ANI PHARMACEUTICALS INC
Form 10-K
February 27, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2018

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

For the transition period from _____ to _____.

Commission file number 001-31812

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

210 Main Street West

Baudette, Minnesota	**56623**
(Address of principal executive offices)	(Zip Code)

(218) 634-3500

(Registrant's telephone number, including area code)

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

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

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

None

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ¨ NO x

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES x NO ¨

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

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨
	Emerging growth company ¨

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2018 was $609.3 million (based upon the last reported sale price of $66.80 per share on June 30, 2018, on The NASDAQ Global Market).

As of February 20, 2019, 11,851,329 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 2019 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, 2018

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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.

In this annual report, references to “ANI Pharmaceuticals,” “ANI,” the “Company,” “we,” “us,” and “our” refer, unless the con requires otherwise, to ANI Pharmaceuticals, Inc., a Delaware c-corporation, and its consolidated subsidiaries. References to “named executive 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.

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, regulatory environment, 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.

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NOTE REGARDING TRADEMARKS

Cortenema®, Cortrophin® Gel, Cortrophin-Zinc®, Inderal® LA, Inderal® XL, InnoPran XL®, Lithobid®, Reglan®, and Vancocin® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiaries. Atacand® and Atacand HCT® are the property of AstraZeneca AB and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products. Arimidex® and Casodex® are the property of AstraZeneca UK Limited and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products.

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 three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, 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, 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. In December 2018, we repurchased $25.0 million of our outstanding Notes. At the same time, we unwound a corresponding portion of the bond hedge and warrant. In December 2017, we entered into a five-year senior secured credit facility (the “Credit Agreement”) with Citizens Bank N.A. The Credit Agreement is comprised of a $75.0 million five-year secured term loan (the “Term Loan”) and a $50.0 million senior secured revolving credit facility (the “Revolving Credit Facility”). In December 2018, we refinanced our $125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the “Credit Facility”) for up to $265.2 million. The principal new feature of the Credit Facility is a $118.0 million Delayed Draw Term Loan (the “DDTL”), which can only be drawn on in order to pay down the Company’s remaining 3.0% Convertible Senior Notes, which will mature in December 2019. The Credit Facility also extended the maturity of the $72.2 million secured term loan balance to December 2023. In addition, the Credit Facility increased the previous $50.0 million line of credit (the “Revolver”) to $75.0 million. As of December 31, 2018, we had not drawn on the Revolver or DDTL.

With the additional funds resulting from the public and convertible debt offerings, and from the Credit Agreement, we have acquired Abbreviate New Drug Applications (“ANDAs”), New Drug Applications (“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, 11 products in 2016, six products in 2017, and 11 products in 2018, bringing our portfolio of products to 42 as of December 31, 2018. In addition, in January 2016, we acquired the Cortrophin gel and Cortrophin-Zinc NDAs. We have continued to focus on the re-commercialization of these products while increasing our portfolio of generic and mature brand products.

On August 6, 2018, our subsidiary, ANI Pharmaceuticals Canada Inc. (“ANI Canada”), acquired all the issued and outstanding equity interests of WellSpring Pharma Services Inc. (“WellSpring”), a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Pursuant to these customary adjustments, the total purchase consideration was $16.7 million. The consideration was paid entirely from cash on hand. In conjunction with the transaction, we acquired WellSpring’s pharmaceutical manufacturing facility, laboratory, and offices, its current book of commercial business, as well as an organized workforce. Following the consummation of the transaction, WellSpring was merged into ANI Canada with the resulting entity’s name being ANI Pharmaceuticals Canada Inc.

Unless otherwise required by the context, references in this Annual Report on Form 10-K to the "Company," "we," us," and "our" refer to ANI Pharmaceuticals, Inc., a Delaware corporation formed in April 2001. 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 three facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, Ontario, we manufacture oral solid dose products, as well as semi-solids, 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 objective is to create long term shareholder value by building a sustainable and growing base business in generic and mature brand pharmaceutical products while advancing an opportunity to re-commercialize Cortrophin gel and Cortrophin-Zinc.

