ANI PHARMACEUTICALS INC
Form 10-K
February 23, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

.. TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

Commission file number 001-31812

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
210 Main Street West **Baudette, Minnesota**	**56623**
(Address of principal executive offices)	(Zip Code)

(218) 634-3500

(Registrant's telephone number, including area code)

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

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**The NASDAQ Global Market**

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. 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 Act. YES ¨ NO x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. 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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ¨ NO x

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2015, was $526.8 million (based upon the last reported sale price of $62.05 per share on June 30, 2015, on The NASDAQ Global Market).

As of February 12, 2016, 11,449,364 shares of common stock and 10,864 shares of Class C Special stock of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2016 annual meeting of stockholders to be filed within 120 days after the end of the period covered by this Annual Report on Form 10-K are incorporated by reference into Part III of this Annual Report on Form 10-K.

ANI PHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2015

TABLE OF CONTENTS

Available Information

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, “ANI Pharmaceuticals,” “ANI,” the “Company,” “we,” “us,” or “our”) files annual, quarterly and current reports, proxy statements and other information required by the Securities Exchange Act of 1934, as amended (the "Exchange Act"), with the Securities and Exchange Commission ("SEC"). We make available free of charge on our website (www.anipharmaceuticals.com) our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and any amendments to those filings as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. Also posted on our website in the “Investors – Corporate Governance” section are our Corporate Governance Guidelines, Code of Ethics and the charters for the Audit and Finance, Compensation, and Nominating and Corporate Governance Committees. Information on, or accessible through, our website is not a part of, and is not incorporated into, this report or any other SEC filing. Copies of our SEC filings or corporate governance materials are available without charge upon written request to Investor Relations, c/o ANI Pharmaceuticals, Inc., 210 Main Street West, Baudette, Minnesota, 56623.

Any materials we file with the SEC are also publicly available through the SEC’s website (www.sec.gov) or may be read and copied at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

In this annual report, references to “ANI Pharmaceuticals,” “ANI,” the “Company,” “we,” “us,” and “our” refer, unless the con requires otherwise, to ANI Pharmaceuticals, Inc., a Delaware c-corporation, and its consolidated subsidiaries. References to “named executive directors” refer to our current named executive officers, except where the context requires otherwise. References to the "Merger" refer to the merger of BioSante Pharmaceuticals, Inc. ("BioSante") and ANIP, completed on June 19, 2013, wherein ANI Merger Sub, Inc., a wholly owned subsidiary of BioSante, merged with and into ANIP with ANIP continuing as the surviving company and becoming a wholly owned subsidiary of BioSante. On July 17, 2013, BioSante changed its name to ANI Pharmaceuticals, Inc. References to the "reverse stock split" refer to the one-for-six reverse stock split effected on July 17, 2013.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Exchange Act. Such statements include, but are not limited to, statements about future operations, products, financial position, operating results prospects, pipelines or potential markets therefor, and other statements that are not historical in nature, particularly those that utilize terminology such as “anticipates,” “will,” “expects,” “plans,” “potential,” “future,” “believes,” “intends,” “continue,” other words of similar meaning, derivations of such words, and the use of future dates.

Uncertainties and risks may cause our actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that we may face with respect to importing raw materials, increased competition, acquisitions, delays or failure in obtaining product approvals from the U.S. Food and Drug Administration ("FDA"), general business and economic conditions, market trends, product development, regulatory, and other approvals and marketing.

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to the "Risk Factors" section in Part I, Item 1A. of this Annual Report on Form 10-K and in other cautionary statements and risks included in other reports we file with the SEC. New risks emerge from time to time. It is not possible for our management to predict all risks. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

NOTE REGARDING TRADEMARKS

Cortenema®, Cortrophin®, Cortrophin-Zinc®, Lithobid®, Reglan®, and Vancocin® are registered trademarks subject to trademark protection and are owned by ANI.

PART I

Item 1. Business

ANI Pharmaceuticals is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations. We have two pharmaceutical manufacturing facilities located in Baudette, Minnesota, which are capable of producing oral solid dose products, as well as liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. Our strategy is to use our assets to develop, acquire, manufacture, and market branded and generic specialty prescription pharmaceuticals.

On June 19, 2013, pursuant to a merger agreement dated as of April 12, 2013, ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. ("ANIP") became a wholly-owned subsidiary of BioSante Pharmaceuticals, Inc. (“BioSante”) in an all-stock, tax-free reorganization (the "Merger"). The Merger was accounted for as a reverse acquisition, pursuant to which ANIP was considered the acquiring entity for accounting purposes. Since the Merger, we have been operating under the leadership of the ANIP management team and ANIP's historical results of operations have replaced BioSante's historical results of operations for all periods prior to the Merger. The results of operations of both companies are included in our consolidated financial statements for all periods after completion of the Merger.

BioSante was a publicly-held pharmaceutical company focused on developing high value, medically-needed products. ANIP entered into the Merger to secure additional capital and gain access to capital market opportunities as a public company.

In addition, in July 2013, our stockholders approved and we subsequently effected (i) a one-for-six reverse stock split of our common stock and class C special stock, with a proportional reduction in the number of authorized shares of our common stock, class C special stock and blank check preferred stock, and (ii) a change of name from “BioSante Pharmaceuticals, Inc.” to “ANI Pharmaceuticals, Inc.” Unless otherwise required by the context, references in this Annual Report on Form 10-K to the "Company," "we," us," and "our" refer to ANI Pharmaceuticals, Inc., a Delaware corporation formed in April 2001, formerly known as BioSante Pharmaceuticals, Inc. Our principal executive offices are located at 210 Main Street West, Baudette, Minnesota, 56623, our telephone number is (218) 634-3500, and our website address is www.anipharmaceuticals.com.

Mission and Strategy

We are an integrated specialty pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations. Our two facilities have a combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet. The facilities are specialized with diverse capabilities, enabling us to manufacture liquid, powder, and oral solid-dose products, topicals, controlled substances, and products that must be manufactured in a fully contained environment. We also perform contract manufacturing for other pharmaceutical companies.

In addition to laboratories that support the requirements of raw material, finished product, and stability testing, we have a 1,000 square foot pilot laboratory offering liquid, suspension and solid dose development capabilities. This pilot laboratory offers a full range of analytical capabilities including method development, validation and de-formulation, and is licensed by the Drug Enforcement Administration (“DEA”). Finally, a separate development suite located within our high-potency manufacturing facility offers additional capabilities for product development.

Our strategy is to use our assets to develop, acquire, manufacture, and market branded and generic specialty prescription pharmaceuticals. By executing this strategy, we believe we will be able to continue to grow our business, expand and diversify our product portfolio, and create long-term value for our investors.

We believe our strategies effectively leverage our human and capital assets and will result in measurable growth of our business. Since 2011, we have successfully:

- Increased prescription product sales through a combination of market share gains on existing products and new product launches, including Methazolamide, Etodolac, Propafenone, Vancomycin, Oxycodone oral solution, Nimodipine, and Flecainide.
- Acquired the New Drug Applications ("NDA") for and began marketing Reglan, Lithobid, and Vancocin.
- Filed six Abbreviated New Drug Applications ("ANDAs").
- Increased our product pipeline, through development, partnership, and acquisition, to 85 total products.
- Closed a public offering of common stock, netting $46.7 million.
- Closed a public offering of $143.8 million of convertible debt, with simultaneous bond hedge and warrant transactions.
- Acquired NDAs for Testosterone 1% Gel, Corticotropin, and Corticotropin-Zinc.

We believe that our cash resources and forecasted cash flows from operations will be sufficient to enable us to meet our operational needs for the foreseeable future.

Product Development Considerations

We consider a variety of criteria in determining which products to develop or acquire, all of which relate to the level of potential competition and expected profitability upon product launch. These criteria include:

- ***Formulation Complexity.*** Our development and manufacturing capabilities enable us to manufacture pharmaceuticals that are difficult to produce, including highly potent, extended release, combination, and low dosage products. This ability to manufacture a variety of complex products is a competitive strength that we intend to leverage in selecting products to develop or manufacture.
- ***Patent Status.*** We seek to develop products whose branded bioequivalents do not have long-term patent protection or existing patent challenges.
- ***Market Size.*** When determining whether to develop or acquire an individual product, we review the current and expected market size for that product at launch, as well as forecasted price erosion upon conversion from branded to generic pricing. We endeavor to manufacture products with sufficient market size to enable us to enter the market with a strong likelihood of being able to price our products both competitively and at a profit.
- ***Profit Potential.*** We research the availability and cost of active pharmaceutical ingredients in determining which products to develop or acquire. In determining the potential profit of a product, we forecast our anticipated market share, pricing, including expected price erosion caused by competition from other generic manufacturers, and the estimated cost of manufacturing.
- ***Manufacturing.*** We generally seek to develop and manufacture products at our own manufacturing plants in order to optimize the utilization of our facilities, ensure quality control in our products, and maximize profit potential.

Competition. When determining whether to develop or acquire a product, we research existing and expected competition. We seek to develop products for which we can obtain sufficient market share, and may decline to develop a product if we anticipate significant competition. Our specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies are able to compete.

Products and Markets

Products

As of December 31, 2015, our products include both branded and generic pharmaceuticals, specifically:

Generic Products	**Branded Products**
Esterified Estrogen with Methyltestosterone	Cortenema
Etodolac	Lithobid
Flecainide	Reglan
Fluvoxamine	Vancocin
Hydrocortisone Enema	
Methazolamide	
Metoclopramide Syrup	
Nimodipine	
Opium Tincture	
Oxycodone Oral Solution	
Propafenone	
Vancomycin	

Esterified Estrogen with Methyltestosterone ("EEMT") is used to treat moderate to severe vasomotor symptoms of menopause that are not improved by estrogen alone. For the year ended December 31, 2015, EEMT comprised 51% of our net sales, versus 42% of net sales in 2014 and 33% of net sales in 2013.

Etodolac is used to treat mild to moderate pain caused by osteoarthritis and rheumatoid arthritis, as well as other conditions.

Flecainide is used to treat arrhythmia (irregular heartbeat) in patients and to help patients maintain a normal heart rate.

Fluvoxamine is used to treat patients with obsessive-compulsive disorder and social anxiety disorder. It is generally used when the patient's symptoms interfere with the patient's ability to function socially and occupationally.

Hydrocortisone Enema and its branded equivalent, Cortenema, are used for the treatment of ulcerative colitis, especially distal forms, including ulcerative proctitis, ulcerative proctosigmoiditis, and left-sided ulcerative colitis. The products have also proved useful in some cases involving the transverse and ascending colons.

Methazolamide is indicated in the treatment of ocular conditions where lowering intraocular pressure is likely to be of therapeutic benefit, such as chronic open-angle glaucoma, secondary glaucoma, and preoperatively in acute angle-closure glaucoma where lowering the intraocular pressure is desired before surgery.

Metoclopramide and its branded equivalent, Reglan, are prescribed for periods of four to twelve weeks in adults with symptomatic, documented gastroesophageal reflux who fail to respond to conventional therapy. The products relieve daytime heartburn and heartburn after meals and also help ulcers in the esophagus to heal. The products also relieve symptoms associated with acute and recurrent diabetic gastric stasis and help treat symptoms such as nausea, vomiting, heartburn, feeling full long after a meal, and loss of appetite.

Nimodipine is used to improve neurological outcomes by reducing the incidence and severity of ischemic deficits in patients with subarachnoid hemorrhage from ruptured brain aneurysms.

Opium Tincture is used is to treat diarrhea in adults by slowing the movement of the intestines and decreasing the number and frequency of bowel movements.

Oxycodone oral solution is used to relieve acute moderate to severe pain and chronic pain.

Propafenone is used to treat arrhythmia (irregular heartbeat) in patients and to help patients maintain a normal heart rate.

Lithobid is indicated in the treatment of manic episodes of bipolar disorder. Lithobid is also indicated as a maintenance treatment for individuals with a diagnosis of bipolar disorder. Maintenance therapy reduces the frequency and intensity of manic episodes.

Vancomycin and its branded equivalent, Vancocin, are indicated for the treatment of C. difficile-associated diarrhea, as well as enterocolitis caused by staphylococcus aureus (including methicillin-resistant strains). The capsules are not effective for other types of infections, as the drugs are not systematically absorbed.

Markets

In determining which products to pursue for development, we target products that are complex to manufacture and therefore have higher barriers to entry. These factors provide opportunities for growth, utilizing our competitive strengths at the same time that they decrease the number of potential competitors in the markets for these products. These markets currently include controlled substances, oncolytics, hormones and steroids, and complex formulations, including extended release and combination products.

Controlled Substances

One of our manufacturing facilities in Baudette, Minnesota is licensed by the DEA for the manufacture and distribution of Schedule II controlled substances, which are drugs considered to have a high abuse risk but that also have safe and accepted medical uses. In addition to our existing pipeline of four ANDAs, we have identified additional product development opportunities in this market.

Oncolytics

Due to the capabilities of our containment facility and our expertise in manufacturing segregation, we are focused on developing and manufacturing niche oncolytic (anti-cancer) drugs. In particular, we are targeting products subject to priority review by the FDA, more specifically those with no blocking patents and no generic competition. We filed an ANDA for an anti-cancer drug with the FDA in 2014, and have received a Target Action Date of February 26, 2016, per FDA communications.

Hormone and Steroid Drugs

The market for hormone and steroid drugs includes hormone therapy to alleviate menopausal symptoms in women, contraceptives, testosterone replacement therapies for men, and therapies for treating hormone-sensitive cancers.

Hormone Therapy ("HT") has been an accepted medical treatment for alleviating the symptoms of menopause since the 1930s, with formal FDA approval for that use granted in 1942. Initially, HT consisted of estrogen only, but has evolved to include combination therapies of estrogen, progesterone and androgens. We target niche products in the HT and steroid product market for several reasons, including:

- Hormone and steroid products are a core competency based on our manufacturing and product development teams' long history of manufacturing these types of products; and
- The aging baby boom population, of which women represent a majority, is expected to support continued growth in the HT market.

Complex Formulations

Our manufacturing facilities can be used to manufacture complex formulations, including, but not limited to, extended release and combination products, which have higher barriers to entry and, therefore, fewer competitors. In addition to our two products currently on the market, our pipeline includes five extended-release products and six combination products.

Contract Manufacturing

We manufacture pharmaceutical products for several branded and generic companies, who outsource production in order to:

- Free-up internal resources to focus on sales and marketing as well as research and development;
- Employ internal capacity to manufacture higher volume or more critical products; and
- Utilize our specialized equipment and expertise.

Given our specialized manufacturing capabilities, we are focused on attracting niche contract manufacturing opportunities that offer high margins.

Manufacturing, Suppliers, and Raw Materials

We require a supply of quality raw materials, including active pharmaceutical ingredients ("API"), and components to manufacture and package our pharmaceutical products. In order to manufacture Opium Tincture and Oxycodone oral solution, we must submit a request to the DEA for a quota to purchase the amount of opium and oxycodone needed to manufacture the respective products. Without approved quotas from the DEA, we would not be able to purchase these ingredients from our suppliers.

We source the raw materials for our products from both domestic and international suppliers that we select on the basis of their quality, reliability of supply, and long-term financial stability. Generally, we qualify only a single source of API for use in each product due to the cost and time required to validate and qualify a second source of supply. Any change in one of our API suppliers must usually be approved through a Prior Approval Supplement ("PAS") by the FDA. Certain of our APIs for our drug products, including those that are marketed without approved NDAs or ANDAs, such as EEMT, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported API due to FDA inspections.

Government Regulation

The pharmaceutical industry is highly regulated by multiple U.S. government agencies, such as the FDA, the DEA, and the Centers for Medicare and Medicaid Services ("CMS"). As a result, we are subject to extensive and complex rules and regulations, which are subject to revision from time to time. While we have experience with these

regulations, there can be no assurance that we will be able to fully comply with all applicable regulations.

Branded and Generic Pharmaceutical Products

All prescription pharmaceutical products, whether branded or generic, must be approved by the FDA. All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. Information to support the bioequivalence of generic drug products or the safety and effectiveness of new drug products for their intended use is also required to be submitted. There are generally two types of applications used for obtaining FDA approval of new products:

New Drug Application ("NDA")—An NDA is filed when approval is sought to market a newly developed branded product and, in certain instances, for a new dosage form, a new delivery system, or a new indication for an approved drug. We market Cortenema, generic Hydrocortisone Enema, Lithobid, generic Fluvoxamine, Reglan, Vancocin, and generic Vancomycin under approved NDAs.

Abbreviated New Drug Application ("ANDA")—An ANDA is filed when approval is sought to market a generic equivalent of a drug approved under an NDA. We market Etodolac, Flecainide, Methazolamide, Metoclopramide, Nimodipine, Oxycodone oral solution, and Propafenone under approved ANDAs.

The ANDA development process is generally less time-consuming and less complex than the NDA development process. It typically does not require new preclinical and clinical studies, because it relies on the studies establishing safety and efficacy conducted for the branded drug approved through the NDA process. The ANDA process, however, typically requires one or more bioequivalence studies to show that the ANDA drug is bioequivalent to the previously approved reference listed drug ("RLD").

The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") provides that generic drugs may enter the market after the approval of an ANDA, which requires (1) that bioequivalence to the branded product be demonstrated through clinical studies, and (2) either the expiration, invalidation or circumvention of any patents or the end of any other relevant market exclusivity periods related to the branded drug.

Accordingly, generic products generally provide a safe, effective, and cost-efficient alternative to users of branded products. Growth in the generic pharmaceutical industry has been driven by the increased market acceptance of generic drugs, as well as the number of branded drugs for which patent terms and/or other market exclusivities have expired.

Generic products are generally commercialized after the expiration of patent protection for the branded product and after the end of a period of non-patent market exclusivity. In addition to patent exclusivity, the holder of the NDA may be entitled to a period of non-patent market exclusivity, during which the FDA cannot approve an application for a generic product. Also, if the NDA is a new chemical entity ("NCE"), the FDA may not approve an ANDA for a generic product for up to five years following approval of the NDA for the NCE. If an NDA is not an NCE, but the holder of the NDA conducted clinical trials essential to approval of the NDA or a supplement thereto, the FDA may not approve a generic equivalent to the NDA for three years. Certain other periods of exclusivity may be available if the branded drug is indicated for treatment of a rare disease or is studied for pediatric indications.

In order to obtain FDA approval of NDAs and ANDAs, our manufacturing procedures and operations must conform to FDA requirements and guidelines, generally referred to as "cGMP." The requirements for FDA approval encompass all aspects of the production process, including validation and recordkeeping, the standards around which are continuously changing and evolving. As a result, we must consistently monitor and comply with these changes.

Our facilities, procedures, operations and testing of products are subject to periodic inspection by the FDA, the DEA, and other authorities. In addition, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with cGMP and other FDA regulations. Our suppliers are subject to similar regulations and periodic inspections.

Controlled Substances

The DEA regulates certain drug products containing controlled substances, pursuant to the U.S. Controlled Substances Act ("CSA"). Opium, which is a significant component of our Opium Tincture product, is classified as a controlled substance. Oxycodone, a significant component of our Oxycodone oral solution product, is also classified as a controlled substance. CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security, and distribution.

Recordkeeping requirements include accounting for the amount of product received, manufactured, stored, and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts, and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

In addition, we must submit a request to the DEA for a quota to purchase the amount of opium and oxycodone we need to manufacture Opium Tincture and Oxycodone oral solution. Without approved quotas from the DEA, we would not be able to purchase these ingredients from our suppliers. As a result, we are dependent upon the DEA to approve quotas large enough to support our continued manufacture of Opium Tincture and Oxycodone oral solution.

Unapproved Products

Two of our products, EEMT and Opium Tincture, are marketed without approved NDAs or ANDAs. The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While we believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products.

Medicaid/Medicare

Medicaid and Medicare, both of which are U.S. federal health care programs administered by CMS, are major purchasers of pharmaceutical products, including those we produce.

