achieved. The CVR had an acquisition date fair value of \$49.0 million. We accounted for the acquisition as a business combination requiring that the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. On March 2, 2015, the Company announced that the European Commission has granted Allergan's subsidiary Durata Therapeutics International B.V., marketing authorization for Xydalba<sup>TM</sup> (dalbavancin) for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults. The approval triggered the first CVR payment. The difference between the fair value of the CVR

on the date of acquisition of \$24.5 million and the payment made of \$30.9 million, or \$6.4 million, was recorded as an operating expense in the year ended December 31, 2015. In January 2016, the Company received approval from the FDA for an expanded label which will include a single dose of Dalvance®, which triggers a second CVR payment in the year ending December 31, 2016.

# **Furiex**

On July 2, 2014, the Company acquired Furiex Pharmaceuticals, Inc. ("Furiex") in an all-cash transaction (the "Furiex Acquisition") valued at \$1,156.2 million (including the assumption of debt) and up to approximately \$360.0 million in a CVR payable based on which controlled substance schedule designation that eluxadoline, Furiex's lead product, receive following approval, which had an acquisition accounting fair value of \$88.0 million on the date of acquisition (included in the value of \$1,156.2 million). In the second quarter of 2015, the Company received approval from the FDA of the eluxadoline product, Viberzi<sup>®</sup>. Viberzi<sup>®</sup> is a first-in-class, locally-acting mu opioid receptor agonist and delta opioid receptor antagonist for treating symptoms of diarrhea-predominant irritable bowel syndrome (IBS-d), a condition that affects approximately 28 million patients in the United States and Europe. In

connection with the close of the Furiex Acquisition, the Company further announced that it closed the transaction related to the sale of Furiex's royalties on Alogliptin and Prilig® to Royalty Pharma for \$408.6 million in cash consideration.

# **Contingent Consideration**

In the year ended December 31, 2015, the Company received a schedule IV ("C-IV") designation from the Drug Enforcement Agency ("DEA") for Viber 2 and recognized an expense of \$29.8 million as a component of R&D expense. This expense represents the difference between the final CVR payment amount of \$118.5 million, or \$10 for each CVR outstanding, versus the probability-weighted CVR fair value initially established in acquisition accounting, adjusted for accretion. This amount was paid as of December 31, 2015.

#### Forest Laboratories

On July 1, 2014, the Company acquired Forest Laboratories, Inc. ("Legacy Forest") for \$30.9 billion including outstanding indebtedness assumed of \$3.3 billion, equity consideration of \$20.6 billion, which includes outstanding equity awards, and cash consideration of \$7.1 billion (the "Forest Acquisition"). Under the terms of the transaction, Legacy Forest shareholders received 89.8 million Allergan plc (formerly Actavis plc) ordinary shares, 6.1 million Allergan plc non-qualified stock options and 1.1 million Allergan plc share units. Legacy Forest was a leading, fully integrated, specialty pharmaceutical company largely focused on the United States market. Legacy Forest marketed a portfolio of branded drug products and developed new medicines to treat patients suffering from diseases principally in the following therapeutic areas: central nervous system, cardiovascular, gastrointestinal, respiratory, anti-infective, and cystic fibrosis.

### Silom Medical Company

On April 1, 2014, the Company acquired Silom Medical Company ("Silom"), a privately held generic pharmaceutical company focused on developing and marketing therapies in Thailand, for consideration of approximately \$103.0 million in cash (the "Silom Acquisition"). The Silom Acquisition expanded the Company's position in the Thai generic pharmaceutical market, with leading positions in the ophthalmic and respiratory therapeutic categories and a strong cardiovascular franchise. We accounted for the acquisition as a business combination requiring that the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. The assets and liabilities acquired, as well as the results of operations for the acquired Silom business are part of the assets being divested in the Teva Transaction and are included as a component of income from discontinued operations. In addition the acquired financial position is included in assets and liabilities held for sale.

#### **Divestitures**

# Corona Facility

During the year ended December 31, 2014, we held for sale assets in our Corona, California manufacturing facility. As a result, the Company recognized an impairment charge as a component of discontinued operations of \$20.0 million in the year ended December 31, 2014, including a write-off of property, plant and equipment, net, due to the integration of Warner Chilcott of \$5.8 million. The Company completed the sale of these assets during the year ended December 31, 2015 with no material impact to the Company's results of operations.

