UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2016

☐ **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 ☒

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 ☒

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 ☒ 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 ☒ 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. ☒

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 ☒
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 ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2016 was $475.9 million (based upon the last reported sale price of $55.82 per share on June 30, 2016, on The NASDAQ Global Market).

As of February 21, 2017, 11,589,686 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 2017 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, 2016

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 context requires otherwise, to ANI Pharmaceuticals, Inc., a Delaware c-corporation, and its consolidated subsidiaries. References to “named executive officers” 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, contract manufacturing arrangements, 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®, Corticotrophin®, Corticotrophin-Zinc®, Inderal® LA, Lithobid®, Reglan®, and Vancocin® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiaries.

PART I

Item 1. Business

ANI Pharmaceuticals is an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing, and marketing high quality 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 pharmaceutical manufacturing facilities located in Baudette, Minnesota 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. In July 2013, we changed our name from “BioSante Pharmaceuticals, Inc.” to “ANI Pharmaceuticals, Inc.”

In March 2014, we completed a follow-on public offering of common stock, yielding net proceeds of $46.7 million. In December 2014, we issued $143.8 million of our Convertible Senior Notes (the “Notes”) in a registered public offering, yielding net proceeds of $122.6 million.

With the additional funds resulting from the public and convertible debt offerings, we have acquired ANDAs, NDAs, and product rights, and have also entered into agreements to obtain the distribution rights for various products. As a result of these acquisitions and distribution agreements, we launched three products in 2014, six products in 2015, and 11 products in 2016, bringing our portfolio of products to 25 as of December 31, 2016.

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. 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 focused on delivering value to our customers by developing, manufacturing, and marketing high quality 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. At our two facilities located in Baudette, Minnesota, we manufacture oral solid dose products, as well as liquids and topicals, controlled substances, and potent 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 2012, we have successfully:

- Increased prescription product sales through a combination of market share gains on existing products and new product launches.
- Acquired the New Drug Applications ("NDA") for and began marketing Lithobid, Vancocin, and Inderal LA.
- Filed five Abbreviated New Drug Applications ("ANDAs").
- Increased our product pipeline, through development, partnership, and acquisition, to 78 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 the NDAs for Corticotropin and Corticotropin Zinc in January 2016; have since assembled a Corticotropin re-commercialization team of scientists, established a laboratory exclusively for Corticotropin analytical method development, contracted with an accomplished contract manufacturer, and initiated manufacturing of Corticotropin active pharmaceutical ingredient.

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 the expected price erosion caused by competition from other generic manufacturers, and the estimated cost to manufacture the products.
- ***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, 2016, our products include both branded and generic pharmaceuticals, specifically:

Generic Products	Branded Products
Erythromycin Ethylsuccinate	Cortenema
Esterified Estrogen with Methyltestosterone	Inderal LA
Etodolac	Lithobid
Fenofibrate	Reglan
Flecainide	Vancocin
Fluvoxamine	
Hydrocortisone Enema	
Hydrocortisone Rectal Cream (1% and 2.5%)	
Lithium Carbonate ER	
Mesalamine Enema	
Methazolamide	
Metoclopramide Syrup	
Nilutamide	
Nimodipine	
Opium Tincture	
Oxycodone Capsules	
Oxycodone Oral Solution	
Propafenone	
Propranolol ER	
Vancomycin	

Erythromycin Ethylsuccinate is used to treat infections caused by susceptible strains of designated organisms for selected diseases.

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, 2016, EEMT comprised 23% of our net sales, versus 51% of net sales in 2015, and 42% of net sales in 2014.

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

Fenofibrate is a peroxisome proliferator receptor alpha activator indicated as an adjunct with diet to reduce elevated LDL-C, Total-C, TG and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia. Fenofibrate is also indicated as an adjunct with diet for adult patients with severe hypertriglyceridemia.

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.

Hydrocortisone Rectal Cream is used for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Lithium Carbonate ER and its branded equivalent, Lithobid, are indicated in the treatment of manic episodes of bipolar disorder. Lithium Carbonate ER and Lithobid are also indicated as a maintenance treatment for individuals with a diagnosis of bipolar disorder. Maintenance therapy reduces the frequency and intensity of manic episodes.

Mesalamine Enema is used to treat active to moderate distal ulcerative colitis, proctosigmoiditis, or proctitis.

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.

Nilutamide is indicated for use in combination with surgical castration for the treatment of metastatic prostate cancer.

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 capsules are indicated for the management of acute moderate to severe pain and chronic pain.

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.

Propranolol ER and its branded equivalent, Inderal LA, are indicated in the management of hypertension, to decrease angina frequency and increase exercise tolerance in patients with angina pectoris, for the prophylaxis of common migraine headache, and to improve New York Heart Association (“NYHA”) functional class in symptomatic patients with hypertrophic subaortic stenosis.

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 three Schedule II products currently on the market, our pipeline includes three ANDAs 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 currently have one oncolytic product on the market.

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 five complex formulation 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, Oxycodone oral solution, and Oxycodone capsules, 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 the 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 Fenofibrate, generic Fluvoxamine, generic Hydrocortisone Enema, Inderal LA, generic Lithium Carbonate ER, Lithobid, generic Mesalamine, generic Propranolol ER, 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 Erythromycin Ethylsuccinate, Etodolac, Flecainide, Hydrocortisone rectal cream, Methazolamide, Metoclopramide oral solution, Nilutamide, Nimodipine, Oxycodone capsules, 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 and Oxycodone capsule products, 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, Oxycodone oral solution, and Oxycodone capsules. 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, Oxycodone oral solution, and Oxycodone capsules.

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 Fenofibrate, Fluvoxamine, Hydrocortisone Enema, Lithium Carbonate ER, Mesalamine, Propranolol ER, 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.

Recently, members of the new presidential administration have made statements and begun taking actions to potentially seek repeal of all or portions of the ACA and Congress may replace the current legislation with new legislation. There is uncertainty with respect to the impact the new presidential administration may have, if any, and any changes will likely take time to unfold and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. We cannot predict the ultimate content, timing, or effect of any healthcare reform legislation or the impact of potential legislation on us.

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, 2016, 2015, and 2014, our research and development expenses were $2.9 million, $2.9 million, and $2.7 million, respectively.

Sofgen Pharmaceuticals

August 2013 Sofgen Agreement

In August 2013, we entered into an agreement with Sofgen Pharmaceuticals (“Sofgen”) to develop Nimodipine (the “August 2013 Sofgen Agreement”). In general, Sofgen was responsible for the development, manufacturing, and regulatory submission of the product, and we made payments based on the completion of certain milestones. In December 2015, we launched Nimodipine under our label. Sofgen manufactures the drug and we 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 owns all the rights, title, and interest in Nimodipine. 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 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 July 2016, we launched our Nilutamide product under the agreement.

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. In August 2016, we and Ricon agreed to a partial termination of the agreement, with only the Nilutamide product remaining under the agreement.

Patents, Trademarks, and Licenses

We own the trademark names for each of our branded products, Cortenema, Corticotropin, Corticotropin-Zinc, Inderal LA, 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. 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 under certain specified circumstances.

Distribution Agreements

In addition to selling products under our own NDAs and ANDAs, we enter into marketing and distribution agreements with third parties in which we sell products under ANDAs or NDAs owned or licensed by these third parties. These products are sold under our own label.

In 2016, we entered into an agreement with Meda Pharmaceuticals, Inc. ("Meda") to market and distribute Mesalamine, an authorized generic of their Rowasa ® product. We are primarily responsible for marketing and distributing the product and pay Meda a percentage of gross profits on sales of the product. The agreement may be terminated by either party under certain specified circumstances.

In January 2016, we purchased from H2-Pharma, LLC ("H2") the exclusive rights to market, sell, and distribute Fenofibrate, an authorized generic of Lipofen®, and generic hydrocortisone rectal cream (1% and 2.5%). Under the agreement for the Fenofibrate product, we are primarily responsible for marketing and distributing the product and pay a percentage of gross profits on sales of the product. We launched the Fenofibrate product under our own label in May 2016. The agreement may be terminated by either party under certain specified circumstances. Under the agreement for the hydrocortisone rectal cream product, we are primarily responsible for marketing and distributing the product and pay a percentage of gross profits on sales of the product. We launched both strengths of hydrocortisone rectal cream under our own label in April 2016. The agreement may be terminated by either party under certain specified circumstances.

Customers

Our customers purchase and distribute our products. Our products are sold by four major retail pharmacy chains: CVS, Rite Aid, Walgreens, and Wal-Mart, and are included in the source programs of four major national wholesalers: AmerisourceBergen, Cardinal Health, McKesson, and Morris Dickson. In addition, our customers include national mail order houses, including Anda, CVS Caremark, and ExpressScripts, 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, 2016, approximately 68% of our net revenues were attributable to three wholesalers: McKesson Corporation (28%), AmerisourceBergen Corporation (22%), and Cardinal Health, Inc. (18%). For the years ended December 31, 2015 and 2014, McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Corporation, together accounted for approximately 64% and 69% 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, Amerisource Bergen has begun handling product distribution for Walgreens. Similarly, Cardinal Health and CVS established a partnership in which Cardinal performs product distribution for CVS. McKesson also entered into strategic alliances with both Wal-Mart and Rite Aid. Due to these 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: AmerisourceBergen, Cardinal, McKesson, 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: CVS, Rite Aid, Walgreens, 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, CVS Caremark, and ExpressScripts.
- ***Group Purchasing Organizations.*** We have contracts with group purchasing organizations in the United States, such as the Federal Supply Schedule ("FSS"), Innovatix, MedAssets, Minnesota Multi-State, Optisource, and Premiere.

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, Impax Laboratories, Lannett, Mallinckrodt, Mylan, Par Pharmaceutical, 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, have faced 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. In August 2016, we settled the outstanding California 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 and paid all losses in settlement of the California cases. 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.

Backlog

We had a backlog of $0.8 million, $0.5 million, and $1.2 million at December 31, 2016, 2015, and 2014, respectively, relating to contract manufacturing purchase orders from customers.

Employees

As of December 31, 2016 our workforce included 143 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, 2016, 2015, and 2014 were $128.6 million, $76.3 million, and $56.0 million, respectively. Net income for the years ended December 31, 2016, 2015, and 2014 was $3.9 million, $15.4 million, and $28.7 million, respectively. Total assets at December 31, 2016, 2015, and 2014 were $322.9 million, $285.3 million, and $259.6 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 27% of our total revenue in 2016, 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, 2016, 2015, and 2014, revenues for EEMT were 23%, 51%, and 42% of total revenue, respectively, and revenues from Opium Tincture were 4%, 7%, and 11% 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, 2016, 2015, and 2014 were 1.2%, 2.1%, and 2.2% of total revenues, respectively. Our royalties on the net sales of these unapproved products for the years ended December 31, 2016, 2015, and 2014 were less than 1% of total revenues.

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.

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 are entirely dependent on periodic approval by the Drug Enforcement Administration ("DEA") for the supply of the API needed to make our Opium Tincture, Oxycodone oral solution, and Oxycodone capsule products. An inability to obtain such approvals would reduce or eliminate our revenues from Opium Tincture, Oxycodone oral solution, and Oxycodone capsules, 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 DEA and are subject to sanctions if we are unable to comply with related regulatory requirements.

The 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, Oxycodone oral solution, and Oxycodone capsules. 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, Oxycodone oral solution, and Oxycodone capsules 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 and the formation of strategic partnerships among and between 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 28%, 22%, and 18% of net revenues, respectively, during the year ended December 31, 2016. As of December 31, 2016, accounts receivable from these three customers was approximately 83% of accounts receivable, net. 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.

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, have faced 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. In August 2016, we settled the outstanding California 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 and paid all losses in settlement of the California cases. 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.

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." 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.

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. All prescription pharmaceutical products distributed in the U.S. must be serialized with unique product identifiers by November 27, 2017, with the final requirement for tracking the products commencing on November 27, 2023. 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. In addition, if we are unable to comply with DSCSA as of the required dates, we could face penalties or be unable to sell our products.

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. Recently, members of the new presidential administration have made statements and begun taking actions to potentially seek repeal of all or portions of the ACA and Congress may replace the current legislation with new legislation. There is uncertainty with respect to the impact the new presidential administration may have, if any, and any changes will likely take time to unfold and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. We cannot predict the ultimate content, timing, or effect of any healthcare reform legislation or the impact of potential legislation on us, which could have a material adverse effect on our business, financial position, and operating results.

Risks Related to our Business

32% of our net revenues in 2016 resulted from sales of EEMT, Lithobid, and Vancocin. During the same period, these products accounted for only 4% 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, 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 25% of our inventory from one supplier during the year ended December 31, 2016. We purchased approximately 33% and 42% of our inventory from two suppliers during the years ended December 31, 2015 and 2014, respectively. 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 or maintain 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.

Several of our products are manufactured by third parties, which we cannot control.

We rely on third parties to manufacture our Erythromycin Ethylsuccinate, Fenofibrate, Hydrocortisone rectal cream, Inderal LA, Nimodipine, Propranolol ER, Vancocin, and Vancomycin products. We expect our reliance on third party manufacturers to continue 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 Erythromycin Ethylsuccinate, Fenofibrate, Hydrocortisone rectal cream, Inderal LA, Nimodipine, Propranolol ER, Vancocin, Vancomycin, or future products, which could have a material adverse effect on our business, financial position, and operating results.

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 and continue to increase due to our acquisitions of Inderal LA, Lithobid, and Vancocin, as well as the acquisition of a distribution agreement under which we market our Fenofibrate product, 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 Inderal LA, Lithobid, and Vancocin, and the acquisition of a distribution agreement under which we market our Fenofibrate product. 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 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 Fenofibrate, Inderal LA, Lithobid, and Vancocin, which in turn could adversely affect our business, financial position, and operating results.

Our accruals for the Medicare Coverage Gap Discount Program have increased due to our acquisition of Inderal LA as well as the acquisition of a distribution agreement under which we market our Fenofibrate product, 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 accruals for the rebates under the Medicare Coverage Gap Discount Program have increased due to our acquisition of Inderal LA and the acquisition of a distribution agreement under which we market our Fenofibrate product. We accrue for these rebates at the time of sale based on our estimates of the amount of product that will be prescribed to patients in the Medicare Coverage Gap Discount program, which is primarily for the benefit of persons aged 65 years and over. As our Fenofibrate, Inderal LA, and Propranolol ER products, all of which were launched in 2016, are often used by patients in this age range, our estimates of these rebates have grown. Increases in Medicare Coverage Gap Discount rebates could decrease our revenues from product sales, including Fenofibrate, Inderal LA, and Propranolol ER, which in turn could adversely affect our business, financial position, and operating results.

We have entered into distribution agreements under which we market products under ANDAs and NDAs owned by third parties. Any change s to these agreements could have a material adverse effect on our business, financial position, and operating results.

In 2016, we entered into several distribution agreements to market and distribute products under our own label that are sold under ANDAs and NDAs owned by third parties, over which we have no control. Generally, the responsibility for maintaining the ANDAs and NDAs lies with these third parties. If any regulatory issues were to arise with the underlying ANDA or NDA for one of these products, we could be required to discontinue sales of the product, which could have an adverse effect on 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 have found and engaged a third party to develop the API form of the products. We will also need to find and engage a third party capable of manufacturing 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, Corticotropin, Corticotropin-Zinc, Reglan, Lithobid, Inderal LA, 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.

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 was subject to substantial limitations and ANIP Acquisition Company's NOL and tax credit carryforwards were fully utilized in 2016. These limitations, in turn, could result in increased future tax payments, which could be material.

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 2016 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 ANDAs for previously marketed generic products, NDAs and product rights for our branded products and an NDA for male testosterone gel, marketing and distribution rights related to certain generic products, and a non-compete agreement. These assets are being amortized over their useful lives of two to 10 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. We recorded an intangible asset impairment charge of $6.7 million in the year ended December 31, 2016 in relation to our testosterone gel NDA asset and 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.

Our Revolving Credit Loan Facility imposes a number of significant restrictions and covenants that limit our flexibility in operating our business.

Our Revolving Credit Loan Facility imposes a number of customary and significant restrictions and covenants, subject to certain exceptions, that limit our ability to, among other things:

- incur, create, assume, or guarantee additional indebtedness;
- pay dividends on capital stock or redeem or repurchase capital stock;
- grant or permit certain liens on our assets;
- merge, consolidate, or transfer substantially all of our assets;
- enter into certain transactions with affiliates;
- make capital expenditures in excess of $7.5 million per fiscal year;
- sell, lease, or dispose of property and assets; and
- make certain investments or acquisitions or enter in mergers or consolidations.

In addition, the Revolving Credit Loan Facility also imposes a financial covenant requiring compliance with a minimum fixed charge coverage ratio of 1.10 to 1.00 during certain covenant testing that is triggered if availability under the Citizens Agreement is below the greater of 12.5% of the revolving commitment and $3.75 million for three consecutive business days.

A breach of any of the restrictions and covenants in the Revolving Credit Loan Facility could result in a default. Upon the occurrence of an event of default under our Revolving Credit Loan Facility, the lenders could elect to declare all amounts outstanding thereunder to be immediately due and payable and terminate all commitments to extend further credit, which could have a material adverse effect on our business, financial position, and operating results.

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, 2016. 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, 2016, the average daily trading volume of our common stock on the NASDAQ Global Select market was approximately 211 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.

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.

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 also own a cold storage facility located in Baudette, Minnesota.

We lease space for a finance office in Wilmington, Delaware. The lease will expire in September 2018. We also lease space for a regulatory affairs office in Raleigh, North Carolina. The lease 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, 2016 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, have faced 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. In August 2016, we settled the outstanding California 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 and paid all losses in settlement of the California cases. 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.

We launched Erythromycin Ethylsuccinate (“EES”) on September 27, 2016 under a previously approved ANDA. In August, we filed with the FDA to reintroduce this product under a Changes Being Effected in 30 Days submission (a “CBE-30 submission”). Under a CBE-30 submission, certain defined changes to an ANDA can be made if the FDA does not object in writing within 30 days. The FDA’s regulations, guidance documents, and historic actions support the filing of a CBE-30 for the types of changes that we proposed for our EES ANDA. We received no formal written letter from the FDA within 30 days of the CBE-30 submission date, and as such, launched the product in accordance with FDA regulations. On December 16, 2016, and nearly four months after our CBE-30 submission, the FDA sent us a formal written notice that a Prior Approval Supplement (“PAS”) was required for this ANDA. Under a PAS, proposed changes to an ANDA cannot be implemented without prior review and approval by the FDA. Because we did not receive this notice in the timeframe prescribed by the FDA’s regulations, we believe that our supplemental ANDA is valid, and as such continue to market the product. In addition, we filed a PAS which was accepted by the FDA and has an assigned action date of June 2017. We reserve all of our legal options in this matter.

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, 2016 and 2015:

	Common Stock Price			
	2016		2015	
	High	Low	High	Low
First Quarter	$ 46.01	$ 26.80	$ 71.78	$ 50.70
Second Quarter	$ 57.91	$ 32.46	$ 72.61	$ 47.56
Third Quarter	$ 70.92	$ 53.80	$ 73.54	$ 37.20
Fourth Quarter	$ 69.85	$ 47.25	$ 50.07	$ 36.15

Stockholder Information

As of February 21, 2017, there were approximately 150 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, 2016 and 2015. We do not anticipate paying cash dividends in the near term. Our $30.0 million line of credit arrangement with Citizens Bank Capital, a division of Citizens Asset Finance, Inc., limits our ability to pay dividends or redeem or repurchase shares of our capital stock, and as such, we are not permitted to do so unless we are in compliance with certain financial covenants.

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

None.