Medicaid is administered by the states and jointly funded by the federal and state governments. Its focus is on low income populations. State drug coverage policies under Medicaid may vary significantly state by state. The Patient Protection and Affordable Care Act (“PPACA”), as amended by the Health Care and Education and Reconciliation Act of 2010, together known as the Affordable Care Act ("ACA"), required states to expand their Medicaid programs to individuals with incomes up to 138% of the federal poverty level. Although the United States Supreme Court in 2011 made the Medicaid expansion optional, many states are expanding their Medicaid programs. This expansion of Medicaid coverage may increase usage of pharmaceutical products.

The ACA also made changes to Medicaid law that could negatively impact us. In particular, pharmaceutical manufacturers must enter into rebate agreements with state Medicaid agencies, which require manufacturers to pay rebates based on their drugs dispensed to Medicaid beneficiaries. The ACA raised the rebate percentages for both generic and branded pharmaceuticals effective January 1, 2010. The required rebate is currently 13% of the average manufacturer price for sales of Medicaid-reimbursed products marketed under ANDAs. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of 23.1% of the average manufacturer price or the difference between the average manufacturer price and the "best price" (as defined in the Medicaid statute) during a specific period. Federal and/or state governments may continue to enact measures aimed at reducing the cost of drugs to the Medicaid program.

Medicare is run by the federal government and is largely focused on the elderly and disabled. The Medicare Modernization Act of 2003 (“MMA”) created Medicare Part D to provide prescription drug coverage for Medicare beneficiaries. The MMA has increased usage of pharmaceuticals, a trend that we believe will continue to benefit the generic pharmaceutical industry. The ACA made some changes to Part D to make it easier for Medicare beneficiaries to obtain drugs, such as reducing coinsurance amounts. The ACA also required pharmaceutical companies to provide discounts to Medicare Part D beneficiaries for the cost of branded prescription drugs. Under the Medicare Coverage Gap Discount Program authorized by the ACA, any pharmaceutical product marketed under an NDA, regardless of whether the product is marketed as a "generic," is subject to the discount requirement. Our Hydrocortisone Enema, Fluvoxamine, and Vancomycin products, while marketed as "generics," are marketed under approved NDAs and, therefore, are subject to the discount requirement. While we may benefit from Medicare changes that have reduced obstacles to drug usage, resulting sales increases, if any, may be offset by existing and future legislative efforts to curb the cost of drugs to the Medicare program.

Most of our products are covered by Medicaid and Medicare. 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, and we could be subject to federal or state false claims litigation.

Research and Development

We develop new generic products through a combination of internal development and fee-for-service arrangements with other firms. Additionally, we license and co-develop products through collaborations with other companies as noted below. During the years ended December 31, 2015, 2014, and 2013, our research and development expenses were $2.9 million, $2.7 million, and $1.7 million, respectively.

IDT Australia Limited

In August 2015, we entered into a distribution agreement with IDT Australia Limited ("IDT") to market several products in the U.S. (the "IDT Agreement"). The products, all of which are approved ANDAs, require various FDA filings and approvals prior to commercialization. In general, IDT will be responsible for regulatory submissions to the FDA and the manufacturing of certain products. We made an upfront payment to IDT of $1.0 million and will make additional milestone payments upon FDA approval for commercialization of certain products. Upon approval, IDT will manufacture some of the products and we will manufacture the other products. We will market and distribute all the products under our label in the United States, remitting a percentage of profits from sales of the drugs to IDT. The $1.0 million upfront payment was recorded as a marketing and distribution rights intangible asset and will be amortized in full over its seven-year useful life.

Dexcel

In June 2014, we entered into a collaboration agreement with Dexcel Pharma Technologies Ltd ("Dexcel") to commercialize and sell a generic drug product (the " Dexcel Agreement"). The product is subject to FDA approval of an ANDA filing. In general, Dexcel will be responsible for the manufacturing and regulatory submissions to the FDA, including obtaining approval of the ANDA, and we will make payments based on the completion of certain milestones. Upon approval, Dexcel will manufacture the drug and we will market and distribute the product under our label in the United States, remitting a percentage of profits from sales of the drug to Dexcel.

Under the Dexcel Agreement, Dexcel will own all the rights, title, and interest in the product. During the term, both parties are prohibited from developing, selling, or distributing any product in the United States that is identical or bioequivalent to the product covered under the agreement. The agreement can be terminated or amended under certain specified circumstances. The agreement’s initial term is five years from the launch of the product, which term can be renewed for two year terms if both parties agree, until either party terminates the agreement.

Sofgen Pharmaceuticals

August 2013 Sofgen Agreement

In August 2013, we entered into an agreement with Sofgen Pharmaceuticals (“Sofgen”) to develop an oral soft gel prescription product indicated for cardiovascular health (the “August 2013 Sofgen Agreement”). The product will be subject to an ANDA filing once developed. In general, Sofgen will be responsible for the development, manufacturing and regulatory submission of the product, including preparation of the ANDA, and we will make payments based on the completion of certain milestones. Upon approval, Sofgen will manufacture the drug and we will market and distribute the product under our label in the United States, remitting a percentage of profits from sales of the drug to Sofgen.

Under the August 2013 Sofgen Agreement, Sofgen will own all the rights, title and interest in the product. During the term, both parties are prohibited from developing, manufacturing, selling or distributing any product in the United States that is identical or bioequivalent to the product covered under the agreement. The agreement may be terminated or amended under certain specified circumstances.

April 2014 Sofgen Agreement

In April 2014, we entered into a second collaboration agreement with Sofgen to develop an oral soft gel prescription product (the "April 2014 Sofgen Agreement"). The product will also be subject to an ANDA filing once developed. In general, Sofgen will be responsible for the development, manufacturing and regulatory submission of the product, including preparation of the ANDA, and we will make payments based on the completion of certain milestones. Upon approval, Sofgen will manufacture the drug and we will be market and distribute the product under our label in the United States, remitting a percentage of profits from sales of the drug to Sofgen.

Under the April 2014 Sofgen Agreement, Sofgen will own all the rights, title and interest in the product. During the term, both parties are prohibited from developing, selling or distributing any product in the United States that is identical or bioequivalent to the product covered under the agreement. The agreement can be terminated or amended under certain specified circumstances. The agreement’s initial term is ten years from the launch of the product, which term will automatically renew for two year terms until either party terminates the agreement.

RiconPharma LLC

In July 2011, we entered into a collaborative arrangement with RiconPharma LLC (“RiconPharma”). Under the parties' master product development and collaboration agreement (the “RiconPharma Agreement”), we and RiconPharma have agreed to collaborate in a cost, asset and profit sharing arrangement for the development, manufacturing, regulatory approval and marketing of pharmaceutical products in the United States.

In general, RiconPharma is responsible for developing the products and we are responsible for manufacturing, sales, marketing and distribution of the products. The parties are jointly responsible for directing any bioequivalence studies. We are responsible for obtaining and maintaining all necessary regulatory approvals, including the preparation of all ANDAs.

Under the RiconPharma Agreement and unless otherwise specified in an amendment, the parties will own equally all the rights, title and interest in the products. To the extent permitted by applicable law, we will be identified on the product packaging as the manufacturer and distributor of the product. During the term, both parties are prohibited from developing, manufacturing, selling or distributing any products that are identical or bioequivalent to products covered under the agreement. The agreement may be terminated or amended under certain specified circumstances.

Patents, Trademarks, and Licenses

We own the trademark names for each of our branded products, Cortenema, Cortrophin, Cortrophin-Zinc, Lithobid, Reglan, and Vancocin. Generally, the branded pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. We do not own or license any patents associated with these products. Further, patent protection and market exclusivity for these branded products have expired. Therefore, we consider the trademark names to be of material value and we act to protect these rights from infringement. However, our business is not dependent upon any single trademark. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and may be renewed indefinitely. We believe that sales of our branded products have benefited and will continue to benefit from the value of the product name.

We have licensed the right to manufacture and market Fluvoxamine Maleate, an authorized generic version of Luvox® IR, from Jazz Pharmaceuticals, which in turn acquired the rights to Luvox® IR from Solvay Pharmaceuticals, Inc. This license is in addition to a manufacturing and supply agreement with Jazz Pharmaceuticals, under which we manufacture and supply Jazz Pharmaceuticals' requirements for Luvox® IR. Under the license agreement, Jazz Pharmaceuticals transferred responsibility for the related NDA to us. The license agreement may be terminated by Jazz Pharmaceuticals if the Solvay license agreement is terminated, if we breach or default in the performance or observance of any material provisions of the agreement or the related supply agreement and such breach or default is not cured within 60 days after written notice is received, in the case of voluntary or involuntary bankruptcy filings by/against us, if we do not make royalty payments when due, or in the event we receive an adverse finding letter from the FDA relating to the NDA and is either not able to cure or provide evidence of a reasonable plan to cure within 30 days of receipt of such adverse finding letter, among other events. We may terminate the agreement with the consent of Jazz Pharmaceuticals, such consent not to be unreasonably withheld.

Customers

Our customers purchase and distribute our products. Our products are sold by four major retail pharmacy chains: Walgreens, CVS, RiteAid and Wal-Mart, and are included in the source programs of four major national wholesalers: Cardinal, McKesson, AmerisourceBergen and Morris Dickson. In addition, our customers include national mail order houses, including Anda, ExpressScripts, and Omnicare, as well as group purchasing organizations.

In recent years, the wholesale distributor network for pharmaceutical products has been subject to increasing consolidation, which has increased the concentration of our wholesale customers. In addition, the number of retail market chains and, in particular, the number of independent drug stores and small chains, has decreased as retail consolidation has occurred, also increasing the concentration of our retail customers. As a result of this trend toward consolidation, a smaller number of companies each control a larger share of pharmaceutical distribution channels. For the year ended December 31, 2015, approximately 64% of our net revenues were attributable to three wholesalers: McKesson Corporation (26%), Cardinal Health, Inc. (20%), and AmerisourceBergen Corporation (18%). For the years ended December 31, 2014 and 2013, AmerisourceBergen Corporation, McKesson Corporation, and Cardinal Health, Inc. accounted for approximately 69% and 55% of our net revenues, respectively. In addition, as noted below, our customers also distribute our products. The loss of any of these customers, including in their role as distributors, could have a material adverse effect on our business.

Due to a strategic partnership between Amerisource Bergen and Walgreens established in 2014, Amerisource Bergen has begun handling product distribution for Walgreens. Due to this and other strategic partnerships between wholesalers and pharmacy chains, we have experienced, and expect to continue to experience, increases in net sales to the wholesalers, with corresponding decreases in net sales to the pharmacy chains.

Consistent with industry practice, we maintain a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. See "Management's Discussion and Analysis of Results of Operations and Financial Condition—Critical Accounting Estimates" for a discussion of our accruals for chargebacks, rebates, returns, and other allowances.

Sales, Marketing, and Distribution

We market, sell, and distribute our products in the United States. Our products are distributed through the following channels:

- ***Wholesalers.*** We have contracts with four major wholesalers in the United States: Cardinal, McKesson, AmerisourceBergen, and Morris Dickson, as well as access to their respective retail source programs.
- ***Retail Market Chains.*** We conduct business with four major retail chains in the United States: Walgreens, CVS, RiteAid, and Wal-Mart.
- ***Distributors and Mail Order Pharmacies.*** We have contracts with several major distributors and mail order pharmacies in the United States, including Anda, ExpressScripts, and Omnicare.
- ***Group Purchasing Organizations.*** We have contracts with group purchasing organizations in the United States, such as Premiere, MedAssets, Minnesota Multi-State, and the Federal Supply Schedule ("FSS").

Competition

Our products face limited competition due to complexities in formulation, active pharmaceutical ingredient sourcing, materials handling and manufacturing, and regulatory hurdles. Nevertheless, we compete with numerous other pharmaceutical companies, including large, global pharmaceutical manufacturers capable of addressing these complexities and hurdles with respect to products that we currently produce and products that are in our pipeline. In addition, our products are subject to competition from other generic products and non-prescription alternative therapies.

Our branded pharmaceutical products currently face competition from generic products and may continue to face competition from generic products in the future. In order to launch a generic product, a manufacturer must apply to the FDA for an ANDA showing that the generic product is therapeutically equivalent to the RLD. (See "Government Regulation.")

The primary means of competition among generic drug manufacturers are pricing, contract terms, service levels, and reliability. To compete effectively, we seek to consistently produce high-quality, reliable, and effective products. We also establish active working relationships with each of our customers, continually gather important market information in order to respond successfully to requests for proposals, maintain sufficient inventories to assure high service levels, and work to reduce product costs by sourcing and qualifying alternative suppliers whenever possible.

Our sales can be impacted by new studies that indicate that a competitor's product has greater efficacy than one of our products. If competitors introduce new products with therapeutic or cost advantages, our products can be subject to progressive price reductions and/or decreased volume of sales.

Principal competitors for the pharmaceutical market in which we do business include Amneal Pharmaceuticals, Creekwood Pharmaceuticals, Endo Pharmaceuticals, Glenmark Pharmaceuticals, Lannett, Mallinckrodt, Mylan, Par Pharmaceutical Companies, Purdue Pharma, Roxane Laboratories, Sandoz, Teva Pharmaceuticals, USA, and Watson Pharmaceuticals.

Pharmaceutical Industry Trends

In recent years, the pharmaceutical industry has experienced significant consolidation, particularly in distribution channels and amongst generic and brand drug companies.

The wholesale distributor network for pharmaceutical products has been subject to increasing consolidation, which has increased the concentration of our wholesale customers. In addition, the number of retail market chains and, in particular, the number of independent drug stores and small chains, has decreased as retail consolidation has occurred, also increasing the concentration of our retail customers. As a result of this trend toward consolidation, a smaller number of companies each control a larger share of pharmaceutical distribution channels.

In addition, consolidation amongst pharmaceutical companies has created opportunities by reducing the number of competitors. However, as competitors grow larger through consolidation, so do their resources. Larger competitors may be able to aggressively decrease prices in order to gain market share on certain products and may have resources that would allow them to more effectively market their products to potential customers.

Product Liability

Product liability litigation represents an inherent risk to all firms in the pharmaceutical industry. We utilize traditional third-party insurance policies with regard to our product liability claims. Such insurance coverage at any given time reflects current market conditions, including cost and availability, when the policy is written.

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including ANI, are facing allegations from plaintiffs in various states, including California, New Jersey, and Pennsylvania, claiming bodily injuries as a result of ingestion of metoclopramide or its brand name, Reglan, prior to the FDA's February 2009 Black Box warning requirement. In August 2012, we were dismissed with prejudice from all New Jersey cases. We consider our exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide that we manufactured prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) our market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once we received a request for change of labeling from the FDA, we submitted our proposed changes within 30 days, and such changes were subsequently approved by the FDA.

At the present time, we are unable to assess the likely outcome of the cases in the remaining states. Our insurance company has assumed the defense of this matter. We cannot provide assurances that the outcome of these matters will not have an adverse effect on our business, financial position, and operating results. Furthermore, like all pharmaceutical manufacturers, we may be exposed to other product liability claims in the future, which could limit our coverage under future insurance policies or cause those policies to become more expensive, which could harm our business, financial condition, and operating results.

Backlog

We had a backlog of $0.5 million, $1.2 million, and $2.1 million at December 31, 2015, 2014, and 2013, respectively, relating to contract manufacturing purchase orders from customers.

Employees

As of December 31, 2015 our workforce included 108 full-time employees.

Seasonality of Business

We do not believe our business is subject to seasonality. However, our business can be affected by the business practices of our business partners. To the extent that the availability of inventory or materials from or development practices of our partners is seasonal, our sales may be subject to fluctuations quarter to quarter or year to year.

Segment Information

We operate in one segment and all our operations are in the United States. Total revenues from external customers for the years ended December 31, 2015, 2014, and 2013 were $76.3 million, $56.0 million, and $30.1 million, respectively. Net income for the years ended December 31, 2015, 2014, and 2013 was $15.4 million, $28.7 million, and $0.3 million, respectively. Total assets at December 31, 2015, 2014, and 2013 were $285.3 million, $259.6 million, and $44.5 million, respectively.

Item 1A. Risk Factors

The following are significant factors known to us that could materially harm our business, financial position or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this report. The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, also may adversely affect our business, financial position and operating results. If any of these risks actually occur, our business, financial position, and operating results could suffer significantly. As a result, the market price of our common stock could decline and investors could lose all or part of their investment.

Risks Related to our Industry

Two of our products, which together comprised 58% of our total revenue in 2015, are marketed without approved New Drug Applications ("NDAs") or Abbreviated New Drug Applications ("ANDAs") and we can offer no assurances that the U.S. Food and Drug Administration ("FDA") will not require us to either seek approval for these products or withdraw them from the market. In either case, our business, financial position, and operating results could be materially adversely affected.

Two of our products, Esterified Estrogen with Methyltestosterone ("EEMT") and Opium Tincture, are marketed without approved NDAs or ANDAs. During the years ended December 31, 2015, 2014, and 2013, revenues for EEMT were 51%, 42%, and 33% of total revenue, respectively, and revenues from Opium Tincture were 7%, 11%, and 16% of total revenue, respectively.

The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While we believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products.

In addition, we manufacture a group of products on behalf of a contract manufacturing customer and receive royalties on the customer's sales of products, which are marketed by that customer without an FDA-approved NDA or ANDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for

the group of products or withdraw them from the market, which could materially adversely affect our contract manufacturing and royalty revenues. Our contract manufacturing revenues from this group of unapproved products for the years ended December 31, 2015, 2014, and 2013 were 2.1%, 2.2%, and 6.5% of total revenues, respectively. Our royalties on the net sales of these unapproved products for the years ended December 31, 2015, 2014, and 2013 were 0.4%, 0.5%, and 1.1% of total revenues, respectively.

Imported active pharmaceutical ingredients ("API") are subject to inspection by the FDA and the FDA can refuse to permit the importation of API for use in products that are marketed without approved NDAs or ANDAs. We are entirely dependent on imported API to make EEMT. If the FDA detained or refused to allow the importation of such API, our revenues from EEMT would be reduced or eliminated and our business, financial position, and operating results could be materially adversely affected.

We source some of the API for our products, including those that are marketed without approved NDAs or ANDAs, from international suppliers. From time to time, due to FDA inspections, we have experienced temporary disruptions in the supply of imported API, including for EEMT. Any prolonged disruption in the supply of imported API could materially affect our ability to manufacture and distribute our products, such as EEMT, reduce or eliminate our revenues from EEMT, and have a material adverse effect on our business, financial position, and operating results. In addition, as regulatory fees and compliance oversight of API manufacturers increase, this could result in certain companies discontinuing their supply of API to ANI, which would materially affect ANI's ability to manufacture its products.

The FDA does not provide guidance on safety labeling for products that are marketed without approved NDAs or ANDAs. As a result, we are dependent on our internal post-approval drug safety surveillance program to identify necessary safety-related changes to the labels for EEMT and Opium Tincture.

Pharmaceutical product labels contain important safety information including Black Box warnings, contraindications, dosing and administration, adverse reactions, drug interactions, use in specific populations such as pregnant women, pediatric, and geriatric patients, and other warnings and precautions. Pharmaceutical manufacturers may change product labels when post-approval drug safety surveillance programs identify previously unknown side-effects, drug interactions, and other risks. Manufacturers may also change product labels after conducting post-approval clinical studies and may receive or seek guidance from the FDA regarding updating safety labeling information. However, the FDA does not provide guidance on labeling for products that are marketed without approved NDAs or ANDAs. As a result, we are dependent on our internal post-approval drug safety surveillance program to identify necessary safety-related changes to the labels for EEMT and Opium Tincture, which could increase our potential liability with respect to failure-to-warn claims for these products. Such claims, even if successfully defended, could have an adverse impact on our business, financial position, and operating results.

We are entirely dependent on periodic approval by the Drug Enforcement Administration for the supply of the API needed to make our Opium Tincture and Oxycodone oral solution products. An inability to obtain such approvals would reduce or eliminate our revenues from Opium Tincture and Oxycodone oral solution, and could have a material adverse effect on our business, financial position, and operating results. In addition, we are subject to strict regulation by the Drug Enforcement Administration and are subject to sanctions if we are unable to comply with related regulatory requirements.