We believe our strategies effectively leverage our human and capital assets and will result in measurable growth of our business. Since 2014, we have successfully:

- Increased prescription product sales through a combination of market share gains on existing products and new product launches.
- Acquired the NDAs for and began marketing Atacand, Atacand HCT, Arimidex, Casodex, Lithobid, Vancocin, Inderal LA, Inderal XL, and InnoPran XL.
- Filed one ANDA.
- Increased our product pipeline, through development, partnership, and acquisition, to 75 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, $25.0 of which we repurchased in December 2018.
- Entered into a $265.2 million credit agreement with Citizens Bank, N.A.
- Acquired WellSpring Pharma Services Inc.
- Acquired the NDAs for Cortrophin gel and Cortrophin-Zinc in January 2016; have since assembled a Cortrophin re-commercialization team of scientists, executed a long-term supply agreement with a supplier of pig pituitary

glands, our primary raw material for corticotrophin active pharmaceutical ingredient ("API"), executed a long-term supply agreement with a corticotrophin API manufacturer, with whom we have advanced the manufacture of corticotropin API via manufacture of both intermediate and commercial-scale batches, and executed a long-term commercial supply agreement with a Cortrophin gel fill/finish contract manufacturer.

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, 2018, our products include both branded and generic pharmaceuticals, specifically:

Generic Products	**Branded Products**
Candesartan Hydrochlorothiazide	Arimidex
Cholestyramine	Atacand
Desipramine Hydrochloride	Atacand HCT
Diphenoxylate Hydrochloride and Atropine Sulfate	Casodex
Erythromycin Ethylsuccinate	Cortenema
Esterified Estrogen with Methyltestosterone	Inderal LA
Etodolac	Inderal XL
Ezetimibe-Simvastatin	InnoPran XL
Felbamate	Lithobid
Fenofibrate	Reglan
Flecainide	Vancocin

Fluvoxamine

Hydrocortisone Enema

Hydrocortisone Rectal Cream (1% and 2.5%)

Indapamide

Lithium Carbonate ER

Mesalamine Enema

Methazolamide

Metoclopramide Syrup

Morphine Sulfate Oral Solution

Nilutamide

Nimodipine

Opium Tincture

Oxycodone Hydrochloride Capsules

Oxycodone Hydrochloride Oral Solution (5 mg/5 mL)

Oxycodone Hydrochloride Oral Solution (100 mg/5 mL)

Pindolol

Propafenone

Propranolol ER

Terbutaline Sulfate

Vancomycin

Arimidex is an aromatase inhibitor indicated for adjuvant treatment of postmenopausal women with hormone receptor-positive early breast cancer.

Atacand is an angiotensin II receptor blocker indicated for treatment of hypertension to lower blood pressure and the treatment of heart failure.

Candesartan hydrochlorothiazide and its branded equivalent, Atacand HCT, combine an angiotensin II receptor antagonist and a diuretic, hydrochlorothiazide, and is used for the treatment of hypertension to lower blood pressure.

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Casodex is an androgen receptor inhibitor indicated for use in combination therapy with a luteinizing hormone-releasing hormone analog for the treatment of Stage D2 metastatic carcinoma of the prostate.

Cholestyramine for Oral Suspension USP is indicated as adjunctive therapy to diet for the reduction of elevated serum cholesterol in patients with primary hypercholesterolemia (elevated low-density lipoprotein “LDL” cholesterol) who do not respond adequately to diet. It is also indicated for the relief of pruritus associated with partial biliary obstruction.

Desipramine Hydrochloride is used to treat depression.

Diphenoxylate Hydrochloride and Atropine Sulfate is used as an adjunctive therapy in the management of diarrhea.

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.

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

Ezetimibe-Simvastatin is used to lower high cholesterol and triglyceride levels to reduce the risk of heart attack, stroke, and blood vessel problems.

Felbamate is an anticonvulsant used in the treatment of epilepsy. It is used to treat partial seizures (with and without generalization) in adults and partial and generalized seizures associated with Lennox–Gastaut syndrome in children.

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.

Indapamide tablets are indicated for the treatment of hypertension, alone or in combination with other antihypertensive drugs. Indapamide is also indicated for the treatment of salt and fluid retention (swelling) associated with congestive heart failure.

Inderal XL is a beta-adrenergic blocker indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

InnoPran XL is a beta-adrenergic blocker indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

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.

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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.

Morphine Sulfate oral solution is indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

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

Oxycodone Hydrochloride oral solution (both 5 mg/5 mL and 100 mg/5 mL) is used to relieve acute moderate to severe pain and chronic pain.

Pindolol is indicated in the management of hypertension. It may be used alone or concomitantly with other antihypertensive agents, particularly with a thiazide-type diuretic.

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.

Terbutaline Sulfate is indicated for the prevention and reversal of bronchospasm in patients 12 years of age or older with asthma and reversible bronchospasm associated with bronchitis and emphysema.

