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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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, 2014
Commission File Number: 1-10827

PAR PHARMACEUTICAL COMPANIES, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**22-3122182**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Ram Ridge Road, Chestnut Ridge, NY	10977
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (845) 573-5500

Securities registered pursuant to Section 12(b) and 12(g) of the Securities Exchange Act of 1934: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act: Yes __ No_X_

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act: Yes _X_ 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 (the "Exchange Act") during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days: Yes _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 Regulations S-T during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in a definitive proxy or information statement incorporated by reference in Part III of the Form 10-K or any amendment to the Form 10-K. [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 definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer [ ] Accelerated filer [ ] Non-accelerated filer [X] Smaller reporting company [ ]

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes __ No _X_

As of March 18, 2014, there was no established public trading market for the Registrant's common stock; therefore the aggregate market value of the common equity is not determinable.

Number of shares of the Registrant's common stock outstanding as of March 12, 2015: 100.

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PART I

Forward-Looking Statements

Certain statements in this Annual Report on Form 10-K constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including those concerning management's expectations with respect to future financial performance, trends and future events, particularly relating to sales of current products and the development, approval and introduction of new products. To the extent that any statements made in this Annual Report on Form 10-K contain information that is not historical, such statements are essentially forward-looking. These statements are often, but not always, made using words such as "estimates," "plans," "projects," "anticipates," "continuing," "ongoing," "expects," "intends," "believes," "forecasts" or similar words and phrases. Such forward-looking statements are subject to known and unknown risks, uncertainties and contingencies, many of which are beyond our control, which could cause actual results and outcomes to differ materially from those expressed in this Annual Report on Form 10-K. Risk factors that might affect such forward-looking statements include those set forth in Item 1A ("Risk Factors") of this Annual Report on Form 10-K and from time to time in our other filings with the Securities and Exchange Commission (the "SEC"), including Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and on general industry and economic conditions. Any forward-looking statements included in this Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K only, and, subject to any applicable law to the contrary, we assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

USE OF TRADEMARKS

We own or have rights to trademarks, service marks or trade names that we use in connection with the operation of our business. For example, our names and logos are protected. Some of the trademarks we own or have the right to use include "Par," "Par Pharmaceutical," "Par Pharmaceutical Companies, Inc.," "Par Formulations," "Nascobal," "Megace," "Vasostrict," "Adrenalin," and "Aplisol." We have applied for trademarks of "Par Specialty Pharmaceuticals" and "Par Sterile Products." We will assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. Other trademarks, service marks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

ITEM 1. Business

Unless the context otherwise requires, the terms "we," "our company," "the Company," "us," "our" and the like refer to Par Pharmaceutical Companies, Inc. and its consolidated subsidiaries.

GENERAL and RECENT DEVELOPMENTS

We were acquired at the close of business on September 28, 2012 through a merger transaction with Sky Growth Acquisition Corporation, a wholly owned subsidiary of Par Pharmaceutical Holdings, Inc. ("Holdings" and formerly known as Sky Growth Holdings Corporation). Holdings was formed by investment funds affiliated with TPG Capital, L.P. ("TPG" and, together with certain affiliated entities, collectively, the "Sponsor"). Holdings is owned by affiliates of the Sponsor and members of management. The acquisition was accomplished through a reverse subsidiary merger of Sky Growth Acquisition Corporation with and into the Company, with the Company being the surviving entity (the "Acquisition"). Subsequent to the Acquisition, we became an indirect, wholly owned subsidiary of Holdings. Prior to the Acquisition, we had operated as a public company with our common stock traded on the New York Stock Exchange.

Par Pharmaceutical Companies, Inc., incorporated in 1978 as Par Pharmaceutical, Inc., is a Delaware holding company that, principally through its wholly owned operating subsidiary, Par Pharmaceutical, Inc., specializes in developing, licensing, manufacturing, marketing and distributing generic drugs in the United States. We have a generics portfolio of approximately 95 products across an extensive range of dosage forms and delivery systems, including immediate and extended release oral solids (tablets, orally disintegrating tablets, capsules and powders), injectables, nasal sprays, ophthalmics and transdermal patches. Our focus is on high-barrier-to-entry products that are difficult to formulate, difficult to manufacture or face complex legal and regulatory challenges. These products often see limited competition and tend to be more profitable than commoditized generic drugs. We have an integrated team-based approach to product development that combines our formulation, regulatory, legal, manufacturing and commercial capabilities. As of December 31, 2014, we had over 200 products in our pipeline, which included 115 Abbreviated New Drug Applications ("ANDA" or "ANDAs") pending with the FDA, including 32 potential first-to-file and six potential first-to-market opportunities. We operate as two business segments: Par Pharmaceutical (or "Par"), which includes both generic products marketed under Par Pharmaceutical and sterile products marketed under Par Sterile Products, LLC ("Par Sterile Products" or "Par Sterile"); and Par Specialty Pharmaceuticals ("Par Specialty" and formerly known as Strativa Pharmaceuticals), which markets two branded products.

Our principal executive offices are located at One Ram Ridge Road, Chestnut Ridge, NY 10977, and our telephone number is (845) 573-5500. Additional information concerning our company can be found on our website at www.parpharm.com, including our

Code of Conduct. Our Code of Conduct applies to all of our directors, officers, employees and representatives. Amendments to our

Code of Conduct and any grant of a waiver from a provision of the Code requiring disclosure under applicable SEC rules will be disclosed on our website. Any of these materials may also be requested in print by writing to Par Pharmaceutical Companies, Inc., Attention: Barry J. Gilman, Deputy General Counsel and Secretary, at One Ram Ridge Road, Chestnut Ridge, NY 10977.

Our fiscal year ends on December 31 of each year presented. Our fiscal quarters end on each calendar quarter end (March 31st, June 30th, and September 30th). Our electronic filings with the SEC, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to these reports, are available on our website, free of charge, as soon as reasonably practicable after we electronically file or furnish them to the SEC. Information on our website is not, and should not be construed to be, part of this Annual Report on Form 10-K. 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. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet website that contains reports and other information regarding issuers, including the Company, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at http://www.sec.gov.

Par Pharmaceutical

Par Pharmaceutical includes generic products marketed under Par Pharmaceutical and sterile products marketed under Par Sterile. The focus of Par Pharmaceutical is to develop, license, manufacture, market and distribute generic prescription drugs in an extensive range of dosage forms and delivery systems, including immediate-release oral solids and alternate dosage forms such as extended-release oral solids, injectables, topicals, nasal sprays, ophthalmics, films and transdermal patches. We sell our products primarily in the United States. As the percentage of branded pharmaceuticals that are expected to lose patent protection increasingly shifts towards alternate dosage forms (dosage forms other than immediate-release oral solid dose), we have made investments in our development capabilities and technologies which better position us to take advantage of this change. On February 20, 2014, we completed our acquisition of Par Sterile, which expanded our capability and presence into the rapidly growing sterile drug market, including injectable products and ophthalmics. Par Pharmaceutical's products are primarily sold through wholesalers, retailers and mail order pharmacies. Par Sterile's products are primarily sold through wholesalers, often via an arrangement with a group purchasing organization, prior to being dispensed at hospitals or directly administered by physicians.

Our approach to product development is to target high-barrier-to-entry, first-to-file or first-to-market generic product opportunities. A "first-to-file" product refers to an ANDA that is the first ANDA filed containing a Paragraph IV patent challenge to the corresponding branded product, which offers the opportunity for 180 days of generic marketing exclusivity if approved by the FDA and if we are successful in litigating the patent challenge. A "first-to-market" product refers to a product that is the first marketed generic equivalent of a branded product for reasons apart from statutory marketing exclusivity, such as the generic equivalent of a branded product that is difficult to formulate or manufacture. Our potential first-to-file and first-to-market opportunities account for approximately 33% of our pipeline of 115 ANDAs. In addition, we plan to continue acquiring assets from and/or entering into partnership arrangements with companies that can deliver similar product opportunities.

Over the past two years, we introduced generic versions of several major pharmaceutical products, including Exforge®, Lovaza®, Precedex®, Lamictal® XR, Luvox CR® and Focalin XR®.

Within our generic products division, we also market "authorized generics," which are generic versions of brand drugs licensed to us by brand drug companies. Authorized generics do not face any regulatory barriers to introduction and may be sold during (and after) the statutory exclusivity period granted to the first-to-file generic equivalent to the brand product. In 2014, we introduced three authorized generics; entecavir (Baraclude®) licensed from Bristol-Myers Squibb Company, budesonide nasal spray (Rhinocort Aqua®) licensed from AstraZeneca and digoxin (Lanoxin®) licensed from Covis Pharma S.à.r.l. As of December 31, 2014, we also marketed authorized generic versions of budesonide capsules (Entocort EC®), metoprolol succinate ER (Toprol-XL®) and candesartan cilexetil (Atacand®) licensed from AstraZeneca.

Par Specialty Pharmaceuticals

Par Specialty Pharmaceuticals is focused on the marketing and distribution of two branded prescription products, Nascobal® (cyanocobalamin, USP) Nasal Spray ("Nascobal"), and Megace® ES. Nascobal® is a prescription vitamin B12 treatment indicated for maintenance of remission in certain pernicious anemia patients in a once-weekly intranasal administration, which may be preferable to periodic subcutaneous or intramuscular injections. Megace® ES is indicated for the treatment of anorexia, cachexia or any unexplained significant weight loss in patients with a diagnosis of AIDS.

Branded products usually benefit from patent protection, which can reduce competition and provide market exclusivity for the products. This exclusivity generally allows a branded product to remain profitable for a relatively longer period of time as compared to generic products. Par Specialty's products are marketed in the United States by our brand sales force, which communicates the therapeutic and health benefits of our products to healthcare providers and managed care organizations. In the near term we plan to continue to invest in the marketing and sales of Nascobal® Nasal Spray. In addition, we plan to continue to consider new strategic licenses and product acquisitions to expand our branded product portfolio for the longer term.

Nascobal® has one Orange Book patent running through March 2024 and two running through June 2024. Since January 31, 2013, our brand field sales force of approximately 60 people began focusing the majority of their detailing efforts on Nascobal® Nasal Spray, as explained below.

Megace® ES historically provided us with a relatively consistent revenue stream, which has declined and, we expect, will further decline over time due to the effects of our reduced product detailing and an increasingly difficult reimbursement climate. Further, in 2011 we sued a generic pharmaceutical manufacturer that filed an ANDA with a Paragraph IV certification seeking FDA approval of a generic version of Megace® ES on grounds of patent infringement, and we sued a second Paragraph IV filer in 2013. On February 21, 2014, the District Court issued a decision in favor of the first generic filer, finding all asserted patent claims invalid for obviousness, and we appealed to the U.S. Court of Appeals for the Federal Circuit. The first generic filer has received final FDA approval of its ANDA and announced its intent to launch its generic product. On August 12, 2014, the District Court granted our motion for preliminary injunction enjoining the first filer's launch of its generic product pending disposition of the case on appeal, requiring us to post a $10.0 million bond. On December 3, 2014, the Federal Circuit reversed the District Court's decision, remanding for further findings of fact. On March 9, 2015, the District Court granted our motion for preliminary injunction enjoining the first filer's launch of its generic product pending disposition of the case on remand, requiring us to post a $6.0 million bond. Any such launch of a generic version of Megace® ES would have a material adverse impact on our brand sales of the product. For more information, please see Note 19 - Commitments, Contingencies and Other Matters: Legal Proceedings.