The Drug Enforcement Administration (“DEA”) regulates products containing controlled substances, such as opiates, pursuant to the U.S. Controlled Substances Act (“CSA”). The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

In addition, each year, we must submit a request to the DEA for a quota to purchase the amount of API needed to manufacture Opium Tincture and Oxycodone oral solution. Without approved quotas from the DEA, we would not be able to purchase these ingredients from our suppliers. As a result, we are entirely dependent upon the DEA to approve, on an annual basis, a quota of API that is sufficiently large to support our plans for the continued manufacture of Opium Tincture and Oxycodone oral solution at commercial levels.

Pharmaceutical product quality standards are steadily increasing and all products, including those already approved, may need to meet current standards. If our products are not able to meet these standards, we may be required to discontinue marketing and/or recall such products from the market.

Steadily increasing quality standards are applicable to pharmaceutical products still under development and those already approved and on the market. These standards result from product quality initiatives implemented by the FDA, such as criteria for residual solvents, and updated U.S. Pharmacopeial Convention ("USP") Reference Standards. The USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide. Pharmaceutical products approved prior to the implementation of new quality standards, including those produced by us, may not meet these standards, which could require us to discontinue marketing and/or recall such products from the market, either of which could adversely affect our business, financial position, and operating results.

The continuing trend toward consolidation of customer groups could result in declines in the sales volume and prices of our products, and increased fees charged by customers, each of which could have a material adverse effect on our business, financial position, and operating results.

Consolidation among wholesale distributors, chain drug stores, and group purchasing organizations has resulted in a smaller number of companies, each controlling a larger share of pharmaceutical distribution channels. For example, our net revenues are concentrated among three customers representing 26%, 20%, and 18% of net revenues, respectively, during the year ended December 31, 2015. As of December 31, 2015, accounts receivable from these three customers was approximately 73% of our net accounts receivable. Drug wholesalers and retail pharmacy chains, which represent an essential part of the distribution chain for generic pharmaceutical products, have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in declines in our sales volumes if a customer is consolidated into another company that purchases products from a competitor. In addition, the consolidation of drug wholesalers and retail pharmacy chains could result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing our business and enabling those groups to charge us increased fees. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to extract price discounts on our products. The result of these developments may have a material adverse effect on our business, financial position, and operating results.

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 adversely affect our business, financial position, and operating results.

The regulations regarding reporting and payment obligations with respect to Medicaid rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to the risk of errors. Our calculations and methodologies are subject to review and challenge by governmental agencies, and it is possible that such reviews could result in changes. Any determination by governmental agencies that we have failed to comply with our reporting and payment obligations could subject us to penalties and sanctions, which could have a material adverse effect on our business, financial position, and operating results.

We may become subject to federal and state false claims litigation brought by private individuals and the government.

We are subject to state and federal laws that govern the submission of claims for reimbursement. The Federal False Claims Act (“FFCA”), also known as Qui Tam, imposes civil liability and criminal fines on individuals or entities that knowingly submit, or cause to be submitted, false or fraudulent claims for payment to the government. Violations of

the FFCA and other similar laws may result in criminal fines, imprisonment, and civil penalties for each false claim submitted and exclusion from federally funded health care programs, including Medicare and Medicaid. The FFCA also allows private individuals to bring a suit on behalf of the government against an individual or entity for violations of the FFCA. These suits, also known as Qui Tam actions, may be brought by, with only a few exceptions, any private citizen who has material information of a false claim that has not yet been previously disclosed. These suits have increased significantly in recent years because the FFCA allows an individual to share in any amounts paid to the federal government from a successful Qui Tam action. If our past or present operations are found to be in violation of any of such laws or other applicable governmental regulations, we may be subject to civil and criminal penalties, damages, fines, exclusion from federal health care programs, and/or the curtailment or restructuring of our operations, any of which could materially adversely affect our business, financial position, and operating results. Actions brought against ANI for violations of these laws, even if successfully defended, could also have a material adverse effect on our business, financial position, and operating results.

We face significant uncertainty with respect to the litigation brought against us and other manufacturers of metoclopramide and cannot provide assurances that the outcome of the matter will not have an adverse effect on our business, financial position, and operating results. In addition, we may be exposed to other product liability claims in the future.

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including ANI, are facing allegations from plaintiffs in various states, including California, New Jersey, and Pennsylvania, claiming bodily injuries as a result of ingestion of metoclopramide or its brand name, Reglan, prior to the FDA's February 2009 Black Box warning requirement. In August 2012, we were dismissed with prejudice from all New Jersey cases. We consider our exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide that we manufactured prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) our market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once we received a request for change of labeling from the FDA, we submitted our proposed changes within 30 days, and such changes were subsequently approved by the FDA.

At the present time, we are unable to assess the likely outcome of the cases in the remaining states. Our insurance company has assumed the defense of this matter. We cannot provide assurances that the outcome of these matters will not have an adverse effect on our business, financial position, and operating results. Furthermore, like all pharmaceutical manufacturers, we may be exposed to other product liability claims in the future, which could limit our coverage under future insurance policies or cause those policies to become more expensive, which could harm our business, financial position, and operating results.

A proposed FDA rule allowing generic companies to distribute revised labels that differ from the corresponding reference listed drug ("RLD") could have an adverse effect on our operations because of a potential increase in litigation exposure.

On November 13, 2013, the FDA issued a proposed rule (Docket No. FDA-2013-N-0500) titled "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products." In December 2015, the FDA announced that the rule would be released in July 2016. Pursuant to the rule, the FDA will change existing regulations to allow generic drug application holders, in advance of the FDA's review, to distribute revised labeling, to reflect safety-related changes based on newly acquired information. Currently, the labels of generic drugs must conform to those of the corresponding RLD and any failure-to-warn claims against generic companies are preempted under U.S. Federal law. Once this rule is released, we could be found liable under such failure-to-warn claims if we do not revise our labeling to reflect safety-related changes promptly upon receipt of applicable safety information. While we proactively conduct surveillance for reported safety issues with our products, we cannot guarantee that this will prevent us from being found liable under a failure-to-warn claim. When this proposed regulatory change is adopted, it could increase our potential liability with respect to failure-to-warn claims, which, even if successfully defended, could have an adverse impact on our business, financial position, and operating results.

16

The use of legal, regulatory, and legislative strategies by competitors, both branded and generic, including "authorized generics," citizen's petitions, and legislative proposals, may increase the costs to develop and market our generic products, could delay or prevent new product introductions, and could reduce significantly our profit potential. These factors could have a material adverse effect on our business, financial position, and operating results.

Our competitors, both branded and generic, often pursue legal, regulatory, and/or legislative strategies to prevent or delay competition from generic alternatives to branded products. These strategies include, but are not limited to:

- entering into agreements whereby other generic companies will begin to market an authorized generic, a generic equivalent of a branded product, at the same time generic competition initially enters the market;
- launching a generic version of their own branded product at the same time generic competition initially enters the market;
- filing citizen petitions with the FDA or other regulatory bodies, including timing the filings so as to thwart generic competition by causing delays of generic product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence or meet other approval requirements;
- initiating legislative and regulatory efforts to limit the substitution of generic versions of branded pharmaceuticals;
- filing suits for patent infringement that may delay regulatory approval of generic products;
- introducing "next-generation" products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the first generic product;
- obtaining extensions of market exclusivity by conducting clinical trials of branded drugs in pediatric populations or by other potential methods;
- persuading regulatory bodies to withdraw the approval of branded name drugs for which the patents are about to expire, thus allowing the branded company to obtain new patented products serving as substitutes for the products withdrawn; and
- seeking to obtain new patents on drugs for which patent protection is about to expire.

If we cannot compete with such strategies, our business, financial position, and operating results could be adversely impacted.

If third-party payers deny coverage, substitute another company’s product for our product, or offer inadequate levels of reimbursement, we may not be able to market our products effectively or we may be required to offer our products at prices lower than anticipated.

Third-party payers are increasingly challenging the prices charged for medical products and services. For example, third-party payers may deny coverage, choose to provide coverage for a competitor’s bioequivalent product rather than our product, or offer limited reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA, is not used in accordance with cost-effective treatment methods as determined by the

third-party payer, or is experimental, unnecessary or inappropriate. Prices also could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. If third-party payers deny coverage or limit reimbursement, we may not be able to market our products effectively or we may be required to offer our products at prices lower than anticipated.

We are subject to federal, state and local laws and regulations, and complying with these may cause us to incur significant additional costs.

The pharmaceutical industry is subject to regulation by various federal authorities, including the FDA, the DEA, and state governmental authorities. Federal and state statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale, and distribution of our products. Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunctions, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, civil penalties, debarment and criminal prosecution.

All U.S. facilities where prescription drugs are manufactured, tested, packaged, stored, or distributed must comply with FDA current good manufacturing practices (“cGMPs”). All of our products are manufactured, tested, packaged, stored, and distributed according to cGMP regulations. The FDA performs periodic audits to ensure that our facilities remain in compliance with all applicable regulations. If it finds violations of cGMP, the FDA could make its concerns public and could impose sanctions including, among others, fines, product recalls, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, injunctions and civil or criminal prosecution. If imposed, enforcement actions could have a material adverse effect on our business, financial position, and operating results. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal compliance programs in place that we believe are adequate, the FDA may conclude that these programs do not meet regulatory standards. If compliance is deemed deficient in any significant way, it could have a material adverse effect on our business.

The U.S. government has enacted the Federal Drug Supply Chain Security Act ("DSCSA") that requires development of an electronic pedigree to track and trace each prescription drug at the salable unit level through the distribution system, which will be effective incrementally over a 10-year period. Compliance with DSCSA and future U.S. federal or state electronic pedigree requirements may increase the Company's operational expenses and impose significant administrative burdens.

Our research, product development, and manufacturing activities involve the controlled use of hazardous materials, and we may incur significant costs in complying with numerous laws and regulations. We are subject to laws and regulations enforced by the FDA, the DEA, and other regulatory statutes including the Occupational Safety and Health Act (“OSHA”), the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture such products, and resulting waste products. For example, some of our products, including EEMT, must be manufactured in a fully contained environment due to their potency and/or toxicity, and compliance with related OSHA requirements is costly.

We cannot completely eliminate the risk of contamination or injury, by accident or as the result of intentional acts, from these materials. In the event of an accident, we could be held liable for any damages that result, and any resulting liability could exceed our resources. We may also incur significant costs in complying with environmental laws and regulations in the future. We are also subject to laws generally applicable to businesses, including but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm our business, financial position, and operating results.

Uncertainties associated with the impact of published studies regarding the adverse health effects of certain forms of hormone therapy could affect adversely the market for our hormone products.

The market for hormone therapy products has been affected negatively by the Women's Health Initiative (“WHI”) study and other studies that have found that the overall health risks from the use of certain hormone therapy products may exceed the benefits from the use of those products among postmenopausal women. In July 2002, the National Institutes of Health (“NIH”) released data from its WHI study on the risks and benefits associated with long-term use of oral hormone therapy by women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin among postmenopausal women. Also, in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant hormone therapy study being conducted in the United Kingdom also was halted. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory portion of the WHI study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment.

Researchers continue to analyze data from both arms of the WHI study and other studies. Some reports indicate that the safety of estrogen products may be affected by the age of the woman at initiation of therapy. The markets for female hormone therapies for menopausal symptoms declined as a result of these published studies. The release of any follow-up or other studies that show adverse effects from hormone therapy, including in particular, hormone therapies similar to the our products, also could adversely affect our business, financial position, and operating results.

Continuing studies of our products could produce negative results, which could require us to implement risk management programs, or discontinue product marketing. In addition, ongoing post-approval drug safety surveillance of our products could result in the submission of adverse event reports to the FDA.

Studies of the proper utilization, safety, and efficacy of pharmaceutical products are being conducted by the industry, government agencies, and others on a continuous basis. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety, and efficacy of current and previously marketed products, including those that we produce. In addition, we are required by the FDA to submit reports of adverse events involving the use of our products. In some cases, studies and safety surveillance programs have resulted, and in the future may result, in the one or more of the following:

- product label changes including FDA-mandated Black Box warnings;
- risk management programs such as patient registries;
- reduced product sales due to concerns among patients and physicians; and
- discontinuance of product marketing.

These situations, should they occur with respect to any of our products, could have a material adverse effect on our business, financial position, and operating results.

Companies with greater resources than us could lobby Congress and other regulators for additional regulations that would benefit their businesses and negatively affect us.

We are at the early stages of growth and currently do not engage in lobbying activities. In the U.S., some companies have lobbied Congress for amendments to the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) 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 an NDA is under regulatory review, some companies have proposed extending the patent term by the full amount of time spent in clinical trials rather than by only one half of the time 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 products may be delayed, reduced, or eliminated, which could have a material adverse effect on our business, financial position, and operating results.

Healthcare reform legislation could have a material adverse effect on our business, financial position, and operating results.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of, and reimbursement for healthcare services in the U.S., and it is likely that federal and state legislatures and health agencies will continue to focus on health care reform in the future. The Patient Protection and Affordable Care Act ("PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA (collectively, "the ACA"), were signed into law in March 2010. While the ACA may increase the number of patients who have insurance coverage for our products and may otherwise increase drug coverage, it also includes provisions such as, among others, the assessment of a pharmaceutical manufacturer fee, the requirement that manufacturers provide discounts to Medicare beneficiaries through the Medicare Coverage Gap Discount program, and an increase in the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs.

The cost-containment measures that government programs and healthcare insurers are instituting both as a result of general cost pressure in the industry and healthcare reforms contained in the ACA may prevent us from maintaining prices for our products that are sufficient for us to realize profits and may otherwise harm our business, financial position, and operating results. In addition, to the extent that our products are marketed outside of the U.S., foreign government pricing controls and other regulations may prevent us from maintaining prices for such products that are sufficient for us to realize profits and may otherwise harm our business, financial position, and operating results.

We are unable to predict the future course of federal or state healthcare legislation. The ACA and further changes in the law or regulatory framework that reduce our revenues or increase our costs could have a material adverse effect on our business, financial position, and operating results.

Risks Related to our Business

63% of our net revenues in 2015 resulted from sales of EEMT, Lithobid, and Vancocin. During the same period, these products accounted for only 13% of our cost of sales. If we experience increased competition for EEMT, or increased prescription erosion for Lithobid or Vancocin, our profitability could be reduced significantly and our business, financial position and operating results could be materially adversely affected.

We experienced an increase in the number of competitors selling EEMT toward the end of 2015, which led to a decrease in our market share and a decrease in revenues from sales of EEMT. If additional competitors enter the market, our market share could decline further. In addition, we sell EEMT without an approved NDA or ANDA and can provide no assurances that the FDA will not require us to seek approval for the product or withdraw it from the market. If the FDA required us to obtain an approved NDA or ANDA in order to sell EEMT, our business, financial position, and operating results would be materially adversely affected. The costs of and time involved in obtaining an approved NDA or ANDA would be significant and we may determine not to pursue such approvals. Unless we were successful in increasing sales of other products to replace any revenue lost from the sale of our EEMT product, whether due to competition, FDA actions or otherwise, our business, financial position, and operating results would be materially harmed.

Lithobid and Vancocin are no longer patent-protected and face intense competition from lower-priced generics. In addition, both products compete with different drugs that treat the same conditions. These factors have resulted in a consistent rate of decline in the number of prescriptions for Lithobid and Vancocin. The introduction of additional competing generic and branded products could result in an even faster rate of prescription erosion, which could have a material adverse effect on our business, financial position, and operating results.

We depend on a limited number of suppliers for API. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers must usually be approved through a Prior Approval Supplement by the FDA.

Our ability to manufacture and distribute products is dependent, in part, upon ingredients and components supplied by others, including entities based outside the U.S. We purchased approximately 33% and 42% from two suppliers during the years ended December 31, 2015 and 2014, respectively, and 37% of our inventory from three suppliers during the year ended December 31, 2013. Any disruption in the supply of these ingredients or components or any problems in

their quality could materially affect our ability to manufacture and distribute our products and could result in legal liabilities that could materially affect our ability to realize profits or otherwise harm our business, financial, and operating results. Virtually all of our contracts for the supply of pharmaceutical products to customers contain "failure to supply" clauses. Therefore, our ability to source sufficient quantities of API for manufacturing is critical. We source the raw materials for our products, including API from both domestic and international suppliers. As the API typically comprises the majority of a product's manufactured cost, and qualifying an alternative is costly and time-consuming, API suppliers must be selected carefully based on quality, reliability of supply and long-term financial stability.

Our anticipated revenue growth and profitability, if achieved, is dependent upon our ability to develop, license, or acquire, and commercialize new products on a timely basis in relation to our competitors' product introductions, and to address all regulatory requirements applicable to the development and commercialization of new products. Our failure to do so successfully could impair our growth strategy and plans and could have a material adverse effect on our business, financial position, and operating results.

Our future revenues and profitability are dependent upon our ability to successfully develop, license or acquire, and commercialize, pharmaceutical products in a timely manner. Product development is inherently risky and time-consuming. Likewise, product licensing involves inherent risks, including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to the supply of product meeting specifications and terms such as license scope or termination rights. The development and commercialization process also requires substantial time, effort and financial resources. We may not be successful in commercializing products on a timely basis, if at all, which could adversely affect our business, financial position, and operating results.

The FDA must approve any new prescription product before it can be marketed in the U.S. The process of obtaining regulatory approval to manufacture and market branded and generic pharmaceutical products is rigorous, time consuming, costly and largely unpredictable. We may be unable to obtain requisite approvals on a timely basis for branded or generic products that we may develop, license or acquire. Moreover, if we obtain regulatory approval for a drug, we may be limited with respect to the indicated uses and delivery methods for which the drug may be marketed, which in turn could restrict the potential market for the drug. Also, for products pending approval, we may obtain raw materials or produce batches of inventory. In the event that regulatory approval is denied or delayed, we could be exposed to the risk of any such inventory becoming obsolete. The timing and cost of obtaining regulatory approvals could adversely affect our product introduction plans, business, financial position, and operating results.

The approval process for generic pharmaceutical products often results in the FDA granting simultaneous final approval to a number of generic pharmaceutical products at the time a patent claim for a corresponding branded product or other market exclusivity expires. This often forces a generic firm to face immediate competition when it introduces a generic product into the market. Additionally, further generic approvals often continue to be granted for a given product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices, as well as reduced margins, for generic products compared to branded products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle. As a result, we could be unable to grow or maintain market share with respect to our generic pharmaceutical products, which could have a material adverse effect on our ability to market that product profitably and on our business, financial position, and operating results.

Furthermore, if we are unable to address all regulatory requirements applicable to the development and commercialization of new products in a timely manner, our product introduction plans, business, financial position, and operating results could be materially adversely affected.

The FDA regulates and monitors all promotion and advertising of prescription drugs after approval. All promotion must be consistent with the conditions of approval and submitted to the agency. Failure to adhere to FDA promotional requirements can result in enforcement letters, warning letters, changes to existing promotional material, and corrective notices to healthcare professionals. Promotion of a prescription drug for uses not approved by the FDA can have serious consequences and result in lawsuits by private parties, state governments and the federal government, significant civil and criminal penalties, and compliance agreements that require a company to change current practices and prevent unlawful activity in the future.

Several of the products we have acquired cannot be manufactured in our facilities. If we are unable to secure qualified contract manufacturers for those products or if a contract manufacturer fails to comply with federal, state, and local laws and regulations, our business, financial position, and operating results could be materially, adversely affected.

We have acquired, and may continue to acquire, a variety of products that we seek to commercialize. Some of these products, including injectables and softgel capsules, are products that we cannot manufacture in our facilities. As a result, we may seek partners to contract manufacture the products on our behalf. Like our company, these firms must comply with cGMPs and other federal, state, and local laws and regulations regarding pharmaceutical manufacturing. Noncompliance by those firms may result in warning letters, fines, product recalls, and partial or total suspension of production and distribution. If we are unable to find qualified contract manufacturers or if a contract manufacturer fails to comply with federal, state, and local laws and regulations, we may be unable to commercialize these products, which could have a material adverse effect on our business, financial position, and operating results, including an impairment of the acquired product.

Future acquisitions and investments could disrupt our business and harm our financial position and operating results.