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 of Schedule II controlled substances. Our manufacturing facility in Oakville, Ontario is licensed by Health Canada for the manufacture of Schedule II controlled substances. Controlled substances are drugs considered to have a high abuse risk but that also have safe and accepted medical uses. In addition to our five Schedule II products currently on the market, our pipeline includes one ANDA 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 three oncolytic products 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 11 complex formulation products currently on the market, our pipeline includes eight extended-release products and five 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.

On August 6, 2018, we acquired all the issued and outstanding equity interests of WellSpring Pharma Services Inc., a Canadian company that performs contract development and manufacturing of pharmaceutical products. In conjunction with the transaction, we acquired WellSpring's pharmaceutical manufacturing facility, laboratory, and offices, its current book of contract manufacturing business, as well as an organized workforce. As a result of this transaction, we perform contract manufacturing in both our Baudette, Minnesota and Oakville, Ontario facilities.

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 Morphine Sulfate oral solution, Opium Tincture, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride capsules, we must submit a request to the DEA for a quota to purchase the amount of morphine sulfate, opium, and oxycodone hydrochloride 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, which we carefully select. 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. The process of obtaining an approval of such a PAS can require between four and 18 months. While we also generally qualify a single source for non-API raw materials, the process required to qualify an alternative source of a non-API raw material is typically much less rigorous. If we were to change the supplier of a raw material for a product, the cost for the material could be greater than the amount we

paid with the previous supplier. Changes in suppliers are rare, but could occur as a result of a supplier's business failing, an issue arising from an FDA inspection, or failure to maintain our required standards of quality. As a result, we select suppliers with great care, based on various factors including quality, reliability of supply, and long-term financial stability. 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 in the U.S. and Canada is highly regulated by multiple U.S. and Canadian government agencies, such as the FDA, the DEA, the Centers for Medicare and Medicaid Services ("CMS"), and Health Canada. 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 distributed in the U.S., 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 Arimidex, Atacand, Atacand HCT, Casodex, Cortenema, generic Candesartan Hydrochlorothiazide, generic Fenofibrate, generic Fluvoxamine Maleate, generic Hydrocortisone Enema, generic Terbutaline Sulfate, Inderal LA, Inderal XL, InnoPran XL, 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 Cholestyramine, Desipramine Hydrochloride, Diphenoxylate Hydrochloride and Atropine Sulfate, Erythromycin Ethylsuccinate, Etodolac, Ezetimibe-Simvastatin, Felbamate, Flecainide, Hydrocortisone rectal cream (1% and 2.5%), Indapamide, Methazolamide, Metoclopramide oral solution, Morphine Sulfate oral solution, Nilutamide, Nimodipine, Oxycodone Hydrochloride capsules, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), Pindolol, 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, Health Canada, and other authorities. In addition, the FDA and Health Canada conduct pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with cGMP and other FDA and Health Canada 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”). Morphine Sulfate, which is a significant component of our Morphine Sulfate oral solution product, is classified as a controlled substance. Opium, which is a significant component of our Opium Tincture product, is also classified as a controlled substance. Oxycodone Hydrochloride, a significant component of our Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride 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 morphine sulfate, opium, and oxycodone hydrochloride we need to manufacture Morphine Sulfate oral solution, Opium Tincture, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride 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 Morphine Sulfate oral solution, Opium Tincture, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride 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.

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 Candesartan Hydrochlorothiazide, 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.

Patents, Trademarks, and Licenses

We own the trademark names for most of our branded products, including Cortenema, Cortrophin gel, Cortrophin-Zinc, Inderal LA, Inderal XL, InnoPran XL, Lithobid, Reglan, and Vancocin. We license the trademark names for Atacand, Atacand HCT, Arimidex, and Casodex. With the exception of a license for patent technology for InnoPran XL and Inderal XL, we do not own or license any patents associated with these products. Further, patent protection and market exclusivity for these branded products have expired, with the exception of the InnoPran XL and Inderal XL products, who have market exclusivity until 2022. 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. In addition, we receive royalties from a license for patent rights initially owned by Cell Genesys, Inc., which merged with BioSante in 2009. The royalties are received as a result of sales and milestones related to the Yescarta® product. In 2018, we recorded $1.8 million of royalties related to the license of these patent rights.

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.

We market and distribute Fenofibrate, an authorized generic of Lipofen®, under an agreement with Kowa Pharmaceuticals America, Inc. Under the agreement, we retain 7.5% 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.