In January 2013, we initiated a restructuring of Par Specialty in anticipation of entering into a settlement agreement and corporate integrity agreement that terminated the investigation by the U.S. Department of Justice ("DOJ") into Par Specialty's marketing of Megace® ES. We reduced our Par Specialty workforce by approximately 70 people, with the majority of the reductions in the sales force. On March 5, 2013, we entered into the settlement agreement with the DOJ. The settlement agreement provided for a payment by the Company of an aggregate amount of approximately $45 million (plus interest and fees) and included a plea agreement with the New Jersey Criminal Division of the DOJ in which the Company admitted to a single count of misdemeanor misbranding, a civil settlement with the DOJ, a state settlement encompassing 49 states (one state declined to participate due to the small amount of its potential recovery), and a release from each of these entities in favor of the Company related to the practices at issue in the terminated investigation. Additionally, we entered into a corporate integrity agreement ("CIA") with the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG"). In exchange for agreeing to enter into the CIA, we received assurance that the OIG will not exercise its ability to permissively exclude the Company from doing business with the federal government. The CIA includes such requirements as enhanced training time, enhanced monitoring of certain functions, and annual reports to the OIG through an independent review organization. Although our compliance activities increased under the CIA, we believe the terms to be reasonable and not unduly burdensome.

Recent Acquisitions

On February 20, 2014, we completed our acquisition of JHP Group Holdings, Inc. and its subsidiaries, including JHP Pharmaceuticals, LLC (now known as Par Sterile Products, LLC), a leading specialty pharmaceutical company that develops, manufactures and markets sterile injectable products, for $490 million, subject to certain customary post-closing adjustments. Par Sterile Products focuses on the U.S. sterile injectable drug market, manufactures and sells branded and generic aseptic injectable pharmaceuticals in hospital and clinical settings, and provides contract manufacturing services for global pharmaceutical companies. Par Sterile Products' sterile manufacturing facility in Rochester, Michigan has the capability to manufacture small-scale clinical through large-scale commercial products. We funded this transaction and associated expenses with debt financing, which is subject to customary conditions, and an equity commitment from certain investment funds associated with TPG Capital.

On November 1, 2013, Par Formulations entered into a definitive agreement (the "Nuray I Purchase Agreement") with Nuray Chemicals Private Limited, a privately-held company based in Chennai, Tamil Nadu, India ("Nuray"), to purchase Nuray's API development and manufacturing business located in Chengalput MGR District, Tamil Nadu, India ("Nuray I ") for up to $19 million in cash and contingent payments. In August 2014, prior to closing the Nuray I Purchase Agreement, Par Formulations began to evaluate the acquisition of Nuray's API development and manufacturing business located in Alathur Karchipuram District, Tamil Nadu, India ("Nuray II"). On December 23, 2014, Par Formulations entered into a definitive agreement (the "Nuray II Purchase Agreement") with Nuray to purchase Nuray II for up to $20 million in cash and contingent payments. The Nuray I Purchase Agreement terminated upon the execution of the Nuray II Purchase Agreement. The closing of the Nuray II acquisition is subject to the receipt of applicable regulatory approvals and other customary closing terms and conditions. The operating results of Nuray II will be included in our consolidated financial results from the date of the closing of the acquisition as part of the Par Pharmaceutical segment. We will fund the purchase from cash on hand.

On February 17, 2012, we completed our acquisition of Par Formulations Private Limited ("Par Formulations" and formerly Edict Pharmaceuticals Private Limited), a Chennai, India-based developer and manufacturer of generic pharmaceuticals, for approximately $37 million. The acquired assets included numerous in-process research and development products, a pipeline of 11 pending ANDAs, including one confirmed first-to-file, and a facility with manufacturing capabilities and research and development capabilities located in India. The addition of Par Formulations broadens our research and development capabilities.

On November 17, 2011, we completed our acquisition of Anchen Incorporated and its subsidiary Anchen Pharmaceuticals, Inc. (collectively, "Anchen"), a privately held generic pharmaceutical company, for $413 million. The Anchen assets acquired included five marketed generic products, a number of in-process research and development products, which included a pipeline of 29

pending ANDAs, including five confirmed first-to-file, and leased facilities with manufacturing capabilities and research and development capabilities located in California. Anchen enhanced our modified release and research and development capabilities. Equally important, Anchen also has provided us manufacturing flexibility through its established commercial infrastructure. In 2013, we successfully introduced three of these products, including the generic versions of Luvox CR®, Trilipix® and Kapvay®.

OUR INDUSTRY

Prescription pharmaceutical products in the U.S. market are sold either as branded or generic products. Generic drugs are the pharmaceutical and therapeutic equivalents of branded products and are usually marketed under their generic (chemical) names rather than by brand names. Typically, a generic drug may not be marketed until the expiration of applicable patent(s) on the corresponding branded product, unless a resolution of patent litigation results in an earlier opportunity to enter the market. Generic drugs are the same as branded products in dosage form, safety, efficacy, route of administration, quality, performance characteristics and intended use, but they are sold generally at prices below those of the corresponding branded products. Generic drugs provide a cost-effective alternative for consumers, while maintaining the same high quality, efficacy, safety profile, purity and stability of the branded product. An ANDA is required to be filed and approved by the FDA in order to manufacture a generic drug for sale in the United States. The time required to obtain FDA approval of ANDAs is on average approximately 42 months after initial filing. The aggregate number of ANDAs submitted to the FDA in 2014 was 1,221. There have been recent changes in FDA submission requirements and we believe that those companies that are able to prepare high quality submissions are comparatively advantaged.

According to IMS Health, generic pharmaceuticals account for approximately 86% of all prescriptions dispensed as of January 2014. According to EvaluatePharma, the worldwide generics market was estimated to be worth $74 billion in sales in 2014 and is expected to grow an average rate of approximately 6.3% per year over the next six years.

PRODUCT INFORMATION

We distribute numerous drugs across an extensive range of dosage forms and delivery systems, including immediate and extended release oral solids (tablets, orally disintegrating tablets, capsules and powders), injectables, nasal sprays, ophthalmics, and transdermal patches. We have a generics portfolio of approximately 95 products across an extensive range of dosage forms and delivery systems. In addition to our current products, our pipeline consists of new products that will further expand and diversify our portfolio. We believe our broad suite of products has allowed us to increase our market presence and develop long term relationships with customers. In recent years, we introduced products across dosage forms such as generic versions of Actiq® (transmucosal lozenge), Entocort® EC (capsule), Precedex® (injectable), and Maxalt-MLT® (ODT), as well as Adrenalin® (injectable), which is marketed by Par Sterile as a branded pharmaceutical product.

We hold the ANDAs and New Drug Applications ("NDA" or "NDAs") for the drugs that we manufacture, including our branded products Megace® ES and Nascobal®. We seek to introduce new products through our research and development program, and through distribution and other agreements, including licensing of generic, branded, and authorized generic products, with pharmaceutical companies located in various parts of the world. As such, we have pursued and continue to pursue arrangements and relationships that share development costs and generate profits from jointly-developed products.

We detail our more significant revenue producing products in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, and in our Notes to Consolidated Financial Statements elsewhere in this Annual Report on Form 10-K.

Our generic products cover a wide range of therapeutic categories. We do not specialize in or concentrate on any therapeutic categories; instead, our strategy focuses on high-barrier-to-entry, first-to-file or first-to-market opportunities. By specializing in high barrier-to-entry products that are either difficult to manufacture or require complex legal challenges, we seek to market products that have limited competition where we can maintain market exclusivity or two or fewer competitors for extended periods. As a result, more than half of our generic adjusted gross profit in 2014 was garnered from products that are either exclusive or have two or fewer competitors, which we believe leads to more sustainable market share and profitability for our product portfolio. In recent years, we have introduced generic versions of several major pharmaceuticals with high barriers to entry such as Lovaza® (complex and difficult-to-source API), Precedex® (unique dosage form), Luvox CR® (controlled-release product) and Focalin XR® (controlled substance).

In addition, we have a track record of partnership with several large brand pharmaceutical companies as an authorized generics partner, which we believe is a result of our broad distribution network and strong trade presence. We also believe we are a partner of choice to large generic companies for product divestitures that arise as a result of industry consolidation, and for smaller development organizations looking for a partner that has deep experience with product development, patent litigation strategy and a strong market presence. Recent examples include our introduction of authorized generic versions as noted above, our November 2012 acquisition of a mix of marketed products, ANDAs awaiting FDA approval and one late-stage development product in connection with Watson Pharmaceuticals' acquisition of Actavis Group, and our partnership with Glenmark Pharmaceuticals Ltd. for the right to distribute generic Zetia®.

RESEARCH AND DEVELOPMENT

Par Pharmaceutical

We have invested significant resources and focus on our Par Pharmaceutical division to expand our technology capabilities to develop a range of products in-house, including immediate-release oral solids and alternate dosage forms such as extended-release oral solids, injectables, topicals, nasal sprays, ophthalmics, films and transdermal patches. As of December 31, 2014, our pipeline included over 200 products, 115 of which are pending at the FDA, including 32 potential first-to-file and six potential first-to-market opportunities, and approximately 100 more products in development.

Our research and development activities for generic products consist principally of (i) identifying and conducting patent and market research on branded drugs for which patent protection has expired or is expected to expire in the near future, (ii) identifying and conducting patent and market research on branded drugs for which we believe the patents are invalid or for which we believe we can develop a non-infringing formulation, (iii) researching and developing new product formulations based upon such drugs and (iv) introducing technology to improve production efficiency and enhance product quality. The scientific process of developing new products and obtaining FDA approval is complex, costly and time-consuming; there can be no assurance that any products will be developed, regardless of the amount of time and money spent on research and development. The development of products may be curtailed at any stage of development due to the introduction of competing generic products or other reasons.

The research and development of our generic pharmaceutical products, including pre-formulation research, process and formulation development, required studies and FDA review and approval, has historically taken approximately two to three years to complete. In addition, ANDAs containing a Paragraph IV patent challenge are subject to a 30-month "stay" of regulatory approval during the resolution of related patent litigation. Accordingly, we typically select products for development that we intend to market several years in the future. However, the length of time necessary to bring a product to market can vary significantly and depends on, among other things, the availability of funding, challenges relating to formulation or establishing bioequivalence, and patent challenges associated with the product.

We contract with outside laboratories to conduct bioequivalence studies, which, in the case of oral solids, generally are required in order to obtain FDA approval. These studies are used to establish that there is an absence of a significant difference in the rate and extent for absorption of the generic product and the corresponding branded drug. Each bioequivalence study can cost up to approximately $4 million. In some instances, we may also be required to perform clinical studies in patients, which could cost up to approximately $9 million. In January 2015, we acquired bioequivalence and clinical end point study capabilities through our acquisition of Par Biosciences Private Limited (formerly known as Ethics Bio Lab Private Limited), which will decrease our dependence on third parties for such services in the future.