# 2013 Significant Business Developments

The following are the material transactions that were completed in the year ended December 31, 2013.

# Acquisitions

# Warner Chilcott

On October 1, 2013, the Company acquired of Warner Chilcott plc ("Warner Chilcott") in a stock for stock transaction for a value, including the assumption of debt, of \$9.2 billion (the "Warner Chilcott Acquisition"). Warner Chilcott was a leading specialty pharmaceutical company focused on the women's healthcare, gastroenterology, urology and dermatology segments of the branded pharmaceuticals market, primarily in North America.

#### Medicines360

On June 10, 2013, we entered into an exclusive license agreement with Medicines360 to market, sell and distribute Medicines360 LNG20 intrauterine device ("LNG20") in the U.S. and in Canada for a payment of approximately \$52.3 million. According to the terms of the agreement, we are also required to pay Medicines360 certain regulatory and sales based milestone payments totaling up to nearly \$125.0 million plus royalties. Medicines360 retained the rights to market the product in the U.S. public sector, including family planning clinics that provide services to low-income women. LNG20 is currently marketed as Liletta® and was originally developed by Uteron Pharma Operations SPRL in Belgium (now a subsidiary of the Company). We accounted for the acquisition as a business combination requiring that the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date.

# Acquisition of Uteron Pharma, S.A.

On January 23, 2013, the Company completed the acquisition of Uteron Pharma, S.A. for approximately \$142.0 million in cash, plus assumption of debt and other liabilities of \$7.7 million and up to \$155.0 million in potential future milestone payments (the "Uteron Acquisition"). The acquisition expanded the Company's specialty brand pipeline of women's health products including two potential near term commercial opportunities in contraception and infertility, and one oral contraceptive project projected to launch by 2018 at the time of the acquisition. Several additional products that were then in earlier stages of development were also acquired in the Uteron Acquisition. We accounted for the acquisition as a business combination requiring that the assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date.

At June 30, 2014, after an identified triggering event, the acquired in-process research and development ("IPR&D") intangible asset related to Estelle, a novel natural estrogen-based 28 day cycle oral contraceptive for the prevention of pregnancy, of \$13.1 million was deemed to be fully impaired. Consequently, the \$22.8 million contingent liability related to Estelle was written off, resulting in a net gain of \$9.7 million as a component of R&D expense. At June 30, 2014, after an identified triggering event, the acquired IPR&D intangible asset related to Colvir, a treatment of premalignant Human Papilloma Virus (HPV) lesions of the uterine, of \$2.0 million was deemed to be fully impaired. Consequently the \$1.5 million contingent liability was also written off, resulting in a net loss of \$0.5 million.

# **Divestitures**

# Western European Assets

During the year ended December 31, 2013, we held for sale our then current generic commercial infrastructure in France, Italy, Spain, Portugal, Belgium, Germany and the Netherlands, including products, marketing authorizations and dossier license rights. On January 17, 2014, we announced our intention to enter into an agreement with Aurobindo Pharma Limited ("Aurobindo") to sell these businesses. On April 1, 2014, the Company completed the sale of the assets in Western Europe.

In connection with the sale of our Western European assets, we entered into a supply agreement whereby the Company will supply product to Aurobindo over a period of five years. In the second quarter of 2014, we allocated the fair value of the consideration for the sale of the Western European assets of \$65.0 million to each element of the agreement, including the supply of product.

As a result of the transactions, we recognized as a component of discontinued operations, income / (loss) on the net assets held for sale of \$3.4 million and \$(34.3) million in the years ended December 31, 2014 and 2013, respectively. In addition, the Company recognized a loss on the disposal of the assets in the year ended December 31, 2014 of \$20.9 million and deferred revenue of \$10.1 million to be recognized over the course of the supply agreement as a

component of discontinued operations.