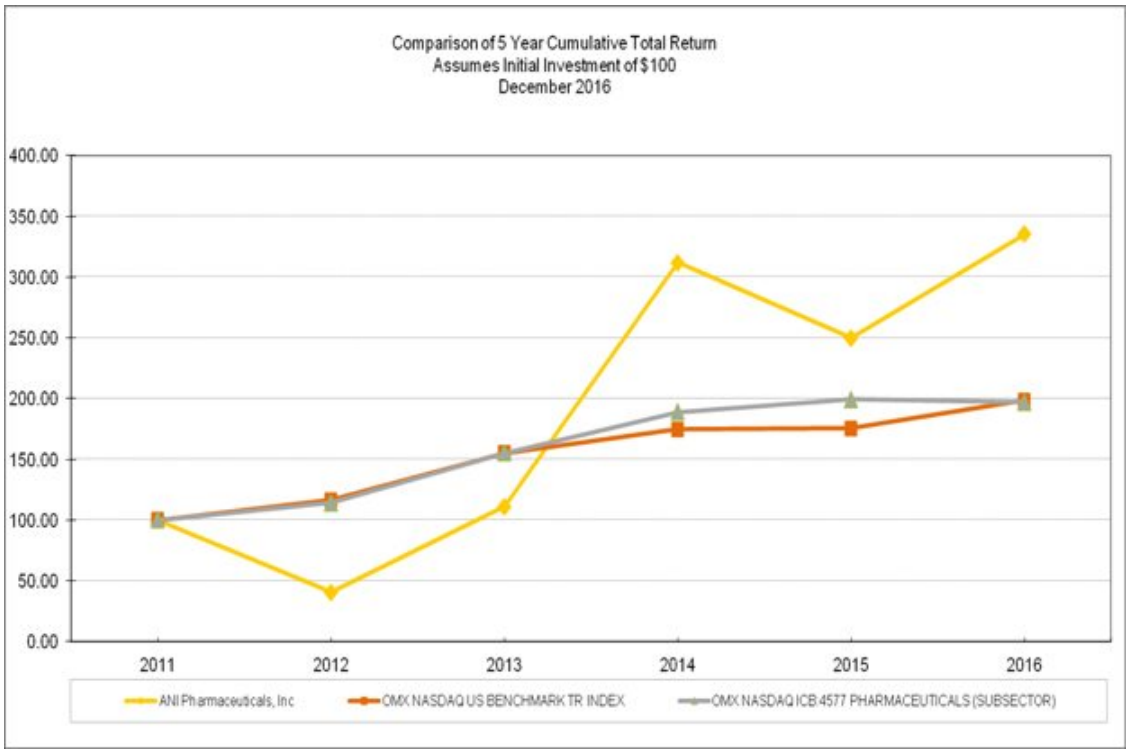
Issuer Purchases of Equity Securities

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, 2011, 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. 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, 2016. The information has been derived from our audited consolidated financial statements for each of the years ended December 31, 2016, 2015, 2014, 2013, and 2012. 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)	2016	2015	2014	2013 [1]	2012 [2]
Statement of Earnings Data:					
Net revenues	$ 128,622	$ 76,322	$ 55,970	$ 30,082	$ 20,371
Total operating expenses	108,543	43,622	35,964	29,184	20,413
Operating income/(loss) from continuing operations	20,079	32,700	20,006	898	(42)
Net income/(loss) from continuing operations	$ 3,934	$ 15,375	$ 28,747	$ 106	$ (1,574)
Basic and diluted income/(loss) from continuing operations per share:					
Basic income/(loss) per share from continuing operations	$ 0.34	$ 1.34	$ 2.61	$ (0.96)	$ N/A
Diluted income/(loss) per share from continuing operations	$ 0.34	$ 1.32	$ 2.59	$ (0.96)	$ N/A
Balance Sheet Data:					
Total assets	$ 322,864	$ 285,265	$ 259,558	$ 44,500	$ 13,748
Total convertible notes, net of discount and deferred financing costs	120,643	113,427	106,540	-	-
Total redeemable convertible preferred stock	-	-	-	-	48,751
Total stockholder's equity/(deficit)	$ 169,648	$ 160,082	$ 139,785	$ 40,962	$ (42,715)

[1] On June 19, 2013, BioSante Pharmaceuticals, Inc. ("BioSante") acquired ANIP Acquisition Company ("ANIP") in an all-stock, tax-free reorganization, 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 year ended December 31, 2012 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 focused on delivering value to our customers by developing, manufacturing, and marketing high quality 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 Abbreviated Drug Applications ("ANDAs") for 31 generic products, the New Drug Application ("NDA") for Lithobid, and the NDA for Vancocin, along with two related ANDAs. We also launched our Methazolamide product. In addition, 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 acquired ANDAS for 23 generic products, the NDA for Testosterone gel, and entered into a distribution agreement with IDT Australia Limited ("IDT") to market several generic products in the U.S. We also launched six products during the year.

In 2016, we acquired the NDAs and product rights for Corticotropin, Corticotropin-Zinc, and Inderal LA, and acquired the rights to market and distribute our Fenofibrate and Hydrocortisone rectal cream products. We also entered into a three year senior secured asset-based revolving credit facility for up to $30.0 million. During the 2016 year, we launched 11 products.

Recent Developments

In January 2016, we acquired from Merck Sharp & Dohme B.V. (“Merck”) the NDAs for Corticotropin and Corticotropin-Zinc for $75.0 million in cash and a percentage of future net sales. Corticotropin may be employed for many different disorders such as rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, respiratory diseases, hematologic disorders, and neoplastic diseases. More specifically, Corticotropin is used to treat conditions such as multiple sclerosis, psoriatic or rheumatoid arthritis, ankylosing spondylitis, lupus, severe allergic reactions, breathing disorders, and inflammatory conditions of the eyes. Corticotropin can reduce the symptoms of many disorders where corticosteroid therapy has failed, but it is not a cure for these conditions. Since acquiring the NDAs, we have assembled a Corticotropin re-commercialization team of scientists and subject matter experts who have extensive experience with the development and manufacturing of animal-derived pharmaceutical products. We have also established a laboratory exclusively for Corticotropin analytical method development. The team has already achieved several key milestones, including identifying and initiating the development of analytical methods that will be required to re-commercialize Corticotropin, a critical portion of the sNDA filing. At the same time, we have also secured the supply of porcine pituitaries necessary for both small and commercial-scale active pharmaceutical ingredient manufacturing, which is also pivotal for the re-launch of Corticotropin. Finally, we have contracted with an accomplished and experienced contract manufacturer and initiated manufacturing of Corticotropin active pharmaceutical ingredient. In 2016, we incurred a total of approximately $1.1 million of research and development and sales, general, and administrative expense in support of the re-commercialization of the Corticotropin products.

Also in January 2016, we acquired from H2-Pharma LLC (“H2”) the exclusive rights to distribute an authorized generic of Lipofen® (fenofibrate capsules) and 1% and 2.5% hydrocortisone rectal cream for total consideration of $10.0 million. Fenofibrate is a peroxisome proliferator receptor alpha activator indicated as an adjunct with diet to reduce elevated LDL-C, Total-C, TG and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia. Fenofibrate is also indicated as an adjunct with diet for adult patients with severe hypertriglyceridemia. Hydrocortisone rectal cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. In April 2016, we launched both strengths of the hydrocortisone rectal cream under our label, and in May 2016, we launched the authorized generic of Lipofen® under our label.

In April 2016, we acquired from Cranford Pharmaceuticals, LLC (“Cranford”) the rights, title, and interest in the NDA for Inderal LA, as well as certain documentation, trademark rights, and finished goods for $60.0 million in cash up front and milestone payments based on future gross profits from sales of products under the NDA. Inderal LA and its authorized generic, Propranolol ER, are indicated in the management of hypertension, to decrease angina frequency and increase exercise tolerance in patients with angina pectoris, for the prophylaxis of common migraine headache, and to improve New York Heart Association (“NYHA”) functional class in symptomatic patients with hypertrophic subaortic stenosis. We also launched the Inderal LA and Propranolol ER products in April 2016.

In July 2016, we received approval from the Food and Drug Administration ("FDA") of the ANDA for nilutamide tablets. Nilutamide tablets are indicated for use in combination with surgical castration for the treatment of metastatic prostate cancer. The nilutamide product was developed as part of our collaborative arrangement with Ricon, and we launched the product immediately following receipt of FDA approval.

In September 2016, we launched our Erythromycin Ethylsuccinate for Oral Suspension product, which is indicated in the treatment of infections caused by susceptible strains of designated organisms for selected diseases. This was the first product launch from the basket of ANDAs for 22 previously marketed generic drug products that we acquired in July 2015.

Including the launches noted above, we launched 11 total products in 2016, bringing our total product portfolio to 25 as of December 31, 2016.

General

The following table summarizes our results of operations for the years ended December 31, 2016, 2015, and 2014.

(in thousands)	Years Ended December 31,		
	2016	2015	2014
Net revenues	$ 128,622	$ 76,322	$ 55,970
Operating expenses			
Cost of sales (excluding depreciation and amortization)	48,780	12,692	11,473
Research and development	2,906	2,874	2,678
Selling, general, and administrative	27,829	21,156	17,935
Depreciation and amortization	22,343	6,900	3,878
Intangible asset impairment charge	6,685	-	-
Operating income	20,079	32,700	20,006
Interest expense, net	(11,327)	(11,008)	(787)
Other (expense)/income, net	(74)	41	160
Income before (provision)/benefit for income taxes	8,678	21,733	19,379
(Provision)/benefit for income taxes	(4,744)	(6,358)	9,368
Net income	$ 3,934	$ 15,375	$ 28,747

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

	Years Ended December 31,		
	2016	2015	2014
Net revenues	100.0%	100.0%	100.0%
Operating expenses			
Cost of sales (excluding depreciation and amortization)	37.9%	16.6%	20.5%
Research and development	2.3%	3.8%	4.8%
Selling, general, and administrative	21.6%	27.7%	32.1%
Depreciation and amortization	17.4%	9.1%	6.9%
Intangible asset impairment charge	5.2%	-%	-%
Operating income	15.6%	42.8%	35.7%
Interest expense, net	(8.8)%	(14.4)%	(1.4)%
Other (expense)/income, net	(0.1)%	0.1%	0.3%
Income before (provision)/benefit for income taxes	6.7%	28.5%	34.6%
(Provision)/benefit for income taxes	(3.7)%	(8.4)%	16.8%
Net income	3.0%	20.1%	51.4%

Results of Operations for the Years Ended December 31, 2016 and 2015

Net Revenues

(in thousands)	Years Ended December 31,			
	2016	2015	Change	% Change
Generic pharmaceutical products	$ 95,201	$ 55,169	$ 40,032	72.6%
Branded pharmaceutical products	26,443	11,003	15,440	140.3%
Contract manufacturing	5,537	4,883	654	13.4%
Contract services and other income	1,441	5,267	(3,826)	(72.6)%
Total net revenues	$ 128,622	$ 76,322	$ 52,300	68.5%

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 sales of certain products.

Net revenues for the year ended December 31, 2016 were $128.6 million compared to $76.3 million for the same period in 2015, an increase of $52.3 million, or 68.5%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $95.2 million during the year ended December 31, 2016, an increase of 72.6% compared to $55.2 million for the same period in 2015. The primary reason for the increase was sales of Propranolol ER and other products launched in the second quarter of 2016, sales of Nilutamide and Erythromycin Ethylsuccinate, both of which were launched in the third quarter of 2016, as well as a full year of sales of Vancomycin, which was launched under our own label in the fourth quarter of 2015. These increases were tempered by volume decreases in Esterified Estrogen with Methyltestosterone (“EEMT”) sales. In 2017, we anticipate increases in generic pharmaceutical product revenues related to our recently-launched products, as well as additional products we expect to launch in 2017.

  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, 2016 and 2015 were $34.3 million and $44.3 million, respectively.

- Net revenues for branded pharmaceutical products were $26.4 million during the year ended December 31, 2016 an increase of 140.3% compared to the $11.0 million for the same period in 2015. The primary reason for the increase was sales of Inderal LA, which was launched in the second quarter of 2016 and, to a lesser extent, by increased unit sales of Vancocin. The increase was partially offset by lower unit sales of Reglan due to decreased purchases by a customer and decreased unit sales for Lithobid. We experience periodic larger orders for our Vancocin product that relate to clinical trials. Such orders constituted $2.4 million and $2.1 million of our branded pharmaceutical product revenue for the years ended December 31, 2016 and 2015, respectively, and we cannot be sure that such purchases will occur in future periods. In 2017, we anticipate increases in branded pharmaceutical product revenues related to a full year of sales of Inderal LA.

- Contract manufacturing revenues were $5.5 million during the year ended December 31, 2016, an increase of 13.4% compared to $4.9 million for the same period in 2015, 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, 2016 and 2015 were $1.5 million and $1.6 million, respectively.

- Contract services and other income were $1.4 million during the year ended December 31, 2016, a decrease of 72.6% from $5.3 million for the same period in 2015, due primarily to the lack of royalties received on sales of the authorized generic of Vancocin. In the fourth quarter of 2015, we launched an authorized generic of Vancocin under our own label, which replaced the authorized generic product previously on the market. This decrease was partially offset by royalties related to sales of Fenofibrate, the authorized generic of Lipofen®, the marketing and distribution rights to which we acquired in January 2016. We launched Fenofibrate under our own label in the second quarter of 2016. In the fourth quarter of 2016, we also received a $0.6 million royalty payment related to a license for patent rights initially owned by Cell Genesys, which merged with BioSante in 2009. We cannot predict the level of this royalty stream, or if it will continue, in future periods.

  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 less than 1% of total revenues for the years ended December 31, 2016 and 2015.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Years Ended December 31,			
	2016	2015	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 48,780	$ 12,692	$ 36,088	284.3%

Cost of sales consists of direct labor, including manufacturing and packaging, active and inactive pharmaceutical ingredients, freight costs, packaging components, and royalties related to profit-sharing arrangements. Cost of sales does 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, 2016, cost of sales increased to $48.8 million from $12.7 million for the same period in 2015, an increase of $36.1 million or 284.3%, primarily as a result of increased sales of products subject to profit-sharing arrangements, as well as increased volumes and the impact on cost of sales of the excess of fair value over cost for Inderal LA and Propranolol ER inventory acquired in 2016 through an asset acquisition transaction, and subsequently sold during the period. We anticipate that our cost of sales will continue to increase in 2017, due to new product launches and the full year impact of sales of certain products launched in 2016 that are subject to profit-sharing arrangements.

Cost of sales as a percentage of net revenues increased to 37.9% during the year ended December 31, 2016, from 16.6% during same period in 2015, primarily as a result of increased sales of products subject to profit-sharing arrangements, a trend we expect to continue, and the $5.9 million impact on cost of sales (4.6% as a percent of net revenues) of the excess of fair value over cost for Inderal LA and Propranolol ER inventory sold during the period. We anticipate that our cost of sales as a percentage of net revenues will increase in 2017, due to the full year impact of sales of certain products launched in 2016 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 Active Pharmaceutical Ingredients ("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, 2016, we purchased 25% of our inventory from one supplier. As of December 31, 2016, amounts payable to this supplier were immaterial. In the year ended December 31, 2015, we purchased 33% of our inventory from two suppliers.

In order to manufacture Opium Tincture, Oxycodone oral solution, and Oxycodone capsules, we must submit a request to the Drug Enforcement Agency ("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, Oxycodone oral solution, and Oxycodone capsules.

Other Operating Expenses

(in thousands)	Years Ended December 31,			
	2016	2015	Change	% Change
Research and development	$ 2,906	$ 2,874	$ 32	1.1%
Selling, general, and administrative	27,829	21,156	6,673	31.5%
Depreciation and amortization	22,343	6,900	15,443	223.8%
Intangible asset impairment charge	6,685	-	6,685	NM(1)
Total other operating expenses	$ 59,763	$ 30,930	$ 28,833	93.2%

(1) Not Meaningful

Other operating expenses consist of research and development costs, selling, general, and administrative expenses, depreciation and amortization, and impairment charges.

For the year ended December 31, 2016, other operating expenses increased to $59.8 million from $30.9 million for the same period in 2015, an increase of $28.8 million, or 93.2%, primarily as a result of the following factors:

- Research and development expenses increased were $2.9 million during both years ended December 31, 2016 and 2015. The slight increase was due to timing of work on development projects. Current projects include work on the ANDAs purchased in 2014 and 2015, as well as the Corticotropin re-commercialization project and collaborations with partners. We anticipate that research and development costs will continue to increase in 2017, in support of our strategy to expand our product portfolio and as we continue to focus on the development of our Corticotropin products.

- Selling, general, and administrative expenses increased from $21.2 million to $27.8 million, an increase of 31.5%, primarily due to increased stock-based compensation expense and increases in personnel and related costs, including $1.3 million of expenses related to the transition of our CFO in the second quarter of 2016. All expense related to the transition was recognized in the second quarter of 2016. We anticipate that selling, general, and administrative expenses will continue to increase in 2017, as we support anticipated additional revenue growth.

- Depreciation and amortization increased from $6.9 million to $22.3 million, an increase of 223.8%, due primarily to the amortization of the NDAs for Corticotropin and Corticotropin-Zinc and marketing and distribution rights acquired from H2-Pharma, LLC, both of which were acquired in January 2016, and the amortization of the rights, title, and interest in the NDA for Inderal LA, which was acquired in April 2016, as well as recognizing a full year of amortization of the ANDAs acquired in July 2015. We anticipate that depreciation and amortization expense will continue to increase in 2017, as we recognize a full year of amortization on the product rights and NDA for Inderal LA.

- As discussed under Intangible Assets in our Critical Accounting Estimates, we recognized an impairment charge of $6.7 million in relation to our testosterone gel NDA asset during the year ended December 31, 2016. No impairment losses related to intangible assets were recognized in the year ended December 31, 2015.

Other Expense, net

(in thousands)	Years Ended December 31,			
	2016	2015	Change	% Change
Interest expense, net	$ (11,327)	$ (11,008)	$ (319)	2.9%
Other (expense)/income, net	(74)	41	(115)	(280.5)%
Total other expense, net	$ (11,401)	$ (10,967)	$ (434)	4.0%

For the year ended December 31, 2016, we recognized other expense, net of $11.4 million, a decrease of $0.4 million from other expense of $11.0 million for the same period in 2015. Interest expense, net for both periods consists primarily of interest expense on our convertible debt. For the years ended December 31, 2016 and 2015, there was $0.2 million and $56 thousand of interest capitalized into construction in progress, respectively.

Provision for Income Taxes

	Years Ended December 31,			
	2016	2015	Change	% Change
Provision for income taxes	$ (4,744)	$ (6,358)	$ 1,614	(25.4)%

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.

For the year ended December 31, 2016, we recognized income tax expense of $4.7 million, versus $6.4 million in the prior year period, a provision decrease of $1.6 million. Of the $4.7 million of total tax expense, $13.0 million is current expense, $0.6 million is the impact on the provision related to the excess tax benefit from stock-based compensation awards, and $0.1 million is a change in valuation allowance. These were partially offset by a $9.0 million net deferred tax benefit.

The effective tax rate for the year ended December 31, 2016 was 54.7% of pre-tax income reported in the period. The effective tax rate for the period was primarily driven by permanent differences related to our international tax structure surrounding our Corticotropin NDAs, which resulted in significant non-deductible amortization, research and development expenses, and interest expense in 2016. In addition, the effective tax rate was impacted by other permanent differences, changes in temporary differences, and by the tax effect of discreet items. These discreet items included changes in our estimated pre-tax income resulting from various asset acquisitions that occurred during the periods and associated changes to temporary differences arising from those asset acquisitions, changes in temporary differences as a result of our impairment charge related to our testosterone gel NDA asset, as well as the impact of current period awards of stock-based compensation, stock option exercises, vesting of restricted stock, and disqualifying dispositions of incentive stock options, all of which impact the estimated annual effective rate in the period in which they occur. We expect that our effective tax rate for 2017 may be lower than that in 2016 as a result of the dissolution of the international tax structure surrounding our Corticotropin NDAs.

The effective tax rate for the year ended December 31, 2015 was 29.3% of pre-tax income reported in the period. The effective tax rate for the period was primarily driven by changes in temporary differences, permanent differences, state income tax rates, and the impact of awards of stock-based compensation, stock option exercises, vesting of restricted stock, and disqualifying dispositions of incentive stock options, all of which impact the estimated annual effective rate in the period in which they occur.

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.

  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, 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. We experience periodic larger orders for our Vancocin product that relate to clinical trials. Such orders constituted $2.1 million of our branded pharmaceutical product revenue for the year ended December 31, 2015.

- 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 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 less than 1% of total revenues 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. 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.

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.

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 in 2014 and 2015 and collaborations with partners.

- 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.

- 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.

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, net of $11.0 million, an increase of $10.4 million from other expense of $0.6 million for the same period in 2014. 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)%

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.