Customers

Our customers purchase and distribute our products. Our products are sold by three major retail pharmacy chains: CVS, Rite Aid, and Walgreens. Our customers include five major national wholesalers: AmerisourceBergen, Cardinal Health, McKesson, Anda, and Morris Dickson. In addition, our customers include national mail order houses, including CVS Caremark, Humana, 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, 2018, approximately 81% of our net revenues were attributable to three wholesalers: McKesson Corporation (21%), AmerisourceBergen Corporation (33%), and Cardinal Health, Inc. (23%). For the years ended December 31, 2017 and 2016, McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Corporation, together accounted for approximately 78% and 68% 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 handles product distribution for Walgreens. Similarly, Cardinal Health and CVS established a partnership in which Cardinal performs some product distribution for CVS. McKesson also entered into a strategic alliance with both Wal-Mart and Rite Aid. As a result of 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 conduct business with five major wholesalers in the United States: AmerisourceBergen, Cardinal, McKesson, Anda, and Morris Dickson.
- ***Retail Market Chains.*** We conduct business with three major retail chains in the United States: CVS, Rite Aid, and Walgreens.
- ***Distributors and Mail Order Pharmacies.*** We have contracts with several major distributors and mail order pharmacies in the United States, including CVS Caremark, Humana, and ExpressScripts.

Group Purchasing Organizations. We have contracts with group purchasing organizations in the United States, such as ClarusONE, Rx Sourcing Strategies, Walgreens Boots Alliance Development Group, Red Oak Sourcing, Premier Inc., Managed Health Care Associates Inc., Innovatix, MedAssets, Minnesota Multi-State, Optisource, and The Premier Group.

Competition

Certain of 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 we expect them to 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, Inc., Alvogen, Inc., Apotex Inc., Glenmark Pharmaceuticals Ltd, Hikma Pharmaceuticals plc, Method Pharmaceuticals, LLC, Mylan N.V., Par Pharmaceutical, Inc., Perrigo Company plc, Rising Pharmaceuticals, Inc., Sun Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc.

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 complaints. In August 2016, we settled the outstanding California short form complaints and in February 2018, we settled the remaining four complaints that were not captured in the 2016 settlement. 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 define backlog as firm orders received prior to December 31, 2018 that have not been shipped as of December 31, 2018. We had a backlog of $6.3 million, $0.5 million, and $0.8 million at December 31, 2018, 2017, and 2016, respectively, relating to contract manufacturing purchase orders from customers.

Employees

As of December 31, 2018, we had 299 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.

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

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 21%, 23%, and 33% of net revenues, respectively, during the year ended December 31, 2018. As of December 31, 2018, accounts receivable from these three customers was approximately 81% 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.

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.

Two of our products, which together comprised 12% of our total revenue in 2018, 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, 2018, 2017, and 2016, revenues for EEMT were 11%, 13%, and 23% of total revenue, respectively, and revenues from Opium Tincture were 1%, 2%, and 4% 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, 2018, 2017, and 2016 were 1.0%, 1.1%, and 1.2% of total revenues, respectively. Our royalties on the net sales of these unapproved products for the years ended December 31, 2018, 2017, and 2016 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.

We are entirely dependent on periodic approval by the Drug Enforcement Administration ("DEA") for the supply of the API needed to make our Morphine Sulfate oral solution, Opium Tincture, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride capsule products. An inability to obtain such approvals would reduce or eliminate our revenues from Morphine Sulfate oral solution, Opium Tincture, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride 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 Morphine Sulfate oral solution, Opium Tincture, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride 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 Morphine Sulfate oral solution, Opium Tincture, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride capsules at commercial levels. In 2017, the DEA announced that the administration would decrease the total quotas approved for Schedule II opioid painkillers. The DEA did decrease quotas approved for Schedule II opioid painkillers in 2018, which resulted in moderate decreases to our quotas for certain of our products. If the DEA does not approve our requested quotas, we may be unable to obtain sufficient API to manufacture these products at levels required by our customers, which could have an adverse impact on our business, financial position, and operating results.

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.

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 complaints. In August 2016, we settled the outstanding California short form complaints and in February 2018, we settled the remaining four complaints that were not captured in the 2016 settlement. 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 may not be able to maintain sufficient product liability insurance to cover claims against us.