# **Business Description**

Prescription pharmaceutical products in the United States generally are marketed as either generic or brand pharmaceuticals. Results in continuing operations in the United States are primarily due to brand pharmaceuticals. Branded pharmaceutical products are marketed under brand names through programs that are designed to generate physician and consumer loyalty. The Company markets aesthetic products in the U.S. and internationally through programs designed to generate physician loyalty. Through our Anda Distribution segment, we distribute pharmaceutical products that have been commercialized by us and others, to independent pharmacies, pharmacy chains, pharmacy buying groups and physicians' offices.

Generic pharmaceutical products, which we account for in discontinued operations, are bioequivalents of, or in cases of protein-based biologic therapies, biosimilar to, their respective brand products and provide a cost-efficient alternative to branded products.

As a result of the differences between the types of products we market and/or distribute and the methods by which we distribute these products, we operate and manage our business in four distinct operating segments: US Brands, US Medical Aesthetics, International Brands and Anda Distribution. The operating segments are organized as follows:

- •The US Brands segment includes sales and expenses relating to branded products within the United States, including certain Botox® therapies.
- •The US Medical Aesthetics segment includes sales and expenses relating to aesthetics and dermatology products within the United States, including certain Botox® therapies.
- •The International Brands segment includes sales and expenses relating to products sold outside of the United States.
- •The Anda Distribution segment includes distribution of generic and branded pharmaceutical products manufactured by third parties, as well as by the Company, primarily to independent pharmacies, pharmacy chains, pharmacy buying groups and physicians' offices. The Anda Distribution segment operating results exclude sales of products developed, acquired, or licensed by the US Brands, US Medical Aesthetics and International Brands segments. As the generics business is now reported within discontinued operations, the Anda Distribution segment includes revenues and expenses related to Company manufactured generics products sold through Anda Distribution. Business Strategy

We apply three key strategies to achieve growth for our US Brands, US Medical Aesthetics and International Brands businesses: (i) internal development of differentiated and high-demand products, (ii) establishment of strategic alliances and collaborations and (iii) acquisition of products and companies that complement our current business. Our Anda Distribution business distributes products for approximately 340 suppliers and is focused on providing next-day delivery and responsive service to its customers. Our Anda Distribution business distributes a number of branded products in the United States. Growth in our Anda Distribution business will be largely dependent upon customer expansion, FDA approval of new generic products in the U.S. and expansion of our base of suppliers.

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.

### **US** Brands

Newly developed pharmaceutical products normally are patented or have market exclusivity and, as a result, 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 markets that we serve. These patented and off-patent trademarked products are brand pharmaceutical products. In March 2015, as a result of the Allergan Acquisition, we began promoting a number of additional branded products including, but not limited to Alphagan® /Combigan® , Botox®, Lumigan® /Ganfort® and Restasis®. In July 2014, as a result of the Forest Acquisition, we began promoting a number of additional branded products including, but not limited to Bystolic®, Canasa®, Carafate®, Fetzima®, Linzess®, Namenda®, Namenda XR®, Saphris®, Teflaro® and Viibryd®. In October 2013, as a result of the Warner Chilcott Acquisition, we began promoting a number of brand products, including, but not limited to, Actonel®, Asacol® HD, Atelvia®, Delzicol®, Estrace® Cream, Enablex®, Lo Loestrin® Fe and Minastrin® 24 Fe.

Net revenues in our US Brands segment were \$9,134.3 million, \$4,511.2 million, and \$1,001.2 million, or approximately 60.6%, 66.9% and 38.5% of our total net revenues in the years ended December 31, 2015, 2014, and 2013, respectively.

### **US Brands Strategy**

We market our brand products through our active sales professionals in the United States. Our sales and marketing efforts focus on general and specialty physicians who specialize in the diagnosis and treatment of particular medical conditions. Each group offers products to satisfy the unique needs of these physicians. We believe this focused sales and marketing approach enables us to foster close professional relationships with specialty physicians, as well as cover the primary care physicians who also prescribe in selected therapeutic areas. We believe that the current structure of sales professionals is very adaptable to the additional products we plan to add to our brand portfolio.

We have maintained an ongoing effort to enhance efficiencies and reduce costs in our manufacturing operations.