Our growth will depend, in part, on our continued ability to develop, commercialize, and expand our products, including in response to changing regulatory and competitive pressures. In some circumstances, we may determine to accelerate our growth through the acquisition of complementary businesses and technologies rather than through internal development. The identification of suitable acquisition candidates or products can be difficult, time-consuming and costly, and we may not be able to successfully complete or successfully execute strategies for identified acquisitions. The risks faced in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition and/or product integration challenges;
- coordination of research and development and sales and marketing functions;
- retention of key employees from the acquired company;
- integration of the acquired company's accounting information, management, human resources and other administrative systems;
- the need to implement or improve controls, procedures, and policies at a business that prior to the acquisition may have lacked effective controls, procedures and policies;
- liability for activities of the acquired company and/or products before the acquisition, including patent infringement claims, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company or product, including claims from product users, former stockholders or other third parties.

In any acquisition that we may undertake, our failure to address these risks or other problems encountered in connection with any acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities, and harm our business generally. Future acquisitions could also result in dilutive issuances of our equity securities, the incurrence of additional debt, contingent liabilities, amortization expenses, incremental operating expenses or the write-off of goodwill, any of which could harm our business, financial position, and operating results.

Our Medicaid rebate accruals have increased significantly due to our acquisitions of Lithobid and Vancocin and the estimates on which our accruals are based are subject to change. Any such change could have a material adverse effect on our business, financial position, and operating results.

Our Medicaid rebate accruals have increased significantly due to our acquisitions of Lithobid and Vancocin. We accrue for these rebates at the time of sale based on our estimates of the amount of our product that will be prescribed to Medicaid beneficiaries. The resulting accruals are significant, and as Medicaid utilization trends change, we may need to change our estimates accordingly. We cannot guarantee that actual results will not differ from our estimates. In addition, the Patient Protection and Affordable Care Act ("PPACA") included a significant expansion of state Medicaid programs. As more individuals become eligible for coverage under these programs, Medicaid utilization of our products could increase, resulting in a corresponding increase in our rebate payments. Increases in Medicaid rebate payments could decrease our revenues from product sales, including Lithobid and Vancocin, which in turn could adversely affect our business, financial position, and operating results.

In January 2016, we acquired two NDAs for $75.0 million and a percentage of future net sales of products under the NDAs. If we are unable to commercialize these products, it could have a material adverse effect on our business, financial position, and operating results.

In January 2016, we acquired the right, title and interest in the NDA for Corticotropin, 40 units/mL and 80 units/mL and the NDA for Corticotropin-Zinc, 40 units/mL, along with certain documentation and trademark applications, for $75.0 million and a percentage of future net sales of the products under the NDAs. In order to commercialize the products, we will need to find and engage one or more third parties capable of manufacturing both the active pharmaceutical ingredient and the finished dosage form of the products, and obtain approval from the FDA of a supplementary NDA filing. In addition, we will need to market the products directly to physicians and negotiate with third-party payers to provide coverage and adequate levels of reimbursement for the products, none of which is required for our current products. If we are unable to perform any of these steps, we may be unable to commercialize the products, which could have a material adverse effect on our business, financial position, and operating results.

We face vigorous competition from other pharmaceutical manufacturers that threatens the commercial acceptance and pricing of our products. If we are unable to successfully compete, such competition could have a material adverse effect on our business, financial position, and operating results.

The generic pharmaceutical industry is highly competitive. We face intense competition from U.S. and foreign manufacturers, many of whom are significantly larger than us. Our competitors may be able to develop products and processes competitive with or superior to ours for many reasons, including but not limited to the possibility that they may have:

- greater financial resources;
- proprietary processes or delivery systems;
- larger research and development and marketing staffs;
- larger production capabilities;
- more products; or
- more experience in developing new drugs.

Any of our significant competitors, due to one or more of these and other factors, could have a material adverse effect on our business, financial position, and operating results.

Our approved products may not achieve commercialization at levels of market acceptance that allow us to achieve profitability, which could have a material adverse effect on our business, financial position, and operating results.

We seek to develop, license or acquire products that we can commercialize at levels of market acceptance that would allow us to recoup our costs, grow market share, and achieve profitability. Even if we are able to obtain regulatory approvals for our pharmaceutical products, if we fail to predict accurately demand for such products, our business, financial position, and operating results could be adversely affected. Levels of market acceptance for our products could be impacted by several factors, including but not limited to:

- availability of alternative products from our competitors;
- our products' pricing relative to that of our competitors;
- our marketing effectiveness relative to that of our competitors;
- timing of our market entry;
- our ability to market our products effectively to the retail level; and
- acceptance of our products by government and private formularies.

Some of these factors are outside of our control and, if any arise, our profitability, business, financial position, and operating results could be materially adversely affected.

We have entered into several collaborative arrangements that may not result in marketable products.

We have entered into several collaborative arrangements to develop generic products for us to market in the U.S. We can offer no assurances that these arrangements will result in additional approved products, or that we will be able to market the products at a profit. In addition, any expenses related to clinical trials, or additional studies required by the FDA, that we may incur in connection with these collaborative arrangements may negatively affect our business, financial position, and operating results. Specifically:

- clinical trials could be more costly than we anticipate;
- formulation development could take longer and be more costly than we expect; and
- we may be required to obtain specialized equipment in order to manufacture products on a commercial scale.

Any of these events could have a material adverse effect on our business, financial position, and operating results.

We expect to spend a significant amount of resources on research and development efforts, and such efforts may not result in marketable products. Failure to successfully introduce products into the market could have a material adverse effect on our business, financial position, and operating results.

We conduct research and development primarily to enable us to manufacture and market approved products in accordance with applicable regulations. Research and development is expensive and time-consuming. As we seek to develop new products, or recommercialize products that were previously approved, our research expenses will increase, potentially significantly, and we cannot be certain that we will recover our investment in a product, even if that product is commercialized. If we spend significant resources on research and development efforts and are not able to introduce new products, our business, financial position, and operating results may be materially adversely affected.

We own two manufacturing facilities that produce the majority of our products. Production at either or both of these facilities could be interrupted, which could cause us to fail to deliver sufficient product to customers on a timely basis and have a material adverse effect on our business, financial position, and operating results.

Our manufacturing operations are based in two facilities. While these facilities are sufficient for our current needs, the facilities are highly specialized and any damage to or need for replacement of all or any significant function of our facilities could be very costly and time-consuming and could impair or prohibit production and shipping. A significant disruption at either of the facilities, even on a short-term basis, whether due to a labor strike, adverse quality or compliance observation, vandalism, natural disaster, storm or other environmental damage, or other events could impair our ability to produce and ship products on a timely basis and, among other consequences, could subject us to "failure to supply" claims from our customers, as discussed below. Although we believe we carry commercially reasonable business interruption and liability insurance, we might suffer losses because of business interruptions that exceed the coverage available under our insurance policies or for which we do not have coverage. Any of these events could have a material adverse effect on our business, financial position, and operating results.

Virtually all our contracts for the supply of products to our customers contain "failure to supply" clauses. Under these clauses, if we are unable to supply the requested quantity of product within a certain period after receipt of a customer's purchase order, the customer is entitled to procure a substitute product elsewhere and we must reimburse the customer for the difference between our contract price and the price the customer was forced to pay to procure the substitute product. This difference can be substantial because of the much higher spot price at which the customer must cover its requirements, and can be far in excess of the revenue that we would otherwise have received on the sale of our own product. Therefore, our ability to produce and ship a sufficient quantity of product on a consistent basis is critical. Failure to deliver products could have a material adverse effect on our business, financial position, and operating results.

We rely on third parties to assist with our clinical studies. If these third parties do not perform as required or expected, or if they are not in compliance with FDA rules and regulations, our clinical studies may be extended, delayed or terminated, or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the products being tested in such studies. Further, we may be required to audit or redo previously completed trials or recall already-approved commercial products.

We rely on third parties, such as medical institutions, clinical investigators and contract laboratories, to assist with our clinical studies. We are responsible for confirming that our studies are conducted in accordance with applicable regulations and that each of our clinical studies is conducted in accordance with our general investigational plan and protocol. The FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices for conducting, monitoring, recording and reporting the results of clinical studies, to assure that data and reported results are accurate and that the clinical study participants are adequately protected. Our reliance on these third parties does not relieve us of these responsibilities. If the third parties assisting us with our clinical studies do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with the FDA's good clinical practice regulations, do not adhere to our protocols or otherwise fail to generate reliable clinical data, we may

need to enter into new arrangements with alternative third parties and our clinical studies may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the products being tested in such studies. For our already-approved commercial products, we may be required to audit or redo previously completed trials or recall our products from the market, which could have a material adverse effect on our business, financial position, and operating results.

We do not own or license any material patents associated with our products, and our ability to protect and control unpatented trade secrets, know-how, and other technological innovation is limited.

Generally, the branded pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. We do not own or license any material patents associated with our products and therefore do not enjoy the same level of intellectual property protection with respect to such products as would a pharmaceutical manufacturer that markets a patented product. We have limited ability to protect and control trade secrets, know-how, and other technological innovation, all of which are unpatented. Others independently may develop similar or better proprietary information and techniques and disclose them publicly. In addition, others may gain access to our trade secrets, and we may not be able to protect our rights to our unpatented trade secrets. In addition, confidentiality agreements and other measures may not provide protection for our trade secrets in the event of unauthorized use or disclosure of such information. Failure to protect and control such trade secrets, know-how and innovation could harm the value of our trade secrets, know-how and other technological innovation, which could have a material adverse effect on our business, financial position, and operating results.

Inability to protect our intellectual property in the U.S. and foreign countries could negatively affect sales of our branded products.

We own trademarks for each of our branded products, including Cortenema, Cortrophin, Cortrophin-Zinc, Reglan, Lithobid, and Vancocin. While we will seek to protect those trademarks through timely renewal in applicable jurisdictions, we may not be able to renew our trademarks in a timely manner or to prevent third parties from using our trademarks, which could have a material adverse effect on our business, financial position, and operating results.

We have very limited staffing and are dependent upon key employees, the loss of whom could adversely affect our operations. Competition for talent is intense, especially in northern Minnesota, where the population is small. If we cannot attract and retain qualified personnel, the growth and success of our business could be adversely affected.

Our success is dependent upon the efforts of a relatively small management team and staff. We have employment arrangements in place with our executive and other officers, but none of these executive and other officers are bound legally to remain employed with ANI for any specific term. We do not have key person life insurance policies covering our executive and other officers or any of our other employees. If key individuals were to leave ANI, our business could be affected adversely if suitable replacement personnel are not recruited quickly. The population in northern Minnesota, where our manufacturing resources are located, is small, and as a result, there is a limited number qualified personnel available in all functional areas, which could make it difficult to retain and attract the qualified personnel necessary for the development and growth of our business. If we were unable to attract and retain qualified personnel, our business, financial position, and operating results could be materially adversely affected.

Our Vancocin, Vancomycin, and Nimodipine products are manufactured by third parties, which we cannot control.

We rely on third parties to manufacture our Vancocin, Vancomycin, and Nimodipine products. We expect our reliance on third party manufacturers to increase in the future as we receive approvals for new products to be manufactured through our collaborative arrangements, and as we seek additional growth opportunities outside of the capabilities of our current manufacturing facilities. If we are unable to secure third-party manufacturers for these products on commercially acceptable terms, we may not be able to market and distribute such products at a profit. Any delays or difficulties with third-party manufacturers could adversely affect the marketing and distribution of Vancocin, Vancomycin, Nimodipine, or future products, which could have a material adverse effect on our business, financial position, and operating results.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate the business effectively.

We rely significantly on our information technology and manufacturing infrastructure to effectively manage and maintain inventory and financial reports, manufacture and ship products, and invoice customers in a timely manner. Any failure, accidents, inadequacy, or interruption of that infrastructure or security lapse of that technology, including cybersecurity incidents, could harm our ability to operate our business effectively. Our ability to manage and maintain inventory and financial reports, manufacture and ship products, and invoice customers timely depends significantly on our general ledger, our contracted electronic data interface system, and other information systems. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of confidential or otherwise protected information and corruption of data. Cybersecurity incidents resulting in the failure of our information systems to operate effectively or to integrate with other systems, or a breach in security or other unauthorized access of these systems, may affect our ability to manage and maintain inventory and financial reports, and result in delays in product fulfillment and reduced efficiency of operations. A breach in security, unauthorized access resulting in misappropriation, theft, or sabotage with respect to proprietary and confidential information, including research or clinical data could require significant capital investments to remediate any such failure, problem or breach, all of which could adversely affect our business, financial position, and operating results.

Risks Related to Accounting, Tax, and SEC Rules and Regulations

Our ability to utilize our net operating loss and tax credit carryforwards in the future is subject to substantial limitations and we may not be able to use some identified net operating loss and tax credit carryforwards, which could result in increased tax payments in future periods.

Under Section 382 of the Internal Revenue Code, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss ("NOL") carryforwards and other pre-change tax attributes to offset its post-change income may be limited. On June 19, 2013, BioSante experienced an ownership change. Accordingly, our ability to utilize BioSante's NOL and tax credit carryforwards attributable to periods prior to June 19, 2013 is subject to substantial limitations. In addition, as a result of our common stock offering that closed on March 10, 2014, we believe that ANIP Acquisition Company experienced an ownership change. Accordingly, our ability to utilize ANIP Acquisition Company's NOL and tax credit carryforwards attributable to periods prior to the offering is subject to substantial limitations. These limitations, in turn, could result in increased future tax payments, which could be material.

We face risks associated with our recently established subsidiary in the Netherlands.

In the fourth quarter of 2015, we established a subsidiary in the Netherlands. Successfully managing operations in a foreign country depends on many factors such as:

- compliance with foreign tax rules and regulations, including proper establishment of intercompany transfer pricing;
- compliance with other foreign regulatory and legal requirements, including local trade, labor, and safety laws;
- unexpected changes to any of the aforementioned laws and regulations;
- difficulty enforcing agreements; and
- our ability to reinvest earnings and cash as appropriate.

Many of these factors are beyond our control, and any one of them could result in increased costs, decreased net sales, and diversion of management's attention, any or all of which could materially adversely impact our business, financial position, and operating results.

We use a variety of estimates, judgments, and assumptions in preparing our consolidated financial statements. Estimates, judgments, and assumptions are inherently subject to change, and any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses and income. Any such changes

could have a material adverse effect on our business, financial position, and operating results.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires us to make estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the period. There are inherent uncertainties involved in estimates, judgments and assumptions, and any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position, and operating results.

In the consolidated financial statements included in the periodic reports filed with the SEC, estimates, judgments, and assumptions are used for, but not limited to, revenue recognition, allowance for doubtful accounts, accruals for chargebacks, rebates, returns and other allowances, allowance for inventory obsolescence, stock-based compensation, valuation of financial instruments and intangible assets, allowances for contingencies and litigation, deferred tax valuation allowance, and the depreciable lives of fixed and intangible assets. Actual results could differ from those estimates. Estimates, judgments and assumptions are inherently subject to change in the future, and any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses, and income. Any such changes could have a material adverse effect on our business, financial position, and operating results.

Changes in estimates regarding the fair value of goodwill or intangible assets may result in an adverse impact to our business, financial position, and operating results.

We test goodwill for impairment annually, or more frequently if changes in circumstances indicate that the carrying amount of goodwill might not be recoverable. Judgment is used in determining when these events and circumstances arise. We perform our review of goodwill based on our one reporting unit. If we determine that the carrying value of our assets may not be recoverable, we assess, using judgment and estimates, the fair value of our assets and to determine the amount of any impairment loss, if any. Changes in judgments and estimates may result in the recognition of an impairment loss, which could have a material negative impact on our business, financial position, and operating results. While our testing in fiscal 2015 did not result in an impairment charge related to goodwill, there can be no assurances that our goodwill won't be impaired in the future.

Our material definite-lived intangible assets consist of product rights for previously marketed generic products, product rights for our branded products Lithobid and Vancocin, an NDA for male testosterone gel and marketing and distribution rights related to certain generic products. These assets are being amortized over their useful lives of seven to 11 years. For these definite-lived intangible assets, we perform an impairment analysis when events or circumstances indicate that the carrying value of the assets may not be recoverable. An impairment loss is recognized if, based on our impairment analysis, the carrying amount of the asset is not recoverable and its carrying amount exceeds its fair value. Any significant change in market conditions, estimates or judgments used to determine expected future cash flows that indicate a reduction in carrying value may give rise to impairment in the period that the change becomes known. An impairment charge could have a material negative impact on our business, financial position, and operating results. While we did not recognize an impairment charge related to our intangible assets in 2015, there can be no assurances that our intangible assets won't be impaired in the future.

Our management is required to devote substantial time to comply with public company regulations. If we are unable to comply with these regulations, investors could lose confidence in us, which could have a material adverse effect on our stock price, business, financial position, and operating results.

As a public company, we are required to comply with significant legal, accounting and other requirements that ANIP Acquisition Company did not face as a private company and as such, have incurred significant regulatory compliance-related expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act as well as rules implemented by the SEC and The NASDAQ Global Market, impose various requirements on public companies, including those related to corporate governance practices. Our management and other personnel devote a substantial amount of time to these requirements. Some members of management do not have significant experience in addressing these requirements. Moreover, these rules and regulations have increased our legal and financial compliance costs relative to those of previous years and make some activities more time consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The Committee of Sponsoring Organizations of the Treadway Commission ("COSO") provides a framework for companies to assess and improve their internal control systems. Our compliance with these requirements has required that we incur substantial accounting and related expenses and expend significant management efforts. Moreover, if we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, are unable to assert that our internal controls over financial reporting are effective, or identify deficiencies that are deemed to be material weaknesses, investors could lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by The NASDAQ Global Market, the SEC or other regulatory authorities. Any of these events could have a material adverse effect on our business, financial position, and operating results.

Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce revenues in future fiscal periods.

We, like other generic drug manufacturers, have agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates. Under many of these arrangements, we may match lower prices offered to customers by competitors. If we choose to lower our prices, we generally give the customer a credit on the products that the customer is holding in inventory, which could reduce sales revenue and gross margin for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesalers with whom we have contracts for their sales to hospitals, group purchasing organizations, pharmacies or other customers. A chargeback is the difference between the price at which we invoice the wholesaler and the price that the wholesaler's end-customer pays for a product. Although we establish reserves based on prior experience and our best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that our reserves are adequate or that actual product returns, allowances, and chargebacks will not exceed our estimates.

Risks Related to our Debt

Making interest and principal payments on our Convertible Senior Notes due 2019 (the "Notes"), which were issued as of December 10, 2014, requires and will continue to require a significant amount of cash, and we may not have sufficient cash flows from our business to make future interest and principal payments.

Our ability to continue to make scheduled interest payments and to make future principal payments or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not continue to generate cash flows from operations sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flows, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including the Notes, which would have a material adverse effect on our business, financial position, and operating results.

The conditional conversion feature of the Notes, if triggered, may adversely affect our financial results. In addition, if we were to undergo a fundamental change, we would need to repurchase the Notes, which could adversely affect our business, financial position, and operating results.

In the event the conditional conversion feature of the Notes is triggered, holders of Notes will be entitled to convert the Notes at any time during specified periods at their option. If one or more holders elect to convert their Notes, or if one or more holders elect to require us to repurchase their Notes in case of a fundamental change, as described below, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional shares), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity.

In addition, holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change, as at a price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. A “fundamental change” is deemed to occur if: (i) a person or group, other than us, directly or indirectly becomes the beneficial owner of common equity representing more than 50% of or voting power, (ii) consummation of a transaction that would result in the conversion or exchange of our common stock into other securities, cash, or assets, (iii) the sale of substantially all our assets, (iv) a change in the majority of our board of directors, (v) our stockholders approve a plan of liquidation, or (vi) our common stock ceases to be listed on the New York Stock Exchange, the NASDAQ Global Select Market, or the NASDAQ Global Market. If one or more holders requires us to repurchase their Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional shares), we would be required to make cash payments as a result of the Notes being converted, which could adversely affect our liquidity. However, we may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Notes surrendered or being converted. In addition, our ability to repurchase the Notes or to pay cash upon conversions of the Notes may be limited by law, by regulatory authority, or by agreements governing any future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Notes as required by the indenture would constitute a default under the indenture. If the repayment of the related indebtedness were accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes or make cash payments upon conversions thereof, which would have a negative impact on our business, financial position, and operating results

Provisions in the indenture for the Notes may deter or prevent a business combination.