Liquidity and Capital Resources

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

(in thousands)	December 31,	
	2016	2015
Cash and cash equivalents	$ 27,365	$ 154,684
Accounts receivable, net	45,895	21,932
Inventories, net	26,183	13,387
Prepaid income taxes	-	1,127
Prepaid expenses and other current assets	3,564	1,453
Total current assets	$ 103,007	$ 192,583
Accounts payable	$ 3,399	$ 2,066
Accrued expenses and other	927	617
Accrued royalties	11,956	606
Accrued compensation and related expenses	1,631	1,188
Current income taxes payable	2,398	-
Accrued government rebates	5,891	4,631
Returned goods reserve	5,756	2,648
Total current liabilities	$ 31,948	$ 11,756

At December 31, 2016, we had $27.4 million in unrestricted cash and cash equivalents. At December 31, 2015, we had $154.7 million in unrestricted cash and cash equivalents. We generated $27.5 million of cash from operations in the year ended December 31, 2016. In the first quarter of 2016, we purchased from Merck Sharp & Dohme B.V. the NDAs and associated product rights and manufacturing licenses for Corticotropin and Corticotropin-Zinc for $75.0 million in cash and a percentage of future net sales of the products under the NDAs. In the first quarter of 2016 we purchased from H2-Pharma, LLC the rights to market, sell, and distribute two products for $8.8 million in cash and the assumption of an accrued royalty of $1.2 million, for a total of $10.0 million in consideration. In the second quarter of 2016, we purchased from Cranford Pharmaceuticals, LLC the rights, title, and interest in the NDA for Inderal LA, as well as certain documentation, trademark rights, and finished goods for $60.0 million in cash and milestone payments based on future gross profits from sales of products under the NDA. In addition, at closing, we transferred $5.0 million to an escrow account as security for future milestone payments.

In May 2016, we entered into a credit arrangement (the “Line of Credit”) with Citizens Bank Capital, a division of Citizens Asset Finance, Inc. that provided for a $30.0 million asset-based revolving credit loan facility. As of December 31, 2016, we had no outstanding balance on the Line of Credit, and our available borrowing base was $30.0 million.

In February 2017, we entered into an agreement with Cranford Pharmaceuticals, LLC to purchase a distribution license, trademark and certain finished goods inventory for Inderal® XL for $20.2 million in cash. The transaction closed in February 2017, and we made the $20.2 million cash payment using cash on hand.

In February 2017, we entered into an agreement with Holmdel Pharmaceuticals, LP to purchase the NDA, trademark and certain finished goods inventory for InnoPran XL®, including a license to an Orange Book listed patent, for $30.6 million in cash. The transaction closed in February 2017, and we made the $30.6 million cash payment using $30.0 million of funds from our Line of Credit (Note 2 of Item 8. Consolidated Financial Statements) and $0.6 million of 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.

Our working capital ratio, defined as total current assets divided by total current liabilities, is 3.2 as of December 31, 2016. 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.

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 28%, 22%, and 18% of net revenues during the year ended December 31, 2016. As of December 31, 2016, accounts receivable from these three customers totaled approximately 83% of accounts receivable, net. As a result, negotiated payment terms with these customers have a material impact on our liquidity and working capital.

Three of our pharmaceutical products, EEMT, Inderal LA, and Propranolol ER, accounted for approximately 44% of our net revenues in 2016. Two of our generic pharmaceutical products, EEMT and Opium Tincture, accounted for approximately 58% and 53% of net revenues in 2015 and 2014, 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. Increases and decreases in revenue related to these products have had a significant impact on our financial results and if revenues from any of these products 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 May 2016, we entered into a credit arrangement (the "Line of Credit") with Citizens Bank Capital, a division of Citizens Asset Finance, Inc. that provided for a $30.0 million asset-based revolving credit loan facility. As of December 31, 2016, we had no outstanding balance on the Line of Credit, and our available borrowing base was $30.0 million.

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.

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.

Customer Payments

In addition to the financings in prior years, payments from customers are a significant source of cash and were our primary source of cash in 2016 and 2015.

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.

Uses of Cash

Our primary cash requirements are to fund operations, including research and development programs and collaborations, to support general and administrative activities, to purchase equipment and machinery to expand our manufacturing capabilities as our product lines grow, 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.

In the first quarter of 2016, we purchased from Merck Sharp & Dohme B.V. the NDAs and associated product rights and manufacturing licenses for Corticotropin and Corticotropin-Zinc for $75.0 million in cash and a percentage of future net sales of the products under the NDAs. In the first quarter of 2016 we purchased from H2-Pharma, LLC the rights to market, sell, and distribute two products for $8.8 million in cash and the assumption of an accrued royalty of $1.2 million, for a total of $10.0 million in consideration. In the second quarter of 2016, we purchased from Cranford Pharmaceuticals, LLC the rights, title, and interest in the NDA for Inderal LA, as well as certain documentation, trademark rights, and finished goods for $60.0 million in cash and milestone payments based on future gross profits from sales of products under the NDA. At closing, we also transferred $5.0 million to an escrow account as security for future milestone payments. In 2016, we had $4.6 million of capital expenditures.

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 in cash at closing and a $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 2015, we had $2.2 million of capital expenditures.

In the first quarter of 2014, we acquired the ANDAs related to 31 products for $12.5 million. In the third quarter of 2014, we acquired the product rights and NDA for 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. Also in the third quarter of 2014, we acquired the U.S. intellectual property rights and NDA for Vancocin, as well as two related ANDAs and certain equipment and inventory, for $11.0 million. In 2014, we had $1.1 million of capital expenditures.

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,		
	2016	**2015**	**2014**
Operating Activities	$ 27,472	$ 17,264	$ 22,033
Investing Activities	$ (154,062)	$ (32,683)	$ (35,754)
Financing Activities	$ (729)	$ 1,066	$ 171,653

Net Cash Provided by Operating Activities

Net cash provided by operating activities was $27.5 million for the year ended December 31, 2016, compared to $17.3 million during the same period in 2015, an increase of $10.2 million between the periods. This increase was principally due to increased sales volume and corresponding gross profit dollars, somewhat tempered by increased expenditures in support of the growth of the business.

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 increased expenditures in support of the growth of the business, partially offset by increased sales volume and corresponding gross profit dollars.

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2016 was $154.1 million, principally due to the January 2016 asset acquisition of the NDAs for Corticotropin and Corticotropin-Zinc for $75.0 million, the January 2016 payment of $8.8 million to H2-Pharma, LLC for marketing and distribution rights associated with two products, the April 2016 payment of $60.0 million for the asset acquisition of the NDA for Inderal LA, an increase in restricted cash of $5.0 million from the transfer of $5.0 million to an escrow account as security for future milestone payments in relation to the Inderal LA asset acquisition, and $4.6 million of capital expenditures during the period.

Net cash used in investing activities was $32.7 million for the year ended December 31, 2015, 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 (Used In)/Provided by Financing Activities

Net cash used in financing activities was $0.7 million for the year ended December 31, 2016, principally due to the $2.5 million repurchase of the Company's common stock under our Stock Repurchase Program and $0.3 million of debt issuance costs paid in relation to the Line of Credit, partially offset by $1.6 million of proceeds from stock option exercises and $0.6 million of excess tax benefit from share-based compensation awards.

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 .

Contractual Obligations

The following table summarizes our long-term contractual obligations and commitments as of December 31, 2016.

(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]	12,579	4,313	8,266	-	-
Operating lease obligations	349	99	163	87	-
Purchase obligations [3]	16,616	10,675	5,141	800	-
Total	$ 173,294	$ 15,087	$ 157,320	$ 887	$ -

[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 2, 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] Purchase obligations primarily includes contractual obligations for inventory purchase minimums and service agreements.

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, government 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.

We record revenue related to marketing and distribution agreements with third parties in which we sell products under ANDAs or NDAs owned or licensed by these third parties. We have assessed and determined that we are the principal for sales under each of these marketing and distribution agreements and recognize the revenue on a gross basis when risk and title are passed 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. Under these agreements, we pay these third parties a specified percentage of the gross profit earned on sales of the products. These profit-sharing percentages are recognized in cost of sales in our consolidated statements of earnings and are accrued in accrued royalties in our consolidated balance sheets until payment has occurred.

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 $1.4 million, $5.3 million, and $3.2 million of revenue related to contract services in 2016, 2015, and 2014, 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, 2016, 2015, and 2014. 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, our net revenues would be affected by $15.3 million for the year ended December 31, 2016.

Accruals for Chargebacks, Rebates, Returns, and Other Allowances

Our generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, government 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. Due to our substantial increase in sales from 2015 to 2016, our accruals for chargebacks, government rebates, product returns, administrative fees and other rebates, and prompt payment discounts increased significantly in the year ended December 31, 2016. We anticipate that these accruals will continue to increase in 2017 as we recognize a full year of sales of products launched in 2016, as well as additional products we expect to launch in 2017.

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 government 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 customers, Medicare, and state and federal 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, 2016, 2015, and 2014. 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 would be affected by $11.4 million for the year ended December 31, 2016.

Government Rebates

As discussed in Note 1 of Item 8. Consolidated Financial Statements, our estimates for government rebates are based upon several factors. Our estimates for Medicaid rebates are 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. Our estimates for Medicare rebates are based on historical experience. 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 and Medicare enrollment and which products are covered by Medicaid and Medicare could change.

We have not made any material changes to our policy for estimating government rebates during the years ended December 31, 2016, 2015, and 2014. We anticipate that we will have further increases in our quarterly Medicaid rebate amounts related to sales of our Fenofibrate, Inderal LA, Lithobid and Vancocin products and increases in our quarterly Medicare rebates related to sales of our Fenofibrate and Inderal LA products. If actual results were not consistent with our estimates, we could be exposed to losses or gains that could be material, as changes to government rebate estimates could cause an increase or decrease in revenue recognized during the year and decrease or increase the government rebate reserve. If there were a 10% change in the government rebate estimates throughout the year, our net revenues would be affected by $1.0 million for the year ended December 31, 2016.

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, 2016, 2015, and 2014. 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 would be affected by $1.0 million for the year ended December 31, 2016.

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, 2016, 2015, and 2014. 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 would be affected by $1.3 million for the year ended December 31, 2016.

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, 2016, 2015, and 2014. 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 would increase by $0.6 million for the year ended December 31, 2016.

Intangible Assets

As discussed in Note 1 of Item 8. Consolidated Financial Statements, our definite-lived intangible assets have a carrying value of $175.8 million as of December 31, 2016. These assets include ANDAs, NDAs and product rights, marketing and distribution rights, and a non-compete agreement. These intangible assets were originally 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 product rights, marketing and distribution rights, and non-compete agreement are amortized over their remaining estimated useful lives, ranging from two to 10 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. If the fair value of an intangible asset is determined to be lower than its carrying value, we could be exposed to an impairment charge that could be material.

In conjunction with our 2013 merger with BioSante (the "Merger"), we acquired a testosterone gel product that was licensed to Teva (the "Testosterone Gel NDA") and this product was assigned an intangible asset value of $10.9 million in accounting for the Merger. In May 2015, Teva transferred the rights of the product back to ANI. In exchange, we will pay Teva a royalty of up to $5.0 million, at a rate of 5% of the consideration we receive as a result of commercial sale of the product. We assessed the value of the Testosterone Gel NDA under the new arrangement and determined that the net asset value was recoverable as of the May 2015 transfer date and subsequent balance sheet dates. We began the commercialization process for the product during the second half of 2015 and it continued throughout 2016. In late 2016, we determined that the development and manufacturing costs required to commercialize the product had increased and would pose a significant barrier to commercializing the product ourselves. Generic competition in the testosterone replacement market had increased substantially by the end of 2016, leading to significant decreases in pricing for the product. In the fourth quarter, management began putting forth efforts to sell the Testosterone Gel NDA rather than commercialize it ourselves. As a result of all these factors, in the fourth quarter of 2016, we determined that the facts and circumstances indicated that the asset could be impaired. We performed an impairment assessment, which indicated that the fair value of the asset was lower than the carrying value. We determined the fair value of the Testosterone Gel NDA by using a discounted cash flows model. As a result of this assessment, we recorded an intangible asset impairment of $6.7 million in the year ended December 31, 2016. We also determined in the fourth quarter of 2016 that the asset met the criteria for being held for sale. The Testosterone Gel NDA is now recorded as a short-term asset held for sale in the prepaid expenses and other assets caption in the accompanying consolidated balance sheets at $0.9 million, which is the fair value of the asset less estimated costs to sell. We are no longer amortizing the Testosterone Gel NDA.

No events or circumstances arose in 2016 that indicated that the carrying value of any of our other definite-lived intangible assets may not be recoverable. If the fair value of an intangible asset is determined to be lower than its carrying value, we could be exposed to an impairment charge that could be material.

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, 2016 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

Our Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan") includes stock options and restricted stock, which are awarded in exchange for employee and non-employee director services. In July 2016, we commenced administration of our Employee Stock Purchase Plan ("ESPP"). In 2016, the stock-based compensation expense related to the ESPP was $25 thousand. 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 incurred under the 2008 Plan and included in our consolidated statements of earnings:

(in thousands)	Years Ended December 31,		
	2016	2015	2014
Cost of sales	$ 60	$ 82	$ 104
Research and development	$ 112	$ 109	$ 69
Selling, general, and administrative	$ 5,870	$ 3,665	$ 3,250

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, and future employee stock option exercise behaviors. Changes in these assumptions can affect the fair value estimate.

Through 2016, we have estimated the awards that will ultimately vest, using 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. As of January 1, 2017, in accordance with new guidance from the Financial Accounting Standards Board ("FASB"), we will no longer estimate forfeitures, instead we will account for forfeitures as they occur. 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 before (Provision)/Benefit for Income Taxes would be affected by $0.6 million for the year ended December 31, 2016.

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 Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In January 2017, the FASB issued guidance to simplify the measurement of goodwill. The guidance eliminates Step 2 from the goodwill impairment test. Instead, under the amendments in this guidance, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss. The guidance also eliminates the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted for interim or annual goodwill impairment tests performed for testing dates after January 1, 2017. The guidance must be adopted on a prospective basis. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

In January 2017, the FASB issued guidance clarifying the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities is not a business, provides a framework to assist entities in evaluating whether both an input and substantive process are present, and narrows the definition of the term output. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The guidance must be adopted on a prospective basis. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

In November 2016, the FASB issued guidance to reduce diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The revised guidance requires that amounts generally described as restricted cash and restricted cash equivalents be included in with cash and cash equivalents when reconciling the beginning of period and end of period total amounts shown on the statement of cash flows. The guidance is effective for the fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis. We will adopt this guidance as of January 1, 2017, on a retrospective basis, and all periods will be presented under this guidance. The adoption of this new guidance will result in the inclusion of our $5.0 million of restricted cash in the cash and cash equivalents balance in our consolidated statement of cash flows for all reporting periods presented in 2017 and onward.

In August 2016, the FASB issued guidance on the classification of certain cash receipts and cash payments in the statement of cash flows, including those related to debt prepayment or debt extinguishment costs, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance, and distributions received from equity method investees. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis and must be applied to all periods presented, but may be applied prospectively if retrospective application would be impracticable. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated statements of cash flows.

In June 2016, the FASB issued guidance with respect to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The adoption of certain amendments of this guidance must be applied on a modified retrospective basis and the adoption of the remaining amendments must be applied on a prospective basis. We currently expect that the adoption of this guidance will likely change the way we assess the collectability of our receivables and recoverability of other financial instruments. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

In March 2016, the FASB issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards, consisting of changes in the accounting for excess tax benefits and tax deficiencies, and changes in the accounting for forfeitures associated with share-based awards, among other things. We will adopt this guidance as of January 1, 2017. Pursuant to the adoption requirements for excess tax benefits and tax deficiencies, we will no longer recognize excess tax benefits or tax deficiencies in APIC; rather, we will recognize them prospectively as a component of our current period income tax expense. We will not reverse our current APIC pool, which was $3.1 million as of December 31, 2016, and we will present the impact of classifying excess tax benefits as an operating activity in the Statement of Cash Flows on a prospective basis. Pursuant to the adoption requirements for forfeitures, we will account for forfeitures as they occur rather than using an estimated forfeiture rate; we estimate that this change in accounting will result in a $14 thousand cumulative-effect adjustment increasing our accumulated deficit as of January 1, 2017. The adoption of the remaining amendments is not expected to have a material impact on our consolidated financial statements.

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We currently expect that the adoption of this guidance will likely change the way we account for our operating leases and will likely result in recording the future benefits of those leases and the related minimum lease payments on our consolidated balance sheets. We have not yet begun to evaluate the specific impacts of this guidance.

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. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. We do not intend to adopt the guidance early. We expect that the adoption of this guidance will likely change the way we recognize revenue generated under customer contracts. However, we are currently reviewing our contracts with customers to determine if the accounting for these contracts will be impacted by the adoption of this guidance and, if so, if that impact will be material to our consolidated financial statements. We have not yet determined the manner in which we will adopt this guidance.

Recently Adopted Accounting Pronouncements

In March 2016, the FASB issued guidance to clarify the requirements for assessing whether contingent call or put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. The amendments of this guidance were effective for reporting periods beginning after December 15, 2016, and early adoption was permitted. Entities were required to apply the guidance to existing debt instruments using a modified retrospective transition method as of the beginning of the fiscal year of adoption. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a modified retrospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

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 the last in first out ("LIFO") method 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 was effective for reporting periods beginning after December 15, 2016. The guidance was required to be applied prospectively, with earlier application permitted. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated 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 was effective for reporting periods beginning after December 15, 2015, and could be adopted on either a prospective or retrospective basis. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In August 2014, the FASB issued guidance requiring management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity's ability to continue as a going concern. The guidance 1) provides a definition for the term "substantial doubt," 2) requires an evaluation every reporting period, interim periods included, 3) provides principles for considering the mitigating effect of management's plans to alleviate the substantial doubt, 4) requires certain disclosures if the substantial doubt is alleviated as a result of management's plans, 5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and 6) requires an assessment period of one year from the date the financial statements are issued. The guidance was effective for reporting periods ending after December 15, 2016, and early adoption was permitted. We adopted this guidance effective January 1, 2016. The adoption of this guidance did not have a material impact on our consolidated financial statements.

Off-Balance Sheet Arrangements

As of December 31, 2016, 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, equity risk, foreign currency exchange rate risk, commodity price risk, and other relevant market rate or price risks. Of these risks, interest rate risk and equity risk could have a significant impact on our results of operations.

As of December 31, 2016, our principal 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 changes, the fair value of our Notes, and their likelihood of being converted, will change accordingly. As a result, we face equity risk in relation to our Notes.

On May 12, 2016, we entered into a credit agreement (the "Line of Credit") with Citizens Business Capital, a division of Citizens Asset Finance, Inc. (the "Citizens Agreement"). The Citizens Agreement provides for a $30.0 million asset-based revolving credit loan facility. Amounts drawn bear an interest rate equal to, at our option, either a LIBOR rate plus 1.25%, 1.50%, or 1.75% per annum, depending upon availability under the Citizens Agreement or an alternative base rate plus either 0.25%, 0.50%, or 0.75% per annum, depending upon availability under the Citizens Agreement. We will incur a commitment fee on undrawn amounts equal to 0.25% per annum. As of December 31, 2016, we had no outstanding balance on the Line of Credit.

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, 2016 by approximately $3 thousand.

Item 8. CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
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, 2016 and 2015, 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, 2016. 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, 2016 and 2015, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2016 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, 2016, 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 March 2, 2017 expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

New York, New York
March 2, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
ANI Pharmaceuticals, Inc. and Subsidiaries

We have audited ANI Pharmaceuticals, Inc. and Subsidiaries' (the "Company") internal control over financial reporting as of December 31, 2016, 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.

An entity'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. An entity'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 entity are being made only in accordance with authorizations of management and directors of the entity; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the entity'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, 2016, 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, 2016 and 2015, 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, 2016, and our report dated March 2, 2017 expressed an unqualified opinion thereon.