From time to time, we enter into product development and license agreements with various third parties with respect to the development or marketing of new products. Pursuant to these agreements, we have advanced funds to several unaffiliated companies for products in various stages of development.

Par Specialty Pharmaceuticals

Our current strategy for developing the Par Specialty branded products portfolio is to bypass the substantial investments associated with the development of branded drugs, and instead to focus on the profitability of Nascobal® Nasal Spray. In addition, we will consider opportunities to add to our portfolio of branded drugs through in-licensing and the acquisition of late-stage development products or currently marketed products.

MARKETING AND CUSTOMERS

We market our generic products principally to wholesalers, drug store chains, supermarket chains, mass merchandisers, distributors, mail order accounts, hospitals and the government. Par Specialty Pharmaceuticals products are marketed by its sales force of approximately 60 people, which communicates the therapeutic and health benefits of our branded products to healthcare providers and managed care organizations. Some of our wholesalers and distributors purchase products and warehouse those products for certain retail drug store chains, independent pharmacies and managed health care organizations. Customers in the managed health care market include health maintenance organizations, nursing homes, hospitals, clinics, pharmacy benefit management companies and mail order customers.

We have approximately 120 customers, some of which are part of large buying groups. In the year ended December 31, 2014, our four largest customers in terms of net sales accounted for approximately 70% of our total net revenue. We do not have written agreements that guarantee future business with any of these major customers, and the loss of any one or more of these customers or the substantial reduction in orders from any of such customers could have a material adverse effect on our operating results, prospects and financial condition.

Manufacturing

We are committed to high product quality standards and allocate significant resources and focus to quality assurance. Our quality

control and manufacturing excellence. We operate five FDA approved manufacturing facilities, four of which are located in the United States (Chestnut Ridge, New York; Rochester, Michigan; Irvine, California; and as of January 9, 2015, Stratford, Connecticut) and one

in India (Chennai), with ample capacity and room for expansion. These facilities handle the production, assembly, quality assurance testing and packaging of our products. We estimate that for the products we manufacture internally, our U.S. facilities contributed 98% of our manufacturing production based on revenues compared to 2% in India. Our facilities have passed all recent FDA inspections and we have not received any warning letters from the FDA with respect to manufacturing plants we have operated since before 2000. Manufacturing and supply reliability has become increasingly valuable to customers as the FDA has increased scrutiny of generics manufacturers.

In addition, we have strategic alliances and relationships with several pharmaceutical and chemical companies that provide us with products for sale under various distribution, manufacturing, development and licensing agreements. As of December 31, 2014, we manufactured and/or distributed a total of approximately 95 products. Of these, we manufactured and distributed approximately 70 products, and we distributed approximately 25 products that were manufactured by others.

ORDER BACKLOG

The value of open purchase orders (gross sales basis) which management believes to be firm as of December 31, 2014, was approximately $69 million. These orders represent unfilled orders as of December 31, 2014, along with orders that were scheduled to be shipped at December 31, 2014. Open orders are subject to cancellation without penalty.

COMPETITION

The pharmaceutical industry is highly competitive. At times, we may not be able to differentiate our products from our competitors' products, successfully develop or introduce new products that are less expensive than our competitors' products, or offer purchasers payment and other commercial terms as favorable as those offered by our competitors. We believe that our principal generic competitors are Teva Pharmaceutical Industries Limited ("Teva"), Sandoz (a division of Novartis AG) ("Sandoz"), Mylan Inc. ("Mylan") and Actavis plc ("Actavis"), based upon the markets in which we compete. Our strategy focuses on high-value, first-to-file or first-to-market opportunities, regardless of therapeutic category. By specializing in high-barrier-to-entry products that are either difficult to manufacture or require complex legal challenges, we endeavor to market more profitable and longer-lived products relative to our competitors. There can be no assurance, however, that this strategy will enable us to compete successfully in the industry or that we will be able to develop and implement any new or additional viable strategies.

The Hatch-Waxman amendments to the FDCA provide for a period of 180 days of generic marketing exclusivity for each applicant that is first-to-file an ANDA containing a Paragraph IV certification. The holder of an approved first-to-file ANDA that is successful in challenging the applicable branded drug patent(s) generally enjoys higher market share and revenue during this period of marketing exclusivity. At the expiration of the exclusivity period, other generic distributors may enter the market, resulting in a significant price decline for the drug. In some instances, price declines have exceeded 90%. As a result of price declines, we may at our discretion provide price adjustments to our customers for the difference between our new (lower) price and the price at which we previously sold the product then held in inventory by our customers. These types of price adjustments are commonly known as shelf stock adjustments. There are circumstances under which, as a matter of business strategy, we may decide not to provide price adjustments to certain customers, and consequently, we may receive returns of our customers' unsold products and lose future sales volume to competitors rather than reduce our pricing.

Competition in the generic drug industry has also increased due to the advent of authorized generics. Authorized generics are generic pharmaceutical products that are introduced by brand companies, either directly or through third parties, under the brand's NDA approval. Authorized generics may be sold during (and after) the statutory exclusivity period granted to the first-to-file generic equivalent to the branded product. This is a significant source of competition for us, because brand companies do not face any regulatory barriers to introducing a generic version of their own branded drugs. Further, authorized generics may be sold during any period of generic marketing exclusivity granted to a generic company, which significantly undercuts the profits that a generic company could otherwise receive as an exclusive marketer of a generic product. Such actions have the effect of reducing the potential market share and profitability of our generic products and may inhibit us from introducing generic products corresponding to certain branded drugs. We have also marketed authorized generics in partnership with brand companies, including during the exclusivity periods of our generic competitors.

Increased price competition has also resulted from consolidation among wholesalers and retailers and the formation of large buying groups, which has caused reductions in sales prices and gross margin. This competitive environment has led to an increase in customer demand for downward price adjustments from the distributors of generic pharmaceutical products. Such price reductions are likely to continue, or even increase, which could have a material adverse effect on our revenue and gross margin.

The principal competitive factors in the generic pharmaceutical market include:

- introduction of other generic drug manufacturers' products in direct competition with our products,
- introduction of authorized generic products in direct competition with our products, particularly during exclusivity periods,
- consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups,
- ability of generic competitors to quickly enter the market after the expiration of patents or exclusivity periods, diminishing the amount and duration of significant profits,
- the willingness of generic drug customers, including wholesale and retail customers, to switch among products of different

pharmaceutical manufacturers;

- pricing pressures by competitors and customers,

- a company's reputation as a manufacturer and distributor of quality products,
- a company's level of service (including maintaining sufficient inventory levels for timely deliveries),
- product appearance and labeling, and
- a company's breadth of product offerings.

Our branded products benefit from patent protection, making them subject to Paragraph IV patent challenges that could jeopardize our market exclusivity for these products. Consequently, competition from generic equivalents following a successful Paragraph IV patent challenge against one of our branded products could have an adverse effect on Par Specialty. In addition, after patent protections expire, generic products can be sold in the market at a significantly lower cost than the branded version, and, where available, may be required or encouraged in preference to the branded version under third party reimbursement programs. Generic products may also be substituted for branded products by pharmacies, and state laws sometimes require pharmacies to effect such substitution. Par Specialty also faces competition from other brand drug companies. Many of our brand competitors have longer operating histories, broader product portfolios and greater financial, research and development, marketing and other resources than we do. Consequently, many of our brand competitors may be able to develop products superior to our own. Furthermore, we may not be able to differentiate our products from those of our brand competitors or offer customers payment and other commercial terms as favorable as those offered by our brand competitors. The markets in which we compete and intend to compete are undergoing, and are expected to continue to undergo, rapid and significant change. We expect brand competition to intensify as technological advances and consolidations continue.

RAW MATERIALS

The raw materials essential to our manufacturing business are purchased primarily from U.S. distributors of bulk pharmaceutical chemicals manufactured by foreign companies. To date, we have experienced no significant difficulties in obtaining raw materials and expect that raw materials will generally continue to be available in the future. However, because the federal drug application process requires specification of raw material suppliers, if raw materials from a specified supplier were to become unavailable, FDA approval of a new supplier would be required. A delay of six months or more in the manufacture and marketing of the drug involved while a new supplier becomes qualified by the FDA and its manufacturing process is determined to meet FDA standards could, depending on the particular product, have a material adverse effect on our results of operations and financial condition. Generally, we attempt to mitigate the potential effects of any such situation by providing for, where economically and otherwise feasible, two or more suppliers of raw materials for the drugs that we manufacture. In addition, we may attempt to enter into a contract with a raw material supplier in an effort to ensure adequate supply for certain products.

EMPLOYEES

At December 31, 2014, we had approximately 1,600 employees, of which approximately 200 employees are covered by a collective bargaining agreement. We consider our employee relations to be good.

GOVERNMENT REGULATION

The development, manufacturing, sales, marketing and distribution of our products are subject to extensive regulation by the U.S. federal government, principally the FDA, and, as applicable, the Drug Enforcement Agency, FTC and state and local governments. For both currently marketed and future products, failure to comply with applicable regulatory requirements can, among other things, result in suspension of regulatory approval and possible civil and criminal sanctions. Regulations, enforcement positions, statutes and legal interpretations applicable to the pharmaceutical industry are constantly evolving and are not always clear. Significant changes in regulations, enforcement positions, statutes and legal interpretations could have a material adverse effect on our financial condition and results of operations.

Additionally, future healthcare legislation or other legislative proposals at the federal and state levels could bring about major changes in the affected health care systems, including statutory restrictions on the means that can be employed by brand and generic pharmaceutical companies to settle Paragraph IV patent litigations. We cannot predict the outcome of such initiatives, but such initiatives, if passed, could result in significant costs to us in terms of costs of compliance and penalties associated with failure to comply.

The FDCA, the Controlled Substances Act and other federal statutes and regulations govern the development, testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, import and export, and advertising and promotion of our products. Non-compliance with applicable regulations can result in judicially and/or administratively imposed sanctions, including the initiation of product seizures, injunctions, fines and criminal prosecutions. Administrative enforcement measures may involve the recall of products, as well as the refusal of an applicable government authority to enter into supply contracts or to approve NDAs and ANDAs. The FDA also has the authority to withdraw its approval of drugs in accordance with its regulatory due process procedures.

New Drug Applications and Abbreviated New Drug Applications

FDA approval is required before any new drug, including a generic equivalent of a previously approved branded drug, may be

marketed. To obtain FDA approval for a new drug, a prospective manufacturer must, among other things, demonstrate that its manufacturing facilities comply with the FDA's current Good Manufacturing Practices ("cGMP") regulations, which is discussed in

further detail below. The FDA may inspect the manufacturer's facilities to ensure such compliance prior to approval or at any other time. The manufacturer is required to comply with cGMP regulations at all times during the manufacture and processing of drugs. To comply with the standards set forth in these regulations, we must continue to expend significant time, money and effort in the areas of production, quality control and quality assurance.