Product liability insurance for the healthcare industry is generally expensive to the extent it is available at all. We may not be able to maintain such insurance on acceptable terms or be able to secure increased coverage if the commercialization of our products progresses, nor can we be sure that claims against us will be covered by our product liability insurance. Moreover, the existing coverage of our insurance policy or any rights of indemnification and contribution that we may have may not be sufficient to offset existing or future claims. A successful claim against us, in excess of insurance coverage and not subject to any indemnification or contribution, could have a material adverse effect on our future business, financial condition, and results of operations.

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. On June 30, 2017, the FDA issued draft guidance that indicated that they are delaying enforcement of those requirements until November 27, 2018 to provide manufacturers additional time and avoid supply disruptions. ANI started manufacturing serialization-compliant products in November 2018. The final requirement for tracking the products will commence 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.

Our operations in an international market subject us to additional regulatory oversight both in the international market and in the U.S., as well as economic, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results.

We are subject to certain risks associated with having assets and operations located in a foreign jurisdiction, including our operations in Canada. Our Canadian operations are subject to regulation by Health Canada and other federal, provincial, and local regulatory authorities. Health Canada regulates the testing, manufacture, labeling, marketing, and sale of pharmaceutical products manufactured and distributed in Canada. Our operations in this jurisdiction may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, and increased government regulation, which could have a material adverse effect on our business, financial position, and operating results.

Currency fluctuations and changes in exchange rates could have a material adverse effect on our business, financial position, and operating results.

A portion of our transactions are denominated in a foreign currency, the Canadian dollar. Because we engage in certain transactions in a foreign currency, we are subject to the effects of exchange rate fluctuations. If the U.S. dollar depreciates against the Canadian dollar, the expenses we recognize from Canadian-denominated transactions made by our Canadian subsidiary could be translated at an unfavorable rate, leading to foreign exchange losses. Foreign exchange gains or losses as a result of exchange rate fluctuations in any given period could harm our operating results and negatively impact our financial position and results of operations.

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 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.

Risks Related to our Business

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.

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 ("PAS") 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 13% of our inventory from one supplier during the year ended December 31, 2018. We purchased approximately 23% of our inventory from two suppliers during the year ended December 31, 2017 and approximately 25% of our inventory from one supplier during the year ended December 31, 2016. 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 from both domestic and international suppliers, which we carefully select. 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

PAS by the FDA. The process of obtaining an approval of such a PAS can require between four and 18 months. While we also generally qualify a single source for non-API raw materials, the process required to qualify an alternative source of a non-API raw material is typically much less rigorous. If we were to change the supplier of a raw material for a product, the cost for the material could be greater than the amount we paid with the previous supplier. Changes in suppliers are rare, but could occur as a result of a supplier's business failing, an issue arising from an FDA inspection, or failure to maintain our required standards of quality. As a result, we select suppliers with great care, based on various factors including quality, reliability of supply, and long-term financial stability. 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.

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 and/or packaged by third parties, which we cannot control.

We rely on third parties to manufacture and/or package our Arimidex, Atacand, Atacand HCT, Candesartan, Casodex, Cholestyramine, Desipramine, Ezetimibe-Simvastatin, Felbamate, Fenofibrate, Hydrocortisone rectal cream, Inderal LA, Inderal XL, InnoPran XL, Nimodipine, and Propranolol ER products. We relied on third parties to manufacture and/or package our Erythromycin Ethylsuccinate, Vancocin, and Vancomycin products for part of 2018. 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 Arimidex, Atacand, Atacand HCT, Candesartan, Casodex, Cholestyramine, Desipramine, Ezetimibe-Simvastatin, Felbamate, Fenofibrate, Hydrocortisone rectal cream, Inderal LA, Inderal XL, InnoPran XL, Nimodipine, Propranolol ER, or future products, which could have a material adverse effect on our business, financial position, and operating results.

Our branded products may become subject to increased generic competition.

Many of our branded products have not been patent-protected for several years and no longer have market exclusivity. As a result, trends moving toward increased substitution and reimbursement of generics for cost-containment purposes may reduce and limit the sales of our mature brand products. Additionally, increased focus by the FDA on approval of generic products may accelerate this trend. If generic products are substituted for these branded products, our revenue

from these products will decrease, which could have an 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 and subsequent sales of branded products and authorized generics of branded products, such as Arimidex, Atacand, Lithium Carbonate, and Propranolol ER, 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 and subsequent sales of branded products and authorized generics of branded products, such as Arimidex, Atacand, Lithium Carbonate, and Propranolol ER, as well as 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 Arimidex, Atacand, Fenofibrate, Lithium Carbonate, and Propranolol ER 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 acquisitions of Inderal LA, InnoPran XL, Vancomycin, 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 acquisitions of Inderal LA, InnoPran XL, Vancomycin, 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, InnoPran XL, and Vancomycin products 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, InnoPran XL, and Vancomycin, 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 changes to these agreements could have a material adverse effect on our business, financial position, and operating results.