If a fundamental change occurs prior to the maturity date of the Notes, holders of the Notes will have the right, at their option, to require us to repurchase all or a portion of their Notes. In addition, if a fundamental change occurs prior to the maturity date of Notes, we will in some cases be required to increase the conversion rate for a holder that elects to convert its Notes in connection with such fundamental change. Also, the indenture for the Notes prohibits us from engaging in certain mergers or acquisitions unless, among other things, the surviving entity assumes our obligations under the Notes. These and other provisions could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to our stockholders.

The convertible note hedge and warrant transactions may affect the value of our common stock.

In connection with the pricing of the Notes, we entered into a convertible note hedge transaction with Nomura Global Financial Products Inc. (“Nomura”). The convertible note hedge transaction reduces the potential dilution to our common stock upon any conversion of Notes and/or offsets any cash payments we are required to make in excess of the principal amount of converted Notes, as the case may be. We also entered into a warrant transaction with Nomura. The warrant transaction could separately have a dilutive effect on our common stock to the extent that the market price of our common stock exceeds the applicable strike price of the warrants.

Nomura, or an affiliate thereof, established its initial hedge position on the convertible note hedge and warrant transactions by entering into various derivative transactions with respect to our common stock concurrently with or shortly after the pricing of the Notes. Nomura, or an affiliate thereof, may modify its hedge position by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions at any time prior to the maturity of the Notes (and is likely to do so during any observation period related to a conversion of Notes). This activity could either cause or help avoid an increase or a decrease in the market price of our common stock.

Accounting for the Notes could have a material effect on our reported financial results.

Accounting for the Notes has and will continue to impact our balance sheet, income statement, and earnings per share. In accounting for the Notes, we will recognize non-cash interest expense, which has and will continue to reduce our net income and earnings per share.

In addition, under certain circumstances, convertible debt instruments (such as the Notes) that may be settled entirely or partly in cash are accounted for utilizing a modified treasury stock method to determine diluted earnings per share, the effect of which is that the shares issuable upon conversion of the Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Notes exceeds their principal amount. Under the modified treasury stock method, for diluted earnings per share purposes, the transaction is treated as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. Under the current standards, if we were to settle some or all of the Notes with shares of our common stock instead of with cash, we would be unable to use the treasury method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the Notes, our diluted earnings per share would be adversely affected.

Risks Related to our Common Stock

Our principal stockholders, directors, and executive officers own a significant percentage of our stock and will be able to exercise meaningful influence over our business.

Our current principal stockholders, directors and executive officers beneficially own approximately 31% of our outstanding capital stock entitled to vote as of December 31, 2015. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from stockholders generally and may vote in a way with which other stockholders disagree and which may be adverse to their interests. This concentration of ownership may have the effect of delaying, preventing, or deterring a change of control of ANI, could deprive stockholders of an opportunity to receive a premium for their common stock as part of a sale of ANI, and might ultimately affect the market price of our common stock.

Shares of our common stock are relatively illiquid which may affect the market price of our common stock.

For the twelve months ended December 31, 2015, the average daily trading volume of our common stock on the NASDAQ Global Select market was approximately 332 thousand shares. Because of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership and trading of a relatively small volume of our common stock may have a greater impact on the market price for our shares than would be the case if our public float were larger.

Raising additional funds by issuing additional equity securities may cause dilution to our current stockholders. Raising additional funds by issuing new debt financing may restrict our operations.

We may seek to raise additional funds through the issuance of equity or equity-linked securities. If we were to raise funds through the issuance of equity or equity-linked securities, the percentage ownership of our stockholders could be diluted, potentially significantly, and these newly issued securities may have rights, preferences, or privileges senior to those of our existing stockholders. In addition, the issuance of any equity securities could be at a discount to the then-prevailing market price of our common stock.

If we require new debt financing, there is no assurance that such a transaction will be available on terms acceptable to us, or at all. In addition, we could be subject to onerous repayment terms or covenants that restrict our ability to operate our business and make distributions to our stockholders. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock, or make investments. We can offer no assurance that any equity or debt financing transaction will be available on terms acceptable to us, or at all.

The market price of our common stock has been volatile, and an investment in our common stock could decline in value.

The market price of our common stock has fluctuated in the past, has increased significantly since the completion of the Merger, and is likely to continue to fluctuate in the future. From time to time, the securities of small capitalization, pharmaceutical companies, including ANI, experience significant market price fluctuations, often unrelated to these companies' operating performance. In particular, the market price of our common stock may fluctuate significantly due to a variety of factors, many of which are beyond our control and that may not be related to our operating performance, including, but not limited to:

- general stock market and general economic conditions in the U.S. and abroad, even if not directly related to our business;
- any inability to manufacture EEMT, whether due to FDA determinations or otherwise;
- disruptions in the supply of API and other ingredients used in our current and future products;
- announced or completed acquisitions of businesses or products by us or by our competitors;
- actual or anticipated governmental agency actions, including decisions or actions by the FDA or FDA advisory committee panels with respect to our current products, products in development, or our competitors' products;
- changes in anticipated or actual timing of our product development programs;
- competition in our industry;
- the entering into of new strategic partnering arrangements or termination of existing strategic partnering arrangements;
- public concern as to the safety or efficacy of our products;
- our need and ability to obtain additional financing;
- purchases related to our stock repurchase program;
- changes in laws or regulations applicable to our products or business;
- period-to-period fluctuations in our financial results;
- changes in key management;
- issuance of shares of our common stock or sales of our common stock by our stockholders;
- failure of securities analysts to initiate and maintain coverage on our business and, with respect to any analyst coverage, our failure to meet analyst estimates or the expectations of investors;
- announcements by us or our competitors of new products or services;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- actual or anticipated changes in our operating results or fluctuations in our operating results;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles; and
- slow or negative growth of our products or markets.

In addition, the occurrence of any of the risks described in this report or in subsequent reports we file with the SEC could have a material adverse impact on the market price of our common stock. Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities or for other reasons. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm our business, financial position, and operating results, as well as the market price of our common stock.

Our stock repurchase program could affect the price of our common stock and increase volatility. The repurchase program may be suspended or terminated at any time, which could result in a decrease in the trading price of our common stock.

In October 2015, we announced that our board of directors had approved the repurchase of up to $25.0 million of our outstanding common stock through December 31, 2016. Under the stock repurchase program, we are authorized to repurchase, from time-to-time, shares of our outstanding common stock on the open market. The timing and actual number of shares repurchased will depend on a variety of factors, including market and business conditions, the timing of open trading windows, trading price, and the nature of other investment opportunities. Repurchases pursuant to our stock repurchase program could affect our stock price and increase the volatility of our common stock. The existence of a stock repurchase program could also cause our stock price to be higher than it would be in the absence of such a program and could potentially reduce the market liquidity for our stock. Although the stock repurchase program is intended to enhance long-term stockholder value, we cannot provide assurance that this will occur, because the market price of our common stock may decline below the levels at which we repurchased shares of common stock. The stock repurchase program may be suspended or terminated at any time, and we have no obligation to repurchase any amount of our common stock under the program. Any failure to repurchase shares after we have announced our intention to do so may negatively impact our reputation and investor confidence in us, as well as the market price of our common stock.

Provisions in our charter documents and Delaware law could discourage or prevent a takeover, even if such a transaction would be beneficial to our stockholders.

Provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire ANI, even if doing so would be beneficial to our stockholders. These provisions include:

- authorizing the issuance of “blank check” preferred shares that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates;
- advance notice provisions in connection with stockholder proposals and director nominations that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors; and
- as a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents certain stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of at least two-thirds of our outstanding common stock not held by such 15% or greater stockholder.

Any provision of our certificate of incorporation and bylaws or Delaware law that has the effect of delaying, preventing or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate offices are located at 210 Main Street West, Baudette, Minnesota 56623. The facility, which we own, includes oral solid dose and liquid manufacturing and packaging, warehouse facilities, analytical, stability and microbiological laboratory space, and employee, office and mechanical space. We also own a manufacturing facility that includes oral solid dose manufacturing and packaging for pharmaceutical products that must be manufactured in a fully contained environment, warehouse facilities, and employee, office and mechanical space. This facility is also located in Baudette, Minnesota.

We lease office space for our financial headquarters in Wilmington, Delaware. The lease will expire in September 2018. As of December 31, 2015, we leased office space in Laguna Beach, California for an executive office. This lease expires in February 2016.

In January 2016, we entered into a lease for office space for our regulatory affairs office in Raleigh, North Carolina. This lease will begin in March 2016 and will expire in April 2021.

We consider our leased and owned properties suitable and adequate for our current and foreseeable needs.

Item 3. Legal Proceedings

A discussion of legal matters as of December 31, 2015 follows:

Louisiana Medicaid Lawsuit

On September 11, 2013, the Attorney General of the State of Louisiana filed a lawsuit in Louisiana state court against numerous pharmaceutical companies, including us, under various state laws, alleging that each defendant caused the state’s Medicaid agency to provide reimbursement for drug products that allegedly were not approved by the FDA and therefore allegedly not reimbursable under the federal Medicaid program. The lawsuit relates to three cough and cold prescription products manufactured and sold by our former Gulfport, Mississippi operation, which was sold in September 2010. Through its lawsuit, the state seeks unspecified damages, statutory fines, penalties, attorneys’ fees and costs. While we cannot predict the outcome of the lawsuit at this time, we could be subject to material damages, penalties and fines. We intend to vigorously defend against all claims in the lawsuit.

Other Commitments and Contingencies

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including ANI, are facing allegations from plaintiffs in various states, including California, New Jersey, and Pennsylvania, claiming bodily injuries as a result of ingestion of metoclopramide or its brand name, Reglan, prior to the FDA's February 2009 Black Box warning requirement. In August 2012, we were dismissed with prejudice from all New Jersey cases. We consider our exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide that we manufactured prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) our market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once we received a request for change of labeling from the FDA, we submitted our proposed changes within 30 days, and such changes were subsequently approved by the FDA.

At the present time, we are unable to assess the likely outcome of the cases in the remaining states. Our insurance company has assumed the defense of this matter. We cannot provide assurances that the outcome of these matters will not have an adverse effect on our business, financial condition, and operating results. Furthermore, like all pharmaceutical manufacturers, we may be exposed to other product liability claims in the future, which could limit our coverage under future insurance policies or cause those policies to become more expensive, which could harm our business, financial condition, and operating results.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock trades on the NASDAQ Global Market under the symbol "ANIP." The following table shows the high and low sales price for ANIP common stock as reported by the NASDAQ Global Market for each quarter in the years ended December 31, 2015 and 2014:

	Common Stock Price			
	2015		2014	
	High	Low	High	Low
First Quarter	$71.78	$50.70	$38.74	$18.52
Second Quarter	$72.61	$47.56	$37.74	$19.90
Third Quarter	$73.54	$37.20	$38.17	$25.17
Fourth Quarter	$50.07	$36.15	$61.43	$24.24

Stockholder Information

As of February 12, 2016, there were approximately 160 shareholders of record of our common stock, which does not include stockholders that beneficially own shares held in a "nominee" or in "street" name, and six holders of record of Class C stock.

Dividends

We did not pay cash dividends in the years ended December 31, 2015 and 2014. We do not anticipate paying cash dividends in the near term.

Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities

None.

Issuer Purchases of Equity Securities

None.

Performance Graph

The graph below compares the five-year cumulative total stockholder return on our common stock, the NASDAQ Stock Market (US) Index, and the NASDAQ Pharmaceuticals Index, assuming the investment of $100.00 on December 31, 2010, with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance.

On June 19, 2013, ANI Merger Sub, Inc., a wholly owned subsidiary of BioSante Pharmaceuticals, Inc. (“BioSante”), merged with and into ANIP Acquisition Company (“ANIP”), with ANIP continuing as the surviving company and becoming a wholly owned subsidiary of BioSante (the “Merger”) (Note 2, Business Combination, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K). On July 17, 2013, BioSante changed its name to ANI Pharmaceuticals, Inc. The five year cumulative total stockholder return on our common stock includes the performance of BioSante common stock for periods prior to the Merger and ANI Pharmaceuticals, Inc. common stock for periods subsequent to the Merger.

Item 6. Selected Consolidated Financial Data

The following table sets forth selected financial data as of and for the five years ended December 31, 2015. The information has been derived from our audited consolidated financial statements for each of the years ended December 31, 2015, 2014, 2013, 2012, and 2011. The data presented below should be read in conjunction with our consolidated financial statements, the notes to our consolidated financial statements, and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Years Ended December 31,				
(in thousands, except per share data)	2015	2014	**2013[1]**	**2012[2]**	**2011[2]**
Statement of Operations Data:					
Net revenues	$76,322	$55,970	$30,082	$20,371	$16,515
Total operating expenses	43,622	35,964	29,184	20,413	16,510
Operating income/(loss) from continuing operations	32,700	20,006	898	(42)	5
Net income/(loss) from continuing operations	$15,375	$28,747	$106	$(1,574)	$(2,552)
Basic and diluted income/(loss) from continuing operations per share:					
Basic income/(loss) per share from continuing operations	$1.34	$2.61	$(0.96)	$ N/A	$ N/A
Diluted income/(loss) per share from continuing operations	$1.32	$2.59	$(0.96)	$ N/A	$ N/A
Balance Sheet Data:					
Total assets	$285,265	$259,558	$44,500	$13,748	$12,676
Total convertible notes, net of discount and deferred financing costs	113,427	106,540	-	-	-
Total redeemable convertible preferred stock	-	-	-	48,751	24,216
Total stockholder's equity/(deficit)	$160,082	$139,785	$40,962	$(42,715)	$(34,284)

[1] On June 19, 2013, BioSante Pharmaceuticals, Inc. ("BioSante") acquired ANIP Acquisition Company ("ANIP") in an all-stock, tax-free reorganization (Note 2, Business Combination, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K), in which ANIP became a wholly-owned subsidiary of BioSante. BioSante was renamed ANI Pharmaceuticals, Inc. The Merger was accounted for as a reverse acquisition pursuant to which ANIP was considered the acquiring entity for accounting purposes. As such, ANIP's historical results of operations replace BioSante's historical results of operations for all periods prior to the Merger. The results of operations of both companies are included in our consolidated financial statements for all periods after the completion of the Merger.

[2] Earnings per common share is not calculable for the years ended December 31, 2012 and 2011 because common shareholders from ANIP did not receive consideration from the June 19, 2013 Merger with BioSante. In a reverse

merger, the weighted average shares outstanding used to calculate basic earnings per share for periods prior to the merger is the weighted average shares outstanding of the common shares of the accounting acquirer (in this case, ANIP) multiplied by the exchange ratio. In the Merger, only holders of ANIP's Series D preferred stock received consideration. Because ANIP's common shareholders did not receive any consideration in the Merger, their exchange ratio is zero, creating a weighted average shares outstanding of zero for periods prior to the Merger.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Please read the following discussion in conjunction with Item 1A. ("Risk Factors") and our audited consolidated financial statements included elsewhere in this annual report. Some of the statements in the following discussion are forward-looking statements. See the discussion about forward-looking statements on page 1 of this Annual Report on Form 10-K.

Executive Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, "ANI," the "Company," "we," "us," or "our") is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations. We have two pharmaceutical manufacturing facilities located in Baudette, Minnesota, which are capable of producing oral solid dose products, as well as liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment.

Our strategy is to use our assets to develop, acquire, manufacture, and market branded and generic specialty prescription pharmaceuticals. By executing this strategy, we believe we will be able to continue to grow our business, expand and diversify our product portfolio, and create long-term value for our investors.

On June 19, 2013, BioSante Pharmaceuticals, Inc. ("BioSante") acquired ANIP Acquisition Company ("ANIP") in an all-stock, tax-free reorganization (the "Merger"), in which ANIP became a wholly-owned subsidiary of BioSante. BioSante was subsequently renamed ANI Pharmaceuticals, Inc. The Merger was accounted for as a reverse acquisition pursuant to which ANIP was considered the acquiring entity for accounting purposes. As such, ANIP's historical results of operations replace BioSante's historical results of operations for all periods prior to the Merger. The results of operations of both companies are included in our consolidated financial statements for all periods after completion of the Merger.

In 2014, we acquired ANDAs for 31 generic products, the NDA for Lithobid, and the NDA for Vancocin, along with two related ANDAs. We also launched our Methazolamide product, and entered into collaborative arrangements for generic drug products with Sofgen Pharmaceuticals and with Dexcel Pharma Technologies Ltd. Finally, in 2014, we completed a follow-on public offering of common stock, yielding net proceeds of $46.7 million, and closed a public offering of $143.8 million of 3.0% Convertible Senior Notes due in 2019 (the "Notes"), with simultaneous bond hedge and warrant transactions.

In 2015, we achieved the following:

- Acquired ANDAs for 23 generic products.
- Acquired an NDA for Testosterone gel.
- Entered into a distribution agreement with IDT Australia Limited ("IDT") to market several generic products in the U.S.
- Entered into an agreement to acquire two NDAs for Corticotropin and Corticotropin-Zinc. The transaction closed in January 2016.
- Launched six products: Etodolac, Propafenone, Oxycodone oral solution, Vancomycin, Nimodipine, and Flecainide.

General

The following table summarizes our results of operations for the years ended December 31, 2015, 2014, and 2013.

(in thousands)	Years Ended December 31,		
	2015	2014	2013
Net revenues	$76,322	$55,970	$30,082
Operating expenses			
Cost of sales (excluding depreciation and amortization)	12,692	11,473	9,974
Research and development	2,874	2,678	1,712
Selling, general, and administrative	21,156	17,935	16,388
Depreciation and amortization	6,900	3,878	1,110
Operating income from continuing operations	32,700	20,006	898
Interest expense	(11,008)	(787)	(467)
Other income/(expense)	41	160	(305)
Income from continuing operations before benefit for income taxes	21,733	19,379	126
(Provision)/benefit for income taxes	(6,358)	9,368	(20)
Net income from continuing operations	15,375	28,747	106
Gain on discontinued operation, net of provision for income taxes	-	-	195
Net income	$15,375	$28,747	$301

The following table sets forth, for the periods indicated, the percentage that items in our consolidated statements of earnings bear to net revenues.

	Years Ended December 31,		
	2015	2014	2013
Net revenues	100.0%	100.0%	100.0%
Operating expenses			
Cost of sales (excluding depreciation and amortization)	16.6 %	20.5 %	33.2 %
Research and development	3.8 %	4.8 %	5.7 %
Selling, general, and administrative	27.7 %	32.1 %	54.5 %
Depreciation and amortization	9.1 %	6.9 %	3.6 %
Operating income from continuing operations	42.8 %	35.7 %	3.0 %
Interest expense	(14.4)%	(1.4)%	(1.6)%
Other income/(expense)	0.1 %	0.3 %	(1.0)%
Income from continuing operations before benefit for income taxes	28.5 %	34.6 %	0.4 %
(Provision)/benefit for income taxes	(8.4)%	16.8 %	- %
Net income from continuing operations	20.1 %	51.4 %	0.4 %
Gain on discontinued operation, net of provision for income taxes	- %	- %	0.6 %

Net income	20.1 %	51.4 %	1.0 %

Results of Operations for the Years Ended December 31, 2015 and 2014

Net Revenues

(in thousands)	Years Ended December 31,			
	2015	2014	Change	% Change
Generic pharmaceutical products	$ 55,169	$ 35,852	$19,317	53.9 %
Branded pharmaceutical products	11,003	11,010	(7)	(0.1)%
Contract manufacturing	4,883	5,931	(1,048)	(17.7)%
Contract services and other income	5,267	3,177	2,090	65.8 %
Total net revenues	$ 76,322	$ 55,970	$20,352	36.4 %

Net revenues for the year ended December 31, 2015 were $76.3 million compared to $56.0 million for the same period in 2014, an increase of $20.4 million, or 36.4%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $55.2 million during the year ended December 31, 2015, an increase of 53.9% compared to $35.9 million for the same period in 2014. The primary reason for the increase was increased EEMT revenues, due to increases in prices per bottle, as well as sales of Methazolamide, launched in the fourth quarter of 2014, Etodolac and Propafenone, both of which were launched in the first quarter of 2015, and Vancomycin, launched in the fourth quarter of 2015. We also experienced increased sales for our HC Enema product, due to price increases. In 2016, we anticipate increases in generic pharmaceutical product revenues related to our recently-launched products, as well as additional products we expect to launch in 2016.