/s/ EisnerAmper LLP

New York, New York
March 2, 2017

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

	December 31, 2016	*December 31, 2015*
Assets		
Current Assets		
Cash and cash equivalents	$ 27,365	$ 154,684
Accounts receivable, net of $31,535 and $13,586 of adjustments for chargebacks and other allowances at December 31, 2016 and 2015, respectively	45,895	21,932
Inventories, net	26,183	13,387
Prepaid income taxes	-	1,127
Prepaid expenses and other current assets	3,564	1,453
Total Current Assets	103,007	192,583
Property and equipment, net	10,998	7,131
Restricted cash	5,002	-
Deferred tax asset, net of valuation allowance	26,227	17,316
Intangible assets, net	175,792	66,397
Goodwill	1,838	1,838
Total Assets	$ 322,864	$ 285,265
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 3,389	$ 2,066
Accrued expenses and other	927	617
Accrued royalties	11,956	606
Accrued compensation and related expenses	1,631	1,188
Current income taxes payable	2,398	-
Accrued government rebates	5,891	4,631
Returned goods reserve	5,756	2,648
Total Current Liabilities	31,948	11,756
Long-term Liabilities		
Long-term royalties	625	-
Convertible notes, net of discount and deferred financing costs	120,643	113,427
Total Liabilities	$ 153,216	$ 125,183
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 11,588,701 shares issued and outstanding at December 31, 2016; 11,498,228 shares issued and outstanding at December 31, 2015	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at December 31, 2016 and 2015, respectively	-	-
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at December 31, 2016 and 2015, respectively	-	-
Additional paid-in capital	172,563	164,431
Accumulated deficit	(2,916)	(4,350)
Total Stockholders' Equity	169,648	160,082
Total Liabilities and Stockholders' Equity	$ 322,864	$ 285,265

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,		
	2016	*2015*	*2014*
Net Revenues	$ 128,622	$ 76,322	$ 55,970
Operating Expenses			
Cost of sales (excluding depreciation and amortization)	48,780	12,692	11,473
Research and development	2,906	2,874	2,678
Selling, general, and administrative	27,829	21,156	17,935
Depreciation and amortization	22,343	6,900	3,878
Intangible asset impairment charge	6,685	-	-
Total Operating Expenses	108,543	43,622	35,964
Operating Income	20,079	32,700	20,006
Other Expense, net			
Interest expense, net	(11,327)	(11,008)	(787)
Other (expense)/income, net	(74)	41	160
Income Before (Provision)/Benefit for Income Taxes	8,678	21,733	19,379
(Provision)/benefit for income taxes	(4,744)	(6,358)	9,368
Net Income	$ 3,934	$ 15,375	$ 28,747
Basic and Diluted Earnings Per Share:			
Basic Earnings Per Share	$ 0.34	$ 1.34	$ 2.61
Diluted Earnings Per Share	$ 0.34	$ 1.32	$ 2.59
Basic Weighted-Average Shares Outstanding	11,445	11,370	10,941
Diluted Weighted-Average Shares Outstanding	11,573	11,557	11,053

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, 2016, 2015, and 2014
(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, 2013	$ 1	9,629	$ -	$ 89,501	9	$ (68)	$ (48,472)	$ 40,962
Stock-based Compensation Expense	-	-	-	3,423	-	-	-	3,423
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 Stock-based Compensation Arrangements	-	-	-	-	7	(113)	-	(113)
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
Stock-based Compensation Expense	-	-	-	6,067	-	-	-	6,067
Changes in Treasury Stock Related to Stock-based Compensation Arrangements	-	-	-	-	10	(122)	-	(122)
Issuance of Common Shares upon Stock Option and ESPP Exercise	-	119	-	1,448	(10)	122	-	1,570
Repurchase of Common Stock under Stock Repurchase Program	-	(65)	-	-	-	-	(2,500)	(2,500)
Issuance of Restricted Stock Awards	-	37	-	-	-	-	-	-
Excess Tax Benefit from Share-based Compensation Awards	-	-	-	617	-	-	-	617
Net Income	-	-	-	-	-	-	3,934	3,934
Balance, December 31, 2016	$ 1	11,589	$ -	$ 172,563	-	$ -	$ (2,916)	$ 169,648

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,	*2016*	*2015*	*2014*
Cash Flows From Operating Activities			
Net income	$ 3,934	$ 15,375	$ 28,747
Adjustments to reconcile net loss to net cash and cash equivalents provided by operating activities:			
Stock-based compensation	6,067	3,856	3,423
Deferred taxes	(8,911)	(1,877)	(14,459)
Depreciation and amortization	22,343	6,900	3,878
Non-cash interest relating to convertible notes and loan cost amortization	7,281	6,831	559
Intangible asset impairment charge	6,685	-	-
Changes in operating assets and liabilities:			
Accounts receivable, net	(23,963)	(4,635)	(4,784)
Inventories, net	(1,938)	(5,869)	(3,468)
Prepaid expenses and other current assets	(647)	(314)	(558)
Accounts payable	1,076	(1,027)	225
Accrued royalties	6,269	(96)	702
Accrued compensation and related expenses	443	(160)	575
Current income taxes, net	3,525	(5,380)	4,233
Accrued government rebates	1,260	2,367	2,011
Returned goods reserve	3,108	1,203	709
Accrued expenses and other	940	90	240
Net Cash and Cash Equivalents Provided by Operating Activities	27,472	17,264	22,033
Cash Flows From Investing Activities			
Changes in restricted cash	(5,002)	-	-
Acquisition of product rights and other related assets	(144,494)	(30,500)	(34,634)
Acquisition of property and equipment	(4,566)	(2,183)	(1,120)
Net Cash and Cash Equivalents Used in Investing Activities	(154,062)	(32,683)	(35,754)
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)
Payment of debt issuance costs	(294)	-	-
Proceeds from stock option exercises	1,570	819	819
Proceeds from warrant exercise	-	-	750
Excess tax benefit from share-based compensation awards	617	360	784
Repurchase of common stock under the stock repurchase program	(2,500)	-	-
Treasury stock purchases for restricted stock vestings and forfeitures	(122)	(113)	-
Net Cash and Cash Equivalents (Used in)/Provided by Financing Activities	(729)	1,066	171,653
Change in Cash and Cash Equivalents	(127,319)	(14,353)	157,932
Cash and cash equivalents, beginning of period	154,684	169,037	11,105
Cash and cash equivalents, end of period	$ 27,365	$ 154,684	$ 169,037
Supplemental disclosure for cash flow information:			
Cash paid for interest, net of amounts capitalized	$ 4,078	$ 4,149	$ -
Cash paid for income taxes, net	$ 9,537	$ 13,255	$ 147
Supplemental non-cash investing and financing activities:			
Accrued royalties related to asset purchase	$ 3,882	$ -	$ -
Property and equipment purchased and included in accounts payable	$ 247	$ 439	$ -

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

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 an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. ANI was organized as a Delaware corporation in April 2001. At our two facilities located in Baudette, Minnesota, we manufacture oral solid dose products, as well as liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. 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"), 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 12 months following the issuance of this report.

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.

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.

Foreign Currency

The company has subsidiaries located outside of the U.S. All existing subsidiaries currently conduct substantially all their transactions in U.S. dollars, or are otherwise dependent upon the U.S. parent for funding. Accordingly, these subsidiaries use the U.S. dollar as their functional currency. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar.

Foreign currency transaction gains and losses are included in the determination of net income.

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, administrative fees and rebates, government 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, purchase price allocations, and the depreciable lives of long-lived assets. Because of the uncertainties inherent in such estimates, actual results could differ from those estimates.

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

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, 2016, three customers represented approximately 28%, 22%, and 18% of net revenues, respectively. As of December 31, 2016, accounts receivable from these customers totaled 83% of net accounts receivable. During the year ended December 31, 2015, three customers represented approximately 26%, 20%, and 18% of net revenues, respectively. During the year ended December 31, 2014, three customers represented approximately 30%, 25%, and 14% of net revenues, respectively.

Vendor Concentration

We source the raw materials for products, including active pharmaceutical ingredients ("API"), from both domestic and international suppliers. 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. As a result, we are dependent upon our current vendors to supply reliably the API required for ongoing product manufacturing. During the year ended December 31, 2016, we purchased approximately 25% of our inventory from one supplier. As of December 31, 2016, amounts payable to this supplier were immaterial. During the year ended December 31, 2015, we purchased approximately 33% of our inventory from two suppliers. During the year ended December 31, 2014, we purchased approximately 42% of our inventory from two suppliers.

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.

We record revenue related to marketing and distribution agreements with third parties in which we sell products under Abbreviated New Drug Applications ("ANDAs") or New Drug Applications ("NDAs") owned or licensed by these third parties. We have assessed and determined that we are the principal for sales under each of these marketing and distribution agreements and recognize the revenue on a gross basis when risk and title are passed 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. Under these agreements, we pay these third parties a specified percentage of the gross profit earned on sales of the products. These profit-sharing percentages are recognized in cost of sales in our consolidated statements of earnings and are accrued in accrued royalties in our consolidated balance sheets until payment has occurred.

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.

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

Cash and Cash Equivalents

We consider all highly liquid instruments with maturities of three months or less when purchased to be cash equivalents. All interest bearing and non-interest bearing accounts are guaranteed by the Federal Deposit Insurance Corporation ("FDIC") up to $250 thousand. The majority of our cash balances are in excess of FDIC coverage. We consider this to be a normal business risk.

Accounts Receivable

We extend credit to customers on an unsecured basis. We use the allowance method to provide for doubtful accounts based on our evaluation of the collectability of accounts receivable, whereby we provide an allowance for doubtful accounts equal to the estimated uncollectible amounts. Our estimate is based on historical collection experience and a review of the current status of trade accounts receivable. We determine trade receivables to be delinquent when greater than 30 days past due. Receivables are written off when it is determined that amounts are uncollectible. We determined that no allowance for doubtful accounts was necessary as of December 31, 2016 and 2015.

Accruals for Chargebacks, Rebates, Returns, and Other Allowances

Our generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, government 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 exceed 50% of generic and branded gross product sales, 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. Due to our substantial increase in sales from 2015 to 2016, our accruals for chargebacks, government rebates, product returns, administrative fees and other rebates, and prompt payment discounts increased significantly in the year ended December 31, 2016. We anticipate that these accruals will continue to increase in 2017 as we recognize a full year of sales of products launched in 2016, as well as additional products we expect to launch in 2017.

We continually monitor and re-evaluate the accruals as additional information becomes available, which includes, among other things, trade inventory levels, customer product mix, products returned by customers, and trends in government rebates experience. We adjust 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 upon issuance of credit to the customer.

Chargebacks

Chargebacks, primarily from wholesalers, result from arrangements we have with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide a chargeback credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price, typically Wholesale Acquisition Cost ("WAC").

Chargeback credits are calculated as follows:

Prior period chargebacks claimed by wholesalers are analyzed to determine the actual average selling price ("ASP") for each product. This calculation is performed by product by wholesaler. ASPs can be affected by several factors such as:

- A change in customer mix
- A change in negotiated terms with customers
- A change in the volume of off-contract purchases
- Changes in WAC

As necessary, we adjust ASPs based on anticipated changes in the factors above.

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

The difference between ASP and WAC is recorded as a reduction in both gross revenues in the consolidated statements of earnings and accounts receivable in the consolidated balance sheets, at the time we recognize revenue from the product sale.

To evaluate the adequacy of our chargeback accruals, we obtain on-hand inventory counts from the wholesalers. This inventory is multiplied by the chargeback amount, the difference between ASP and WAC, to arrive at total expected future chargebacks, which is then compared to the chargeback accruals. We continually monitor chargeback activity and adjust ASPs when we believe that actual selling prices will differ from current ASPs.

Government Rebates

Our government rebates reserve consists of estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. The two largest government programs that impact our net revenue and our government rebates reserve are federal and state Medicaid rebate programs and Medicare.

We participate in certain qualifying federal and state Medicaid rebate programs whereby discounts and rebates are provided to participating programs after the final dispensing of the product by a pharmacy to a Medicaid plan participant. Medicaid rebates are typically billed up to 120 days after the product is shipped. Medicaid rebate amounts per product unit are established by law, based on the Average Manufacturer Price ("AMP"), which is reported on a monthly and quarterly basis, and, in the case of branded products, best price, which is reported on a quarterly basis. Our Medicaid reserves are based on expected claims from state Medicaid programs. Estimates for expected claims are driven by patient usage, sales mix, calculated AMP or best price, as well as inventory in the distribution channel that will be subject to a Medicaid rebate. As a result of the delay between selling the products and rebate billing, our Medicaid rebate reserve includes both an estimate of outstanding claims for end-customer sales that have occurred but for which the related claim has not been billed, as well as an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants.

Many of our products are also covered under Medicare. We, like all pharmaceutical companies, must provide a discount for any products sold under NDAs to Medicare Part D participants. This applies to all products sold under NDAs, regardless of whether the products are marketed as branded or generic. Our estimates for these discounts are based on historical experience with Medicare rebates for our products. While such experience has allowed for reasonable estimations in the past, history may not always be an accurate indicator of future rebates. Medicare rebates are typically billed up to 120 days after the product is shipped. As a result of the delay between selling the products and rebate billing, our Medicare rebate reserve includes both an estimate of outstanding claims for end-customer sales that have occurred but for which the related claim has not been billed, as well as an estimate for future claims that will be made when inventory in the distribution channel is sold through to Medicare Part D participants.

To evaluate the adequacy of our government rebate reserves, we review the reserves on a quarterly basis against actual claims data to ensure the liability is fairly stated. We continually monitor our government rebate reserve and adjust our estimates if we believe that actual government rebates may differ from our established accruals. Accruals for government rebates are recorded as a reduction to gross revenues in the consolidated statements of earnings and as an increase to accrued government rebates in the consolidated balance sheets.

Returns

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. Our product returns are settled through the issuance of a credit to the customer. Our estimate for returns is based upon 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 continually monitor our estimates for returns and make adjustments when we believe that actual product returns may differ from the established accruals. Accruals for returns are recorded as a reduction to gross revenues in the consolidated statements of earnings and as an increase to the return goods reserve in the consolidated balance sheets.

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

Administrative Fees and Other Rebates

Administrative fees or rebates are offered to wholesalers, group purchasing organizations and indirect customers. We accrue for fees and rebates, by product by wholesaler, at the time of sale based on contracted rates and ASPs.

To evaluate the adequacy of our administrative fee accruals, we obtain on-hand inventory counts from the wholesalers. This inventory is multiplied by the ASPs to arrive at total expected future sales, which is then multiplied by contracted rates. The result is then compared to the administrative fee accruals. We continually monitor administrative fee activity and adjust our accruals when we believe that actual administrative fees will differ from the accruals. Accruals for administrative fees and other rebates are recorded as a reduction in both gross revenues in the consolidated statements of earnings and accounts receivable in the consolidated balance sheets.

Prompt Payment Discounts

We often grant sales discounts for prompt payment. The reserve for prompt payment discounts is based on invoices outstanding. We assume, based on past experience, that all available discounts will be taken. Accruals for prompt payment discounts are recorded as a reduction in both gross revenues in the consolidated statements of earnings and accounts receivable in the consolidated balance sheets.

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the years ended December 31, 2016, 2015, and 2014:

(in thousands)	Accruals for Chargebacks, Returns, and Other Allowances				
	Chargebacks	Government Rebates	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2013	$ 4,076	$ 253	$ 736	$ 735	$ 332
Accruals/Adjustments	35,740	2,692	1,493	5,212	1,820
Credits Taken Against Reserve	(32,951)	(681)	(784)	(4,460)	(1,681)
Balance at December 31, 2014	$ 6,865	$ 2,264	$ 1,445	$ 1,487	$ 471
Accruals/Adjustments	51,933	6,719	2,808	6,136	2,744
Credits Taken Against Reserve	(47,417)	(4,352)	(1,605)	(5,970)	(2,541)
Balance at December 31, 2015	$ 11,381	$ 4,631	$ 2,648	$ 1,653	$ 674
Accruals/Adjustments	114,433	9,671	10,271	12,747	5,517
Credits Taken Against Reserve	(99,029)	(8,411)	(7,163)	(10,850)	(4,637)
Balance at December 31, 2016	$ 26,785	$ 5,891	$ 5,756	$ 3,550	$ 1,554

Inventories

Inventories consist of raw materials, packaging materials, work-in-progress, and finished goods. Inventories are stated at the lower of standard cost or net realizable value. We periodically review and adjust standard costs, which generally approximate weighted average cost.

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

Property and Equipment

Property and equipment are recorded at cost. Expenditures for repairs and maintenance are charged to expense as incurred. Depreciation is recorded on a straight-line basis over estimated useful lives as follows:

Buildings and improvements	20 - 40 years
Machinery, furniture, and equipment	3 - 10 years

Construction in progress consists of multiple projects, primarily related to new equipment to expand our manufacturing capability as our product lines continue to grow. Construction in progress includes the cost of construction and other direct costs attributable to the construction, along with capitalized interest. Depreciation is not recorded on construction in progress until such time as the assets are placed in service.

We review property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. No impairment loss related to property and equipment was recognized during the years ended December 31, 2016, 2015, and 2014. Assets held for disposal are reportable at the lower of the carrying amount or fair value, less costs to sell. No assets were held for disposal as of December 31, 2016 and 2015.

Intangible Assets

Intangible assets were acquired as part of the Merger and several asset purchase transactions. These assets include ANDAs for a total of 54 previously marketed generic products we acquired in 2014 and 2015, NDAs and product rights for our branded products Lithobid, Vancocin, Inderal LA, and Corticotropin, an NDA for male testosterone gel, acquired marketing and distribution rights, a non-compete agreement, and fully amortized product rights for Reglan and a generic product. These intangible assets were originally 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 product rights, marketing and distribution rights, and non-compete agreement are amortized over their remaining estimated useful lives, ranging from two to 10 years, based on the straight-line method. Management reviews definite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable, in a manner similar to that for property and equipment. We recognized an impairment charge of $6.7 million in relation to our testosterone gel NDA asset during the year ended December 31, 2016 (Note 5). The testosterone gel NDA asset was classified as held for sale as of December 31, 2016. No impairment losses related to intangible assets were recognized in the years ended December 31, 2015 and 2014.

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. 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. We perform our review of goodwill on our one reporting unit.

Before employing detailed impairment testing methodologies, we first evaluate the likelihood of impairment by considering qualitative factors relevant to our reporting unit. When performing the qualitative assessment, we evaluate events and circumstances that would affect the significant inputs used to determine the fair value of the goodwill. Events and circumstances evaluated include: macroeconomic conditions that could affect us, industry and market considerations for the generic pharmaceutical industry that could affect us, cost factors that could affect our performance, our financial performance (including share price), and consideration of any company-specific events that could negatively affect us, our business, or the fair value of our business. If we determine that it is more likely than not that goodwill is impaired, we will then apply detailed testing methodologies. Otherwise, we will conclude that no impairment has occurred.

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

Detailed impairment testing involves comparing the fair value of our one reporting unit to its carrying value, including goodwill. Fair value reflects the price a market participant would be willing to pay in a potential sale of ANI. If the fair value exceeds carrying value, then it is concluded that no goodwill impairment has occurred. If the carrying value of the reporting unit exceeds its fair value, a second step is required to measure possible goodwill impairment loss. The second step includes hypothetically valuing the tangible and intangible assets and liabilities of our one reporting unit as if it had been acquired in a business combination. Then, the implied fair value of our one reporting unit's goodwill is compared to the carrying value of that goodwill. If the carrying value of our one reporting unit's goodwill exceeds the implied fair value of the goodwill, we recognize an impairment loss in an amount equal to the excess, not to exceed the carrying value. No impairment loss related to goodwill was recognized in the years ended December 31, 2016, 2015, and 2014.

Collaborative Arrangements

At times, we have entered into arrangements with various commercial partners to further business opportunities. In collaborative arrangements such as these, when we are actively involved and exposed to the risks and rewards of the activities and are determined to be the principal participant in the collaboration, we classify third party costs incurred and revenues in the consolidated statements of earnings on a gross basis. Otherwise, third party revenues and costs generated by collaborative arrangements are presented on a net basis. Payments between us and the other participants are recorded and classified based on the nature of the payments.

Royalties

We have entered profit-sharing arrangements with third parties in which we sell products under ANDAs or NDAs owned or licensed by these third parties. Under these agreements, we pay these third parties a specified percentage of the gross profit earned on sales of the products. These profit-sharing percentages are recorded in cost of sales in our consolidated statements of earnings when the associated revenue is recognized and are recorded in accrued royalties in our consolidated balance sheets when the associated revenue is recognized and until payment has occurred.