We have 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.

We may not achieve the anticipated benefits from our acquisition of WellSpring Pharma Services Inc. ("WellSpring") and we may face integration difficulties, which could have a material adverse effect on our business, financial position, and operating results.

Our acquisition of WellSpring Pharma Services Inc., now ANI Pharmaceuticals Canada Inc. ("ANI Canada") involved the combination of two companies that operated as independent companies prior to the closing of the business combination. The integration of the business may be more time consuming and require more resources than initially estimated and we may fail to realize some or all of the anticipated benefits of the acquisition if the integration process takes longer than expected or is more costly than expected. The integration process could also result in the diversion of management's attention, the disruption or interruption of, or the loss of momentum in, the businesses of ANI and ANI Canada or inconsistencies in standards, controls, procedures, and policies, any of which could adversely affect our ability to maintain relationships with customers, partners, and employees or our ability to achieve the anticipated

benefits of the acquisition. Any of these could reduce our earnings or otherwise have a material adverse effect 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. We continue to invest in the NDAs and 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 Cortrophin gel, 40 units/mL and 80 units/mL and the NDA for Cortrophin-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. We have and intend to continue to incur significant research and development expense with respect to development of the product. In order to commercialize Cortrophin gel, we have executed long-term commercial supply agreements with a supplier for pig pituitary glands, our primary API raw material. We have also executed long-term supply agreements with a corticotropin API manufacturer and a Cortrophin gel fill/finish contract manufacturer. We have continued to advance the manufacture of the corticotropin API, scaling up from intermediate scale batches to commercial-scale batches of corticotrophin API. We will need to manufacture demo and registration batches of Cortrophin gel at commercial scale and initiate registration stability before we can submit our supplementary NDA to the FDA. We will also need to obtain approval from the FDA of our supplementary NDA filing in order to commercialize the product. 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 re-commercialize 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 three manufacturing facilities that produce the majority of our products. Production at any or all 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 three 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 any 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.

With the exception of a license for patent technology for Inderal XL and InnoPran XL, 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. Except for a license for patent technology for Inderal XL and InnoPran XL, 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 the trademark names for most of our branded products, including, Cortenema, Cortrophin Gel, Cortrophin-Zinc, Inderal LA, Inderal XL, InnoPran XL, Lithobid, Reglan, and Vancocin. We license the trademark names for Atacand, Atacand HCT, Arimidex, and Casodex. 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 two of our manufacturing facilities are located, is small, and as a result, there is a limited

number of 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. While we have invested in the protection of data and information technology, 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. These limitations, in turn, could result in increased future tax payments, which could be material.

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

As a company based in the U.S. with a subsidiary in Canada, we are subject to, or potentially subject to, income taxes as well as non-income based taxes in this jurisdiction as well as the U.S. Significant judgment is required in determining our international provision for income taxes and other tax liabilities. Changes in tax laws or tax rulings may have a significantly adverse impact on our effective tax rate. In addition, we have potential tax exposures resulting from the varying application of statutes, regulations, and interpretations, which include exposures on intercompany terms of cross-border arrangements between our U.S. operations and our Canadian subsidiary in relation to various aspects of our business, including tech transfers and contract manufacturing. Tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions; such challenges may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase and which could have a material adverse effect on our business, financial position and results of operations and our ability to satisfy our debt obligations.

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 assets and liabilities, 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 2018 did not result in an impairment charge related to goodwill, there can be no assurances that our goodwill will not 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, marketing and distribution rights related to certain generic products, and a non-compete agreement. These assets are being amortized over their useful lives of four 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. No impairment charge was recognized during the year ended December 31, 2018. We recorded impairment charges of $0.9 million and $6.7 million in the years ended December 31, 2017 and 2016, respectively, 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 remaining Convertible Senior Notes (the "Notes"), which are due December 1, 2019, requires and will continue to require a significant amount of cash. In addition, the amended and restated Senior Secured Credit Facility (the "Credit Facility") limits our ability to draw funds under the delayed draw term loan feature in order to pay down our remaining Notes if certain material adverse events occur.