#### **US Brands Product Portfolio**

As of December 31, 2015, our portfolio of branded pharmaceutical products within the US Brands segment includes the following key promoted products:

Product	Active Ingredient	Therapeutic Classification
Alphagan®/Combigan®	Brimonidine tartrate	Selective alpha <sub>2</sub> agonist
Asacol®/Delzicol®	Mesalamine	Ulcerative colitis
Botox <sup>®</sup>	Onabotulimtoxin	Acetylcholine release inhibitor
Bystolic®	Nebivolol	Hypertension
Carafate®/Sulcrate®	Sucralfate	Ulcerative colitis
Dalvance <sup>®</sup>	Dalbavancin	Acute bacterial skin infections
Estrace® Cream	Estradiol	Hormone therapy
Linzess®/Constella®	Linaclotide	Irritable bowel syndrome
Lo Loestrin® Fe	Ethinyl estradiol and	Oral contraceptive
	norethindrone	
Lumigan®/Ganfort®	Bimatoprost	Prostaglandin analogue
Minastrin® 24 Fe	Ethinyl estradiol and	Oral contraceptive
	norethindrone	
Namenda XR®	Memantine HCl	Dementia
Namzaric®	Memantine HCl	Dementia
Restasis <sup>®</sup>	Cyclosporine	Topical immunomodulator
Saphris <sup>®</sup>	Asenapine	Schizophrenia, bipolar mania
Teflaro <sup>®</sup>	Ceftaroline fosamil	Acute bacterial skin infections, community-acquired
		bacterial pneumonia
Viberzi <sup>®</sup>	Eluxadoline	Irritable bowel syndrome
Viibryd®/Fetzima®	Vilazodone	Major depressive disorders
•	HCl/Levomilnacipran	
Zenpep <sup>®</sup>	Pancrelipase	Exocrine pancreatic insufficiency

# **US Medical Aesthetics**

Our US Medical Aesthetics business offers a wide range of silicone gel and saline breast implant options as well as a comprehensive, science-based facial aesthetic portfolio. Net revenues in our US Medical Aesthetics segment were \$1,513.9 million, or approximately 10.0% of our total net revenues in the year ended December 31, 2015. The US Medical Aesthetics segment is primarily attributable to the Allergan Acquisition. As such, there are no comparable sales for the years ended December 31, 2014 and 2013.

# **US Medical Aesthetics Strategy**

Our US Medical Aesthetics business is focused on maintaining a leading position within the U.S. market. We market our products through our active sales professionals in the United States. Our sales and marketing efforts focus on specialty physicians and surgeons who specialize in aesthetics. We believe this focused sales and marketing approach enables us to foster close professional relationships with specialty physicians.

### US Medical Aesthetics Product Portfolio

As of December 31, 2015, our portfolio of products within the US Medical Aesthetics segment includes the following key promoted products:

Product	Active Ingredient	Therapeutic Classification
Aczone <sup>®</sup>	Dapzone	Acne
$\mathrm{Botox}^{\circledR}$	Botulinum toxin	Musculoskeletal agent
Breast Implants	Silicone	Reconstructive plastic surgery
Juvederm®/Voluma®	Hyaluronic acid	Nasolabial folds

# **International Brands**

Our International Brands segment offers a wide array of branded and aesthetics products outside of the United States, primarily attributable to products acquired in the Allergan Acquisition. Net revenues in our International Brands segment were \$2,187.3 million,

\$203.5 million, and \$40.2 million, or approximately 14.5%, 3.0% and 1.5% of our total net revenues in the years ended December 31, 2015, 2014, and 2013, respectively.

# **International Brands Strategy**

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

### International Brands Product Portfolio

Our International Brands segment offers a wide array of branded and aesthetics products outside of the United States, primarily attributable to products acquired in the Allergan Acquisition.