As described in Item 1. Business – Government Regulations – Unapproved Products, we market EEMT and Opium Tincture without FDA-approved NDAs. The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While we believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. Our combined net revenues for these products for the years ended December 31, 2015 and 2014 were $44.3 million and $29.8 million, respectively.

- Net revenues for branded pharmaceutical products were $11.0 million during both the years ended December 31, 2015 and 2014. The slight change was the result of an increase due to realizing a full year of revenue from our Lithobid and Vancocin products, which we acquired in the third quarter of 2014. This increase was offset by lower

unit sales of Reglan, due to decreased purchases by a customer, and increased Medicaid utilization and Medicaid rebates for Lithobid and Vancocin, all of which are trends we expect to continue. We experience periodic larger orders for our Vancocin product that relate to clinical trials. Such orders constituted $1.6 million of our branded pharmaceutical product revenue for the year ended December 31, 2015 and we cannot be sure that such purchases will occur in future periods.

Contract manufacturing revenues were $4.9 million during the year ended December 31, 2015, a decrease of 17.7% compared to $5.9 million for the same period in 2014, due to the timing and volume of orders from contract manufacturing customers in the period. As described in Item 1. Business – Government Regulations – Unapproved Products, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the years ended December 31, 2015 and 2014 were $1.6 million and $1.2 million, respectively.

- Contract services and other income were $5.3 million during the year ended December 31, 2015, an increase of 65.8% from $3.2 million for the same period in 2014, due primarily to royalties received on sales of the authorized generic of Vancocin, the product rights to which were acquired in the third quarter of 2014. In the second quarter of 2015, our authorized generic partner for Vancocin adjusted its estimates for chargebacks, rebates, and other deductions from gross sales for the last five months of 2014, which resulted in a $1.4 million increase in royalty revenue. In the fourth quarter of 2015, our authorized generic partner for Vancocin again adjusted its estimate for chargebacks, rebates, and other deductions from gross sales for the first ten months of 2015, which resulted in a $0.2 million increase in royalty revenue. In November 2015, we launched an authorized generic for Vancocin under our own label, which replaced the authorized generic product previously on the market. As a result, we anticipate a decrease in contract services and other income in future periods with a corresponding increase in generic pharmaceutical product revenue.

As described in Item 1. Business – Government Regulations – Unapproved Products, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products were $0.3 million for both the years ended December 31, 2015 and 2014.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Years Ended December 31,			
	2015	2014	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 12,692	$ 11,473	$ 1,219	10.6 %

For the year ended December 31, 2015, cost of sales increased to $12.7 million from $11.5 million for the same period in 2014, an increase of $1.2 million or 10.6%, primarily as a result of increased sales in the period, particularly sales of products that are subject to profit-sharing arrangements. We anticipate that our cost of sales will continue to increase in 2016, due to new product launches and the full year impact of sales of certain products launched in 2015 that are subject to profit-sharing arrangements. Cost of sales as a percentage of net revenues decreased to 16.6% during the year ended December 31, 2015, from 20.5% during same period in 2014, primarily as a result of price increases for our EEMT and HC Enema products, and a favorable shift in product mix toward higher margin products, including EEMT, and two branded products, Lithobid and Vancocin, which we acquired in the third quarter of 2014. We anticipate that our cost of sales as a percentage of net revenues will increase in 2016, due to the full year impact of sales of certain products launched in 2015 that are subject to profit-sharing arrangements, as well as the anticipated launches of new products that are subject to profit-sharing arrangements.

We source the raw materials for our products, including API, from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the cost and time required to validate a second source of supply. Changes in API suppliers usually must be approved by the FDA, which can take 18 months

or longer. As a result, we are dependent upon our current vendors to reliably supply the API required for ongoing product manufacturing. In addition, certain of our API for our drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported APIs due to FDA inspections. During the year ended December 31, 2015, we purchased 33% of our inventory from two suppliers. As of December 31, 2015, amounts payable to these suppliers were immaterial. In the year ended December 31, 2014, we purchased 42% of our inventory from two suppliers.

In order to manufacture Opium Tincture and Oxycodone oral solution, we must submit a request to the DEA for a quota to purchase the amount of opium and oxycodone needed to manufacture the respective products. Without approved quotas from the DEA, we would not be able to purchase these ingredients from our suppliers. As a result, we are dependent upon the DEA to annually approve a sufficient quota of API to support the continued manufacture of Opium Tincture and Oxycodone oral solution.

Other Operating Expenses

(in thousands)	Years Ended December 31,				
	2015	2014	Change	% Change	
Research and development	$ 2,874	$ 2,678	$196	7.3	%
Selling, general, and administrative	21,156	17,935	3,221	18.0	%
Depreciation and amortization	6,900	3,878	3,022	77.9	%
Total other operating expenses	$ 30,930	$ 24,491	$6,439	26.3	%

For the year ended December 31, 2015, other operating expenses increased to $30.9 million from $24.5 million for the same period in 2014, an increase of $6.4 million, or 26.3%, primarily as a result of the following factors:

- Research and development expenses increased from $2.7 million to $2.9 million, an increase of 7.3%, due to work on development projects, including the ANDAs purchased from Teva in 2014 and 2015 and collaborations with partners. We anticipate that research and development costs will continue to increase in 2016, in support of our strategy to expand our product portfolio.

- Selling, general, and administrative expenses increased from $17.9 million to $21.2 million, an increase of 18.0%, primarily due to increased expenses associated with business development activities, increased stock-based compensation expense, and increases in personnel and related costs, partially offset by a non-recurring $1.3 million catch-up adjustment in the second quarter of 2014 for non-cash stock-based compensation expense recognized upon shareholder approval of an increase in shares available for issuance under our stock compensation plan. We expect selling, general, and administrative expenses to continue to increase in the future to support anticipated additional revenue growth.

- Depreciation and amortization increased from $3.9 million to $6.9 million, an increase of 77.9%, due to a full year of amortization of the product rights for Lithobid and Vancocin, which rights were purchased during the third quarter of 2014, as well as amortization of the ANDAs acquired in 2015. We expect depreciation and amortization expense to increase in 2016 as we realize a full year of amortization expense related to the ANDAs acquired in 2015, and the amortization expense related to the NDAs for Corticotropin and Corticotropin-Zinc, which were acquired in January 2016 for $75.0 million.

Other Expense, net

(in thousands)	Years Ended December 31,				
	2015	2014	Change	% Change	
Interest expense, net	$ (11,008)	$ (787)	$(10,221)	NM	(1)
Other income, net	41	160	(119)	(74.4)%	

Total other expense, net	$ (10,967)	$ (627)	$(10,340)	NM [1]

[1] Not Meaningful

For the year ended December 31, 2015, we recognized other expense of $11.0 million versus other income of $0.6 million for the same period in 2014, a change of $10.4 million. This change resulted primarily from a $10.2 million increase in interest expense, as only one month of interest expense was recorded related to our convertible debt in 2014, while a full year was recorded in 2015. During the year ended December 31, 2015, there was $56 thousand of interest capitalized into construction in progress. During the year ended December 31, 2014 there was no material interest capitalized into construction in progress.

(Provision)/Benefit for Income Taxes

(in thousands)	Years Ended December 31,			
	2015	2014	Change	% Change
(Provision)/Benefit for income taxes	$ (6,358)	$ 9,368	$(15,726)	(167.9)%

Our provision for income taxes consists of current and deferred components, which include changes in our deferred tax assets, our deferred tax liabilities, and our valuation allowance. In the fourth quarter of 2014, we reversed the majority of the valuation allowance we had recorded against our net deferred tax assets. The reversal was the result of our determination that it is more likely than not that we will realize the benefits of our net deferred tax assets as a result of our expectation of future profitability, among other factors. Prior to the reversal, we had fully reserved for all our net deferred tax assets.

For the year ended December 31, 2015, we recognized income tax expense of $6.4 million, versus a $9.4 million income tax benefit for the same period in 2014. The change of $15.8 million was primarily the result of the 2014 reversal of $16.7 million of the valuation allowance previously recorded against our deferred tax assets. Of the $6.4 million of total tax expense recognized in 2015, $7.9 million is current expense and $0.4 million is the impact on the provision related to the excess tax benefit from stock-based compensation awards. These were partially offset by a $1.9 million net deferred tax benefit.

Results of Operations for the Years Ended December 31, 2014 and 2013

Net Revenues

We derive substantially all of our revenues from sales of generic and branded pharmaceutical products, contract manufacturing, and contract services, which include product development services, laboratory services, and royalties on net profits of certain products.

(in thousands)	Years Ended December 31,			
	2014	2013	Change	% Change
Generic pharmaceutical products	$ 35,852	$ 19,281	$16,571	85.9%
Branded pharmaceutical products	11,010	3,370	7,640	226.7%
Contract manufacturing	5,931	6,018	(87)	(1.4)%
Contract services and other income	3,177	1,413	1,764	124.8%
Total net revenues	$ 55,970	$ 30,082	$25,888	86.1%

Net revenues for the year ended December 31, 2014 were $56.0 million compared to $30.1 million for the same period in 2013, an increase of $25.9 million, or 86.1%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $35.9 million during the year ended December 31, 2014, an increase of 85.9% compared to $19.3 million for the same period in 2013. The primary reason for the increase was a $13.8 million increase in sales of EEMT, which was the result of increases in both market share and prices. In addition, we experienced increased sales for our Opium Tincture, HC Enema, and Fluvoxamine products. In the third quarter of 2013, a significant competitor stopped producing EEMT, which led to an increase in our market share and enabled us to significantly increase the price we charge for the product. However, in the first half of 2014, the same competitor re-entered the market, which negatively impacted our EEMT unit sales beginning in the second quarter of 2014, and which continued in 2015. EEMT revenues for the year ended December 31, 2014 also were reduced by $3.9 million in charges related to price protection contract obligations.

As described in Item 1. Business – Government Regulations – Unapproved Products, we market EEMT and Opium Tincture without FDA-approved NDAs. While we believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. Our combined net revenues for these products for the years ended December 31, 2014 and 2013 were $29.8 million and $14.6 million, respectively.

- Net revenues for branded pharmaceutical products were $11.0 million during the year ended December 31, 2014, an increase of 226.7% compared to $3.4 million for the same period in 2013. The primary reasons for the increase were $3.3 million of sales from our Lithobid product, representing six months of sales and $4.4 million of sales from our Vancocin product, representing five months of sales. The product rights to Lithobid and Vancocin were acquired during the third quarter of 2014. These increases were partially offset by a decrease in sales of Reglan.

- Contract manufacturing revenues were $5.9 million during the year ended December 31, 2014, a decrease of 1.4% compared to $6.0 million for the same period in 2013, due to decreased orders from contract manufacturing customers during 2014. As described in Item 1. Business – Government Regulations – Unapproved Products, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the years ended December 31, 2014 and 2013 were $1.2 million and $2.0 million, respectively.

- Contract services and other income were $3.2 million during the year ended December 31, 2014, an increase of 124.8% from $1.4 million for the same period in 2013, due primarily to royalties received on sales of the authorized generic of Vancocin, the product rights to which were acquired in the third quarter of 2014. This increase was partially offset by a $0.5 million non-recurring payment in December 2013 from Teva in relation to the testosterone gel NDA acquired in the Merger, as well as decreased contract services.

As described in Item 1. Business – Government Regulations – Unapproved Products, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products were $0.3 million for each of the years ended December 31, 2014 and 2013.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Years Ended December 31,			
	2014	2013	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 11,473	$ 9,974	$ 1,499	15.0 %

Cost of sales consists of direct labor, including manufacturing and packaging, active and inactive pharmaceutical ingredients, freight costs, and packaging components. Cost of sales did not include depreciation and amortization expense, which is reported as a separate component of operating expenses on our consolidated statements of earnings.

For the year ended December 31, 2014, cost of sales increased to $11.5 million from $10.0 million for the same period in 2013, an increase of $1.5 million or 15.0%, primarily as a result of an increase in sales of generic pharmaceutical products, as well as royalties due on proceeds from sales of Vancocin and its authorized generic. The contractual requirement to pay these royalties ended December 31, 2014. Cost of sales as a percentage of net revenues decreased to 20.5% during the year ended December 31, 2014, from 33.2% during same period in 2013, primarily as a result of a favorable shift in product mix toward higher margin products, including our two new branded products, Lithobid and Vancocin, and price increases for EEMT.

During the year ended December 31, 2014, we purchased 42% of our inventory from two suppliers. As of December 31, 2014, amounts payable to these suppliers were immaterial. In the year ended December 31, 2013, we purchased 37% of our inventory from three suppliers.

Other Operating Expenses

(in thousands)	Years Ended December 31,				
	2014	2013	Change	% Change	
Research and development	$ 2,678	$ 1,712	$966	56.4	%
Selling, general, and administrative	17,935	16,388	1,547	9.4	%
Depreciation and amortization	3,878	1,110	2,768	249.4	%
Total other operating expenses	$ 24,491	$ 19,210	$5,281	27.5	%

Other operating expenses consisted of research and development costs, selling, general, and administrative expenses, and depreciation and amortization.

For the year ended December 31, 2014, other operating expenses increased to $24.5 million from $19.2 million for the same period in 2013, an increase of $5.3 million, or 27.5%, primarily as a result of the following factors:

- Research and development expenses increased from $1.7 million to $2.7 million, an increase of 56.4%, due primarily to work on new development projects, including the Teva products, internally-developed products, new collaborations, and a filing fee for an ANDA submission of an anti-cancer drug.

- Selling, general, and administrative expenses increased slightly, from $16.4 million to $17.9 million, an increase of 9.4%, primarily due to the increases in personnel and consulting, legal, and other fees related to becoming a public company, as well as increased stock-based compensation expense, including a $1.3 million catch-up charge for non-cash stock-based compensation, which was recognized upon shareholder approval of an increase in shares available for issuance under our stock compensation plan. These increases were partially offset by the lack of $6.2 million of Merger-related expenses incurred in the prior year.

- Depreciation and amortization increased from $1.1 million to $3.9 million, an increase of 249.4%, due to amortization of the ANDAs purchased from Teva in the first quarter of 2014, amortization of product rights for Lithobid and Vancocin purchased during the third quarter of 2014, and a full year of amortization of the testosterone gel NDA acquired in the Merger.

Other Expense, net

(in thousands)	Years Ended December 31,			
	2014	2013	Change	% Change
Interest expense, net	$ (787)	$ (467)	$ (320)	68.5 %

Other income/(expense), net	160	(305)	465	(152.5)%
Total other expense, net	$ (627)	$ (772)	$ 145	(18.8)%

For the year ended December 31, 2014, we recognized other expense of $0.6 million versus other expense of $0.8 million for the same period in 2013, a decrease of $0.1 million, or 18.8%. This change resulted primarily from the following factors:

- Interest expense increased from $0.5 million to $0.8 million as a result of $0.8 million of interest expense incurred on our Notes, issued in December 2014. This interest expense was partially offset by interest earned on our cash balance in 2014. Interest expense in the year ended December 31, 2013 included a termination fee and accelerated amortization of deferred loan costs associated with retiring our revolving line of credit in conjunction with the Merger.

- Other income/(expense) changed from $0.3 million of other expense to $0.2 million of other income, due primarily to the absence of payments of $0.4 million to certain of our investors for monitoring and advisory fees in 2013. Upon completion of the Merger, our obligation to pay monitoring and advisory fees was terminated. Other income of $0.2 million related primarily to the receipt of an abatement for prior year property taxes resulting from a reassessment of the property value for our manufacturing facilities and the reimbursement, pursuant to a legal settlement, of legal fees incurred in prior years.

Benefit/(Provision) for Income Taxes

(in thousands)	Years Ended December 31,			
	2014	2013	Change	% Change
Benefit/(Provision) for income taxes	$ 9,368	$ (20)	$ 9,388	NM [1]

[1] Not Meaningful

The benefit/(provision) for income taxes consists of our current tax provision and our deferred income tax provision, which includes changes in our deferred tax assets ("DTAs"), deferred tax liabilities ("DTLs"), and our valuation allowance.

For the year ended December 31, 2014, we recognized a $9.4 million income tax benefit, compared with a $20 thousand income tax provision for the same period in 2013, a change of $9.4 million, primarily as a result of a $16.7 million reversal of the valuation allowance previously recorded against our DTAs. This reversal was the result of our determination that it is more likely than not that we will realize the benefits of our DTAs as a result of our expectation of future profitability, among other factors. The reversal of the allowance was partially offset by a $5.1 million current income tax provision for the 2014 fiscal year, and $2.3 million of changes to our DTAs and DTLs.

Gain on Discontinued Operation

(in thousands)	Years Ended December 31,			
	2014	2013	Change	% Change
Gain on discontinued operation, net of tax	$ -	$ 195	$ (195)	(100.0)%

Gain on discontinued operation consisted of revenue and expenses associated with our over-the-counter pharmaceutical products operation in Gulfport, Mississippi. This operation was sold in September 2010.

During the year ended December 31, 2013, the gain on discontinued operation, net of $38 thousand of tax, resulted from finalizing a portion of the discontinued operation's remaining liabilities.

Liquidity and Capital Resources

The following table highlights selected liquidity and working capital information from our consolidated balance sheets.

(in thousands)	December 31,	
	2015	2014
Cash and cash equivalents	$154,684	$169,037
Accounts receivable, net	21,932	17,297
Inventories, net	13,387	7,518
Prepaid income taxes	1,127	-
Prepaid expenses and other current assets	1,453	1,139
Total current assets	$192,583	$194,991
Accounts payable	$2,066	$2,654
Accrued expenses	617	567
Accrued royalties	606	702
Accrued compensation and related expenses	1,188	1,348
Accrued income taxes	-	4,253
Accrued Medicaid rebates	4,631	2,264
Returned goods reserve	2,648	1,445
Total current liabilities	$11,756	$13,233

At December 31, 2015, we had $154.7 million in unrestricted cash and cash equivalents. At December 31, 2014, we had $169.0 million in unrestricted cash and cash equivalents. We generated $17.3 million of cash from operations in the year ended December 31, 2015. In the first quarter of 2015, we acquired an ANDA for $4.5 million. In the third quarter of 2015, we acquired ANDAs relating to 22 products for $25.0 million.

In September 2015, we entered into an asset purchase agreement with Merck Sharp & Dohme B.V. to purchase, subject to typical closing conditions including regulatory approvals, certain NDAs and associated product rights and manufacturing licenses for $75.0 million in cash and a percentage of future net sales of the products under the NDAs. The asset acquisition closed in January 2016, and we made the $75.0 million cash payment using cash on hand.

We are focused on expanding our business and product pipeline through collaborations, and also through acquisitions of products and companies. We are continually evaluating potential asset acquisitions and business combinations. To finance such acquisitions, we might raise additional equity capital, incur additional debt, or both.

We believe that our financial resources, consisting of current working capital and anticipated future operating revenue, will be sufficient to enable us to meet our working capital requirements for at least the next 12 months. If our assumptions underlying estimated revenue and expenses are wrong, or if our cash requirements change materially as a result of shifts in our business or strategy, we could require additional financing. If in the future we do not remain profitable or generate cash from operations as anticipated and additional capital is needed to support operations, we may be unable to obtain such financing, or obtain it on favorable terms, in which case we may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as desired.

Our primary cash requirements are to fund operations, including research and development programs and collaborations, to support general and administrative activities, and to expand our business and product pipeline through acquisitions of products and companies. We are continually evaluating potential asset acquisitions and business combinations. Our future capital requirements will depend on many factors, including, but not limited to:

- product mix and pricing for product sales and contract manufacturing;
- pricing and payment terms with customers;
- costs of raw materials and payment terms with suppliers;
- capital expenditures and equipment purchases to support product launches; and
- business and product acquisitions.