Research and Development Expenses

Research and development costs are expensed as incurred and primarily consist of expenses relating to product development. Research and development costs totaled $2.9 million, $2.9 million, and $2.7 million for the years ended December 31, 2016, 2015, and 2014, respectively.

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. 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. In addition, in July 2016, we commenced administration of our Employee Stock Purchase Plan (“ESPP”). We recognize the estimated fair value of stock-based compensation awards and classify the expense where the underlying salaries are classified. We incurred $6.1 million, $3.9 million, and $3.4 million of non-cash, stock-based compensation cost for the years ended December 31, 2016, 2015, and 2014, respectively, of which $25 thousand of the 2016 expense related to the ESPP.

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, and future employee stock option exercise behaviors. Changes in these assumptions can affect the fair value estimate.

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

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 calculate income tax benefits related to stock-based compensation arrangements using the with and without method.

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 jurisdictions in the U.S. 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.

We recognize interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense. We did not have any such amounts accrued as of December 31, 2016, 2015, and 2014.

We consider potential tax effects resulting from discontinued operations and record intra-period tax allocations, when those effects are deemed material.

Earnings per Share

Basic earnings per share is computed by dividing net income available to common shareholders by the weighted-average number of shares of common stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, we calculate diluted earnings per share by dividing net income available to common shareholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options, shares to be purchased under our ESPP, unvested restricted stock awards, stock purchase warrants, and any conversion gain on the Notes, using the treasury stock method. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share.

Our unvested restricted shares and certain of our outstanding warrants contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; in periods of net income, the calculation of basic and diluted earnings per share excludes from the numerator net income (but not net loss) attributable to the unvested restricted shares and to the participating warrants, and excludes the impact of those shares from the denominator.

For purposes of determining diluted earnings per share, we have elected a policy to assume that the principal portion of our 3.0% Convertible Senior Notes due December 1, 2019 (the “Notes,” Note 2) is settled in cash. As such, the principal portion of the Notes has no effect on either the numerator or denominator when determining diluted earnings per share. Any conversion gain is assumed to be settled in shares and is incorporated in diluted earnings per share using the treasury method. The warrants issued in conjunction with the issuance of the Notes are considered to be dilutive when they are in-the-money relative to our average stock price during the period; the bond hedge purchased in conjunction with the issuance of the Notes is always considered to be anti-dilutive.

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

The numerator for earnings per share for the years ended December 31, 2016, 2015, and 2014 are calculated for basic and diluted earnings per share as follows:

(in thousands, except per share amounts)	Basic			Diluted		
	Year Ended December 31,			Year Ended December 31,		
	2016	2015	2014	2016	2015	2014
Net income	$ 3,934	$ 15,375	$ 28,747	$ 3,934	$ 15,375	$ 28,747
Net income allocated to restricted stock	(21)	(85)	(159)	(21)	(84)	(158)
Net income allocated to common shares	$ 3,913	$ 15,290	$ 28,588	$ 3,913	$ 15,291	$ 28,589
Basic Weighted-Average Shares Outstanding	11,445	11,370	10,941	11,445	11,370	10,941
Dilutive effect of stock options and ESPP				128	187	71
Dilutive effect of warrants				-	-	41
Diluted Weighted-Average Shares Outstanding				11,573	11,557	11,053
Earnings per share	$ 0.34	$ 1.34	$ 2.61	$ 0.34	$ 1.32	$ 2.59

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings per share, including the shares underlying the Notes, were 4.5 million, 4.5 million, and 4.7 million for the years ended December 31, 2016, 2015, and 2014, respectively. Anti-dilutive shares consist of out-of-the-money Class C Special stock, out-of-the-money common stock options, common stock options that are anti-dilutive when calculating the impact of the potential dilutive common shares using the treasury stock method, underlying shares related to out-of-the-money bonds issued as convertible debt, and out-of –the-money warrants exercisable for common stock.

Fair Value of Financial Instruments

Our consolidated balance sheets include various financial instruments (primarily cash and cash equivalents, prepaid expenses, accounts receivable, accounts payable, accrued expenses, and other current liabilities) that are carried at cost and that approximate fair value. The fair value of our long-term indebtedness is estimated based on the quoted prices for the same or similar issues, or on the current rates we have been offered for debt of the same remaining maturities. Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value. These tiers include:

- Level 1—Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2—Observable market-based inputs other than quoted prices in active markets for identical assets or liabilities.
- Level 3—Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

See Note 6 for additional information regarding fair value.

Segment Information

We currently operate in a single reportable segment.

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

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In January 2017, the Financial Accounting Standards Board ("FASB") issued guidance to simplify the measurement of goodwill. The guidance eliminates Step 2 from the goodwill impairment test. Instead, under the amendments in this guidance, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss. The guidance also eliminates the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted for interim or annual goodwill impairment tests performed for testing dates after January 1, 2017. The guidance must be adopted on a prospective basis. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

In January 2017, the FASB issued guidance clarifying the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities is not a business, provides a framework to assist entities in evaluating whether both an input and substantive process are present, and narrows the definition of the term output. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The guidance must be adopted on a prospective basis. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

In November 2016, the FASB issued guidance to reduce diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The revised guidance requires that amounts generally described as restricted cash and restricted cash equivalents be included in with cash and cash equivalents when reconciling the beginning of period and end of period total amounts shown on the statement of cash flows. The guidance is effective for the fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis. We will adopt this guidance as of January 1, 2017, on a retrospective basis, and all periods will be presented under this guidance. The adoption of this new guidance will result in the inclusion of our $5.0 million of restricted cash in the cash and cash equivalents balance in our consolidated statement of cash flows for all reporting periods presented in 2017 and onward.

In August 2016, the FASB issued guidance on the classification of certain cash receipts and cash payments in the statement of cash flows, including those related to debt prepayment or debt extinguishment costs, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance, and distributions received from equity method investees. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis and must be applied to all periods presented, but may be applied prospectively if retrospective application would be impracticable. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated statements of cash flows.

In June 2016, the FASB issued guidance with respect to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The adoption of certain amendments of this guidance must be applied on a modified retrospective basis and the adoption of the remaining amendments must be applied on a prospective basis. We currently expect that the adoption of this guidance will likely change the way we assess the collectability of our receivables and recoverability of other financial instruments. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

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

In March 2016, the FASB issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards, consisting of changes in the accounting for excess tax benefits and tax deficiencies, and changes in the accounting for forfeitures associated with share-based awards, among other things. We will adopt this guidance as of January 1, 2017. Pursuant to the adoption requirements for excess tax benefits and tax deficiencies, we will no longer recognize excess tax benefits or tax deficiencies in APIC; rather, we will recognize them prospectively as a component of our current period income tax expense. We will not reverse our current APIC pool, which was $3.1 million as of December 31, 2016, and we will present the impact of classifying excess tax benefits as an operating activity in the Statement of Cash Flows on a prospective basis. Pursuant to the adoption requirements for forfeitures, we will account for forfeitures as they occur rather than using an estimated forfeiture rate; we estimate that this change in accounting will result in a $14 thousand cumulative-effect adjustment increasing our accumulated deficit as of January 1, 2017. The adoption of the remaining amendments is not expected to have a material impact on our consolidated financial statements.

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements. We currently expect that the adoption of this guidance will likely change the way we account for our operating leases and will likely result in recording the future benefits of those leases and the related minimum lease payments on our consolidated balance sheets. We have not yet begun to evaluate the specific impacts of this guidance.

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. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. We do not intend to adopt the guidance early. We expect that the adoption of this guidance will likely change the way we recognize revenue generated under customer contracts. However, we are currently reviewing our contracts with customers to determine if the accounting for these contracts will be impacted by the adoption of this guidance and, if so, if that impact will be material to our consolidated financial statements. We have not yet determined the manner in which we will adopt this guidance.

Recently Adopted Accounting Pronouncements

In March 2016, the FASB issued guidance to clarify the requirements for assessing whether contingent call or put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. The amendments of this guidance were effective for reporting periods beginning after December 15, 2016, and early adoption was permitted. Entities were required to apply the guidance to existing debt instruments using a modified retrospective transition method as of the beginning of the fiscal year of adoption. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a modified retrospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

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

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 the last in first out ("LIFO") method 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 was effective for reporting periods beginning after December 15, 2016. The guidance was required to be applied prospectively, with earlier application permitted. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated 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 was effective for reporting periods beginning after December 15, 2015, and could be adopted on either a prospective or retrospective basis. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In August 2014, the FASB issued guidance requiring management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity's ability to continue as a going concern. The guidance 1) provides a definition for the term "substantial doubt," 2) requires an evaluation every reporting period, interim periods included, 3) provides principles for considering the mitigating effect of management's plans to alleviate the substantial doubt, 4) requires certain disclosures if the substantial doubt is alleviated as a result of management's plans, 5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and 6) requires an assessment period of one year from the date the financial statements are issued. The guidance was effective for reporting periods ending after December 15, 2016, and early adoption was permitted. We adopted this guidance effective January 1, 2016. The adoption of this guidance did not have a material impact on our consolidated financial statements.

We have evaluated all other issued and unadopted Accounting Standards Updates and believe the adoption of these standards will not have a material impact on our consolidated statements of earnings, balance sheets, or cash flows.

2. INDEBTEDNESS

Convertible Senior Notes

In December 2014, we issued $143.8 million of our Notes in a registered public 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 pay 3.0% interest semi-annually in arrears on June 1 and December 1 of each year, starting on June 1, 2015, and are due December 1, 2019. The Notes are convertible into 2,068,792 shares of common stock, based on an initial conversion price of $69.48 per share.

The Notes are convertible at the option of the holder (i) during any calendar quarter beginning after March 31, 2015, if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day, (ii) during the five business days after any five consecutive trading day period in which the trading price per $1,000 principal amount of the Notes for each trading day of such period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; and (iii) on or after June 1, 2019 until the second scheduled trading day immediately preceding the maturity date.

2. INDEBTEDNESS (Continued)

Upon conversion by the holders, we may elect to settle such conversion in shares of our common stock, cash, or a combination thereof. As a result of our cash conversion option, we separately accounted for the value of the embedded conversion option as a debt discount (with an offset to (Additional Paid in Capital) "APIC") of $33.6 million. The value of the embedded conversion option was determined based on the estimated fair value of the debt without the conversion feature, which was determined using market comparables to estimate the fair value of similar non-convertible debt (Note 6); the debt discount is being amortized as additional non-cash interest expense using the effective interest method over the term of the Notes.

Offering costs of $5.5 million were allocated to the debt and equity components in proportion to the allocation of proceeds to the components, as deferred financing costs and equity issuance costs, respectively. The deferred financing costs of $4.2 million are being amortized as additional non-cash interest expense using the straight-line method over the term of the debt, since this method was not significantly different from the effective interest method. Pursuant to guidance issued by the FASB in April 2015, we have classified the deferred financing costs as a direct deduction to the net carrying value of our Convertible Debt. The $1.3 million portion allocated to equity issuance costs was charged to APIC.

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 of our common stock, also with an underlying 2,068,792 common shares. Because the bond hedge and warrant are both indexed to our common stock and otherwise would be classified as equity, we recorded both elements as equity, resulting in a net reduction to APIC of $15.6 million.

The carrying value of the Notes is as follows as of December 31:

(in thousands)	2016	2015
Principal amount	$ 143,750	$ 143,750
Unamortized debt discount	(20,644)	(27,016)
Deferred financing costs	(2,463)	(3,307)
Net Carrying value	$ 120,643	$ 113,427

The following table sets forth the components of total interest expense related to the Notes recognized in the accompanying consolidated statements of earnings for the year ended December 31:

(in thousands)	2016	2015
Contractual coupon	$ 4,312	$ 4,312
Amortization of debt discount	6,372	6,043
Amortization of finance fees	844	844
Capitalized interest	(234)	(56)
	$ 11,294	$ 11,143

The effective interest rate on the Notes as of December 31, 2016 and 2015 was 7.9% and 7.8%, respectively, on an annualized basis.

2. INDEBTEDNESS (Continued)

Line of Credit

In May 2016, we entered into a credit arrangement (the "Line of Credit") with Citizens Bank Capital, a division of Citizens Asset Finance, Inc. (the "Citizens Agreement"). The Citizens Agreement provides for a $30.0 million asset-based revolving credit loan facility, with availability subject to a borrowing base consisting of eligible accounts receivable and inventory and the satisfaction of conditions precedent specified in the Citizens Agreement. The Citizens Agreement provides for an accordion feature, whereby we may increase the revolving commitment up to an additional $10.0 million subject to certain terms and conditions. The Citizens Agreement matures on May 12, 2019, at which time all amounts outstanding will be due and payable. Borrowings under the Citizens Agreement may be used for general corporate purposes, including financing possible future acquisitions and funding working capital. Amounts drawn bear an interest rate equal to, at our option, either a LIBOR rate plus 1.25%, 1.50%, or 1.75% per annum, depending upon availability under the Citizens Agreement, or an alternative base rate plus either 0.25%, 0.50%, or 0.75% per annum, depending upon availability under the Citizens Agreement. We incur a commitment fee on undrawn amounts equal to 0.25% per annum.

The Citizens Agreement is secured by a lien on substantially all of ANI Pharmaceutical Inc.'s and its principal domestic subsidiary's assets and any future domestic subsidiary guarantors' assets. The Citizens Agreement includes covenants, subject to certain exceptions, including covenants that restrict our ability to incur additional indebtedness, acquire or dispose of assets, and make and incur capital expenditures. The Citizens Agreement also imposes a financial covenant requiring compliance with a minimum fixed charge coverage ratio of 1.10 to 1.00 during certain covenant testing that is triggered if availability under the Citizens Agreement is below the greater of 12.5% of the revolving commitment and $3.75 million for three consecutive business days.

As of December 31, 2016, we had no outstanding balance on the Line of Credit. In February 2017, we drew down $30.0 million on the Line of Credit (Note 13). As part of this draw down, we implemented the accordion feature and increased the Line of Credit to $40.0 million.

In the second quarter of 2016, we deferred $0.3 million of debt issuance costs related to the Line of Credit, which will be amortized over the three year life of the Line of Credit. The $0.3 million of deferred debt issuance costs are included in prepaid expenses and other current assets in the accompanying consolidated balance sheet at December 31, 2016. During the period from when we entered into the Line of Credit through December 31, 2016, we recorded $65 thousand of interest expense related to the Line of Credit.

3. INVENTORIES

Inventories consist of the following as of December 31:

(in thousands)	2016	2015
Raw materials	$ 14,138	$ 10,192
Packaging materials	930	998
Work-in-progress	477	456
Finished goods	10,812	1,897
	26,357	13,543
Reserve for excess/obsolete inventories	(174)	(156)
Inventories, net	$ 26,183	$ 13,387

4. PROPERTY, PLANT, AND EQUIPMENT

Property, Plant, and Equipment consist of the following as of December 31:

(in thousands)	2016	2015
Land	$ 160	$ 87
Buildings	3,756	3,682
Machinery, furniture, and equipment	8,176	5,623
Construction in progress	4,293	2,189
	16,385	11,581
Less: accumulated depreciation	(5,387)	(4,450)
Property, Plant, and Equipment, net	$ 10,998	$ 7,131

Depreciation expense for the years ended December 31, 2016, 2015, and 2014 totaled $0.9 million, $0.7 million, and $0.6 million, respectively. During the years ended December 31, 2016 and 2015, there was $0.2 million and $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.

5. INTANGIBLE ASSETS

Goodwill

As a result of the Merger we recorded goodwill of $1.8 million in our one reporting unit. We assess the recoverability of the carrying value of goodwill on an annual basis as of October 31 of each year, and whenever events occur or circumstances changes that would, more likely than not, reduce the fair value of our reporting unit below its carrying value.

For the goodwill impairment analyses performed at October 31, 2016, 2015, and 2014, we performed qualitative assessments to determine whether it was more likely than not that our goodwill asset was impaired in order to determine the necessity of performing a quantitative impairment test, under which management would calculate the asset's fair value. When performing the qualitative assessments, we evaluated events and circumstances that would affect the significant inputs used to determine the fair value of the goodwill. Events and circumstances evaluated include: macroeconomic conditions that could affect us, industry and market considerations for the generic pharmaceutical industry that could affect us, cost factors that could affect our performance, our financial performance (including share price), and consideration of any company-specific events that could negatively affect us, our business, or our fair value. Based on our assessments of the aforementioned factors, it was determined that it was more likely than not that the fair value of our one reporting unit is greater than its carrying amount as of October 31, 2016, 2015, and 2014, and therefore no quantitative testing for impairment was required.

In addition to the qualitative impairment analysis performed at October 31, 2016, there were no events or changes in circumstances that could have reduced the fair value of our reporting unit below its carrying value from October 31, 2016 to December 31, 2016. No impairment loss was recognized during the years ended December 31, 2016, 2015, and 2014, and the balance of goodwill was $1.8 million as of both December 31, 2016 and 2015.

Definite-lived Intangible Assets

Acquisition of Abbreviated New Drug Applications

In July 2015, we purchased ANDAs for 22 previously marketed generic drug products from Teva Pharmaceuticals ("Teva") for $25.0 million in cash and a percentage of future gross profits from product sales. We accounted for this transaction as an asset purchase. The ANDAs are being amortized in full over their estimated useful lives of 10 years.

5. INTANGIBLE ASSETS (Continued)

In March 2015 we purchased an ANDA from Teva for Flecainide, for $4.5 million in cash and a percentage of future gross profits from product sales. We accounted for this transaction as an asset purchase. The ANDA is being amortized in full over its estimated useful life of 10 years.

On December 26, 2013, we entered into an agreement to purchase ANDAs to produce 31 previously marketed generic drug products from Teva for $12.5 million in cash and a percentage of future gross profits from product sales. On January 2, 2014, we paid the first installment of $8.5 million to Teva and we paid the $4.0 million balance on March 6, 2014. The ANDAs are being amortized in full over their estimated useful lives of 10 years.

Acquisition of New Drug Applications and Product Rights

In April 2016, we purchased the rights, title, and interest in the NDA for Inderal LA, as well as certain documentation, trademark rights, and finished goods from Cranford Pharmaceuticals, LLC for $60.0 million in cash up front and milestone payments based on future gross profits from sales of products under the NDA. We made the $60.0 million upfront cash payment using cash on hand, capitalized $0.3 million of costs directly related to the transaction, and recognized $3.9 million of minimum milestone payments for a total purchase price of $64.2 million. We accounted for this transaction as an asset purchase and the resultant $52.4 million NDA asset is being amortized in full over its estimated useful life of 10 years. The resultant $0.6 million non-compete agreement associated with the transaction is being amortized in full over its estimated useful life of seven years.

In September 2015, we entered into an agreement to purchase the NDAs for Corticotropin and Corticotropin-Zinc from Merck Sharp & Dohme B.V. for $75.0 million in cash and a percentage of future net sales. The transaction closed in January 2016, and we made the $75.0 million cash payment using cash on hand. In addition, we capitalized $0.3 million of costs directly related to the transaction. We accounted for this transaction as an asset purchase. The $75.3 million NDA assets are being amortized in full over their estimated useful lives of 10 years.

In conjunction with our 2013 merger with BioSante (the "Merger"), we acquired a testosterone gel product that was licensed to Teva (the "Testosterone Gel NDA") and this product was assigned an intangible asset value of $10.9 million in accounting for the Merger. In May 2015, Teva transferred the rights of the product back to ANI. In exchange, we will pay Teva a royalty of up to $5.0 million, at a rate of 5% of the consideration we receive as a result of commercial sale of the product. We assessed the value of the Testosterone Gel NDA under the new arrangement and determined that the net asset value was recoverable as of the May 2015 transfer date and subsequent balance sheet dates. We began the commercialization process for the product during the second half of 2015 and it continued throughout 2016. In late 2016, we determined that the development and manufacturing costs required to commercialize the product had increased and would pose a significant barrier to commercializing the product ourselves. Generic competition in the testosterone replacement market had increased substantially by the end of 2016, leading to significant decreases in pricing for the product. In the fourth quarter, management began putting forth efforts to sell the Testosterone Gel NDA rather than commercialize it ourselves. As a result of all these factors, in the fourth quarter of 2016, we determined that the facts and circumstances indicated that the asset could be impaired. We performed an impairment assessment, which indicated that the fair value of the asset was lower than the carrying value. We determined the fair value of the Testosterone Gel NDA by using a discounted cash flows model. As a result of this assessment, we recorded an intangible asset impairment of $6.7 million in the year ended December 31, 2016. We also determined in the fourth quarter of 2016 that the asset met the criteria for being held for sale. The Testosterone Gel NDA is now recorded as a short-term asset held for sale in the prepaid expenses and other assets caption in the accompanying consolidated balance sheets at $0.9 million, which is the fair value of the asset less estimated costs to sell. We are no longer amortizing the Testosterone Gel NDA.