Our ability to continue to make scheduled interest payments and to make future principal payments on our debt, 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. We have effectively refinanced our indebtedness via a delayed draw term loan feature (the "DDTL") under our Credit Facility, as the DDTL is to be used to pay down the remaining balance on our Notes. However, we are prohibited from drawing funds under the DDTL if certain material adverse events, as set forth in our Credit Facility, occur. If we are unable to utilize the DDTL, we will be forced to seek alternative means to refinance our indebtedness, which we may not be able to obtain 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 be required 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 the event we undergo 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 (loss) 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 (loss) 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 secured term loan (the "Term Loan"), senior secured revolving credit facility (the "Revolver"), and DDTL contain restrictive and financial covenants. If we are unable to comply with these covenants, we will be in default. A default could result in the acceleration of our outstanding indebtedness, which would have an adverse effect on our business and stock price.

In December 2018, we refinanced our $125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility for up to $265.2 million. Our Term Loan under the Credit Facility as described in Note 3 - Indebtedness, in the notes to the consolidated financial statements in Part II - Item 8 of this Annual Report on Form 10-K, has a loan balance of $72.2 million as of December 31, 2018. As of December 31, 2018, we had not drawn on the Revolver or Delayed Draw Term Loan.

The Credit Facility contains customary covenants that require maintenance of certain specified financial ratios and restricts our ability make certain distributions with respect to our capital stock, prepay other debt, encumber our assets, incur additional indebtedness, make capital expenditures, engage in certain business combinations, transfer, lease or dispose of our assets, alter the character of our business in any material respect or undertake various other corporate activities. Therefore, as a practical matter, these covenants restrict our ability to engage in or benefit from such activities. Further, we must limit our total and senior secured leverage ratios and maintain our fixed charge coverage ratio at or above specified thresholds. In addition, we pledged our assets in order to secure our repayment obligations under the Credit Facility. This pledge may reduce our operating flexibility because it restricts our ability to dispose of our assets or engage in other transactions that may be beneficial to us.

If we are unable to comply with the covenants in the Credit Facility, we will be in default, which could result in the acceleration of our outstanding indebtedness. If such an acceleration occurs, we may not be able to repay our debt and we may not be able to borrow sufficient additional funds to refinance our debt, which would have a material adverse effect on our business, financial position, and operating results.

Changes in the method of determining London Interbank Offered Rate ("LIBOR"), or the replacement of LIBOR with an alternative reference rate, may adversely affect interest expense related to outstanding debt.

Amounts drawn under the Credit Facility may bear interest rates in relation to LIBOR, depending on our selection of repayment options. On July 27, 2017, the Financial Conduct Authority (“FCA”) in the United Kingdom announced that it would phase out LIBOR as a benchmark by the end of 2021. It is unclear whether new methods of calculating LIBOR will be established such that it continues to exist after 2021. The U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U.S. financial institutions, is considering replacing U.S.-dollar LIBOR with the Secured Overnight Financing Rate (“SOFR”), a new index calculated by short-term repurchase agreements, backed by Treasury securities. If LIBOR ceases to exist, we may need to renegotiate the Credit Facility and may not able to do so with terms that are favorable to us. The overall financial market may be disrupted as a result of the phase-out or replacement of LIBOR. Disruption in the financial market or the inability to renegotiate the Credit Facility with favorable terms 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 23% of our outstanding capital stock entitled to vote as of December 31, 2018. 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, 2018, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 98 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, including, but not limited to, regulatory or legal developments with respect to our industry, variations in our financial results or those of companies that are perceived to be similar to us, and rumors or new announcements by third parties, 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. In addition, we own a manufacturing facility located in Oakville, Ontario that includes oral solid dose, semi-solids, and non-sterile liquid manufacturing and packaging, warehouse facilities, analytical, stability, and microbiological laboratory space, and employee office and mechanical space.

We lease spaces for finance offices in Minnetonka, Minnesota and Media, Pennsylvania. The leases will expire in September 2022 and March 2023, respectively. 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, 2018 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.

Civil Action

In November of 2017, we were served with a complaint filed by Arbor Pharmaceuticals, LLC, in the United States District Court, District of Minnesota. The complaint alleges false advertising and unfair competition in violation of Section 43(a) of the Lanham Act, Section 1125(a) of Title 15 of the United States Code, and Minnesota State law, and seeks injunctive relief and damages. The action is currently in the discovery phase. We intend to defend this action vigorously.