Consolidation among wholesale distributors, chain drug stores and group purchasing organizations has resulted in a smaller number of companies each controlling a larger share of pharmaceutical distribution channels. Our net revenues were concentrated among three customers representing 26%, 20%, and 18% of net revenues during the year

ended December 31, 2015. As of December 31, 2015, accounts receivable from these four customers totaled approximately 73% of our net accounts receivable. As a result, negotiated payment terms with these customers have a material impact on our liquidity and working capital.

Two of our generic pharmaceutical products, EEMT and Opium Tincture, accounted for approximately 51% and 7% of our net revenues in 2015, respectively, versus 42% and 11% of net revenues in 2014, respectively, and 33% and 16% of net revenues in 2013, respectively. As a result, market pricing for these products, combined with the costs of raw materials and payment terms with suppliers, have a material impact on our liquidity and working capital. The increase in revenue related to EEMT has had a significant impact on our financial results and if revenues from EEMT were to decrease substantially or entirely, it would have a material, negative impact on our cash flows and liquidity.

Our consolidated financial statements have been prepared on a basis that assumes that we will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. These statements do not include any adjustments that might result if the carrying amount of recorded assets and liabilities are not realized.

Sources and Uses of Cash

Debt Financing

In December 2014, we issued $143.8 million of 3.0% Convertible Senior Notes in a registered public offering (the "December 2014 Offering"), which includes the $18.8 million of Notes issued pursuant to the full exercise of the over-allotment option granted to the underwriters in the December 2014 Offering. After deducting the underwriting discounts and commissions and other expenses (including the net cost of the bond hedge and warrant, discussed below), the net proceeds from the offering were approximately $122.6 million. The Notes were issued in order to raise funds to research, develop and commercialize our drug products; to acquire complementary businesses, products, and technologies that we may identify from time to time; and for other working capital and general corporate purposes. The Notes pay 3.0% interest semi-annually in arrears on June 1 and December 1 of each year, starting on June 1, 2015. The Notes are convertible into 2,068,792 shares of common stock, based on an initial conversion price of $69.48 per share.

A portion of the offering proceeds was used to simultaneously enter into "bond hedge" (or purchased call) and "warrant" (or written call) transactions with an affiliate of one of the offering underwriters (collectively, the "Call Option Overlay"). We entered into the Call Option Overlay to synthetically raise the initial conversion price of the Notes to $96.21 per share and reduce the potential common stock dilution that may arise from the conversion of the Notes. The exercise price of the bond hedge is $69.48 per share, with an underlying 2,068,792 common shares; the exercise price of the warrant is $96.21 per share, also with an underlying 2,068,792 common shares.

At December 31, 2013, we had no debt outstanding.

Equity Financing

In March 2014, we completed a follow-on public offering of 1.6 million shares of our common stock at a public offering price of $31.00 per share (the "March 2014 Offering"). We received gross proceeds of $50.0 million, or net proceeds of $46.7 million after deducting costs of $3.3 million, including the underwriters' fees and commissions, as well as expenses directly related to the March 2014 Offering. The 1.6 million shares sold in the March 2014 Offering includes the exercise in full by the underwriters of their option to purchase an additional 0.2 million shares of common stock.

Warrant Exercises

In January 2014, a warrant-holder exercised warrants to purchase 20 thousand shares at $9 per share. We received $0.2 million as a result of this exercise. In December 2014, a warrant-holder exercised warrants to purchase 63 thousand shares at $9 per share. We received $0.5 million as a result of this exercise.

In December 2013, warrants to purchase an aggregate of 90 thousand shares of common stock were exercised at $9.00 per share. We received $0.8 million as a result of this exercise.

Uses of Cash

In the first quarter of 2015, we acquired the ANDA for Flecainide for $4.5 million. In the third quarter of 2015, we acquired ANDAs related to 22 products for $25.0 million. In the first quarter of 2014, we acquired ANDAs related to 31 products for $12.5 million. In the third quarter of 2014, we acquired the intellectual property rights and NDA associated with Lithobid, as well as raw material inventory, for $11.0 million, not including the $1.0 million contingent payment that was paid in January 2015, and also acquired the U.S. intellectual property rights and NDA associated with Vancocin, two related ANDAs, and certain equipment and inventory for $11.0 million.

In September 2015, we entered into an asset purchase agreement with Merck Sharp & Dohme B.V. to purchase certain NDAs and associated product rights and manufacturing licenses for $75.0 million in cash and a percentage of future net sales of the products under the NDAs. The asset acquisition closed in January 2016, and we made the $75.0 million cash payment using cash on hand.

Discussion of Cash Flows

The following table summarizes the net cash and cash equivalents provided by/(used in) operating activities, investing activities and financing activities for the periods indicated:

(in thousands)	Years Ended December 31,		
	2015	2014	2013
Operating Activities	$17,264	$22,033	$(5,484)
Investing Activities	$(32,683)	$(35,754)	$20,267
Financing Activities	$1,066	$171,653	$(3,689)

Net Cash Provided by/Used in Operating Activities

Net cash provided by operating activities was $17.3 million for the year ended December 31, 2015, compared to $22.0 million during the same period in 2014, a decrease of $4.7 million between the periods. This decrease was due to a decrease in net income and changes in current assets and current liabilities partially offset by changes in non-cash expenses. When adjusted for non-cash expenses, net income from operations for the year ended December 31, 2015 increased by $9.0 million from the same period in 2014.

Increases in current assets and decreases in current liabilities (in each case a use of cash) for the year ended December 31, 2015 totaled $13.8 million compared to $0.1 million for the same period in 2014, an increase of approximately $13.7 million between the periods. Changes in current income taxes, net were a $5.4 million use of cash in 2015, as compared with providing $4.2 million in 2014, an increase in cash use of $9.6 million. Inventory increased by $2.4 million more in 2015 than in 2014. Accounts payable decreased by $1.0 million in 2015 as compared with an increase of $0.2 million in 2014, an increase in cash use of $1.2 million. Accrued compensation and related expenses decreased by $0.2 million in 2015, as compared with an increase of $0.6 million in 2014, an increase in cash use of $0.8 million. Accrued expense, returned goods, and other increased by $0.5 million less in 2015 than 2014. Offsetting these year-on-year increases in cash used, accrued Medicaid rebates increased by $0.4 million more in 2015 than 2014, prepaid expenses and other current assets increased by $0.2 million less in 2015 than in 2014, and accounts receivable increased by $0.1 million less in 2015 than in 2014.

Net cash provided by operating activities was $22.0 million for the year ended December 31, 2014 compared to $5.5 million used in the same period in 2013, a change of $27.5 million between the periods. This increase was primarily due to the increase in net income from 2013 to 2014 and to changes in current assets and current liabilities. There was a $16.1 million increase in cash provided by net income from continuing operations, after adjusting for non-cash expenses. This increase was primarily due to the $28.4 million increase in net income in 2014, as well as increases in non-cash expenses, including an increase of $3.4 million in stock-based compensation expense over 2013 and $2.8

million more in depreciation and amortization expense than the prior year. These increases were partially offset by non-cash changes to deferred tax assets of $14.5 million and the absence of $4.4 million of non-cash expenses related to the Merger in 2013.

Increases in current assets and decreases in current liabilities for the year ended December 31, 2014 totaled $0.1 million compared to $11.4 million for the same period in 2013, a decrease of approximately $11.3 million between the periods. Accounts receivable increased by $2.3 million less in 2014 than 2013. Accrued compensation, income taxes, and Medicaid rebates increased by $3.4 million, $4.2 million, and $1.9 million more than in the prior year, respectively. Accounts payable and other accrued expenses increased by $0.8 million and $1.7 million more than in the prior year, respectively. These increases in cash provided by operations were partially offset by increases in inventory and prepaid expenses, which increased by $2.8 million and $0.4 million more in the year ended December 31, 2014, respectively, than in the prior year periods.

Net Cash Used in/Provided by Investing Activities

Net cash used in investing activities for the year ended December 31, 2015 was $32.7 million, principally due to the March 2015 asset acquisition of the ANDA for Flecainide for $4.5 million, the July 2015 asset acquisition of a ANDAs relating to 22 products for $25.0 million, the August 2015 payment of $1.0 million for marketing and distribution rights, and $2.2 million of capital expenditures during the period.

Net cash used in investing activities was $35.8 million for the year ended December 31, 2014, principally due to the $12.5 million asset acquisition of ANDAs relating to 31 products, an $11.0 million asset purchase related to Lithobid, an $11.0 million asset purchase related to Vancocin, and $1.1 million of capital expenditures during the period.

Net cash provided by investing activities for the year ended December 31, 2013 was $20.3 million, principally due to $18.2 million of cash acquired in the Merger and the release of $2.2 million of restricted cash held for severance payments, partially offset by $0.2 million of capital expenditures during the period.

Net Cash Provided by/Used in Financing Activities

Net cash provided by financing activities was $1.1 million for the year ended December 31, 2015, resulting primarily from $0.8 million of proceeds from stock option exercises and $0.4 million of excess tax benefit from stock-based compensation awards.

Net cash provided by financing activities was $171.7 million for the year ended December 31, 2014, resulting primarily from $122.6 million of net proceeds received for the Notes issued in our December 2014 offering and $46.7 million of net proceeds received in our March 2014 Offering. We also received $0.8 million of proceeds for stock options exercised in 2014 and $0.8 million of proceeds for warrants exercised in 2014.

Net cash used in financing activities was $3.7 million for the year ended December 31, 2013, resulting primarily from the $4.1 million repayment in June 2013 of our revolving line of credit in connection with the Merger and $0.4 million of treasury stock repurchases, partially offset by $0.8 million of proceeds received for a warrant exercised in December 2013.

Contractual Obligations

The following table summarizes our long-term contractual obligations and commitments as of December 31, 2015.

(in thousands)	Payments Due by Period			
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years

Long-term debt obligations [1]	$143,750	$ -	$ -	$143,750	$ -
Interest on long-term debt obligations [2]	16,891	4,313	8,625	3,953	-
Operating lease obligations	132	55	77	-	-
Upfront purchase price of Corticotropin and Corticotropin-Zinc NDAs [3]	75,000	75,000	-	-	-
Purchase obligations	17,989	8,220	8,169	1,600	-
Total	$253,762	$ 87,588	$16,871	$149,303	$ -

[1] Represents our Convertible Senior Notes due December 2019 and assumes that no notes are converted prior to the December 1, 2019 due date. Some or all of this amount could come due earlier if any noteholders convert their notes prior to the due date. (Note 3, Indebtedness, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K.)

[2] Represents 3.0% interest due semi-annually on our Convertible Senior Notes due December 2019 and assumes all interest is paid and the notes are not converted prior to the December 1, 2019 due date. This amount could change if any noteholders convert their notes prior to the due date.

[3] The upfront purchase price of $75.0 million to acquire the NDAs was paid in January 2016. (Note 14, Subsequent Events, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K.)

Critical Accounting Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, Medicaid rebates, returns, and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, deferred taxes and valuation allowance, and the depreciable lives of long-lived assets.

Our significant accounting policies are discussed in Note 1. Description of Business and Summary of Significant Accounting Policies, in the notes to the consolidated financial statements in Part II. Item 8. of this Annual Report on Form 10-K. On an ongoing basis, we evaluate these estimates and assumptions, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition, and operating results.

Revenue Recognition

Revenue is recognized for product sales and contract manufacturing product sales upon passing of risk and title to the customer, when estimates of the selling price and discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured, and we have no further performance obligations. Contract manufacturing arrangements are typically less than two weeks in duration, and therefore the revenue is recognized upon completion of the aforementioned factors rather than using a proportional performance method of revenue recognition. The estimates for discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments reduce gross revenues to net revenues in the accompanying consolidated statements of earnings, and are presented as current liabilities or reductions in accounts receivable in the accompanying consolidated balance sheets (see "Accruals for Chargebacks, Rebates, Returns, and Other Allowances"). Historically, we have not entered into revenue arrangements with multiple elements.

Occasionally, we engage in contract services, which include product development services, laboratory services, and royalties on net sales of certain contract manufactured products. For these services, revenue is recognized according to

the terms of the agreement with the customer, which sometimes include substantive, measurable risk-based milestones, and when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured, and we have no further performance obligations under the agreement. We recognized $5.3 million, $3.2 million, and $1.4 million of revenue related to contract services in 2015, 2014, and 2013, respectively.

Our revenue recognition accounting methodologies contain uncertainties because they require management to make assumptions and to apply judgment to estimate the amount of discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments, which are accounted for as reductions to revenue. We make these estimates based on historical experience.

We have not made any material changes to our revenue recognition policies during the years ended December 31, 2015, 2014, and 2013. We believe it is unlikely that there will be a material change in the future estimates or assumptions used to measure estimates for discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments. However, if actual results were not consistent with our estimates, we could be exposed to losses or gains that could be material, as any changes to these estimates could cause an increase or decrease in revenue recognized during the year. For example, if there were a 10% change to these adjustments throughout the year, Net Revenues and Net Income from Continuing Operations before (Provision)/Benefit for Income Taxes for the year ended December 31, 2015 would be affected by $7.0 million.

Accruals for Chargebacks, Rebates, Returns and Other Allowances

Our generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, Medicaid rebates, product returns, administrative fees, and other rebates and prompt payment discounts. We accrue for these items at the time of sale based on the estimates and methodologies described below. In the aggregate, these accruals, reflected as a decrease to gross sales, exceed 50% of generic and branded gross product sales, reduce gross revenues to net revenues in the consolidated statements of earnings, and are presented as current liabilities or reductions in accounts receivable in the consolidated balance sheets. We continually monitor and re-evaluate the accruals as additional information becomes available, which includes, among other things, updates to trade inventory levels, customer product mix, products returned by customers, and trends in Medicaid rebates experience. We make adjustments to the accruals at the end of each reporting period, to reflect any such updates to the relevant facts and circumstances. Accruals are relieved upon receipt of payment from or issuance of credit to the customer, or payment of rebates and fees to customer and state Medicaid programs.

Chargebacks

As discussed in Note 1 of Item 8. Consolidated Financial Statements, we estimate the amount of chargebacks based our actual historical experience. A number of factors influence current period chargebacks by impacting the average selling price (“ASP”) of products, including customer mix, negotiated terms, volume of off-contract purchases, and wholesale acquisition cost (“WAC”).

We have not made any material changes to our policy for estimating chargeback accruals during the years ended December 31, 2015, 2014, and 2013. We believe it is unlikely that there will be a material change in the future estimates or assumptions used to measure chargeback estimates. However, if actual results were not consistent with our estimates, we could be exposed to losses or gains that could be material, as changes to chargeback estimates could cause an increase or decrease in revenue recognized during the year and increase or decrease accounts receivable. If there were a 10% change in the chargeback estimates throughout the year, our Net Revenues and Net Income from Continuing Operations before (Provision)/Benefit for Income Taxes would be affected by $5.2 million for the year ended December 31, 2015.

Medicaid Rebates

As discussed in Note 1 of Item 8. Consolidated Financial Statements, our estimate for Medicaid rebates is based upon our average manufacturer price, best price, product mix, levels of inventory in the distribution channel that we expect to be subject to Medicaid rebates, and historical experience, which are invoiced in arrears by state Medicaid programs. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate

indicator of future rebate experience, and trends in Medicaid enrollment and which products are covered by Medicaid could change.

We have not made any material changes to our policy for estimating Medicaid rebates during the years ended December 31, 2015, 2014, and 2013. While we anticipate that we will have further increases in our quarterly Medicaid rebate amounts related to sales of our Lithobid and Vancocin products, we do not believe that our assumptions used to measure estimates for Medicaid rebates will change materially. However, if actual results were not consistent with our estimates, we could be exposed to losses or gains that could be material, as changes to Medicaid rebate estimates could cause an increase or decrease in revenue recognized during the year and decrease or increase the Medicaid rebate reserve. If there were a 10% change in the Medicaid rebate estimates throughout the year, our Net Revenues and Net Income from Continuing Operations before (Provision)/Benefit for Income Taxes would be affected by $0.7 million for the year ended December 31, 2015.

Returns

As discussed in Note 1 of Item 8. Consolidated Financial Statements, our estimate for returns is based upon our historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns.

We have not made any material changes to our policy for estimating returns during the years ended December 31, 2015, 2014, and 2013. We believe it is unlikely that there will be a material change in the future estimates or assumptions used to measure estimates of goods returned. However, if actual results were not consistent with our estimates, we could be exposed to losses or gains that could be material, as changes to returns estimates could cause an increase or decrease in revenue recognized during the year and decrease or increase the returned goods reserve. If there were a 10% change in the returns estimates throughout the year, our Net Revenues and Net Income from Continuing Operations before (Provision)/Benefit for Income Taxes would be affected by $0.3 million for the year ended December 31, 2015.

Administrative Fees and Other Rebates

As discussed in Note 1 of Item 8. Consolidated Financial Statements, we accrue for fees and rebates by product by wholesaler, at the time of sale based on contracted rates, ASPs, and on-hand inventory counts obtained from wholesalers.

We have not made any material changes to our policy for estimating administrative fee accruals during the years ended December 31, 2015, 2014, and 2013. We believe it is unlikely that there will be a material change in the future estimates or assumptions used to measure estimates of administrative fees. However, if actual results were not consistent with our estimates, we could be exposed to losses or gains that could be material, as changes to these estimates could cause an increase or decrease in revenue recognized during the year and increase or decrease accounts receivable. If there were a 10% change in the administrative fees estimates throughout the year, our Net Revenues and Net Income from Continuing Operations before (Provision)/Benefit for Income Taxes would be affected by $0.6 million for the year ended December 31, 2015.

Prompt Payment Discounts

As discussed in Note 1 of Item 8. Consolidated Financial Statements, we reserve for sales discounts based on invoices outstanding, assuming, based on past experience, that 100% of available discounts will be taken.

We have not made any material changes to our policy for estimating prompt payment discounts accruals during the years ended December 31, 2015, 2014, and 2013. We believe that it is unlikely that there will be a material change in the future estimates or assumptions used to measure estimates of prompt payment discounts. If customers do not take 100% of available discounts as we estimate, we could need to re-adjust our methodology for calculating the prompt payment discount reserve. If there were a 10% decrease in the prompt payment discounts estimates throughout the year, our Net Revenues and Net Income from Continuing Operations before (Provision)/Benefit for Income Taxes would increase by $0.3 million for the year ended December 31, 2015.

Intangible Assets

Our definite-lived intangible assets have a carrying value of $66.4 million as of December 31, 2015. These assets include ANDAs for a total of 54 previously marketed generic products we acquired in 2014 and 2015, product rights for our branded products Lithobid and Vancocin, the NDA for our male testosterone gel product, marketing and distribution rights related to the IDT Australia Limited agreement, and fully amortized product rights for Reglan and a generic product. These intangible assets originally were recorded at fair value for business combinations and at relative fair value based on the purchase price for asset acquisitions and are stated net of accumulated amortization.

The ANDAs, NDAs, and rights are amortized over their remaining estimated useful lives, ranging from seven to 11 years, based on the straight-line method. The estimated useful lives directly impact the amount of amortization expense recorded for these assets on a quarterly and annual basis.

In addition, we test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. Judgment is used in determining when these events and circumstances arise. If we determine that the carrying value of the assets may not be recoverable, judgment and estimates are used to assess the fair value of the assets and to determine the amount of any impairment loss. No events or circumstances arose in 2015 that would indicate that the carrying value of any of our definite-lived intangible assets may not be recoverable.

Goodwill

Goodwill relates to the Merger and represents the excess of the total purchase consideration over the fair value of acquired assets and assumed liabilities, using the purchase method of accounting. Goodwill is not amortized, but is subject to periodic review for impairment. As a result, the amount of goodwill is directly impacted by the estimates of the fair values of the assets acquired and liabilities assumed.

In addition, goodwill is reviewed annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. Judgment is used in determining when these events and circumstances arise. We perform our review of goodwill on our one reporting unit. If we determine that the carrying value of the assets may not be recoverable, judgment and estimates are used to assess the fair value of the assets and to determine the amount of any impairment loss.

The carrying value of goodwill at December 31, 2015 was $1.8 million. We believe it is unlikely that there will be a material change in the future estimates or assumptions used to test for impairment losses on goodwill. However, if actual results were not consistent with our estimates or assumptions, we could be exposed to an impairment charge that could be material.