As of December 31, 2015, our portfolio of products within the International Brands segment includes the following key promoted products:

Product	Active Ingredient	Therapeutic Classification
Alphagan®/Combigan®	Brimonidine tartrate	Selective alpha <sub>2</sub> agonist
Breast Implants	Silicone	Reconstructive plastic surgery
Botox®	Botulinum toxin	Musculoskeletal agent
Juvederm®/Voluma®	Hyaluronic acid	Nasolabial folds
Lumigan®/Ganfort®	Bimatoprost	Prostaglandin analogue

### Anda Distribution Segment

Our Anda Distribution segment distributes brand pharmaceutical products manufactured by third parties, as well as by Allergan, primarily to independent pharmacies, pharmacy chains, pharmacy buying groups and physicians' offices. Sales are principally generated through our national accounts relationships, an in-house telemarketing staff and through internally developed ordering systems. Additionally, we sell to members of buying groups, which are independent pharmacies that join together to enhance their buying power. We believe that we are able to effectively compete in the distribution market, and therefore optimize our market share, based on three critical elements: (i) competitive pricing, (ii) high levels of inventory for approximately 13,200 SKUs for responsive customer service that includes, among other things, next day delivery to the entire U.S., and (iii) well-established telemarketing relationships with our customers, supplemented by our electronic ordering capabilities. While we purchase most of the SKUs in our Anda Distribution operations from third party manufacturers, we also distribute our own products and our collaborative partners' products.

Revenue growth in our distribution operations will in part be dependent on the launch of new products, offset by the overall level of net price and unit declines on existing distributed products, and will be subject to changes in market share.

# Research and Development

We devote significant resources to the R&D of brand 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 license milestone payments, if any. R&D expenses include the following key components (\$ in millions):

Years Ended December			mber
	31,		
	2015	2014	2013
Brand expenditures	\$2,353.7	\$605.7	\$191.3
Medical expenditures	4.8	-	-
Total R&D	\$2,358.5	\$605.7	\$191.3

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

<sup>·</sup>the application of proprietary drug-delivery technology for new product development in specialty areas;

<sup>•</sup> the acquisition of mid-to-late development-stage brand drugs and biosimilars; and 12

•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, 2015, 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.

Included within discontinued operations is the impact of R&D expenditures for our generic product portfolio. As of December 31, 2015, we had more than 200 ANDAs on file in the United States relating to our generic portfolio. Refer to the "Government Regulation and Regulatory Matters" section below for a description of our process for obtaining FDA approval for our products.

As of December 31, 2015, we are developing a number of branded products, some of which utilize novel drug delivery systems, through a combination of internal and collaborative programs including the following:

			Expected	
			Launch	
Product	Therapeutic Area	Indication	Year	Phase
Restasis MDPF	Eye Care	Dry Eye	2016	Registration
XEN45	Eye Care	Glaucoma	2017	III
Sarecycline	Dermatology	Severe Acne	2018	III
Esmya	Woman's healthcare	Uterine Fibroids	2018	III
Bimatoprost SR	Eye Care	Glaucoma	2018	III
Tavilermide	Eye Care	Dry Eye	2019	III
Relamorelin**	Gastrointestinal	Gastroparesis	2020	II
Ubrogepant	Neurology	Acute Migraine	2020	II
Abicipar	Eye Care	Age Related Macular Degeneration	2020	III
Rapastinel	Psychiatry	Depression	2021	II

<sup>\*\*</sup> As part of our agreement with Rhythm Health, Inc.

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

Financial Information About Segments and Geographic Areas

The Company evaluates segment performance based on segment contribution. Segment contribution represents net revenues less cost of sales (excluding amortization and impairment of acquired intangibles including product rights), selling and marketing expenses, and select general and administrative expenses. The Company does not evaluate the following items at the segment level:

·Revenues and operating expenses within cost of sales (excluding amortization and impairment of acquired intangibles including product rights), selling and marketing expenses, and general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.

•

General and administrative expenses that result from shared infrastructure, including certain expenses located within the United States.

- ·Total assets including capital expenditures.
- ·Other select revenues and operating expenses including R&D expenses, amortization, goodwill impairments, IPR&D 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.

# Customers

In our US Brands, US Medical Aesthetics and International Brands operations, we sell our brand pharmaceutical products primarily to drug wholesalers, retailers and distributors, including national retail drug and food store chains, hospitals, clinics, mail order retailers, government agencies and managed healthcare providers such as health maintenance organizations and other institutions. In our Anda Distribution business, we distribute brand pharmaceutical products to independent pharmacies, alternate care providers (hospitals, nursing homes and mail order pharmacies), pharmacy chains, physicians' offices and buying groups.