In order to obtain FDA approval of a new drug, a manufacturer must demonstrate the drug's safety and efficacy. There currently are two ways to satisfy the FDA's safety and effectiveness requirements:

- ***New Drug Applications (NDAs)***. Unless the procedure discussed in the following paragraph is permitted under the FDCA, a prospective manufacturer generally must submit to the FDA an NDA containing complete pre-clinical and clinical safety and efficacy data or a right of reference to such data. The pre-clinical data must provide an adequate basis for evaluating the safety and scientific rationale for the initiation of clinical trials. Clinical trials are conducted in three sequential phases and may take up to several years to complete. At times, the phases may overlap. Data from pre-clinical testing and clinical trials is submitted to the FDA as an NDA for marketing approval. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the data owner. The applicant may rely upon the FDA's findings of safety and efficacy for an approved product that acts as the "listed drug." The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the listed drug.

- ***Abbreviated New Drug Applications (ANDAs).*** The Hatch-Waxman amendments to the FDCA established a statutory procedure for submission and FDA review and approval of ANDAs for generic versions of branded drugs previously approved by the FDA (such previously approved drugs are referred to as "listed drugs"). Because the safety and efficacy of listed drugs have already been established by the brand company, the FDA waives the requirement for complete clinical trials. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the active pharmaceutical ingredient is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the listed drug. For some drugs (e.g., locally acting drugs like topical anti-fungals), other means of demonstrating bioequivalence may be required by the FDA, especially where rate and/or extent of absorption are difficult or impossible to measure. In addition to the bioequivalence data, an ANDA must contain patent certifications and chemistry, manufacturing, labeling and stability data.

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 bioequivalence studies are conducted or other requirements are satisfied.

The Hatch-Waxman amendments also established certain statutory protections for listed drugs. Under the Hatch-Waxman amendments, approval of an ANDA for a generic drug may not be made effective for interstate marketing until all relevant patents for the listed drug have expired, been withdrawn, delisted, or determined to be invalid, unenforceable, or not infringed by the generic drug applicant submitting a Paragraph IV certification. Prior to enactment of the Hatch-Waxman amendments, the FDA did not consider the patent status of a previously approved drug. In addition, under the Hatch-Waxman amendments, statutory non-patent exclusivity periods are established following approval of certain listed drugs, where specific criteria are met by the drug. For example, for new chemical entities, an ANDA or 505(b)(2) application referencing that drug may not be filed with the FDA until the expiration of five years after approval of that drug, unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA, including a 505(b)(2) NDA, includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. Additionally, drugs approved for so-called "orphan indications" (those diseases for which the patient population is sufficiently small) are entitled to a seven year data exclusivity period. The Hatch-Waxman amendments also provide for extensions of up to five years for certain patents covering drugs to compensate the patent holder for the reduction in the effective market life of the patented drug resulting from the time spent in the federal regulatory review process.

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that, according to the NDA holder/patent holder, cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;

- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or

- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification.

If the ANDA or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

On February 6, 2015, the FDA issued proposed regulations concerning submission of patent information to FDA, patent certifications by ANDA and 505(b)(2) applicants, notices of Paragraph IV certifications, and the 30-month stay. We cannot predict when the regulations might be finalized or whether, if finalized, the regulations will be substantially similar to the proposal. When final regulations are promulgated, we will have a clearer view of their impact on this aspect of our business.

With respect to Par Specialty Pharmaceuticals, our current strategy is to bypass the substantial investments associated with the development of branded drugs and instead to focus on the profitability of our existing branded products and consider opportunities to add to our portfolio through in-licensing and acquisition of late-stage development products or currently marketed products. If we were to undertake the process of developing a branded product and bringing it to market, the first step in obtaining FDA approval for a drug that has not been previously approved is pre-clinical testing. Pre-clinical tests are intended to provide a laboratory evaluation of the product to determine its chemistry, formulation and stability. Toxicology studies are also performed to assess the potential safety and efficacy of the product. The results of these studies are submitted to the FDA as part of an investigational new drug ("IND") application. The toxicology studies are analyzed to ensure that clinical trials can safely proceed. There is a 30-day period in which the FDA can raise concerns regarding the trials proposed in an IND. If the FDA raises any concerns, the developer must address those concerns before the clinical trials can begin. An IND becomes effective after such 30-day period if the FDA does not raise any concerns. Prior to the start of any clinical study, an independent institutional review board must review and approve such study.

There are three main stages of clinical trial development:

- In Phase I, the drug is tested for safety, absorption, tolerance and metabolism in a small number of subjects.
- In Phase II, after successful Phase I evaluations, the drug is tested for efficacy in a limited number of patients. The drug is further tested for safety, absorption, tolerance and metabolism.
- In Phase III, after successful Phase II evaluations, further tests are done to determine safety and efficacy in a larger number of patients who are to represent the population in which the drug will eventually be used.

The developer then submits an NDA containing the results from the pre-clinical and clinical trials. The NDA drug development and approval process takes approximately three to ten years or more.

Pricing Regulation

Successful commercialization of our products depends, in part, on the availability of governmental and third-party payor reimbursement for the cost of our products. Government authorities and third-party payors increasingly are challenging the price of medical products and services. On the government side, there is a heightened focus, at both the federal and state levels, on decreasing costs and reimbursement rates in Medicaid, Medicare and other government insurance programs. This has led to an increase in federal and state legislative initiatives related to drug prices, which could significantly influence the purchase of pharmaceutical products, resulting in lower prices and changes in product demand. If enacted, these changes could lead to reduced payments to pharmacies. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If our current products or future drug candidates are not included on these preferred drug lists, physicians may not be inclined to prescribe them to their Medicaid patients, thereby diminishing the potential market for our products.

Moreover, government regulations regarding reporting and payment obligations are complex, and we are continually evaluating the methods we use to calculate and report the amounts owed with respect to Medicaid and other government pricing programs. Our calculations are subject to review and challenge by various government agencies and authorities, and it is possible that any such review could result either in material changes to the method used for calculating the amounts owed to such agency or the amounts themselves. Because the process for making these calculations, and our judgments supporting these calculations, involve subjective decisions, these calculations are subject to audit. In the event that a government authority challenges or finds ambiguity with regard to our report of payments, such authority may impose civil and/or criminal sanctions, which could have a material adverse effect on our business. From time to time we conduct routine reviews of our government pricing calculations. These reviews may have an impact on government price reporting and rebate calculations used to comply with various government regulations regarding reporting and payment obligations.

Healthcare Reform

In the United States, there have been a number of federal and state proposals during the last several years regarding the pricing of pharmaceutical products and other changes to the healthcare system. It is uncertain what other legislative proposals may be adopted

or what actions federal, state, or private payors may take in response to any healthcare reform proposals or legislation. We cannot predict the effect such reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

By way of example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was signed into law, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. The current legislation includes measures that (i) significantly increase Medicaid rebates through both the expansion of the program and significant increases in rebates; (ii) substantially expand the Public Health System (340B) program to allow other entities to purchase prescription drugs at substantial discounts; (iii) extend the Medicaid rebate rate to a significant portion of Managed Medicaid enrollees; (iv) assess a 50% rebate on Medicaid Part D spending in the coverage gap for branded and authorized generic prescription drugs; and (v) levy a significant excise tax on the industry to fund the healthcare reform. The impacts of these provisions are included in our current financial statements.

Fraud and Abuse Regulation

Pharmaceutical companies are subject to various federal and state laws that are intended to combat health care fraud and abuse, and that govern certain of our business practices, especially our interactions with customers and potential customers through sales and marketing, or research and development activities. These include anti-kickback laws, false claims laws, sunshine laws, privacy laws, and FDA regulation of advertising and promotion of pharmaceutical products.

- Anti-kickback laws, of which the Federal health care programs anti-kickback law is most commonly the subject of enforcement proceedings, prohibit, among other things, the knowing and willful offer or payment of remuneration intended to induce, or in exchange for, ordering (or arranging for or recommending ordering) covered products or services, including our products.
- False claims laws prohibit knowingly presenting, or causing to be presented, claims for payment to third party payers (Medicare and Medicaid) that are false or fraudulent and, under the Federal False Claims Act, a claim is deemed false or fraudulent if it is made pursuant to an illegal kickback.
- Sunshine laws, including the Federal Open Payments law enacted as part of the Affordable Care Act, require pharmaceutical manufacturers to disclose payments and other transfers of value to physicians and certain other health care providers or professionals, and in the case of some state sunshine laws, restrict or prohibit certain such payments.
- Privacy laws, such as the privacy regulations implemented under the Health Insurance Portability and Accountability Act (HIPAA), restrict covered entities from using or disclosing protected health information. Covered entities commonly include physicians, hospitals, and health insurers from which we may seek to acquire data to aid in our research, development, sales and marketing activities. Although pharmaceutical manufacturers are not covered entities under HIPAA, our ability to acquire or use protected health information from covered entities may be affected by privacy laws.
- The FDA regulates the sale and marketing of prescription drug products and, among other things, prohibits pharmaceutical manufacturers from promoting products for unapproved uses.

We have incurred and will continue to incur costs to comply with these laws.

While we intend to comply in all respects with fraud and abuse laws, there has been an increase in government enforcement efforts at both the federal and state level. Numerous cases have been brought against pharmaceutical manufacturers under the Federal False Claims Act, alleging, among other things, that certain sales or marketing-related practices violate the Anti-kickback statute or the FDA's regulations, and many of these cases have resulted in settlement agreements under which the companies were required to change certain practices, pay substantial fines, and operate under the supervision of a Federally-appointed monitor for a period of years. Due to the breadth of these laws and their implementing regulations and the absence of guidance in some cases, it is possible that our practices might be challenged by government authorities. Violations of fraud and abuse laws may be punishable by civil and/or criminal sanctions including fines, civil monetary penalties, as well as the possibility of exclusion of our products from payment by Federal health care programs. Any such violations or challenges could have a material adverse effect on our business.

AWP Litigation

Many government and third-party payors reimburse the purchase of certain prescription drugs based on a drug's Average Wholesale Price or "AWP." In the past several years, state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to AWP, which they have suggested have led to excessive payments by state and federal government agencies for prescription drugs. We and numerous other pharmaceutical companies have been named as defendants in various state and federal court actions alleging improper or fraudulent practices related to the reporting of AWP.

Drug Pedigree Laws

State and federal governments have proposed or passed various drug pedigree laws which can require the tracking of all transactions involving prescription drugs from the manufacturer to the pharmacy (or other dispensing) level. Companies are required to maintain records documenting the chain of custody of prescription drug products beginning with the purchase of such products from the manufacturer. Compliance with these pedigree laws requires implementation of extensive tracking systems and heightened

documentation and coordination with customers and manufacturers. While we fully intend to comply with these laws, there is uncertainty

about future changes in legislation and government enforcement of these laws. Failure to comply could result in fines or penalties, as well as loss of business that could have a material adverse effect on our financial results.

Federal Regulation of Patent Litigation Settlements and Authorized Generic Arrangements

As part of the Medicare Prescription Drug Improvement and Modernization Act of 2003, companies are required to file with the FTC and the DOJ certain types of agreements entered into between brand and generic pharmaceutical companies related to the settlement of patent litigation and/or manufacture, marketing and sale of generic versions of branded drugs. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with brand pharmaceutical companies, and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities.