In August 2014, we entered into an agreement to purchase (the "Vancocin Purchase Agreement") the product rights to Vancocin from Shire ViroPharma Incorporated ("Shire") for $11.0 million in cash. Pursuant to the terms of the Vancocin Purchase Agreement, we acquired the U.S. intellectual property rights and NDA associated with Vancocin, two related ANDAs, and certain equipment and inventory. We accounted for this transaction as an asset purchase. The $10.5 million product rights intangible asset is being amortized in full over its estimated useful life of 10 years.

In July 2014, we entered into an agreement to purchase (the "Lithobid Purchase Agreement") the product rights to Lithobid from Noven Therapeutics, LLC ("Noven") for $11.0 million in cash at closing, and $1.0 million in cash if certain approvals were received from the Food and Drug Administration ("FDA") on or before June 30, 2015. This $1.0 million contingent payment was paid in January 2015. Pursuant to the terms of the Lithobid Purchase Agreement, we acquired the intellectual property rights and NDA associated with Lithobid, as well as a small amount of raw material inventory. We accounted for this transaction as an asset purchase. The $12.0 million product rights intangible asset is being amortized in full over its estimated useful life of 10 years.

Marketing and Distribution Rights

In January 2016, we purchased from H2-Pharma, LLC the rights to market, sell, and distribute the authorized generic of Lipofen® and a generic hydrocortisone rectal cream product, along with the rights to an early-stage development project, for total consideration of $10.0 million. The consideration consisted of a cash payment of $8.8 million and the assumption of $1.2 million in existing royalties owed on the acquired rights. We capitalized $42 thousand of costs directly related to the purchase. We accounted for this transaction as an asset purchase. No value was ascribed to the early-stage development project because the development was still at the preliminary stage, with no expenses incurred or research performed to date. The $10.0 million marketing and distribution rights assets are being amortized in full over their average estimated useful lives of approximately four years.

5. INTANGIBLE ASSETS (Continued)

In August 2015, we entered into a distribution agreement with IDT Australia Limited ("IDT") to market several products in the U.S. 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. We accounted for this transaction as an asset purchase. The $1.0 million upfront payment was recorded as a marketing and distribution rights intangible asset and is being amortized in full over its estimated useful life of seven years.

The components of net definite-lived intangible assets are as follows:

(in thousands)	December 31, 2016		December 31, 2015		Weighted Average
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	Amortization Period
Acquired ANDA intangible assets	$ 42,076	$ (8,390)	$ 42,076	$ (4,287)	10.0 years
NDAs and product rights	150,250	(17,081)	33,422	(5,754)	10 .0 years
Marketing and distribution rights	11,042	(2,662)	1,000	(60)	4.7 years
Non-compete agreement	624	(67)	-	-	7.0 years
	$ 203,992	$ (28,200)	$ 76,498	$ (10,101)	

Definite-lived intangible assets are stated at cost, net of accumulated amortization using the straight line method over the expected useful lives of the intangible assets. Amortization expense was $21.4 million, $6.2 million, and $3.3 million for the years ended December 31, 2016, 2015, and 2014, respectively.

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. We recorded an intangible asset impairment of $6.7 million in the year ended December 31, 2016 in relation to the Testosterone Gel NDA. The testosterone gel NDA asset was classified as held for sale as of December 31, 2016. No events or circumstances arose in 2016, 2015, or 2014 that indicated that the carrying value of any of our other definite-lived intangible assets may not be recoverable. No impairment losses related to intangible assets were recognized in the years ended December 31, 2015 and 2014.

Expected future amortization expense is as follows for the years ending December 31:

(in thousands)	
2017	$ 21,731
2018	21,376
2019	21,376
2020	20,894
2021	19,448
2022 and thereafter	70,967
Total	$ 175,792

6. FAIR VALUE DISCLOSURES

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework which prioritizes and ranks the level of observability of inputs used in measuring fair value.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current liabilities) approximate their carrying values because of their short-term nature. While our Notes are recorded on our consolidated balance sheets at their net carrying value of $120.6 million as of December 31, 2016, the Notes are being traded on the bond market and their full fair value is $166.4 million, based on their closing price on December 31, 2016, a Level 1 input.

Our contingent value rights ("CVRs"), which were granted coincident with our merger with BioSante and expire in June 2023, are considered to be contingent consideration and are classified as liabilities. As such, the CVRs were recorded as purchase consideration at their estimated fair value, using Level 3 inputs, and are marked to market each reporting period until settlement. The fair value of CVRs is estimated using the present value of management's projection of the expected payments pursuant to the terms of the CVR agreement, which is the primary unobservable input. If our projection or expected payments were to increase substantially, the value of the CVRs could increase as a result. The present value of the liability was calculated using a discount rate of 15%. We determined that the fair value of the CVRs was immaterial as of December 31, 2016 and 2015. We also determined that the changes in such fair value were immaterial for the years ended December 31, 2016, 2015, and 2014.

The following table presents our financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2016 and 2015, by level within the fair value hierarchy:

(in thousands)

Description	Fair Value at December 31, 2016	Level 1	Level 2	Level 3
Liabilities				
CVRs	$ -	$ -	$ -	$ -

Description	Fair Value at December 31, 2015	Level 1	Level 2	Level 3
Liabilities				
CVRs	$ -	$ -	$ -	$ -

Financial Liabilities Measured at Fair Value on a Non-Recurring Basis

In December 2014, we issued $143.8M of Notes (Note 2). Because we have the option to cash settle the potential conversion of the Notes in cash, we separated the embedded conversion option feature from the debt feature and account for each component separately, based on the fair value of the debt component assuming no conversion option. The calculation of the fair value of the debt component required the use of Level 3 inputs, and was determined by calculating the fair value of similar non-convertible debt, using a theoretical interest rate of 9%. The theoretical interest rate was determined from market comparables to estimate what the interest rate would have been if there was no conversion option embedded in the Notes. The fair value of the embedded conversion option was calculated using the residual value method and is classified as equity.

6. FAIR VALUE DISCLOSURES (Continued)

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 (Note 2). 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 of our common stock, also with an underlying 2,068,792 common shares. We calculated the fair value of the bond hedge based on the price we paid to purchase the call. We calculated the fair value of the warrant based on the price at which the affiliate purchased the warrants from us. Because the bond hedge and warrant are both indexed to our common stock and otherwise would be classified as equity, we recorded both elements as equity, resulting in a net reduction to APIC of $15.6 million.

Non-Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

We have no non-financial assets and liabilities that are measured at fair value on a recurring basis.

Non-Financial Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

We measure our long-lived assets, including property, plant and equipment, intangible assets and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the years ended December 31, 2015 and 2014.

In the fourth quarter of 2016, the facts and circumstances surrounding our testosterone gel NDA indicated that the asset could be impaired. Our testosterone gel NDA intangible asset was initially acquired as part of the Merger, when we acquired a testosterone gel product that was licensed to Teva. This product was assigned an intangible asset value of $10.9 million in accounting for the Merger. In May 2015, Teva transferred the rights of the product back to ANI. In exchange, we will pay Teva a royalty of up to $5.0 million, at a rate of 5% of the consideration we receive as a result of commercial sale of the product. We assessed the value of the Testosterone Gel NDA under the new arrangement and determined that the net asset value was recoverable as of the May 2015 transfer date and subsequent balance sheet dates. We began the commercialization process for the product during the second half of 2015 and it continued throughout 2016. In late 2016, we determined that the development and manufacturing costs required to commercialize the product had increased and would pose a significant barrier to commercializing the product ourselves. Generic competition in the testosterone replacement market had increased substantially by the end of 2016, leading to significant decreases in pricing for the product. In the fourth quarter, management began putting forth efforts to sell the Testosterone Gel NDA rather than commercialize it ourselves. As a result of all these factors, in the fourth quarter of 2016, we determined that the facts and circumstances indicated that the asset could be impaired. We performed an impairment assessment, which indicated that the fair value of the asset was lower than the carrying value. We determined the fair value of the Testosterone Gel NDA by using a discounted cash flows model. Due to the uncertainty and risk regarding the potential commercialization of the testosterone gel NDA, we used a discount rate of 30% in our valuation. As a result of this assessment, we recorded an intangible asset impairment of $6.7 million in the year ended December 31, 2016. We also determined in the fourth quarter of 2016 that the asset met the criteria for being held for sale. The Testosterone Gel NDA is now recorded as a short-term asset held for sale in the prepaid expenses and other assets caption in the accompanying consolidated balance sheets at $0.9 million, which is the fair value of the asset less estimated costs to sell. We are no longer amortizing the Testosterone Gel NDA. No events or circumstances arose in 2016 that indicated that the carrying value of any of our other definite-lived intangible assets may not be recoverable.

Acquired Non-Financial Assets Measured at Fair Value

In April 2016, we purchased the rights, title, and interest in the NDA for Inderal LA, as well as certain documentation, trademark rights, and finished goods from Cranford Pharmaceuticals, LLC for $60.0 million in cash and milestone payments based on future gross profits from sales of products under the NDA (Note 5). In addition, at closing, we transferred $5.0 million to an escrow account as security for future milestone payments. This escrow account balance is not expected to be released in less than one year and is included in restricted cash in our accompanying consolidated balance sheet as of December 31, 2016. We made the $60.0 million upfront cash payment using cash on hand, capitalized $0.3 million of costs directly related to the transaction, and recognized $3.9 million of minimum milestone payments for a total purchase price of $64.2 million. We accounted for this transaction as an asset purchase. These assets were recorded at their relative fair values, which were determined based on Level 3 unobservable inputs. In order to determine the fair value of the NDA, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 12%. The $52.4 million NDA will be amortized in full over its 10 year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2016 and therefore no impairment loss was recognized for the year ended December 31, 2016. We recorded $10.9 million of finished goods. The fair value of the finished goods was determined based on the estimated sales to be generated from the finished goods, less costs to sell, including a reasonable margin. We recorded the $3.9 million of minimum milestone payments as accrued royalties. We recorded $0.6 million for the non-compete agreement associated with the transaction. In order to determine the fair value of the non-compete agreement, we used the probability-weighted lost cash flows method, using a discount rate of 10%. The non-compete agreement will be amortized in full over its seven year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2016 and therefore no impairment loss was recognized for the year ended December 31, 2016. We also recorded a $0.3 million prepaid balance related to a partially paid purchase order for inventory.

In January 2016, we purchased from Merck Sharp & Dohme B.V. the NDAs for two previously marketed generic drug products for $75.0 million in cash and a percentage of future net sales from product sales (Note 5). In addition, we capitalized $0.3 million in legal costs directly related to the transaction. We accounted for this transaction as an asset purchase. These assets were recorded at their relative fair values, which were determined based on Level 3 unobservable inputs. In order to determine the fair value of the NDAs, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The NDAs will be amortized in full over their 10 year useful lives, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2016 and therefore no impairment loss was recognized for the year ended December 31, 2016.

6. FAIR VALUE DISCLOSURES (Continued)

In January 2016, we purchased from H2-Pharma, LLC the rights to market, sell, and distribute the authorized generic of Lipofen® and a generic hydrocortisone rectal cream product, along with the rights to an early-stage development project, for total consideration of $10.0 million (Note 5). The consideration consisted of a cash payment of $8.8 million and the assumption of $1.2 million in existing royalties owed on the acquired rights. In addition, we capitalized $42 thousand of costs directly related to the transaction. We accounted for this transaction as an asset purchase. These assets were recorded at their relative fair values, which were determined based on Level 3 unobservable inputs. In order to determine the fair value of the rights for purposes of purchase price allocation, we used the present value of the estimate cash flows related to the product rights, using a discount rate of 10%. No value was ascribed to the early-stage development project because the development is still at the preliminary stage, with no expenses incurred or research performed to date. The marketing and distribution rights will be amortized in full over their average estimated useful lives of approximately four years, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified from the date of acquisition to December 31, 2016 and therefore no impairment loss was recognized for the year ended December 31, 2016.

In July 2015, we purchased from Teva the ANDAs for 22 previously marketed generic drug products for $25.0 million in cash and a percentage of future gross profits from product sales (Note 5). The value of the ANDAs was based on the total purchase price of $25.0 million. We accounted for this transaction as an asset purchase. These assets were recorded at their relative fair values, which were determined based on Level 3 unobservable inputs. In order to determine the fair value of the ANDAs, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The $25.0 million of ANDAs will be amortized over their 10 year useful lives, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2016 and therefore no impairment loss was recognized in the years ended December 31, 2015 and 2016.

In March 2015, we purchased from Teva the ANDA for Flecainide for $4.5 million in cash and a percentage of future gross profits from product sales (Note 5). The value of the ANDA was based on the purchase price of $4.5 million. We accounted for this transaction as an asset purchase. This asset was recorded at fair value, which was determined based on Level 3 unobservable inputs. In order to determine the fair value of the ANDA, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The $4.5 million ANDA will be amortized over its 10 year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2016 and therefore no impairment loss was recognized in the years ended December 31, 2015 and 2016.

In August 2014, we acquired from Shire the U.S. product rights associated with Vancocin, certain equipment, and inventory, for total consideration of $11.0 million (Note 5). In addition, we capitalized $0.1 million of legal costs directly related to the transaction. We accounted for this transaction as an asset purchase. These assets were recorded at their relative fair values, which were determined based on Level 3 unobservable inputs. In order to determine the fair value of the product rights, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The $10.5 million of value assigned to the product rights will be amortized over their 10 year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2016 and therefore no impairment loss was recognized in the years ended December 31, 2014, 2015, and 2016. The $0.2 million of value assigned to the equipment was determined based on the amount for which we believe we would be able to sell the equipment. The equipment will be depreciated over its estimated 10 year useful life, and would be re-valued at fair value if deemed to be other-than-temporarily impaired. We recorded $0.4 million of inventory. The value of the raw material inventory was determined based on the most recent purchase price of the material. The value of the finished goods inventory was determined based on the estimated sales to be generated from the finished goods, less costs to sell, including a reasonable margin.

6. FAIR VALUE DISCLOSURES (Continued)

In July 2014, we acquired from Noven the product rights associated with Lithobid, as well as a small amount of raw material inventory, for total consideration of $12.0 million (Note 5). In addition, we capitalized $45 thousand of legal costs directly related to the transaction. We accounted for this transaction as an asset purchase. These assets were recorded at their relative fair values, which were determined based on Level 3 unobservable inputs. In order to determine the fair value of the product rights, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The $12.0 million of ANDAs will be amortized over their 10 year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2016 and therefore no impairment loss was recognized in the years ended December 31, 2014, 2015, and 2016. We recorded $86 thousand of inventory. The value of the raw material inventory was determined based on the most recent purchase price of the material.

In the first quarter of 2014, we purchased from Teva the ANDAs for 31 previously marketed generic drug products for $12.5 million in cash and a percentage of future gross profits from product sales (Note 5). The value of the ANDAs was based on the total purchase price of $12.5 million. We accounted for this transaction as an asset purchase. These assets were recorded at their relative fair values, which were determined based on Level 3 unobservable inputs. In order to determine the fair value of the ANDAs, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The $12.5 million of ANDAs will be amortized over their 10 year useful lives, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2016 and therefore no impairment loss was recognized in the years ended December 31, 2014, 2015, and 2016.

7. STOCKHOLDERS' EQUITY

Authorized shares

We are authorized to issue up to 33.3 million shares of common stock with a par value of $0.0001 per share, 0.8 million shares of class C special stock with a par value of $0.0001 per share, and 1.7 million shares of undesignated preferred stock with a par value of $0.0001 per share at December 31, 2016.

There were 11.6 million and 11.5 million shares of common stock issued and outstanding as of December 31, 2016 and 2015, respectively.

There were 11 thousand shares of class C special stock issued and outstanding as of December 31, 2016 and 2015. Each share of class C special stock entitles its holder to one vote per share. Each share of class C special stock is exchangeable, at the option of the holder, for one share of our common stock, at an exchange price of $90.00 per share, subject to adjustment upon certain capitalization events. Holders of class C special stock are not entitled to receive dividends or to participate in the distribution of our assets if we were to liquidate, dissolve, or wind-up the company. The holders of class C special stock have no cumulative voting, preemptive, subscription, redemption, or sinking fund rights.

There were no shares of undesignated preferred stock outstanding as of December 31, 2016 and 2015.

Equity Offering

On March 10, 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 number of 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.

7. STOCKHOLDERS' EQUITY (Continued)

Stock Repurchase Program

In October 2015, our Board of Directors authorized a program to repurchase up to $25.0 million of our outstanding common stock through December 31, 2016. The authorization allows for repurchases to be conducted through open market or privately negotiated transactions. Shares acquired under the stock repurchase program are returned to the status of authorized but unissued shares of common stock. The stock repurchase program could be suspended, modified, or discontinued at any time at our discretion.

In January 2016, we purchased 65 thousand shares under the stock repurchase program for $2.5 million. This program terminated on December 31, 2016.

Warrants

Warrants to purchase an aggregate of 2.1 million shares of our common stock were outstanding and exercisable as of December 31, 2016:

Issue Date	Number of Underlying Shares of Common Stock (in thousands)	Per Share Exercise Price	Expiration Date
December 4, 2014	1,799	$ 96.21	March 1, 2020
December 5, 2014	270	$ 96.21	March 1, 2020

All outstanding warrants are classified as equity. No warrants were granted, exercised, or expired unexercised during the year ended December 31, 2016.

No warrants were issued or exercised during the year ended December 31, 2015. Warrants to purchase 405 thousand shares of common stock expired during the year ended December 31, 2015.

In December 2014, we issued 2.1 million warrants in conjunction with the issuance of the Notes (Note 2). In January 2014, warrants to purchase an aggregate of 20 thousand shares of common stock were exercised at $9.00 per share. In December 2014, warrants to purchase an aggregate of 63 thousand shares of common stock were exercised at $9.00 per share. Warrants to purchase an aggregate of 198 thousand shares of common stock expired unexercised during the year ended December 31, 2014.

8. STOCK-BASED COMPENSATION

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan, which was approved by shareholders in our May 25, 2016 annual shareholder meeting. The Board of Directors and shareholders approved a maximum of 0.2 million shares of common stock, which were reserved and made available for issuance under the ESPP. Under the ESPP, participants can purchase shares of our stock at a 15% discount. We issued one thousand shares in 2016. In the year ended December 31, 2016, we recognized $2 thousand and $23 thousand of stock-based compensation expense related to the ESPP in cost of sales and sales, general, and administrative expense in our consolidated statements of earnings, respectively.

All equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan"). As of December 31, 2016, 0.2 million shares of our common stock remained available for issuance under the 2008 Plan.

We measure the cost of equity-based service awards based on the grant-date fair value of the award. The cost is recognized over the period during which an employee is required to provide service in exchange for the award or the requisite service period. We recognize stock-based compensation expense ratably over the vesting periods of the awards, adjusted for estimated forfeitures.

8. STOCK-BASED COMPENSATION (Continued)

The following table summarizes stock-based compensation expense incurred under the 2008 Plan and included in our consolidated statements of earnings:

(in thousands)	Years Ended December 31,		
	2016	2015	2014
Cost of sales	$ 60	$ 82	$ 104
Research and development	$ 112	$ 109	$ 69
Selling, general, and administrative	$ 5,870	$ 3,665	$ 3,250

We recognized income tax benefits of $1.0 million, $0.4 million, and $0.6 million for stock-based compensation-related tax deductions in our 2016, 2015, and 2014 consolidated statements of earnings, respectively.