Stock-Based Compensation

We have a stock-based compensation plan that includes stock options and restricted stock, which are awarded in exchange for employee and non-employee director services. We recognize the estimated fair value of stock-based awards and classify the expense where the underlying salaries are classified.

The following table summarizes stock-based compensation expense included in our consolidated statements of earnings:

(in thousands)	Years ended December 31,		
	2015	2014	2013
Cost of sales	$ 82	$ 104	$ -
Research and development	$ 109	$ 69	$ -
Selling, general, and administrative	$ 3,665	$ 3,250	$ 36

Stock-based compensation cost for stock options is determined at the grant date using an option pricing model and stock-based compensation cost for restricted stock is based on the closing market price of the stock at the grant date. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the employee's requisite service period.

Valuation of stock awards requires us to make assumptions and to apply judgment to determine the fair value of the awards. These assumptions and judgments include estimating the future volatility of our stock price, dividend yields, future employee turnover rates, and future employee stock option exercise behaviors. Changes in these assumptions can affect the fair value estimate.

Estimation of awards that will ultimately vest requires judgment for the amounts that will be forfeited due to failure to fulfill service conditions. To the extent actual results or updated estimates differ from current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised. Changes in estimates could affect compensation expense within individual periods. If there were to be a 10% change in our stock-based compensation expense for the year, our Net Income from Continuing Operations before (Provision)/Benefit for Income would be affected by $0.4 million for the year ended December 31, 2015.

Income Taxes

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact to the consolidated financial statements. We are subject to taxation in various U.S. jurisdictions and remain subject to examination by taxing jurisdictions for the years 1998 and all subsequent periods due to the availability of net operating loss carryforwards. To the extent we prevail in matters for which a liability has been established, or are required to pay amounts in excess of our established liability, our effective income tax rate in a given financial statement period could be materially affected. An unfavorable tax settlement generally would require use of our cash and may result in an increase in our effective income tax rate in the period of resolution. A favorable tax settlement may reduce our effective income tax rate and would be recognized in the period of resolution.

We consider potential tax effects resulting from discontinued operations and record intra-period tax allocations, when those effects are deemed material. Our effective income tax rate is also affected by changes in tax law, our level of earnings, and the results of tax audits.

Although we believe that the judgments and estimates discussed herein are reasonable, actual results could differ, and we may be exposed to losses or gains that could be material.

Recently Issued Accounting Standards

In November 2015, the Financial Accounting Standards Board (“FASB”) issued guidance simplifying the balance sheet classification of deferred taxes. The new guidance requires that all deferred taxes be presented as noncurrent, rather than separated into current and noncurrent amounts. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted. In addition, the adoption of guidance can be applied either prospectively or retrospectively to all periods presented. We adopted this guidance for the year ended December 31, 2015 on a retrospective basis, and all periods are presented under this guidance. The adoption of this new guidance resulted in a reclassification of $7.6 million of current Deferred Tax Assets to noncurrent Deferred Tax Assets in the consolidated balance sheet as of December 31, 2014.

In July 2015, the FASB issued guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using LIFO or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The guidance is effective for reporting periods beginning after December 15, 2016. The guidance should be applied prospectively, with earlier application permitted. We will adopt the guidance as of January 1, 2016, on a prospective basis. The adoption of this new guidance is not expected to have a material impact on our financial

statements.

In April 2015, the FASB issued guidance as to whether a cloud computing arrangement (e.g., software as a service, platform as a service, infrastructure as a service, and other similar hosting arrangements) includes a software license and, based on that determination, how to account for such arrangements. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The guidance is effective for reporting periods beginning after December 15, 2015, and can be adopted on either a prospective or retrospective basis. We will adopt the guidance as of January 1, 2016, on a prospective basis. The adoption of this new guidance is not expected to have a material impact on our financial statements.

In April 2015, the FASB issued guidance to simplify the balance sheet disclosure for debt issuance costs. Under the guidance, debt issuance costs related to a recognized debt liability are presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, in the same manner as debt discounts, rather than as an asset. The guidance is effective for reporting periods beginning after December 15, 2015 and must be adopted on a retrospective basis. Early adoption is permitted. We adopted this guidance for the year ended December 31, 2015 on a retrospective basis, and all periods are presented under this guidance. The adoption of this new guidance resulted in a reclassification of $0.8 million of Prepaid Expenses, a current asset, and $3.3 million of Deferred Loan Costs, a noncurrent asset, to the Convertible Debt noncurrent liability in the consolidated balance sheet as of December 31, 2014.

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

Off-Balance Sheet Arrangements

As of December 31, 2015, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market risks include interest rate risk, foreign currency exchange rate risk, commodity price risk, and other relevant market rate or price risks. Of these risks, only interest rate risk could have a significant impact on our results of operations.

As of December 31, 2015, our only debt obligation was related to our Notes. In order to reduce the potential equity dilution that would result upon conversion of the Senior Convertible Notes issued in December 2014, we entered into note hedge transactions with a financial institution affiliated with one of the underwriters of the Senior Convertible Note offering. The note hedge transactions are expected generally, but not guaranteed, to reduce the potential dilution to our common stock and/or offset the cash payments we are required to make in excess of the principal amount upon any conversion of Senior Convertible Notes, in the event that the market price per share of our common stock, as measured under the terms of the Convertible Note Hedge Transactions, is greater than the conversion price of the Senior Convertible Notes, which is initially approximately $69.48. In addition, in order to partially offset the cost of the note hedge transactions, we issued warrants to the hedge counterparty to purchase approximately 2.1 million shares of our common stock at a strike price of $96.21. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock exceeds the strike price of the warrants. In addition, non-performance by the counterparties under the hedge transactions would potentially expose us to dilution of our common stock to the extent our stock price exceeds the conversion price.

Interest on the Notes accrues at a fixed rate of 3.0% on the outstanding principal amount of the Notes and is paid semi-annually every December 1st and June 1st until the Notes mature on December 1, 2019. Since the interest rate is fixed, we have no interest-rate market risk related to the Notes. However, if our stock price increases, the fair value of our Notes, and their likelihood of being converted, will increase accordingly.

We are exposed to risks associated with changes in interest rates. The returns from certain of our cash and cash equivalents will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease the interest income earned on our cash balance in the year ended December 31, 2015 by approximately $14 thousand.

Item 8. CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

ANI Pharmaceuticals, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of ANI Pharmaceuticals, Inc. and Subsidiaries (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of earnings, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2015. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of ANI Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), ANI Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2015, based on criteria established in the 2013 *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated February 23, 2016 expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

New York, New York
February 23, 2016

57

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

ANI Pharmaceuticals, Inc. and Subsidiaries

We have audited ANI Pharmaceuticals, Inc. and Subsidiaries' (the "Company") internal control over financial reporting as of December 31, 2015, based on criteria established in the 2013 *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, ANI Pharmaceuticals, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in the 2013 *Internal Control - Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of ANI Pharmaceutical, Inc. and Subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of earnings, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2015, and our report dated February 23, 2016 expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

New York, New York
February 23, 2016

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2015	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	$ 154,684	$ 169,037
Accounts receivable, net of $13,586 and $8,708 of adjustments for chargebacks and other allowances at December 31, 2015 and 2014, respectively	21,932	17,297
Inventories, net	13,387	7,518
Prepaid income taxes	1,127	-
Prepaid expenses and other current assets	1,453	1,139
Total Current Assets	192,583	194,991
Property and equipment, net	7,131	5,223
Deferred tax asset, net of valuation allowance	17,316	15,439
Intangible assets, net	66,397	42,067
Goodwill	1,838	1,838
Total Assets	$ 285,265	$ 259,558
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 2,066	$ 2,654
Accrued expenses and other	617	567
Accrued royalties	606	702
Accrued compensation and related expenses	1,188	1,348
Current income taxes payable	-	4,253
Accrued Medicaid rebates	4,631	2,264
Returned goods reserve	2,648	1,445
Total Current Liabilities	11,756	13,233
Long-term Liabilities		
Convertible notes, net of discount and deferred financing costs	113,427	106,540
Total Liabilities	$ 125,183	$ 119,773
Commitments and Contingencies (Note 12)		
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 11,498,228 shares issued and oustanding at December 31, 2015; 11,387,860 shares issued and outstanding at December 31, 2014	1	1
	-	-

Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at December 31, 2015 and 2014, respectively		
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at December 31, 2015 and 2014, respectively	-	-
Additional paid-in capital	164,431	159,509
Accumulated deficit	(4,350)	(19,725)
Total Stockholders' Equity	160,082	139,785
Total Liabilities and Stockholders' Equity	$ 285,265	$ 259,558

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Earnings
(in thousands, except per share amounts)

	Years ended December 31,		
	2015	2014	2013
Net Revenues	$76,322	$55,970	$30,082
Operating Expenses			
Cost of sales (excluding depreciation and amortization)	12,692	11,473	9,974
Research and development	2,874	2,678	1,712
Selling, general, and administrative	21,156	17,935	16,388
Depreciation and amortization	6,900	3,878	1,110
Total Operating Expenses	43,622	35,964	29,184
Operating Income from Continuing Operations	32,700	20,006	898
Other Expense, net			
Interest expense, net	(11,008)	(787)	(467)
Other income/(expense), net	41	160	(305)
Income from Continuing Operations Before (Provision)/Benefit for Income Taxes	21,733	19,379	126
(Provision)/Benefit for income taxes	(6,358)	9,368	(20)
Net Income from Continuing Operations	15,375	28,747	106
Discontinued Operation			
Gain on discontinued operation, net of $38 provision for income taxes in the year ended December 31, 2013	-	-	195
Net Income	$15,375	$28,747	$301
Computation of Income/(Loss) from Continuing Operations Attributable to Common Stockholders and Participating Securities:			
Net Income from Continuing Operations	$15,375	$28,747	$106
Preferred stock dividends	-	-	(4,975)
Income/(Loss) from Continuing Operations Attributable to Common Stockholders and Participating Securities	$15,375	$28,747	$(4,869)
Basic Income/(Loss) Per Share:			
Continuing operations	$1.34	$2.61	$(0.96)
Discontinued operation	-	-	0.04
Basic Income/(Loss) Per Share	$1.34	$2.61	$(0.92)

Basic Weighted-Average Shares Outstanding	11,370	10,941	5,071
Diluted Income/(Loss) Per Share:			
Continuing operations	$1.32	$2.59	$(0.96)
Discontinued operation	-	-	0.04
Diluted Income/(Loss) Per Share	$1.32	$2.59	$(0.92)
Diluted Weighted-Average Shares Outstanding	11,557	11,053	5,071

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
For the years ended December 31, 2015, 2014, and 2013
(in thousands)

	Common Stock Par Value	Common Stock Shares	Class C Special Stock	Additional Paid-in Capital	Treasury Stock Shares	Treasury Stock	Accumulated Deficit	Total
Balance, December 31, 2012	$-	4,070	$ -	$ 1,083	-	$ -	$ (43,798)	$ (42,715)
Preferred Stock Dividends	-	-	-	-	-	-	(4,975)	(4,975)
Non-cash Compensation Relating to Business Combination	-	-	-	4,418	-	-	-	4,418
Cancellation of Convertible Preferred Stock	-	-	-	53,726	-	-	-	53,726
Shares Issued in Merger	1	5,469	-	29,794	-	-	-	29,795
Stock-based Compensation Expense	-	-	-	36	-	-	-	36
Purchase of Common Stock for Treasury	-	-	-	-	59	(433)	-	(433)
Issuance of Common Stock upon Warrant Exercise	-	90	-	809	-	-	-	809
Issuance of Restricted Stock Awards	-	-	-	(365)	(50)	365	-	-
Net Income	-	-	-	-	-	-	301	301
Balance, December 31, 2013	$ 1	9,629	$ -	$ 89,501	9	$ (68)	$ (48,472)	$ 40,962
	-	-	-	3,423	-	-	-	3,423

Stock-based Compensation Expense								
Issuance of Common Stock in Equity Offering	-	1,613	-	46,680	-	-	-	46,680
Allocation of proceeds from sale of Convertible Notes to Embedded Conversion Option	-	-	-	20,195	-	-	-	20,195
Cost of Bond-hedge, Net of Proceeds from Sale of Warrant	-	-	-	(2,575)	-	-	-	(2,575)
Issuance of Common Stock upon Warrant Exercise	-	83	-	750	-	-	-	750
Issuance of Common Shares upon Stock Option Exercise	-	43	-	819	-	-	-	819
Issuance of Restricted Stock Awards	-	20	-	(68)	(9)	68	-	-
Excess Tax Benefit from Stock-based Compensation Awards	-	-	-	784	-	-	-	784
Net Income	-	-	-	-	-	-	28,747	28,747
Balance, December 31, 2014	$ 1	11,388	$ -	$ 159,509	-	$ -	$ (19,725)	$ 139,785
Stock-based Compensation Expense	-	-	-	3,856	-	-	-	3,856
Changes in Treasury Stock Related to	-	-	-	-	7	(113)	-	(113

Stock-based Compensation Arrangements								
Issuance of Common Shares upon Stock Option Exercise	-	84	-	706	(5)	113	-	819
Issuance of Restricted Stock Awards	-	26	-	-	(2)	-	-	-
Excess Tax Benefit from Stock-based Compensation Awards	-	-	-	360	-	-	-	360
Net Income	-	-	-	-	-	-	15,375	15,375
Balance, December 31, 2015	$ 1	11,498	$ -	$ 164,431	-	$ -	$ (4,350)	$ 160,082

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(in thousands)

For the years ended December 31,	2015	2014	2013
Cash Flows From Operating Activities			
Net income	$15,375	$28,747	$301
Adjustments to reconcile net loss to net cash and cash equivalents provided by/(used in) operating activities:			
Stock-based compensation	3,856	3,423	36
Deferred taxes	(1,877)	(14,459)	-
Depreciation and amortization	6,900	3,878	1,110
Loss on disposal of property and equipment	40	-	-
Non-cash interest relating to convertible notes and loan cost amortization	6,831	559	217
Non-cash compensation relating to business combination	-	-	4,418
Changes in operating assets and liabilities, net of those acquired in business combination:			
Accounts receivable, net	(4,635)	(4,784)	(7,081)
Inventories, net	(5,869)	(3,468)	(708)
Prepaid expenses and other current assets	(314)	(558)	(188)
Accounts payable	(1,027)	225	(565)
Accrued compensation and related expenses	(160)	575	(2,854)
Current income taxes, net	(5,380)	4,233	20
Accrued Medicaid rebates	2,367	2,011	72
Accrued expenses, returned goods reserve and other	1,157	1,651	(67)
Net Cash and Cash Equivalents Provided by/(Used in) Continuing Operations	17,264	22,033	(5,289)
Net Cash Used in Discontinued Operation	-	-	(195)
Net Cash and Cash Equivalents Provided by/(Used in) Operating Activities	17,264	22,033	(5,484)
Cash Flows From Investing Activities			
Cash acquired in business combination	-	-	18,198
Acquisition of product rights and other related assets	(30,500)	(34,634)	-
Release of restricted cash	-	-	2,260
Acquisition of property and equipment	(2,183)	(1,120)	(191)
Net Cash and Cash Equivalents (Used in)/Provided by Investing Activities	(32,683)	(35,754)	20,267
Cash Flows From Financing Activities			
Net proceeds from equity offering	-	46,680	-
Net proceeds from convertible debt offering	-	138,243	-
Purchase of call option overlay, net	-	(15,623)	-
Repayment of line of credit, net	-	-	(4,065)
Proceeds from stock option exercises	819	819	-
Proceeds from warrant exercise	-	750	809
Excess tax benefit from share-based compensation awards	360	784	-
Treasury stock purchases	(113)	-	(433)
Net Cash and Cash Equivalents Provided by/(Used in) Financing Activities	1,066	171,653	(3,689)

Change in Cash and Cash Equivalents	(14,353)	157,932	11,094
Cash and cash equivalents, beginning of period	169,037	11,105	11
Cash and cash equivalents, end of period	$154,684	$169,037	$11,105
Supplemental disclosure for cash flow information:			
Cash paid for interest	$4,205	$-	$250
Cash paid for income taxes, net	$13,255	$147	-
Supplemental non-cash investing and financing activities:			
Property and equipment purchased and included in accounts payable	$439	$-	$-
Issuance of common stock in connection with business combination	$-	$-	$40,034
Cancellation of Series D, Series C, Series B, and Series A preferred stock	$-	$-	$53,726
Acquired non-cash net assets	$-	$-	$11,597
Preferred stock dividends accrued	$-	$-	$4,975

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

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2015, 2014, and 2013

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, “ANI,” the “Company,” “we,” “us,” or “our”) is a specia pharmaceutical company, developing and marketing generic and branded prescription products. ANI was organized as a Delaware corporation in April 2001. At our two facilities located in Baudette, Minnesota, which have a combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet, we manufacture oral solid dose products, as well as liquids and topicals, including those that must be manufactured in a fully contained environment due to their potency. We also perform contract manufacturing for other pharmaceutical companies.

On June 19, 2013, BioSante Pharmaceuticals, Inc. (“BioSante”) acquired ANIP Acquisition Company (“ANIP”) in an all-stock, tax-free reorganization (the “Merger”) (Note 2), in which ANIP became a wholly-owned subsidiary of BioSante. BioSante was renamed ANI Pharmaceuticals, Inc. The Merger was accounted for as a reverse acquisition pursuant to which ANIP was considered the acquiring entity for accounting purposes. As such, ANIP's historical results of operations replace BioSante's historical results of operations for all periods prior to the Merger. The results of operations of both companies are included in our consolidated financial statements for all periods after completion of the Merger.

Our operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, dependence on significant customers, lack of operating history and uncertainty of future profitability and possible fluctuations in financial results. The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future profitable operations, the ability to generate sufficient cash from operations, and potential other funding sources, including cash on hand, to meet our obligations as they become due. We believe the going-concern basis is appropriate for the accompanying consolidated financial statements based on our current operating plan and business strategy for the next 12 months.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Certain prior period information has been reclassified to conform to the current period presentation.

For the year ended December 31, 2015, we adopted new guidance regarding the presentation of the balance sheet disclosure for debt issuance costs and new guidance regarding the balance sheet classification of deferred taxes. We adopted these on a retrospective basis. To conform to the current period presentation, we reclassified the following amounts in our consolidated balance sheet dated December 31, 2014:

(in thousands)	Original Prior Period Presentation	Amount Reclassified	Current Prior Period Presentation
Deferred tax asset, net of valuation allowance, current	$ 7,643	$ (7,643)	$ -
Prepaid expenses and other current assets	$ 1,983	$ (844)	$ 1,139
Current Assets	$ 203,478	$ (8,487)	$ 194,991
Deferred financing costs, net	$ 3,307	$ (3,307)	$ -
Deferred tax asset, net of valuation allowance	$ 7,796	$ 7,643	$ 15,439
Total Assets	$ 263,709	$ (4,151)	$ 259,558
Convertible notes, net of discount and deferred financing costs	$ 110,691	$ (4,151)	$ 106,540
Liabilities	$ 123,924	$ (4,151)	$ 119,773

Principles of Consolidation

The consolidated financial statements include the accounts of ANI Pharmaceuticals, Inc. and its subsidiaries. All intercompany accounts and transactions are eliminated in consolidation.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2015, 2014, and 2013

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, Medicaid rebates, returns and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, deferred taxes and valuation allowance, and the depreciable lives of long-lived assets. Actual results could differ from those estimates.

Comprehensive Income

We have no components of other comprehensive income and accordingly, no statement of comprehensive income is included in the accompanying consolidated financial statements.

Credit Concentration

Our customers are primarily wholesale distributors, chain drug stores, group purchasing organizations, and other pharmaceutical companies.

During the year ended December 31, 2015, three customers represented approximately 26%, 20%, and 18% of net revenues, respectively. As of December 31, 2015, accounts receivable from these customers totaled 73% of net

accounts receivable. During the year ended December 31, 2014, three customers represented approximately 30%, 25%, and 14% of net revenues, respectively. During the year ended December 31, 2013, three customers represented approximately 27%, 18%, and 10% of net revenues, respectively.

Vendor Concentration

We source the raw materials for its products, including active pharmaceutical ingredients (“A