Other

The U.S. federal government, various states and localities have laws regulating the manufacture and distribution of pharmaceuticals, as well as regulations dealing with the substitution of generic drugs for branded drugs. Our operations are also subject to regulation, licensing requirements and inspection by the states and localities in which our operations are located and/or in which we conduct business.

Certain of our activities are also subject to FTC enforcement actions. The FTC enforces a variety of antitrust and consumer protection laws designed to ensure that the nation's markets function competitively, are vigorous, efficient and free of undue restrictions.

Federal, state, local and foreign laws of general applicability, such as laws regulating working conditions, also govern us. In addition, like other manufacturers, 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 substances, the discharge of pollutants into the air and water and the cleanup of contamination. We are required to maintain and comply with environmental permits and controls 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 incur significant costs or liabilities as a result of any failure to comply with environmental laws, including fines, penalties, third-party claims and the costs of undertaking a clean-up at a current or former site or at a site to which our wastes were transported. In addition, we have grown in part by acquisition, and our diligence may not have identified environmental impacts from historical operations at sites we have acquired in the past or may acquire in the future.

Our Strategy

Our goal is to strengthen our position as a leading pharmaceutical company by developing and commercializing generic drugs with limited competition, high barriers to entry and longer life cycles. In implementing our strategy, we are focused on the following:

Grow our core business in attractive high-value segments. Our strategy focuses on high-value generic products, including first-to-file and first-to-market opportunities. By specializing in high-barrier-to-entry products that are either difficult to manufacture and/or present complex legal and regulatory challenges, we seek to market products that are more profitable and longer-lived relative to our competitors.

Advance our pipeline to continue building our portfolio. We have expanded our development portfolio from approximately 60 products in development at December 31, 2011 to 100 as of December 31, 2014. We have 115 ANDAs pending with the FDA at December 31, 2014, including 32 potential first-to-file and six potential first-to-market opportunities.

Strategically expand our technology capabilities across development and manufacturing. We have made significant investments to enhance our technology platforms and have expanded our capabilities to manufacture products including injectables, nasal sprays, ophthalmics and transdermal patches. We believe this will become an increasingly strategic asset over time. We intend to continue to invest in expanding our technology capabilities across development and manufacturing to develop high-barrier-to-entry products.

Build upon our success in strategic acquisitions and business development. We have an established history of executing and integrating strategic acquisitions that have enhanced and deepened our presence in our industry. Through these acquisitions, we have expanded our portfolio of products, pipeline, manufacturing and technological capabilities. We expect business development to remain a priority for us as we seek to identify and execute on transactions that fit our strategy and focus on high-barrier-to-entry products.

INFORMATION TECHNOLOGY

Our Information Technology ("IT") contributes state-of-the-industry infrastructure for reliable and compliant operations, business-driven solutions that align with our objectives for profitable growth and innovative ideas bound to business performance and efficiency goals. Our IT department is organized into three departments: Business Applications, Technology Operations, and Scientific Systems. Each department maintains its own development, implementation and support teams.

- The Business Applications department purchases, develops, and maintains business applications systems jointly with internal departments. This department follows industry best practices in project management, systems development life cycle, change management, account management, computer systems validation, and data archiving.
- The Technology Operations department purchases, deploys and maintains computing and communication infrastructure systems that enable reliable and efficient business operations. This department follows industry best practices in capacity planning, configuration management, incident/problem prevention and management, disaster recovery, data backup and restoration, data center operations, and security management.
- The Scientific Systems department purchases, develops, and maintains systems that support Quality Control, Regulatory, and Manufacturing operations. This department follows industry best practices in GxP compliance, project management, systems development life cycle, change management, computer systems validation, and data archiving.

ITEM 1A. Risk Factors

The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial also may materially and adversely affect our business, prospects, operating results or financial condition.

Risks Related to Our Business

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

Developing and commercializing a new product is time consuming, costly and subject to numerous factors that may delay or prevent development and commercialization. Our future results of operations will depend to a significant extent upon our ability to successfully commercialize new products in a timely manner. There are numerous difficulties in developing and commercializing new products, including:

- the ability to develop products in a timely manner and in compliance with regulatory requirements;
- the success of the clinical testing process to assure that new products are safe and effective or the bioequivalent to the reference listed drug;
- the risk that any of our products presently under development, if and when fully developed and tested, will not perform as expected;
- delays or unanticipated costs, including delays associated with the FDA listing and approval process and the ability to obtain in a timely manner and maintain required regulatory approvals;
- legal actions against our generic products brought by brand competitors, and legal challenges to our branded product intellectual property;
- the availability, on commercially reasonable terms, of raw materials, including APIs and other key ingredients; and
- our ability to scale-up manufacturing methods to successfully manufacture commercial quantities of products in compliance with regulatory requirements.

As a result of these and other difficulties, products currently in development may or may not receive necessary regulatory approvals on a timely basis or at all. This risk exists particularly with respect to the introduction of branded products because of the uncertainties, higher costs and lengthy time frames associated with research and development of such products and the inherent unproven market acceptance of such products. If any of our products, when acquired or developed and approved, cannot be successfully or timely commercialized, 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.

If we fail to obtain exclusive marketing rights for our generic products or fail to introduce these generic products on a timely basis, our revenues, gross margin and operating results may decline significantly.

The Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act (the "FDCA") provide for a period of 180 days of generic marketing exclusivity for any applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to the corresponding branded drug (commonly referred to as a "Paragraph IV certification"). "First filers" are often able to price the applicable generic drug to yield relatively high gross margins during this 180-day marketing exclusivity period. At various times in the past, a large portion of our revenues have been derived from the sales of generic drugs during such 180-day marketing exclusivity period and from the sale of other generic products for which there otherwise was limited competition.

ANDAs that contain Paragraph IV certifications generally become the subject of patent litigation that can be both lengthy and

costly. There is no certainty that we will prevail in any such litigation, that we will be the first to file and granted the 180-day marketing

exclusivity period, or, if we are granted the 180-day marketing exclusivity period, that we will not forfeit such period. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other first filers. In addition, brand companies often authorize a generic version of the corresponding branded drug to be sold during any period of marketing exclusivity that is awarded (described further below), which reduces gross margins during the marketing exclusivity period. Brand companies may also reduce the price of their branded product to compete directly with generics entering the market, which would similarly have the effect of reducing gross margins. Furthermore, timely commencement of the litigation by the patent owner imposes an automatic stay of ANDA approval by the FDA for 30 months, unless the case is decided in the ANDA applicant's favor during that period. Finally, if the court decision is adverse to the ANDA applicant, the ANDA approval will be delayed until the challenged patent expires, and the applicant forfeits the 180-day marketing exclusivity.

The majority of our revenues are generated by our generic products division. Our future profitability depends, to a significant extent, upon our ability to introduce, on a timely basis, new generic products that are either the first-to-market (or among the first-to-market) or that otherwise can gain significant market share. The timeliness of our product introductions is dependent upon, among other things, the timing of regulatory approval of our products, which to a large extent is outside of our control, as well as the timing of competing products. As additional distributors introduce comparable generic pharmaceutical products, price competition intensifies, market access narrows, and product sales prices and gross margins decline, often significantly and rapidly. Accordingly, our revenues and future profitability are dependent, in large part, upon our ability or the ability of our development partners to file ANDAs with the FDA timely and effectively or to enter into contractual relationships with other parties that have obtained marketing exclusivity. No assurances can be given that we will be able to develop and introduce successful products in the future within the time constraints necessary to be successful. If we or our development partners are unable to continue to timely and effectively file ANDAs with the FDA or to partner with other parties that have obtained marketing exclusivity, our revenues, gross margin and operating results may decline significantly, and our prospects and business may be materially adversely affected.

We face intense competition in the pharmaceutical industry from both brand and generic companies, which could significantly limit our growth and materially adversely affect our financial results.

The pharmaceutical industry is highly competitive. The principal competitive factors in the pharmaceutical market include:

- introduction of other generic drug manufacturers' products in direct competition with our products;
- introduction of authorized generic products in direct competition with our products, particularly during exclusivity periods;
- ability of generic competitors to quickly enter the market after the expiration of patents or exclusivity periods, diminishing the amount and duration of significant profits;
- consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups;
- the willingness of generic drug customers, including wholesale and retail customers, to switch among products of different pharmaceutical manufacturers;
- pricing pressures by competitors and customers;
- a company's reputation as a manufacturer and distributor of quality products;
- a company's level of service (including maintaining sufficient inventory levels for timely deliveries);
- product appearance and labeling; and
- a company's breadth of product offerings.

Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Consequently, many of our competitors may be able to develop products and/or processes competitive with, or superior to, our own. Furthermore, we may not be able to differentiate our products from those of our competitors; to successfully develop or introduce new products-on a timely basis or at all-that are less costly than those of our competitors; or to offer customers payment and other commercial terms as favorable as those offered by our competitors. The markets in which we compete and intend to compete are undergoing, and are expected to continue to undergo, rapid and significant change. We expect competition to intensify as technological advances and consolidations continue. New developments by other manufacturers and distributors could render our products uncompetitive or obsolete.

We believe that our principal generic competitors are Teva, Sandoz, Mylan and Actavis. These companies, among others, collectively compete with the majority of our products. We also face price competition generally as other generic manufacturers enter the market. Any such price competition may be especially pronounced where our competitors source their products from jurisdictions where production costs may be lower (sometimes significantly) than our production costs, especially lower-cost foreign jurisdictions. Any of these factors, in turn, could result in reductions in our sales prices and gross margin. This price competition has led to an increase in customer demands for downward price adjustments by generic pharmaceutical distributors. Our principal strategy in addressing our competition is to offer customers a consistent supply of our generic drugs, as well as to pursue product opportunities with the potential for less competition, such as high-barrier-to-entry first-to-file or first-to-market products. There can be no assurance, however, that this strategy will enable us to compete successfully in the industry or that we will be able to develop and implement any new or additional

viable strategies.

Competition in the generic drug industry has also increased due to the proliferation of authorized generic pharmaceutical products. Authorized generics are generic pharmaceutical products that are introduced by brand companies, either directly or through third parties, under the brand's NDA approval for its own branded drug. Authorized generics do not face any regulatory barriers to introduction and are not prohibited from sale during the 180-day marketing exclusivity period granted to the first-to-file generic applicant. The sale of authorized generics adversely impacts the market share of a generic product that has been granted 180 days of marketing exclusivity. This is a significant source of competition for us, because an authorized generic can materially decrease the profits that we could receive as an otherwise exclusive marketer of a product. Such actions have the effect of reducing the potential market share and profitability of our generic products and may inhibit us from developing and introducing generic pharmaceutical products corresponding to certain branded drugs.

As our competitors introduce their own generic equivalents of our generic pharmaceutical products, our revenues and gross margin from such products generally decline, often rapidly.