Sales to certain of our customers 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	2015	2014	2013
McKesson Corporation	24 %	22 %	11 %
Cardinal Health, Inc.	18 %	16 %	10 %
AmerisourceBergen Corporation	17 %	17 %	6 %

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 and large drug store chains control a significant share of the market. Our Anda Distribution business competes directly with our large wholesaler customers with respect to the distribution of generic products.

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 Brands, US Medical Aesthetics and International Brands businesses, we compete with different companies depending upon product categories, and within each product category, upon dosage strengths and drug delivery systems. Such 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 product business requires us to identify and bring to market new products embodying technological innovations. Successful marketing of brand products depends primarily on the ability to communicate their effectiveness, safety and value to healthcare professionals in private practice, group practices and receive formulary status from managed care organizations. We anticipate that our brand 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. Our competitors in brand products include major brand name manufacturers of pharmaceuticals. Many of our competitors 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. If we directly compete with them for certain contracted business, such as the Pharmacy Benefit Manager business, or for the same markets and/or products, their financial strength could prevent us from capturing a meaningful share of those markets.

In our Anda Distribution segment, we compete with a number of large wholesalers and other distributors of pharmaceuticals, including McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., which distribute both branded and generic pharmaceutical products to their customers. These same companies are significant customers of our US Brands and US Medical Aesthetics businesses. As generic products generally have higher gross margins than branded products for a pharmaceutical distribution business, each of the large wholesalers, on an increasing basis, are offering pricing incentives on branded products if the customers purchase a majority of their

generic pharmaceutical products from the primary wholesaler. As we do not offer as broad a portfolio of branded products to our customers as some of our competitors, we are at times competitively disadvantaged. Increased competition in the generic industry as a whole may result in increased price erosion in the pursuit of market share. Refer to "ITEM 1A. RISK FACTORS — Risks Related to Our Business — Our Anda Distribution operations compete directly with significant customers of our generic and branded businesses" in this document.

As a result of the Teva Transaction, the Company's global generics business is classified as discontinued operations. Our discontinued operations actively competes in the generic pharmaceutical industry. Revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. As patents and regulatory exclusivity for brand name products expire or are successfully challenged, the first off-patent manufacturer to receive regulatory approval for generic equivalents of such products is generally able to achieve significant market penetration. As competing off-patent manufacturers receive regulatory approvals on similar products, market share, revenues and gross profit typically decline, in some cases dramatically. Accordingly, the level of market share, revenues and gross profit attributable to a particular generic product normally is related to the number of competitors in that product's market, pricing and the timing of that product's regulatory approval and launch, in relation to competing approvals and launches. We face competition from other generic drug manufacturers and from brand name companies in the generic market. Many of these companies seek to participate in sales of generic products by, among

other things, collaborating with other generic pharmaceutical companies or by marketing their own generic equivalent to their brand products as "Authorized Generics".

Manufacturing, Suppliers and Materials

As of December 31, 2015, we manufactured many of our own finished products at our plants including major manufacturing sites in:

Location	State / Country
Guarulhos	Brazil
Dupnitsa*	Bulgaria
San Jose	California
San Jose	Costa Rica
Davie*	Florida
Pringy	France
Weiderstadt	Germany
Athens*	Greece
Hafnarfjordur*	Iceland
Ambernath*	India
Goa*	India
Dublin	Ireland
Westport	Ireland
Nerviano*	Italy
Birzebbugia*	Malta
Zetjun*	Malta
Elizabeth*	New Jersey
Coleraine*	Northern Ireland
Cincinnati	Ohio
Fajardo*	Puerto Rico
Manati*	Puerto Rico
Waco	Texas
Barnstable*	UK
Salt Lake City*	Utah

<sup>\*</sup>Facilities are included in the assets being divested as part of the Teva Transaction.

We have implemented several cost reduction initiatives, which included the transfer of several solid dosage products from our Corona, California facility to other facilities throughout our manufacturing network and the ongoing implementation of an operational excellence initiative at certain of our manufacturing facilities. Our manufacturing facilities also include additional plants supporting local markets and alternative dosage forms.