Separation Agreement

On April 26, 2016, we entered into a Separation Agreement and Release (the "Separation Agreement") with our former Chief Financial Officer (the "Former Officer"), who resigned effective May 6, 2016. Under the Separation Agreement, 25,167 stock options previously granted to the Former Officer vested on May 6, 2016. In addition, 4,050 restricted stock awards and 2,000 stock options previously granted to the Former Officer will vest on March 15, 2017, subject to certain conditions. These actions were accounted for as a modification of the underlying awards and the full expense for the modified awards was recorded in the second quarter 2016. In the second quarter of 2016, we recorded $0.9 million of stock-based compensation expense, net of forfeitures, in relation to the Separation Agreement. In the second quarter 2016, we recognized $0.4 million of additional expense related to the Separation Agreement and transition that was not related to stock-based compensation. All expenses related to the Separation Agreement and transition were recognized in the second quarter 2016.

Stock Options

Outstanding stock options granted to employees generally vest over a period of four years and have 10-year contractual terms. Outstanding stock options granted to non-employee directors generally vest over a period of one to three years and have 10-year contractual terms. Upon exercise of an option, we issue new shares of our common stock or issue shares from treasury stock.

For 2016, 2015, and 2014, the fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model, using the following weighted average assumptions:

	Years Ended December 31,		
	2016	2015	2014
Expected option life (years)	5.50 - 6.25	5.50 - 6.25	5.39 - 6.25
Risk-free interest rate	1.14% - 1.55%	1.31% - 1.82%	1.55% - 2.03%
Expected stock price volatility	49.4% - 51.7%	47.9% - 50.5%	50.6% - 55.1%
Dividend yield	—	—	—

We use the simplified method to estimate the life of options. In 2014, 0.3 million options granted by the board of directors but requiring shareholder approval were approved at the May 22, 2014 shareholder's meeting. As a result, the fair values of these options were calculated using the simplified method less the time between the grant date and the date of the approval, or 5.39 years. The risk-free interest rate used is the yield on a U.S. Treasury note as of the grant date with a maturity equal to the estimated life of the option. We calculated an estimated volatility rate based on the closing prices of several competitors that manufacture similar products. We have not issued a cash dividend in the past nor do we have any current plans to do so in the future; therefore, an expected dividend yield of zero was used.

8. STOCK-BASED COMPENSATION (Continued)

On April 7, 2016, the Board of Directors approved grants of options to purchase 63 thousand shares of common stock to our officers and options to purchase 13 thousand shares of common stock to non-employee directors.

On April 16, 2015, the Board of Directors approved grants of options to purchase 47 thousand shares of common stock to our officers and options to purchase 9 thousand shares of common stock to non-employee directors. On October 12, 2015, the Board of Directors approved a grant of options to purchase 3 thousand shares of common stock to a new non-employee director.

On April 1, 2014, the Board of Directors approved grants of options to purchase 59 thousand shares of common stock to our officers and options to purchase 16 thousand shares of common stock to non-employee directors. On August 20, 2014, the Board of Directors approved a grant of options to purchase 25 thousand shares of common stock to one of our officers.

A summary of stock option activity under the Plan during the years ended December 31, 2016, 2015, and 2014 is presented below:

(in thousands, except per share and remaining term data)	Option Shares	Weighted Average Exercise Price	Weighted Average Grant-date Fair Value	Weighted Average Remaining Term (years)	Aggregate Intrinsic Value
Outstanding December 31, 2013	120	$ 50.35		2.4	$ 81
Granted	120	31.59	$ 16.84		
Options previously granted, approved by shareholders	325	6.39			
Exercised	(43)	19.45			638
Forfeited	(4)	6.36			
Expired	(60)	73.96			
Outstanding December 31, 2014	458	$ 14.44		8.7	$ 19,472
Granted	138	62.07	$ 30.08		
Exercised	(89)	9.24			3,937
Forfeited	(33)	11.81			
Expired	-	-			
Outstanding December 31, 2015	474	$ 29.40		8.2	$ 10,136
Granted	265	45.60	$ 22.45		
Exercised	(127)	11.79			5,837
Forfeited	(32)	47.84			
Expired	(2)	139.32			
Outstanding December 31, 2016	578	$ 39.28		8.2	$ 12,928
Exercisable at December 31, 2016	128	$ 30.87		7.1	$ 4,033
Vested or expected to vest at December 31, 2016	567	$ 39.11		8.2	$ 12,776

8. STOCK-BASED COMPENSATION (Continued)

As of December 31, 2016, there was $7.6 million of total unrecognized compensation cost related to non-vested stock options granted under the Plan. The cost is expected to be recognized over a weighted-average period of 2.7 years. During the year ended December 31, 2016, we received $1.6 million in cash from the exercise of stock options and recorded a $0.7 million tax benefit related to these exercises. During the year ended December 31, 2015, we received $0.8 million in cash from the exercise of stock options and recorded a $0.3 million tax benefit related to these exercises. During the year ended December 31, 2014, we received $0.8 million in cash from the exercise of stock options and recorded a $0.1 million tax benefit related to these exercises.

Restricted Stock Awards

Restricted stock awards ("RSAs") granted to employees generally vest over a period of four years. RSAs granted to non-officer directors generally vest over a period of one to three years.

On April 7, 2016, the Board of Directors approved grants of 31 thousand RSAs to employees and 6 thousand to non-officer directors.

On April 16, 2015, the Board of Directors approved grants of 24 thousand RSAs to employees and four thousand to non-officer directors.

On April 1, 2014, the Board of Directors approved grants of 30 thousand RSAs to our officers. The restricted stock was granted subject to shareholder approval of an increase in the total restricted stock available for grant under the 2008 Plan. The increase in total restricted stock available for grant under the 2008 Plan was approved by shareholders at the May 22, 2014 annual meeting and the restricted stock was granted as of May 22, 2014.

Shares of our common stock delivered to employees and directors will be unrestricted upon vesting. During the vesting period, the recipient of the restricted stock has full voting rights as a stockholder and would receive dividends, if declared, even though the restricted stock remains subject to transfer restrictions and will generally be forfeited upon termination of the officer prior to vesting. The fair value of each RSA is based on the market value of our stock on the date of grant.

8. STOCK-BASED COMPENSATION (Continued)

A summary of RSA activity under the Plan during the years ended December 31, 2016, 2015, and 2014 is presented below:

(in thousands, except per share and remaining term data)	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Term (years)
Unvested at December 31, 2013	50	$ 10.20	2.8
Granted	30	29.61	
Vested	(17)	10.20	
Forfeited	-	-	
Unvested at December 31, 2014	63	$ 19.34	2.6
Granted	28	67.26	
Vested	(23)	15.82	
Forfeited	(5)	19.41	
Unvested at December 31, 2015	63	$ 42.72	2.2
Granted	38	40.59	
Vested	(30)	33.89	
Forfeited	(8)	46.05	
Unvested at December 31, 2016	63	$ 45.72	2.2

As of December 31, 2016, there was $2.0 million of total unrecognized compensation cost related to non-vested RSAs granted under the Plan, which is expected to be recognized over a weighted-average period of 2.2 years.

9. INCOME TAXES

Our total provision/(benefit) from income taxes consists of the following for the years ended December 31, 2016, 2015, and 2014:

(in thousands)	2016	2015	2014
Current income tax provision:			
Federal	$ 11,717	$ 7,264	$ 4,034
State	1,321	611	273
Total	13,038	7,875	4,307
Deferred income tax (benefit)/provision:			
Federal	(8,387)	(1,468)	2,113
State	(658)	(409)	154
Total	(9,045)	(1,877)	2,267
Change in valuation allowance	134	-	(16,726)
Excess tax benefit from stock-based compensation awards	617	360	784
Total provision/(benefit) for income taxes	$ 4,744	$ 6,358	$ (9,368)

The difference between our expected income tax provision/(benefit) from applying federal statutory tax rates to the pre-tax income/(loss) and actual income tax provision/(benefit) relates primarily to the effect of the following:

	As of December 31,		
	2016	2015	2014
US Federal statutory rate	35.0%	35.0%	35.0%
State taxes, net of Federal benefit	2.1%	2.1%	1.0%
International tax structure impacts	23.3%	-%	-%
Domestic production activities deduction	(14.4)%	(5.3)%	-%
Change in valuation allowance	1.6%	-%	(86.5)%
Stock-based compensation – no windfall tax benefit	5.7%	1.1%	4.7%
Stock-based compensation – windfall tax benefits	-%	(0.1)%	(1.2)%
Change in tax rates and other	1.4%	(3.5)%	(1.4)%
Total income tax provision/(benefit)	54.7%	29.3%	(48.4)%

9. INCOME TAXES (Continued)

Deferred income taxes reflect the net tax effects of differences between the bases of assets and liabilities for financial reporting and income tax purposes. Our deferred income tax assets and liabilities consisted of the following:

(in thousands)	As of December 31,	
	2016	2015
Deferred tax assets:		
Accruals and advances	$ 3,002	$ 2,153
Bond hedge	10,921	12,243
Accruals for chargebacks and returns	7,137	2,945
Inventory	1,255	1,271
Intangible asset	6,302	3,631
Net operating loss carryforward	5,095	7,938
Other	1,680	1,149
Total deferred tax assets	$ 35,392	$ 31,330
Deferred tax liabilities:		
Depreciation	$ (857)	$ (700)
Debt discount	(7,664)	(10,029)
Intangible assets	(353)	(3,127)
Other	(16)	(16)
Total deferred tax liabilities	$ (8,890)	$ (13,872)
Valuation allowance	(275)	(142)
Total deferred tax asset, net	$ 26,227	$ 17,316

As of December 31, 2016, we had Federal net operating loss carryforwards of approximately $13.7 million, which expire beginning in 2018, and which arose as a result of the Merger. The utilization of the net operating loss carryforwards are limited in future years as prescribed by Section 382 of the U.S. Internal Revenue Code; our current annual limitation of the Federal net operating loss is approximately $0.8 million per year.

We are required to establish a valuation allowance for deferred tax assets if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. We consider the projected future taxable income and tax planning strategies in making this assessment. As of December 31, 2016 and 2015, we have provided a valuation allowance against certain state net operating loss carryforwards of $0.3 million and $0.1 million, respectively.

We are subject to income taxes in numerous jurisdictions in the U.S. Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. We establish liabilities for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. These liabilities are established when we believe that certain positions might be challenged despite our belief that our tax return positions are fully supportable. We adjust these liabilities in light of changing facts and circumstances, such as the outcome of a tax audit. The provision for income taxes includes the impact of changes to the liability that is considered appropriate. We identified no material uncertain tax positions as of December 31, 2016 and 2015.

We are subject to income tax audits in all jurisdictions for which we file tax returns. Tax audits by their nature are often complex and can require several years to complete. Neither ANI Pharmaceuticals, Inc. nor any of its subsidiaries is currently under audit in any jurisdiction. All of our income tax returns remain subject to examination by tax authorities due to the availability of net operating loss carryforwards.

10. COLLABORATIVE ARRANGEMENTS

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 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 July 2016, we launched our Nilutamide product under the agreement.

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. In August 2016, we and Ricon agreed to a partial termination of the agreement, with only the Nilutamide product remaining under the agreement.

We recognize the costs incurred with respect to this agreement as expense and classify the expenses based on the nature of the costs. In the year ended December 31, 2016, we incurred $2.0 million in costs of sales related to the RiconPharma Agreement. In the years ended December 31, 2016, 2015, and 2014, we incurred $23 thousand, $31 thousand, and $0.4 million in research and development expenses related to the RiconPharma Agreement, respectively.

Sofgen Pharmaceuticals

August 2013 Sofgen Agreement

In August 2013, we entered into an agreement with Sofgen Pharmaceuticals ("Sofgen") to develop Nimodipine (the "August 2013 Sofgen Agreement"). In general, Sofgen was responsible for the development, manufacturing, and regulatory submission of the product, and we made payments based on the completion of certain milestones. In December 2015, we launched Nimodipine under our label. Sofgen manufactures the drug and we 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 owns all the rights, title, and interest in Nimodipine. 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.

We recognize the costs incurred with respect to the August 2013 Sofgen Agreement as expense and classify the expenses based on the nature of the costs. In the year ended December 31, 2016, we incurred $0.6 million in cost of sales related to the August 2013 Sofgen Agreement. In the year ended December 31, 2015, we incurred an immaterial amount of cost of sales related to the August 2013 Sofgen Agreement. In the year ended December 31, 2016, we incurred an immaterial amount of research and development expense related to the August 2013 Sofgen Agreement. In the years ended December 31, 2015 and 2014, we incurred $0.4 million and $0.2 million in research and development expenses related to the August 2013 Sofgen Agreement, respectively.

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 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.

10. COLLABORATIVE ARRANGEMENTS (Continued)

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.

We recognize the costs incurred with respect to the April 2014 Sofgen Agreement as expense and classify the expenses based on the nature of the costs. In the year ended December 31, 2016, we did not incur any research and development expenses related to this agreement. In the years ended December 31, 2015 and 2014, we incurred $37 thousand and $0.1 million in research and development expenses related to the agreement, respectively. No revenue has yet been recognized.

11. COMMITMENTS AND CONTINGENCIES

Operating Leases

We lease equipment under operating leases that expire in September 2018 and February 2021. We also lease office space under operating leases that expire in September 2018 and April 2021.

For the annual periods after December 31, 2016, approximate minimum annual rental payments under non-cancelable leases are presented below:

(in thousands)

Year	Minimum Annual Rental Payments
2017	$ 99
2018	97
2019	66
2020	68
2021	19
Thereafter	-
Total	$ 349

Rent expense for the years ended December 31, 2016, 2015, and 2014 totaled $81 thousand, $74 thousand, and $70 thousand, respectively.

Vendor Purchase Minimums

We have supply agreements with four vendors that include purchase minimums. Pursuant to these agreements, we will be required to purchase a total of $9.0 million of API from these four vendors during the year ended December 31, 2017.

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies. The FDA, in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our products. The Drug Enforcement Administration ("DEA") maintains oversight over our products that are considered controlled substances.

Unapproved Products

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, 2016, 2015, and 2014, net revenues for these products totaled $34.3 million, $44.3 million, and $29.8 million, respectively.

11. COMMITMENTS AND CONTINGENCIES (Continued)

The FDA's policy with respect to the continued marketing of unapproved products is stated 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 such 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 marketed as unapproved drugs with potential safety risks or that lack evidence of effectiveness. 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. There can be no assurance, however, that the FDA will continue this policy or not take a contrary position with any individual product or group of products. If the FDA were to take a contrary position, we may be required to seek FDA approval for these products or withdraw such products from the market. If we decide to withdraw the products from the market, our net revenues for generic pharmaceutical products would decline materially, and if we decide to seek FDA approval, we would face increased expenses and might need to suspend sales of the products until such approval was obtained, and there are no assurances that we would receive such approval.

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an 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, 2016, 2015, and 2014 were $1.5 million, $1.6 million, and $1.2 million, respectively.

We received royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract customer without an 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 less than 1% of total revenues for the three years ended December 31, 2016, 2015, and 2014.

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, have faced 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. In August 2016, we settled the outstanding California 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 and paid all losses in settlement of the California cases. 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.

We launched Erythromycin Ethylsuccinate ("EES") on September 27, 2016 under a previously approved ANDA. In August, we filed with the FDA to reintroduce this product under a Changes Being Effected in 30 Days submission (a "CBE-30 submission"). Under a CBE-30 submission, certain defined changes to an ANDA can be made if the FDA does not object in writing within 30 days. The FDA's regulations, guidance documents, and historic actions support the filing of a CBE-30 for the types of changes that we proposed for our EES ANDA. We received no formal written letter from the FDA within 30 days of the CBE-30 submission date, and as such, launched the product in accordance with FDA regulations. On December 16, 2016, and nearly four months after our CBE-30 submission, the FDA sent us a formal written notice that a Prior Approval Supplement ("PAS") was required for this ANDA. Under a PAS, proposed changes to an ANDA cannot be implemented without prior review and approval by the FDA. Because we did not receive this notice in the timeframe prescribed by the FDA's regulations, we believe that our supplemental ANDA is valid, and as such continue to market the product. In addition, we filed a PAS which was accepted by the FDA and has an assigned action date of June 2017. We reserve all of our legal options in this matter.

12. QUARTERLY FINANCIAL DATA (unaudited)

The following table presents unaudited quarterly consolidated operating results for each of our last eight fiscal quarters. The information below has been prepared on a basis consistent with our audited consolidated financial statements.

	2016 Quarters (unaudited)			
(in thousands, except per share data)	First	Second	Third	Fourth
Net revenues	$ 20,555	$ 31,337	$ 38,525	$ 38,205
Total operating expenses	14,889	26,143	30,604	36,907
Operating income	5,666	5,194	7,921	1,298
Net income/(loss)	$ 1,346	$ 1,125	$ 2,543	$ (1,080)
Basic and diluted earnings/(loss) per share:				
Basic earnings/(loss) per share	$ 0.12	$ 0.10	$ 0.22	$ (0.09)
Diluted earnings/(loss) per share	$ 0.12	$ 0.10	$ 0.22	$ (0.09)

	2015 Quarters (unaudited)			
(in thousands, except per share data)	First	Second	Third	Fourth
Net revenues	$ 18,799	$ 19,516	$ 19,972	$ 18,035
Total operating expenses	9,232	11,102	11,521	11,767
Operating income	9,567	8,414	8,451	6,268
Net income	$ 4,369	$ 3,571	$ 4,559	$ 2,876
Basic and diluted earnings per share:				
Basic earnings per share	$ 0.38	$ 0.31	$ 0.40	$ 0.25
Diluted earnings per share	$ 0.38	$ 0.31	$ 0.39	$ 0.25

13. SUBSEQUENT EVENTS

In February 2017, we entered into an agreement with Cranford Pharmaceuticals, LLC to purchase a distribution license, trademark and certain finished goods inventory for Inderal® XL for $20.2 million in cash. The transaction closed in February 2017, and we made the $20.2 million cash payment using cash on hand.

In February 2017, we entered into an agreement with Holmdel Pharmaceuticals, LP to purchase the NDA, trademark and certain finished goods inventory for InnoPran XL®, including a license to an Orange Book listed patent, for $30.6 million in cash. The transaction closed in February 2017, and we made the $30.6 million cash payment using $30.0 million of funds from our Line of Credit (Note 2) and $0.6 million of cash on hand.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management has carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of December 31, 2016. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by a company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of its assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are being made only in accordance with authorizations of management and directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of assets that could have a material effect on our consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control — Integrated Framework (2013).

Based on this assessment, our management has concluded that, as of December 31, 2016, our internal control over financial reporting is effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2016 has been audited by EisnerAmper LLP, an independent registered public accounting firm, as stated in their attestation report, which is included herein.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

As disclosed in our Current Report on 8-K filed on February 24, 2017, on February 23, 2017, we drew down $30 million from our credit agreement with Citizens Bank Capital, a division of Citizens Asset Finance, Inc., dated May 12, 2016 (the "Line of Credit," Note 2 of Item 8. Consolidated Financial Statements), and used such proceeds to fund the purchase of the NDA, trademark and certain finished goods inventory for InnoPran XL® (Note 13 of Item 8. Consolidated Financial Statements). Borrowings under the Line of Credit initially bear an interest rate equal to a LIBOR rate plus 1.75% per annum. In connection with drawing on the Line of Credit, we effected the accordion feature and increased the Line of Credit to $40.0 million.

PART III

Item 10. Directors and Executive Officers of the Registrant

The text of our Code of Ethics, which applies to our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions, is posted on our website, www.anipharmaceuticals.com, under the "Corporate Governance" subsection of the "Investors" section of the site. We will disclose on our website amendments to, and, if any are granted, waivers of, our Code of Ethics for our principal executive officer, principal financial officer, or principal accounting officer, controller, or persons performing similar functions.