Revenues and gross margin derived from generic pharmaceutical products often follow a pattern based on regulatory and competitive factors that we believe are unique to the generic pharmaceutical industry. As the patent(s) for a brand name product or the statutory marketing exclusivity period (if any) expires, the first generic manufacturer to receive regulatory approval for a generic equivalent of the product often is able to capture a substantial share of the market. However, as other generic manufacturers receive regulatory approvals for their own generic versions, that market share, and the price of that product, will typically decline depending on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors. We cannot provide assurance that we will be able to continue to develop such products or that the number of competitors with such products will not increase to such an extent that we may stop marketing a product for which we previously obtained approval, which may have a material adverse impact on our revenues and gross margin.

Due to our dependence on a limited number of products, our business could be materially adversely affected if our key products do not perform as well as expected.

We generate a significant portion of our total revenues and gross margin from the sale of a limited number of products. For the year ended December 31, 2014, our top ten revenue products accounted for approximately 50% of our total net revenues and a significant portion of our gross margin. Any material adverse developments, including increased competition and supply shortages, with respect to the sale or use of these products, or our failure to successfully introduce new key products, could have a material adverse effect on our revenues and gross margin.

The majority of our products are produced at a few locations and a business interruption at one or more of these locations could have a material adverse effect on our business, financial position and results of operations.

We produce the majority of the products that we manufacture at our manufacturing facility in New York, and a significant number at our manufacturing facilities in California and India. Our recently acquired facility in Michigan produces all of our injectable products. Most of our inventory passes through our warehouse in New York. A significant disruption at any of these facilities, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis, which could have a material adverse effect on our business, financial position and results of operations.

Our profitability depends on our major customers. If these relationships do not continue as expected, our business, condition (financial and otherwise), prospects and results of operations could materially suffer.

We have approximately 120 customers, some of which are part of larger buying groups. For the year ended December 31, 2014, our four largest customers in terms of net product sales dollars accounted for approximately 70% of our total revenues, as follows; McKesson Drug (24.7%), Cardinal Health Inc. (18.3%), CVS Health Corporation (14.5%) and AmerisourceBergen Corporation (13.4%). The loss of any one or more of these or any other major customer or the substantial reduction in orders from any one or more of our major customers could have a material adverse effect upon our future operating results and financial condition.

We may experience declines in the sales volume and prices of our products as a result of the continuing trend of consolidation of certain customer groups, which could have a material adverse effect on our business, financial position and results of operations.

Our ability to successfully commercialize any generic or branded pharmaceutical product depends in large part upon the acceptance of the product by third parties, including pharmacies, government formularies, other retailers, physicians and patients. Therefore, our success will depend in large part on market acceptance of our products. We make a significant amount of our sales to a relatively small number of drug wholesalers and retail drug chains. These customers represent an essential part of the distribution chain of our pharmaceutical products. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing our business. Additionally, the emergence of large buying groups representing independent retail

pharmacies and other drug distributors, and the prevalence and influence of managed care organizations and similar institutions, potentially enable those groups to demand larger price discounts on our products. For example, there has been a recent trend of large wholesalers

and retailer customers forming partnerships, such as the alliance between Walgreens and AmerisourceBergen Corporation, the alliance between Rite Aid and McKesson Drug Company and the alliance between CVS and Cardinal Health. The result of these developments may have a material adverse effect on our business, financial position and results of operations.

We depend to a large extent on third-party suppliers and distributors for the raw materials for our products, particularly the chemical compounds comprising the APIs that we use to manufacture our products, as well as for certain finished goods. A prolonged interruption in the supply of such products could have a material adverse effect on our business, financial position and results of operations.

The raw materials essential to our manufacturing business are purchased primarily from U.S. distributors of bulk pharmaceutical chemicals manufactured by foreign companies. If we experience supply interruptions or delays, we may have to obtain substitute materials or products, which in turn would require us to obtain amended or additional regulatory approvals, subjecting us to additional expenditures of significant time and resources. In addition, changes in our raw material suppliers could result in significant delays in production, higher raw material costs and loss of sales and customers, because regulatory authorities must generally approve raw material sources for pharmaceutical products, which may be time consuming. Any significant supply interruption could have a material adverse effect on our business, condition (financial and other), prospects and results of operations. To date, we have experienced no significant difficulties in obtaining raw materials. However, because the federal drug application process requires specification of raw material suppliers, if raw materials from a specified supplier were to become unavailable, FDA approval of a new supplier would be required. A delay in the manufacture and marketing of the drug involved while a new supplier becomes qualified by the FDA and its manufacturing process is determined to meet FDA standards could, depending on the particular product, have a material adverse effect on our results of operations and financial condition. Generally, we attempt to mitigate the potential effects of any such situation by providing for, where economically and otherwise feasible, two or more suppliers of raw materials for the drugs that we manufacture. In addition, we may attempt to enter into a contract with a raw material supplier in an effort to ensure adequate supply for certain of our products.

The testing required for the regulatory approval of our products is conducted primarily by independent third parties. Any failure by any of these third parties to perform this testing properly and in a timely manner may have an adverse effect upon our ability to obtain regulatory approvals.

Our applications for the regulatory approval of our products, including both internally-developed and in-licensed products, incorporate the results of testing and other information that is conducted or gathered primarily by independent third parties (including, for example, manufacturers of raw materials, testing laboratories, CROs or independent research facilities). Our ability to obtain and maintain regulatory approval of the products being tested is dependent upon the quality of the work performed by these third parties, the quality of the third parties' facilities, and the accuracy of the information provided by third parties. We have little or no control over any of these factors. If this testing is not performed properly, our ability to obtain or maintain regulatory approvals, and to launch or continue selling products, could be restricted or delayed. Additionally, while we recently acquired our own CRO in India that may supplant a portion of these services provided by third parties, we have no experience running a CRO and may need to continue to rely on third parties to provide a majority of these services.

We depend on third-party agreements for a portion of our product offering, including certain key products, and any failure to maintain these arrangements or enter into similar arrangements with new partners could result in a material adverse effect.

We have broadened our product offering by entering into a variety of third-party agreements covering any combination of joint development, supply, marketing and/or distribution of products. For example, we have entered into an agreement with Croda Europe, Ltd. for development and supply of API used in our generic omega-3-acid ethyl esters oral capsules product, and with Glenmark Generics ("Glenmark") to market and distribute Glenmark's generic ezetimibe product. For the year ended December 31, 2014, a significant percentage of our total net product sales were generated from products manufactured under contract or under license. We cannot provide assurance that the development or supply efforts of our contractual partners will continue to be successful, that we will be able to renew such agreements or that we will be able to enter into new agreements for additional products. Any alteration to or termination of our current distribution and marketing agreements, any failure to enter into new and similar agreements, or interruption of our product supply under the distribution and marketing agreements, could materially adversely affect our business, condition (financial and otherwise), prospects or results of operations.

Our recent acquisitions and any acquisitions we may undertake in the future involve numerous risks, including the risks that we may be unable to integrate the acquired businesses successfully and that we may assume liabilities that could adversely affect us.

We recently completed several important acquisitions, including our acquisitions of Par Sterile in February 2014 and Innoteq, Inc. ("Innoteq") and Par Biosciences Private Limited ("Par Biosciences" and formerly known as Ethics Bio Lab Private Limited) in January 2015. We also entered into an agreement to acquire an API development and manufacturing facility from Nuray Chemicals Private Limited ("Nuray"). We expect to evaluate strategic acquisitions in the future. Acquisitions involve numerous risks, including

operational risks associated with the integration of acquired businesses. These risks include, but are not limited to:

- difficulties in achieving identified financial revenue synergies, growth opportunities, operating synergies and cost savings;

- difficulties in assimilating the personnel, operations and products of an acquired company, and the potential loss of key employees;
- difficulties in consolidating information technology platforms, business applications and corporate infrastructure;
- difficulties in integrating our corporate culture with local customs and cultures;
- possible overlap between our products or customers and those of an acquired entity that may create conflicts in relationships or other commitments detrimental to the integrated businesses;
- our inability to achieve expected revenues and gross margins for any products we may acquire;
- possible contingent liability that includes, among others, known or unknown environmental, patent or product liability claims;
- the diversion of management's attention from other business concerns; and
- risks and challenges of entering or operating in markets in which we have limited or no prior experience, including the unanticipated effects of export controls, exchange rate fluctuations, foreign legal and regulatory requirements, and foreign political and economic conditions.

In addition, foreign acquisitions involve numerous risks, including those related to the absence of policies and procedures sufficient to assure compliance by a foreign entity with U.S. regulatory and legal requirements. There can be no assurance that we will not be subject to liability arising from conduct which occurred prior to our acquisition of any entity.

We incur significant transaction costs associated with our acquisitions, including substantial fees for investment bankers, attorneys, and accountants. Any acquisition could result in our assumption of unknown and/or unexpected, and perhaps material, liabilities. Additionally, in any acquisition agreement, the negotiated representations, warranties and agreements of the selling parties may not entirely protect us, and liabilities resulting from any breaches may not be subject to indemnification by the suing parties and/or could exceed negotiated indemnity limitations. These factors could impair our growth and ability to compete; divert resources from other potentially more profitable areas; or otherwise cause a material adverse effect on our business, financial position and results of operations.

The financial statements of the companies we have acquired or may acquire in the future are prepared by management of such companies and are not independently verified by our management. In addition, any pro forma financial statements prepared by us to give effect to such acquisitions may not accurately reflect the results of operations of such companies that would have been achieved had the acquisition of such entities been completed at the beginning of the applicable financial reporting periods. Finally, we cannot guarantee that we will continue to acquire businesses at valuations consistent with our prior acquisitions or that we will complete acquisitions at all.

We may make acquisitions of, or investments in, complementary businesses or products, which may be on terms that may not turn out to be commercially advantageous, may require additional debt or equity financing, and may involve numerous risks, including those set forth above.

We regularly review the potential acquisition of technologies, products, product rights and complementary businesses and are currently evaluating, and intend to continue to evaluate, potential product and/or company acquisitions and other business development opportunities. We may choose to enter into such transactions at any time. Nonetheless, we cannot provide assurance that we will be able to identify suitable acquisition or investment candidates. To the extent that we do identify candidates that we believe to be suitable, we cannot provide assurance that we will be able to reach an agreement with the selling party or parties, that the terms we may agree to will be commercially advantageous to us, or that we will be able to successfully consummate such investments or acquisitions even after definitive documents have been signed. If we make any acquisitions or investments, we may finance such acquisitions or investments through our cash reserves, debt financing (such as borrowings available to us under our senior credit facilities (the "Senior Credit Facilities"), including any incremental facilities thereunder), which may increase our leverage, or by issuing additional equity securities, which could dilute the holdings of our then-existing stockholders. If we require financing, we cannot provide assurance that we will be able to obtain required financing when needed on acceptable terms or at all. Any future acquisitions may involve numerous risks, including but not limited to the types of risks set forth above with respect to our recent acquisitions.

Our expansion into international markets subjects us to increased regulatory oversight and regulatory, economic, social and political uncertainties, which could cause a material adverse effect on our business, financial position and results of operations.