We 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 San Jose, California, Coleraine, Northern Ireland and Ambernath, India facilities. Our Ambernath, India facility also manufactures API for third parties.

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 Consolidated Financial Statements" in this document.

In addition, we are dependent on third parties for the supply of the raw materials necessary to develop and manufacture our products, including the API and inactive pharmaceutical ingredients used in many of our 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. 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, which would likely 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 from key manufacturing sites or suppliers that in some cases may be the only source of finished products or raw materials, our ability to deliver our products to the market may be impeded" in this document. Refer to "ITEM 1A — RISK FACTORS — Risks Relating to Investing in the Pharmaceutical Industry — The supply of APIs into Europe may be negatively affected by recent 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 approved or, even if approved, if such patents are circumvented or not upheld in a court of law, or administrative proceedings, including oppositions, re-examinations or interparties 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. 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. Patents covering our Namenda® IR, Estrace® Cream, Actonel® (certain indications), Androderm<sup>®</sup>, Femhrt<sup>®</sup>, INFed<sup>®</sup> and Carafate<sup>®</sup> products have expired and we have no further patent protection on these products.

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 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.

Pharmaceutical companies with brand products are suing companies that produce off-patent forms of their brand name products for alleged patent infringement or other violations of intellectual property rights which may delay or prevent the entry of such a generic product into the market. For instance, when our global generics business files an ANDA in the U.S. seeking approval of a generic equivalent to a branded drug, we may certify under the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act") to the FDA that we do not intend to market our generic drug until any patent listed by the FDA as covering the brand drug has expired, in which case, the ANDA will be approved by the FDA no earlier than the expiration or final finding of invalidity of such patent(s). On the other hand, we could certify that we believe the patent or patents listed as covering the brand drug are invalid and/or will not be

infringed by the manufacture, sale or use of our generic form of the brand drug. In that case, we are required to notify the brand product holder or the patent holder that such patent is invalid or is not infringed. If the patent holder sues us for patent infringement within 45 days from receipt of the notice, the FDA is then prevented from approving our ANDA for 30 months after receipt of the notice unless the lawsuit is resolved in our favor in less time or a shorter period is deemed appropriate by a court.

Litigation alleging infringement of patents, 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 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 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, 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 the United States with some variations dependent upon local market dynamics.

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. There are generally two types of applications for FDA approval that would be applicable to our new products:

- ·NDA. 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 newly developed brand products or for a new dosage form of previously approved drugs.
- ·ANDA. We file an ANDA when we seek approval for off-patent or generic equivalents of a previously approved drug.

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 Investigational New Drug Application ("IND") to the FDA or meet one of the narrow exemptions that exist from the IND requirement.

The FDA can, and does, reject NDAs, require additional clinical trials, or grant approvals on a restricted basis only, even when product candidates performed well in clinical trials. 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 in connection with the product. There are also requirements to conduct pediatric trials for all new NDAs and supplements to NDAs, unless a waiver or deferral applies.

Similarly, FDA approval of an ANDA is required before we may begin marketing an off-patent or generic equivalent of a drug that has been approved under an NDA, or a previously unapproved dosage form of a drug that has been approved under an NDA. The ANDA approval process generally differs from the NDA approval process in that it does not typically require new preclinical and clinical studies; instead, it relies on the clinical studies establishing safety and efficacy conducted for the previously approved NDA drug. The ANDA process, however, typically requires data to show that the ANDA drug is bioequivalent to the previously approved drug. "Bioequivalence" compares the bioavailability of one drug product with another and, when established, indicates whether the rate and extent of absorption of a generic drug in the body are substantially equivalent to the previously approved drug. "Bioavailability" establishes the rate and extent of absorption, as determined by the time dependent concentrations of a drug product in the bloodstream or body needed to produce a therapeutic effect. The ANDA drug development and approval process generally takes

three to four years, which is less time than the NDA drug development and approval process since the ANDA process does not require new clinical trials establishing the safety and efficacy of the drug product.