Information required by this item with respect to our directors will be set forth under the caption "Election of Directors" in our definitive proxy statement for our 2017 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Information required by this item with respect to our executive officers will be set forth under the caption "Executive Officers of the Company" in our definitive proxy statement for our 2017 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Information required by this item with respect to compliance with Section 16(a) of the Exchange Act will be set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for our 2017 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Information required by this item with respect to our audit committee, our audit committee financial expert, and any material changes to the way in which our security holders may recommend nominees to our Board of Directors will be set forth under the caption "Corporate Governance" in our definitive proxy statement for our 2017 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Item 11. Executive Compensation

Information required by this item with respect to executive compensation will be set forth under the caption "Executive Compensation" in our definitive proxy statement for our 2017 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information required by this item with respect to security ownership of certain beneficial owners and management will be set forth under the captions "Security Ownership of Certain Beneficial Owners" and "Security Ownership of Directors and Executive Officers" in our definitive proxy statement for our 2017 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information required by this item with respect to certain relationships and related transactions and director independence will be set forth under the captions "Certain Relationships and Related Transactions" and "Corporate Governance" in our definitive proxy statement for our 2017 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

Information required by this item with respect to principal accounting fees and services will be set forth under the caption "Ratification of Selection of Independent Registered Public Accountants" in our definitive proxy statement for our 2017 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

PART IV.

Item 15. Exhibits, Financial Statement Schedules

Documents filed as part of this report on Form 10-K:

(a) Financial Statements:
The consolidated balance sheets of the Registrant as of December 31, 2016 and 2015, the related consolidated statements of earnings, changes in stockholders' equity, and cash flows for each of the years ended December 31, 2016, 2015, and 2014, the footnotes thereto, and the reports of EisnerAmper LLP, independent registered public accounting firm, are filed herewith.

(b) Financial Statement Schedules:
All schedules have been omitted because they are not applicable or the required information is included in the consolidated financial statements or notes thereto.

(c) Exhibits
Exhibits included or incorporated by reference herein: see Exhibit Index on page 105.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ANI PHARMACEUTICALS, INC.

By: /s/ Arthur S. Przybyl
Arthur S. Przybyl
President and Chief Executive Officer
(principal executive officer)

Date: March 2, 2017

By: /s/ Stephen P. Carey
Stephen P. Carey
Vice President, Finance and
Chief Financial Officer
(principal financial officer)

Date: March 2, 2017

Pursuant to the requirements the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Capacity	Date
/s/ Arthur S. Przybyl Arthur S. Przybyl	Director, President and Chief Executive Officer	March 2, 2017
/s/ Robert E. Brown, Jr. Robert E. Brown, Jr.	Director and Chairman of the Board of Directors	March 2, 2017
/s/ Fred Holubow Fred Holubow	Director	March 2, 2017
/s/ Peter A. Lankau Peter A. Lankau	Director	March 2, 2017
/s/ Tracy L. Marshbanks, Ph.D. Tracy L. Marshbanks, Ph.D.	Director	March 2, 2017
/s/ Thomas A. Penn Thomas A. Penn	Director	March 2, 2017
/s/ Daniel Raynor Daniel Raynor	Director	March 2, 2017

ANI PHARMACEUTICALS, INC.
EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2016

Exhibit No.	Exhibit	Method of Filing
2.1	Amended and Restated Agreement and Plan of Merger, dated as of April 12, 2013, by and among BioSante Pharmaceuticals, Inc., ANI Merger Sub, Inc. and ANIP Acquisition Company (1)	Incorporated by reference to Exhibit 2.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013 (File No. 001-31812)
2.2	Asset Purchase Agreement, dated as of December 26, 2013, by and between ANI Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. (2)	Incorporated by reference to Exhibit 2.2 to ANI's Annual Report on Form 10-K as filed for the fiscal year ended December 31, 2013 (File No. 001-31812)
3.1	Certificate of Amendment of the Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc., dated as of July 17, 2013, Certificate of Amendment of the Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc., dated as of June 1, 2012, and Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013 (File No. 001-31812)
3.2	Amended and Restated Bylaws of ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on February 16, 2017 (File No. 001-31812)
4.1	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. with an Initial Exercise Date of September 2010	Incorporated by reference to Exhibit 4.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 5, 2010 (File No. 001-31812)
4.2	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. with an Initial Exercise Date of June 2010	Incorporated by reference to Exhibit 4.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2010 (File No. 001-31812)
4.3	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. with an Initial Exercise Date of December 2010	Incorporated by reference to Exhibit 4.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 29, 2010 (File No. 001-31812)

Exhibit No.	Exhibit	Method of Filing
4.4	Form of Common Stock Purchase Warrant issued by BioSante Pharmaceuticals, Inc. with an Initial Exercise Date of August 2012	Incorporated by reference to Exhibit 4.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 17, 2012 (File No. 001-31812)
4.5	Indenture, dated December 10, 2014, between ANI Pharmaceuticals, Inc. and The Bank of New York Mellon	Incorporated by reference to Exhibit 4.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 10, 2014 (File No. 001-31812)
4.6	First Supplemental Indenture, dated December 10, 2014, between ANI Pharmaceuticals, Inc. and The Bank of New York Mellon (including the form of the 3.00% Convertible Senior Note due 2019)	Incorporated by reference to Exhibit 4.2 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 10, 2014 (File No. 001-31812)
4.7	Form of Note (included in Exhibit 4.10)	Incorporated by reference to Exhibit 4.2 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 10, 2014 (File No. 001-31812)
10.1*	ANI Pharmaceuticals, Inc. Fourth Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement on Schedule 14A as filed with the Securities and Exchange Commission on April 11, 2014 (File No. 001-31812)
10.2*	Form of Incentive Stock Option Agreement under the ANI Pharmaceuticals, Inc. Fourth Amended and Restated 2008 Stock Incentive Plan (included in Exhibit 10.1)	Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement on Schedule 14A as filed with the Securities and Exchange Commission on April 11, 2014 (File No. 001-31812)
10.3*	Form of Non-Statutory Option Agreement under the ANI Pharmaceuticals, Inc. Fourth Amended and Restated 2008 Stock Incentive Plan (included in Exhibit 10.1)	Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement on Schedule 14A as filed with the Securities and Exchange Commission on April 11, 2014 (File No. 001-31812)
10.4*	BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 12, 2006 (File No. 001-31812)
10.5*	Form of Incentive Stock Option Agreement Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.30 to ANI's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)

Exhibit No.	Exhibit	Method of Filing
10.6*	Form of Non-Statutory Stock Option Agreement Under the BioSante Pharmaceuticals, Inc. Amended and Restated 1998 Stock Plan	Incorporated by reference to Exhibit 10.31 to ANI's Annual Report on Form 10-KSB for the fiscal year ended December 31, 2003 (File No. 001-31812)
10.7*	Form of Indemnification Agreement between BioSante Pharmaceuticals, Inc. and each of its Directors and Executive Officers	Incorporated by reference to Exhibit 10.30 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File No. 001-31812)
10.8	License Agreement, dated June 13, 2000, between Permatec Technologie, AG (renamed as Antares Pharma IPL AG) and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.27 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.9	Amendment No. 1 to the License Agreement, dated May 20, 2001, by and between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.28 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.10	Amendment No. 2 to the License Agreement, dated July 5, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.19 to ANI's Annual Report on Form 10-KSB40 for the fiscal year ended December 31, 2001 (File No. 0-28637)
10.11	Amendment No. 3 to the License Agreement, dated August 30, 2001, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.30 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.12	Amendment No. 4 to the License Agreement, dated August 8, 2002, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.31 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.13	Amendment No. 5 to the License Agreement, dated December 30, 2002, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.32 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)
10.14	Amendment No. 6 to the License Agreement, dated October 20, 2006, between Antares Pharma IPL AG and BioSante Pharmaceuticals, Inc. and Letters, dated October 27, 2006, November 6, 2006, and November 7, 2006, from BioSante Pharmaceuticals to Antares Pharma IPL AG Regarding the License Agreement (2)	Incorporated by reference to Exhibit 10.33 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (File No. 001-31812)

Exhibit No.	Exhibit	Method of Filing
10.15	License Agreement, dated December 3, 2008, by and between BioSante Pharmaceuticals, Inc. and Azur Pharma International II Limited (2)	Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K/A as filed with the Securities and Exchange Commission on June 7, 2010 (File No. 001-31812)
10.16	Amendment No. 1 to License Agreement and Asset Purchase Agreement, dated November 30, 2009, by and between BioSante Pharmaceuticals, Inc. and Azur Pharma International II Limited (2)	Incorporated by reference to Exhibit 10.2 to ANI's Current Report on Form 8-K/A as filed with the Securities and Exchange Commission on June 7, 2010 (File No. 001-31812)
10.17	Development and License Agreement, dated December 27, 2002, between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)
10.18	First Amendment to Development and License Agreement, dated March 13, 2003, between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.3 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)
10.19	Letter Agreement, dated June 4, 2007, between BioSante Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. Regarding Development and License Agreement between Teva Pharmaceuticals USA, Inc. and BioSante Pharmaceuticals, Inc. effective December 27, 2002	Incorporated by reference to Exhibit 10.4 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)
10.20	Third Amendment to Development and License Agreement, effective October 18, 2012, by and between Teva Pharmaceuticals USA, Inc. and BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.5 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2012 (File No. 001-31812)
10.21	Department of Veterans Affairs Federal Supply Schedule Contract Award to ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., effective July 15, 2012, and Product Number Change Request, dated August 22, 2012	Incorporated by reference to Exhibit 10.54 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.22	Sublicense Agreement, dated as of October 30, 2009, by and between ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., and Jazz Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.55 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)

Exhibit No.	Exhibit	Method of Filing
10.23	Master Product Development and Collaboration Agreement, dated as of July 11, 2011, by and among ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and RiconPharma LLC (2)	Incorporated by reference to Exhibit 10.57 to ANI's Amendment No. 1 to Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on January 18, 2013 (File No. 333-185391)
10.24	Amended and Restated Manufacturing and Supply Agreement, dated as of June 10, 2008, between ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., and Alaven Pharmaceuticals, LLC. and Addendum No. 1 thereto, dated as of December 1, 2010, and Addendum No. 2 thereto, dated as of July 10, 2012 (2)	Incorporated by reference to Exhibit 10.58 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.25	Generic Wholesale Service Agreement, dated as of May 1, 2006, between ANI Pharmaceuticals, Inc. and Cardinal Health, First Amendment to Generic Wholesale Service Agreement, dated as of July 10, 2008, Letter Agreement, dated as of July 10, 2008, regarding assignment of the Generic Wholesale Service Agreement to ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., Letter from Cardinal Health, dated December 22, 2008 Regarding Increase in Base Service Fee, and Second Amendment to Generic Wholesale Service Agreement, dated May 7, 2012 (2)	Incorporated by reference to Exhibit 10.59 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.26	Development, Manufacturing and Supply Agreement, dated as of February 5, 2009, by and between ANI Pharmaceuticals, Inc. and County Line Pharmaceuticals, LLC, and Addendum to Development, Manufacturing and Supply Agreement, dated as of June 12, 2012 (2)	Incorporated by reference to Exhibit 10.60 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.27	Manufacturing Transfer and Supply Agreement, dated March 31, 2010, by and between ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., and County Line Pharmaceuticals, LLC, and Addendum to Manufacturing Transfer and Supply Agreement, dated as of June 12, 2012 (2)	Incorporated by reference to Exhibit 10.61 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.28*	Employment Letter Agreement, dated February 25, 2009, by and between ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., and Arthur S. Przybyl	Incorporated by reference to Exhibit 10.62 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.29*	Employment Letter Agreement, dated May 6, 2009, by and between ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., and Charlotte C. Arnold	Incorporated by reference to Exhibit 10.63 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)

Exhibit No.	Exhibit	Method of Filing
10.30*	Employment Agreement, dated as of May 1, 2007, by and between ANIP Acquisition Company and James Marken	Incorporated by reference to Exhibit 10.64 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.31*	Transaction Bonus Agreement, dated September 22, 2012, by and between ANIP Acquisition Company and Arthur Przybyl	Incorporated by reference to Exhibit 10.65 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.32*	Transaction Bonus Agreement, dated September 22, 2012, by and between ANIP Acquisition Company and Charlotte Arnold	Incorporated by reference to Exhibit 10.66 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.33*	Transaction Bonus Agreement, dated September 22, 2012, by and between ANIP Acquisition Company and James Marken	Incorporated by reference to Exhibit 10.67 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.34*	Transaction Bonus Agreement, dated September 22, 2012, by and between ANIP Acquisition Company and Robert Jamnick	Incorporated by reference to Exhibit 10.68 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.35	Letter Agreement regarding fee payment, dated as of October 3, 2012, by and between ANIP Acquisition Company and MVP Management Company	Incorporated by reference to Exhibit 10.69 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.36	Letter Agreement regarding fee payment, dated as of October 3, 2012, by and between ANIP Acquisition Company and Healthcare Value Capital LLC	Incorporated by reference to Exhibit 10.70 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)

Exhibit No.	Exhibit	Method of Filing
10.37	Loan and Security Agreement, dated June 6, 2012, between Alostar Bank of Commerce and ANIP Acquisition Company	Incorporated by reference to Exhibit 10.71 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.38	Note Purchase Agreement, dated as of January 28, 2011, between ANIP Acquisition Company, Meridian Venture Partners II, L.P. and the other parties thereto	Incorporated by reference to Exhibit 10.72 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.39*	Amendment No. 1 to Transaction Bonus Agreement, dated December 28, 2012, by and between ANIP Acquisition Company and Arthur S. Przybyl	Incorporated by reference to Exhibit 10.73 to ANI's Amendment No. 1 to Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on January 18, 2013 (File No. 333-185391)
10.40*	Amendment No. 1 to Transaction Bonus Agreement, dated December 28, 2012, by and between ANIP Acquisition Company and Charlotte Arnold	Incorporated by reference to Exhibit 10.74 to ANI's Amendment No. 1 to Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on January 18, 2013 (File No. 333-185391)
10.41*	Amendment No. 2 to Transaction Bonus Agreement, dated April 12, 2013, by and between ANIP Acquisition Company and Arthur Przybyl	Incorporated by reference to Exhibit 10.81 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on April 26, 2013 (File No. 333-188174)
10.42*	Amendment No. 2 to Transaction Bonus Agreement, dated April 12, 2013, by and between ANIP Acquisition Company and Charlotte Arnold	Incorporated by reference to Exhibit 10.82 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on April 26, 2013 (File No. 333-188174)
10.43*	Amendment No. 1 to Transaction Bonus Agreement, dated April 12, 2013, by and between ANIP Acquisition Company and James Marken	Incorporated by reference to Exhibit 10.83 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on April 26, 2013 (File No. 333-188174)
10.44*	Amendment No. 1 to Transaction Bonus Agreement, dated April 12, 2013, by and between ANIP Acquisition Company and Robert Jamnick	Incorporated by reference to Exhibit 10.84 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on April 26, 2013 (File No. 333-188174)

Exhibit No.	Exhibit	Method of Filing
10.45	First Amendment to Loan and Security Agreement, dated as of April 11, 2013, between Alostar Bank of Commerce and ANIP Acquisition Company	Incorporated by reference to Exhibit 10.85 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on April 26, 2013 (File No. 333-188174)
10.46*	Amendment No. 3 to Transaction Bonus Agreement, dated as of June 18, 2013, by and between ANIP Acquisition Company and Arthur S. Przybyl	Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2013 (File No. 001-31812)
10.47*	Amendment No. 3 to Transaction Bonus Agreement, dated as of June 18, 2013, by and between ANIP Acquisition Company and Charlotte Arnold	Incorporated by reference to Exhibit 10.2 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2013 (File No. 001-31812)
10.48*	Employment Letter Agreement, dated July 12, 2013, by and between ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and Robert Schrepfer	Incorporated by reference to Exhibit 10.52 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 (File No. 001-31812)
10.49	Asset Purchase Agreement between Noven Therapeutics, LLC and ANI Pharmaceuticals, Inc., dated as of July 1, 2014 (2)	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014 (File No. 001-31812)
10.50	Asset Purchase Agreement, dated as of August 1, 2014, among ANI Pharmaceuticals, Inc. and Shire Viropharma Incorporated (2)	Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014 (File No. 001-31812)
10.51	Convertible note hedge transaction confirmation, dated December 4, 2014, by and between Nomura Global Financial Products Inc. and ANI	Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 8, 2014 (File No. 001-31812)
10.52	Warrant transaction confirmation, dated December 4, 2014, by and between Nomura Global Financial Products Inc. and ANI	Incorporated by reference to Exhibit 10.2 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 8, 2014 (File No. 001-31812)
10.53	Additional convertible note hedge transaction confirmation, dated December 5, 2014, by and between Nomura Global Financial Products Inc. and ANI	Incorporated by reference to Exhibit 10.3 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 10, 2014 (File No. 001-31812)

Exhibit No.	Exhibit	Method of Filing
10.54	Additional warrant transaction confirmation, dated December 5, 2014, by and between Nomura Global Financial Products Inc. and ANI	Incorporated by reference to Exhibit 10.4 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 10, 2014 (File No. 001-31812)
10.55	Amendment No. 2 to Asset Purchase Agreement, dated as of July 10, 2015, between Teva Pharmaceuticals, Inc. and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2015 (File No. 001-31812)
10.56	Asset Purchase Agreement, dated as of September 18, 2015, between Merck Sharp & Dohme B.V. and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2015 (File No. 001-31812)
10.57	ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan	Incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement on Schedule 14A filed with the Commission on April 14, 2016
10.58	Asset Purchase Agreement between H2-Pharma, LLC and ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2016 (File No. 001-31812)
10.59	Asset Purchase Agreement between Cranford Pharmaceuticals, LLC and ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2016 (File No. 001-31812)
10.60*	Employment Offer Letter between the Company and Stephen P. Carey	Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K for the fiscal quarter ended April 27, 2016 (File No. 001-31812)
10.61*	Separation Agreement and Release between the Company and Charlotte C. Arnold	Incorporated by reference to Exhibit 10.2 to ANI's Current Report on Form 8-K for the fiscal quarter ended April 27, 2016 (File No. 001-31812)
10.62	Loan and Security Agreement between Citizens Business Capital and ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016 (File No. 001-31812)
21	List of subsidiaries	Filed herewith
23.1	Consent of EisnerAmper LLP	Filed herewith
31.1	Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14	Filed herewith

Exhibit No.	Exhibit	Method of Filing
32.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
101	The following materials from ANI Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2016, formatted in XBRL (Extensible Business Reporting Language): (i) the audited consolidated Balance Sheets, (ii) the audited consolidated Statements of Earnings, (iii) the audited consolidated Statements of Stockholders' Equity; (iv) the audited consolidated Statements of Cash Flows, and (v) Notes to consolidated Financial Statements.	Filed herewith

(1) All exhibits to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. ANI will furnish the omitted exhibits to the SEC upon request by the SEC.

(2) Confidential treatment has been granted with respect to redacted portions of this document.

* Management contract or compensatory plan or arrangement required to be filed as an exhibit to this Annual Report on Form 10-K pursuant to Item 15(a).

Exhibit 21

ANI PHARMACUTICALS, INC.

The following is a list of subsidiaries of ANI Pharmaceuticals, Inc., omitting subsidiaries which, considered in the aggregate as a single subsidiary, would not constitute a significant subsidiary, as of December 31, 2016:

Name	**State of Incorporation**
ANIP Acquisition Company	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements of ANI Pharmaceuticals, Inc. on Form S-8 (Nos. 333-53384, 333-100238, 333-109474, 333-151663, 333-168842, 333-174596, 333-182011, 333-151660, 333-196518, and 333-214416) and on Form S-3 (No. 333-195949) of our reports dated March 2, 2017, on our audits of the consolidated financial statements as of December 31, 2016 and 2015 and for each of the years in the three-year period ended December 31, 2016, and the effectiveness of ANI Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2016, which reports are included in this Annual Report on Form 10-K to be filed on or about March 2, 2017 .

/s/ EisnerAmper LLP

New York, New York
March 2, 2017

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Arthur S. Przybyl, certify that:

1. I have reviewed this Annual Report on Form 10-K of ANI Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2017

/s/ Arthur S. Przybyl
Arthur S. Przybyl
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen P. Carey, certify that:

1. I have reviewed this Annual Report on Form 10-K of ANI Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2017

/s/ Stephen P. Carey
Stephen P. Carey
Vice President, Finance and Chief Financial Officer

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of ANI Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2016 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is provided solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Dated: March 2, 2017

/s/ Arthur S. Przybyl
Arthur S. Przybyl
President and
Chief Executive Officer
(principal executive officer)

Dated: March 2, 2017

/s/ Stephen P. Carey
Stephen P. Carey
Vice President, Finance and
Chief Financial Officer
(principal financial officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.