We are subject to certain risks associated with our plans to commercialize products in the U.K. and other European markets and with having assets and operations located in foreign jurisdictions, including our operations in India and England. We are inexperienced operating in these jurisdictions, and we have no experience in seeking regulatory approvals, marketing or selling products in the U.K. or other European markets. Our operations in these jurisdictions may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, increased government regulation, and, with respect to India, any reversal of India's recent economic liberalization and deregulation policies, as well as social stability and political, economic or diplomatic developments in the future. Certain jurisdictions have, from time to time, experienced

instances of civil unrest and hostilities, both internally and with neighboring countries. Rioting, military activity, terrorist attacks, or armed hostilities could cause our operations there to be adversely affected or suspended. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. In addition, India is known to have experienced governmental corruption and, in some

circumstances, anti-bribery laws may conflict with some local customs and practices. Our international operations may subject us to heightened scrutiny under the U.S. Foreign Corrupt Practices Act ("FCPA"), the UK Bribery Act and similar anti-bribery laws, and could subject us to liability under such laws despite our best efforts to comply with such laws. As a result of our policy to comply with the FCPA, the UK Bribery Act and similar anti-bribery laws, we may be at a competitive disadvantage to competitors that are not subject to, or do not comply with, such laws.

Our competitors or other third parties may allege that we are infringing their intellectual property, forcing us to expend substantial resources in litigation, the outcome of which is uncertain. Any unfavorable outcome of such litigation, including losses related to "at-risk" product launches, could have a material adverse effect on our business, financial position and results of operations.

Companies that produce branded pharmaceutical products routinely bring litigation against ANDA or similar applicants that seek regulatory approval to manufacture and market generic forms of their branded products alleging patent infringement or other violations of intellectual property rights. Patent holders may also bring patent infringement suits against companies that are currently marketing and selling approved generic products. Litigation often involves significant expense and can delay or prevent introduction or sale of our generic products. If patents are held valid, enforceable and infringed by our products, we would, unless we could obtain a license from the patent holder, need to delay selling our corresponding generic product and, if we are already selling our product, cease selling and potentially destroy existing product stock.

There may be situations in which we may make business and legal judgments to market and sell products that are subject to claims of alleged patent infringement prior to final resolution of those claims by the courts, based upon our belief that such patents are invalid, unenforceable, or are not infringed by our marketing and sale of such products. This is referred to in the pharmaceutical industry as an "at-risk" launch. The risk involved in an at-risk launch can be substantial because, if a patent holder ultimately prevails against us, the remedies available to such holder may include, among other things, damages measured by the profits lost by the patent holder, which can be significantly higher than the profits we make from selling the generic version of the product. For example, in September 2014, we paid $100 million to settle claims relating to our at-risk launch of our generic omeprazole/sodium bicarbonate capsules. Par Sterile and its development partner are currently engaged in patent litigation in the U.S. District Court for the District of New Jersey with respect to two zoledronic acid products that Par Sterile, as well as several other generic manufacturers, launched in 2013, following FDA approval of their respective ANDAs but prior to the District Court reaching a finding on the merits of the alleged claims in the litigation. See discussion in Item 3, "Legal Proceedings" elsewhere in the Annual Report on Form 10-K. We could face substantial damages from adverse court decisions in such matters. We could also be at risk for the value of such inventory that we are unable to market or sell.

We are, and will continue to be in the future, a party to legal proceedings that could result in unexpected adverse outcomes.

We are a party to other legal proceedings, including matters involving personnel and employment issues, breach of contract claims and other proceedings arising in the ordinary course of business. In addition, there are an increasing number of investigations and proceedings in the health care industry generally that seek recovery under the statutes and regulations identified in "Business-Government Regulation." We evaluate our exposure to these legal proceedings and establish reserves for the estimated liabilities in accordance with GAAP. Assessing and predicting the outcome of these matters involves substantial uncertainties. Unexpected outcomes in these legal proceedings, or changes in management's evaluations or predictions and accompanying changes in established reserves, could have a material adverse impact on our financial results.

The use of legal, regulatory and legislative strategies by brand competitors, including authorized generics and citizen's petitions, as well as the potential impact of proposed legislation, may increase our costs associated with the introduction or marketing of our generic products, delay or prevent such introduction and/or significantly reduce the profit potential of our products.

Brand drug companies often pursue strategies that may serve to prevent or delay competition from generic alternatives to their branded products. These strategies include, but are not limited to:

- marketing an authorized generic version of a branded product at the same time that we introduce a generic equivalent of that product directly or through agreement with a generic competitor;
- filing "citizen's petitions" with the FDA to thwart generic competition by causing delays of our product approvals;
- using risk evaluation and mitigation strategies ("REMS") - related distribution restrictions or other means of limiting access to their branded products to prevent us from obtaining product samples needed to conduct bioequivalence testing required for ANDA approval, thereby delaying or preventing us from obtaining FDA approval of a generic version of such branded products;
- seeking to secure patent protection of certain "Elements to Assure Safe Use" of a REMS program, which are required medical interventions or other actions healthcare professionals need to execute prior to prescribing or dispensing the drug to the patient, in an attempt to thwart the generic company's ability to avoid infringement of the patents in question or secure approval;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate a generic product's

bioequivalence or “sameness” to the related branded product;

- initiating legislative and administrative efforts in various states to limit the substitution of generic versions of branded pharmaceutical products for the corresponding branded products;
- filing suits for patent infringement that automatically delay FDA approval of generic products;
- introducing "next-generation" products prior to the expiration of market exclusivity for their branded product, which often materially reduces the demand for the generic product for which we may be seeking FDA approval;
- obtaining extensions of market exclusivity by conducting clinical trials of branded drugs in pediatric populations or by other methods as discussed below;
- persuading the FDA to withdraw the approval of branded drugs for which the patents are about to expire, thus allowing the brand company to develop and launch new patented products serving as substitutes for the withdrawn products;
- seeking to obtain new patents on drugs for which patent protection is about to expire;
- filing patent applications that are more complex and costly to challenge;
- seeking temporary restraining orders and injunctions against selling a generic equivalent of their branded product based on alleged misappropriation of trade secrets or breach of confidentiality obligations;
- seeking temporary restraining orders and injunctions against a generic company that has received final FDA approval for a product and is attempting to launch at risk prior to resolution of related patent litigation;
- reducing the marketing of the branded product to healthcare providers, thereby reducing the branded drug's commercial exposure and market size, which in turn adversely affects the market potential of the equivalent generic product; and
- converting branded prescription drugs that are facing potential generic competition to over-the-counter products, thereby significantly impeding the growth of the generic prescription market for the drugs.

The Food and Drug Modernization Act of 1997 includes a pediatric exclusivity provision that may provide an additional six months of market exclusivity for indications of new or currently marketed drugs if certain agreed upon pediatric studies are completed by the applicant. Brand companies are utilizing this provision to extend periods of market exclusivity. Some companies have lobbied Congress for amendments to the Hatch-Waxman legislation that would give them additional advantages over generic competitors. For example, although the term of a company's drug patent can be extended to reflect a portion of the time a New Drug Application ("NDA") is under regulatory review, some companies have proposed extending the patent term by a full year for each year spent in clinical trials, rather than the one-half year that is currently permitted. If proposals like these were to become effective, our entry into the market and our ability to generate revenues associated with new generic products may be delayed, reduced or eliminated, which could have a material adverse effect on our business.

We expend a significant amount of resources on research and development, including milestones on in-licensed products, which may not lead to successful product introductions.

Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. We expend resources on research and development primarily to enable us to manufacture and market FDA-approved pharmaceuticals in accordance with FDA regulations. Typically, research expenses related to the development of innovative compounds and the filing of NDAs are significantly greater than those expenses associated with ANDAs. We have entered into, and may in the future enter into, agreements that require us to make significant milestone payments upon achievement of various research and development events and regulatory approvals. As we continue to develop and in-license new products, we will likely incur increased research and licensing expenses. Because of the inherent risk associated with research and development efforts in the industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful introduction of FDA-approved new pharmaceutical products. Also, after we or our development partners submit an ANDA or NDA, the FDA may request that we conduct additional studies. As a result, we may be unable to reasonably determine the total research and development costs required to develop a particular product. Finally, we cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not ultimately able to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected.

Our branded pharmaceutical expenditures may not result in commercially successful products.

Commercializing branded pharmaceutical products is more costly than generic products. We have made significant investments in the development of the branded segment of our business, Par Specialty. This has led to increased infrastructure costs. We cannot be certain that these business expenditures will result in the successful development or launch of branded products that will prove to be commercially successful or will improve the long-term profitability of our business. Just as our generic products take market share from the corresponding branded products, we will confront the same competitive pressures from other generic pharmaceutical companies that may seek to introduce generic versions of our branded products. Generic products are generally sold at a significantly lower cost than the branded version, and, where available, may be required or encouraged in preference to the branded version under third party reimbursement programs, or may be required by law to be substituted for branded versions by pharmacies. Competition from generic equivalents, accordingly, could have an adverse effect on our Par Specialty segment. While we have endeavored (with our relevant partners, as applicable) to protect our branded assets by securing regulatory exclusivities and intellectual property protections, such

exclusivities and protections are subject to expiry and to legal challenges. For example, on February 21, 2014, a U.S. District Court issued an opinion invalidating on obviousness grounds the single patent we asserted in a litigation we brought against a Paragraph IV challenge

to our Megace® ES product. We appealed the District Court's decision and on December 3, 2014, the U.S. Court of Appeals for the Federal Circuit reversed and remanded the case to the District Court for further findings. See discussion in Item 3, "Legal Proceedings", elsewhere in this Annual Report on Form 10-K. The launch of a generic version of Megace® ES or Nascobal® Nasal Spray would have a material adverse impact on our branded product sales of such product.

We continue to consider product or business acquisitions or licensing arrangements to expand our brand product line. Any growth of the Par Specialty segment will be based largely on the successful commercialization of our existing products and the acquisition or in-licensing of new product opportunities. Our current and future investments in acquisition or license arrangements may not lead to expected, adequate or any returns on investment. In the past, we have invested significant sums in license arrangements for products under development, which have been terminated unsuccessfully. We also may not be able to execute future license or acquisition agreements on reasonable or favorable terms in order to continue to grow or sustain Par Specialty. In addition, we cannot be certain that our branded product expenditures will result in commercially successful launches of these products or will improve the long-term profitability of Par Specialty. For example, in 2010, we launched two branded products that did not meet our commercial expectations, and in 2011 we returned all rights to these two products to our respective third-party development partners, resulting in a write-down of assets specifically related to these products. Any future commercialization efforts that do not meet expectations could similarly result in a write-down of assets related to the relevant products.

Our reporting and payment obligations under the Medicaid rebate program and other governmental purchasing and rebate programs are complex and may involve subjective decisions. Any determination that we have failed to comply with those obligations could subject us to penalties and sanctions, which could have a material adverse effect.