Supplemental NDAs or ANDAs are required for, among other things, approval to transfer certain products from one manufacturing site to another or to change an API supplier, and may be under review for a year or more. In addition, certain products may only be approved for transfer once new bioequivalency studies are conducted or other requirements are satisfied.

To obtain FDA approval of both NDAs and ANDAs, 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. These regulations encompass all aspects of the production process from receipt and qualification of components to distribution procedures for finished products. They are evolving standards; thus, we must continue to expend substantial time, money and effort in all production and quality control areas to maintain compliance. 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 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, ANDAs 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 could cause us to modify certain activities identified during the inspection. A Form 483 notice is generally issued at the conclusion of an FDA inspection and lists conditions 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 achieve correction may be expected to result in an enforcement action.

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, ANDAs 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 us. 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 Generic Drug Enforcement Act of 1992 established penalties for wrongdoing in connection with the development or submission of an ANDA. Under this Act, the FDA has the authority to permanently or temporarily bar companies or individuals from submitting or assisting in the submission of an ANDA, and to temporarily deny approval to and suspend applications to market generic drugs. The FDA may also suspend the distribution of all drugs approved or developed in connection with certain wrongful conduct and/or withdraw approval of an ANDA and seek civil penalties. The FDA can also significantly delay the approval of any pending NDA, ANDA or other regulatory submissions under the Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Policy Act.

U.S. government reimbursement programs include Medicare, Medicaid, TriCare, and State Pharmacy Assistance Programs established according to statute, government regulations and policy. Federal law requires that all pharmaceutical manufacturers, as a condition of having their products receive federal reimbursement under Medicaid, must 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, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "ACA"), the required per-unit rebate for products marketed under ANDAs increased from 11% of the Average Manufacturer Price ("AMP") to 13%. Additionally, for products marketed under NDAs, the manufacturers rebate increased from 15.1% to 23.1% of the average manufacturer price, or the difference between the average manufacturer price and the lowest net sales price to a non-government customer during a specified period. In some states, supplemental rebates are required as a condition of including the manufacturer's drug on the state's Preferred Drug List.

The ACA also made substantial changes to reimbursement when seniors reach the Medicare Part D coverage gap "donut hole." By 2020, Medicare beneficiaries will pay 25% of drug costs when they reach the coverage threshold — the same percentage they were responsible for before they reached that threshold.

The Affordable Care Act 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. Additionally, beginning in 2013, the government/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 started at 2.5%, but will increase to 25% by 2020. At that point, the combined industry discounts and government subsidies will add up to 75% of brand-name drug costs. In addition, the federal government/Medicare Part D plan sponsors subsidize generic drug costs in the coverage gap. In 2015, subsidies on generic drugs were 35% and such subsidies will increase to 75% of generic drug costs in 2020 when the "donut hole" will be completely closed through these subsidies.

The Deficit Reduction Act of 2005 ("DRA") mandated a number of changes in the Medicaid program, including the use of AMP as the basis for reimbursement to pharmaceutical companies that dispense generic drugs under the Medicaid program. Three health care reform bills passed in 2010 significantly changed the definition of AMP, effective October 1, 2010. These legislative changes were part of the ACA and the FAA Air Transportation Modernization & Safety Improvement Act (the "Transportation Bill"). The impact of this legislation was that there were increases in Medicaid reimbursement to pharmacies for generics. These changes became effective on October 1, 2010.

On November 9, 2010, the Center for Medicare and Medicaid Services ("CMS") issued a final rule withdrawing and amending regulations that have governed the calculation of AMP and the establishment of federal upper limits since October 2007. The regulations were withdrawn to mandate AMP calculation under the revised drug rebate statute. The withdrawal required manufacturers to base October 2010 and subsequent months' AMPs on the statutory language until official guidance is issued.

In the absence of regulatory guidance governing the AMP calculation, CMS had instructed pharmaceutical manufacturers to base their AMP calculations on the definitions set forth in the statute, as amended by the ACA, the Health Care and Education Reconciliation Act, and the Transportation Bill. On January 27, 2012, CMS issued proposed rules on Medicaid pharmacy reimbursement using the AMP model. Allergan had adopted policies and procedures to ensure that we are calculating and reporting AMP in a manner that is consistent with the text and intent of the statute and the