The regulations regarding reporting and payment obligations with respect to Medicaid reimbursement and rebates and other governmental programs are complex and, as discussed elsewhere in this Annual Report on Form 10-K, we and other pharmaceutical companies are defendants in a number of suits filed by state attorneys general and have been notified of an investigation by the DOJ with respect to Medicaid reimbursement and rebates. Our calculations and methodologies are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. In addition, because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of errors. Any governmental agencies that have commenced (or that may commence) an investigation of our company could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with regard to how to properly calculate and report payments, and even in the absence of any such ambiguity, a governmental authority may take a position contrary to a position that we have taken and may impose civil and/or criminal sanctions on us. Any such penalties, sanctions, or exclusion from federal health care programs could have a material adverse effect on our business, financial position and results of operations. From time to time we conduct routine reviews of our government pricing calculations. These reviews may have an impact on government price reporting and rebate calculations used to comply with various government regulations regarding reporting and payment obligations.

Our operating results are affected by many factors and may fluctuate significantly on a quarterly basis.

Our operating results may vary substantially from quarter to quarter and may be greater or less than those achieved in the immediately preceding period or in the comparable period of the prior year. Factors that may cause quarterly results to vary include, but are not limited to, the following:

- the amount of new product introductions;
- losses related to inventory write-offs;
- marketing exclusivity, if any, which may be obtained on certain new products;
- the level of competition in the marketplace for certain products;
- our ability to create demand in the marketplace for our branded products;
- availability of raw materials and finished products from suppliers;
- our ability to manufacture products at our manufacturing facilities;
- the scope and outcome of governmental regulatory actions;
- our dependence on a small number of products for a significant portion of net revenue or income;
- legal actions against our generic products brought by brand competitors, and legal challenges to our intellectual property rights brought against our branded products by generic competitors;
- price erosion and customer consolidation; and
- significant payments (such as milestones) payable by us under collaboration, licensing, and development agreements to our partners before the related product has received FDA approval.

The profitability of our product sales is also dependent upon the prices we are able to charge for our products, the costs to

purchase products from third parties, and our ability to manufacture our products in a cost effective manner. If our revenues decline or

do not grow as anticipated, we may not be able to reduce our operating expenses to offset such declines. Failure to achieve anticipated levels of revenues could, therefore, significantly harm our operating results for a particular fiscal period.

In certain circumstances, we issue price adjustments and other sales allowances to our customers. Although we may establish reserves based on our estimates of these amounts, if estimates are incorrect and the reserves are inadequate, it may result in adjustments to these reserves that may have a material adverse effect on our financial position and results of operations.

As described above, the first company to file an ANDA containing a Paragraph IV certification that successfully challenges the patent(s) on a branded product may be granted 180 days of generic market exclusivity by the FDA for that generic product. At the expiration of such exclusivity period, other generic distributors may enter the market, resulting in a significant price decline for the drug (in some instances, price declines have exceeded 90%). When we experience price declines following a period of generic marketing exclusivity, or at any time when a competitor enters the market or offers a lower price with respect to a product we are selling, we may at our discretion decide to lower the price of our product to retain market share and provide price adjustments to our customers for the difference between our new (lower) price and the price at which we previously sold the product which is still held in inventory by our customers. Because the entry of a competitive generic product is unpredictable, we do not establish reserves for such potential adjustments, and therefore the full effect of such adjustments are not reflected in our operating results until they actually occur. There are also circumstances under which we may decide not to provide price adjustments to certain customers, and consequently, as a matter of business strategy, we may risk a greater level of sale returns of products in the customer's existing inventory and lose future sales volume to competitors rather than reduce our pricing.

We establish reserves for chargebacks, rebates and incentives, other sales allowances, and product returns at the time of sale, based on estimates. Although we believe our reserves are adequate as of the date of this Annual Report on Form 10-K, we cannot provide assurances that our reserves will ultimately prove to be adequate. Increases in sales allowances may exceed our estimates due to a variety of reasons, including unanticipated competition or an unexpected change in one or more of our contractual relationships. We will continue to evaluate the effects of competition and will record a price adjustment reserve if and when we deem it necessary. Any failure to establish adequate reserves with respect to sales allowances may result in a material adverse effect on our financial position and results of operations.

If we determine that our goodwill and other intangible assets have become impaired, we may record significant impairment charges, which would adversely affect our results of operations.

Goodwill and other intangible assets represent a significant portion of our assets. Goodwill is the excess of cost over the fair market value of net assets acquired in business combinations. In the future, goodwill and intangible assets may increase as a result of future acquisitions. We review our goodwill and indefinite lived intangible assets at least annually for impairment. Impairment may result from, among other things, deterioration in the performance of acquired businesses, adverse market conditions and adverse changes in applicable laws or regulations, including changes that restrict the activities of an acquired business. Any impairment of goodwill or other intangible assets would result in a non-cash charge against earnings, which would adversely affect our results of operations. For the year ended December 31, 2014, we recorded a non-cash impairment charge of $146.9 million related to an adjustment to the forecasted operating results for two IPR&D intangible asset groups and either Par Pharmaceutical segment products compared to their originally forecasted operating results at the date of acquisition, inclusive of one discontinued product, one partially impaired product primarily due to the contract ending with the partner and a partially impaired IPR&D project from the acquisition of Par Sterile due to an adverse court ruling pertaining to related patent litigation.

We are subject to additional costs and burdens to comply with the terms of the March 5, 2013 resolution of the DOJ's investigation into sales and marketing activities for Megace® ES, and we could be subject to increased monetary penalties and/or other sanctions, including exclusion from federal health care programs, if we fail to comply with its terms.

On March 5, 2013, we settled U.S. federal and 49 state investigations into Par Specialty's sales and marketing activities for Megace® ES by pleading guilty to a misdemeanor misbranding violation of the FDCA and agreeing to pay approximately $45 million in criminal fines and forfeitures and to resolve civil claims. In addition, we entered into a five-year CIA with the Office of Inspector General of the U.S. Department of Health & Human Services ("OIG"). The effective date of the CIA was March 12, 2013. The CIA requires enhancements to our compliance program, fulfillment of reporting and monitoring obligations, and management certifications, among other requirements. Compliance with the terms of the CIA has imposed and will continue to impose additional costs and burdens on us, including in the form of employee training, third party reviews, compliance monitoring, reporting obligations and management attention. If we fail to comply with the CIA, the OIG may impose monetary penalties or exclude us from federal health care programs, including Medicare and Medicaid, which could have a material adverse effect on our cash flows, financial position and results of operations. We may be subject to third party claims and shareholder lawsuits in connection with the settlement.

We have increased exposure to tax liabilities, including foreign tax liabilities.

As a U.S. corporation with subsidiaries in India and England, we are subject to income taxes as well as non-income based taxes in the United States, India and England. Significant judgment is required in determining our worldwide provision for income taxes and

other tax liabilities. Changes in tax laws or tax rulings may have a significantly adverse impact on our effective tax rate. Recent proposals by the current U.S. administration for fundamental U.S. international tax reform, if enacted, could have a significant adverse impact on our effective tax rate. In addition, we have potential tax exposures resulting from the varying application of statutes, regulations and interpretations, which include exposures on intercompany terms of cross-border arrangements among any foreign subsidiaries in relation to various aspects of our business, including research and development activities and manufacturing. Tax authorities in various jurisdictions may disagree with and subsequently challenge the amount of profits taxed in their country, which may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase. This could have a material adverse effect on our business, financial position and results of operations and our ability to satisfy our debt obligations.

We are controlled by the Sponsor, whose interests as an equity holder may conflict with our creditors' interests.

We are controlled by the Sponsor. The Sponsor controls the election of our directors and thereby has the power to control our affairs and policies, including the appointment of management, the issuance of additional equity and the declaration and payment of dividends if allowed under the terms of the credit agreement governing our Senior Credit Facilities, the terms of the indentures governing the Notes and the terms of our other indebtedness outstanding at the time. The Sponsor has no liability for any obligations under or relating to the Notes, and its interests may be in conflict with the interests of our creditors. For example, if we encounter financial difficulties or are unable to pay our debts as they mature, the Sponsor may pursue strategies that favor equity investors over debt investors. In addition, our equity holders may have an interest in pursuing acquisitions, divestitures, financing or other transactions that, in their judgment, could enhance their equity investments, even though such transactions may involve risk to holders of the Notes. Additionally, the Sponsor may make investments in businesses that directly or indirectly compete with us, or may pursue acquisition opportunities that may be complementary to our business and, as a result, those acquisition opportunities may not be available to us. For information concerning our arrangements with the Sponsor, see Item 13, "Certain Relationships and Related Party Transactions" elsewhere in this Annual Report on Form 10-K.

Risks Common to Our Industry

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

In order to assist us in commercializing products, we have obtained from governmental authorities and private health insurers and other organizations, such as health maintenance organizations ("HMOs") and managed care organizations ("MCOs"), authorization to receive reimbursement at varying levels for the cost of certain products and related treatments. Third party payers increasingly challenge pricing of pharmaceutical products. The trend toward managed healthcare in the United States, the growth of organizations such as HMOs and MCOs, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand. The Patient Protection and Affordable Care Act ("PPACA") and the Health Care and Education Reconciliation Act of 2010 were signed into law on March 23, 2010 and March 30, 2010, respectively. These laws are referred to herein as "healthcare reform." A number of provisions of the healthcare reform laws continue to have a negative impact on the price of our products sold to U.S. government entities. As examples, the legislation includes measures that (i) significantly increase Medicaid rebates through both the expansion of the program and significant increases in rebates; (ii) substantially expand the Public Health System (340B) program to allow other entities to purchase prescription drugs at substantial discounts; (iii) extend the Medicaid rebate rate to a significant portion of Managed Medicaid enrollees; (iv) apply a 50% discount to Medicare Part D beneficiary spending in the coverage gap for branded and authorized generic prescription drugs; and (v) levy a significant excise tax on the industry to fund the healthcare reform. Such cost containment measures and healthcare reform affect our ability to sell our products and have a material adverse effect on our business, results of operations and financial condition. Additionally, the Medicare Part D Prescription Drug Benefit established a voluntary outpatient prescription drug benefit for Medicare beneficiaries (primarily the elderly over 65 and the disabled). These beneficiaries may enroll in private drug plans. There are multiple types of Part D plans and numerous plan sponsors, each with its own formulary and product access requirements. The plans have considerable discretion in establishing formularies and tiered co-pay structures and in placing prior authorization and other restrictions on the utilization of specific products. In addition, Part D plan sponsors are permitted and encouraged to negotiate rebates with manufacturers. The Medicare Part D program, which went into effect January 1, 2006, is administered by the Centers for Medicare & Medicaid Services ("CMS") within the Department of Health and Human Services.

CMS has issued extensive regulations and other sub-regulatory guidance documents implementing the Medicare Part D benefit, and the OIG has issued regulations and other guidance in connection with the Medicare Part D program. The federal government can be expected to continue to issue guidance and regulations regarding the obligations of Part D sponsors and their subcontractors. Participating drug plans may establish drug formularies that exclude coverage of specific drugs, and payment levels for drugs negotiated with Part D drug plans may be lower than reimbursement levels available through private health plans or other payers. Moreover, beneficiary co-insurance requirements could influence which products are recommended by physicians and selected by patients. There is no assurance that any drug that we market will be offered by drug plans participating under the Medicare Part D program or of the terms