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 complaints. In August 2016, we settled the outstanding California short form complaints and in February 2018, we settled the remaining four complaints that were not captured in the 2016 settlement. 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.

Our ANDA for Erythromycin Ethylsuccinate ("EES") was originally approved by the FDA on November 27, 1978. We purchased the EES ANDA from Teva on July 10, 2015, and subsequently launched EES on September 27, 2016. In August 2016, 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 continued to market the product. In addition, we filed a PAS which was approved by the FDA on November 2, 2018.

On or about September 20, 2017, the Company and certain of its employees were served with search warrants and/or grand jury subpoenas to produce documents and possibly testify relating to a federal investigation of the generic pharmaceutical industry. The Company has been cooperating and intends to continue cooperating with the investigation. However, no assurance can be given as to the timing or outcome of the investigation.

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."

Stockholder Information

As of February 20, 2019, there were approximately 100 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, 2018 and 2017. We do not anticipate paying cash dividends in the near term. Our Credit Facility with Citizens Bank N.A. 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, 2013, 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, 2018. The information has been derived from our audited consolidated financial statements for each of the years ended December 31, 2018, 2017, 2016, 2015, and 2014. 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)	**2018[1]**	**2017[2]**	2016	2015	2014
Statement of Operations Data:					
Net revenues	$201,576	$176,842	$128,622	$76,322	$55,970
Total operating expenses	166,217	148,513	108,543	43,622	35,964
Operating income from continuing operations	35,359	28,329	20,079	32,700	20,006
(Provision)/benefit for income taxes	(4,557)	(17,425)	(4,744)	(6,358)	9,368
Net income/(loss) from continuing operations	$15,494	$(1,076)	$3,934	$15,375	$28,747
Basic and diluted income/(loss) from continuing operations per share:					
Basic income/(loss) per share from continuing operations	$1.31	$(0.09)	$0.34	$1.34	$2.61
Diluted income/(loss) per share from continuing operations	$1.30	$(0.09)	$0.34	$1.32	$2.59
Balance Sheet Data:					
Total assets	$430,604	$412,138	$322,864	$285,265	$259,558
Total convertible notes, net of discount and deferred financing costs	112,463	128,208	120,643	113,427	106,540
Long-term borrowing, net of deferred financing costs and current borrowing component	67,296	69,946	-	-	-
Total stockholder's equity	$197,263	$174,756	$169,648	$160,082	$139,785

[1] On August 6, 2018, our subsidiary, ANI Pharmaceuticals Canada Inc. ("ANI Canada"), acquired all the issued and outstanding equity interests of WellSpring Pharma Services Inc. ("WellSpring"), a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Pursuant to these customary adjustments, the total purchase consideration was $16.7 million. The consideration was paid entirely from cash on hand.

[2] The Tax Cuts and Jobs Act was enacted on December 22, 2017. The Tax Cuts and Jobs Act includes a number of changes to existing U.S. tax laws, most notably the reduction of the U.S. corporate income tax rate from 35% to 21%, which began in 2018. 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. As a result, we remeasured our deferred tax assets and deferred tax liabilities to reflect the reduction in the enacted U.S. corporate income tax rate, resulting in a $13.4 million increase in income tax expense for the year ended December 31, 2017. See Note 11. Income Taxes, in the

notes to the consolidated financial statements in Part II. Item 8. of this Annual Report on Form 10-K for further information.

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, ANIP Acquisition Company and ANI Pharmaceuticals Canada Inc. (together, "ANI," the "Company," "we," "us," or "our") is an integrated specialty pharmaceutical company focuse 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 three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, Ontario are together capable of producing oral solid dose products, as well as semi-solids, 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.

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 Cortrophin gel, Cortrophin-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.

In 2017, we acquired the right, title, and interest in the NDAs and the U.S. rights to market Atacand, Atacand HCT, Arimidex, and Casodex. In addition, we acquired the NDA, trademarks, and certain finished goods inventory for Inderal XL and InnoPran XL. We also entered into a five-year senior secured credit facility (the “Credit Agreement”) comprised of a $75.0 million five-year term loan (the “Term Loan”) and a $50.0 million senior secured revolving credit facility (the “Revolving Credit Facility”). During the 2017 year, we launched six products.

In 2018, our subsidiary, ANI Pharmaceuticals Canada Inc. (“ANI Canada”), acquired all the issued and outstanding equity interests of WellSpring Pharma Services Inc. (“WellSpring”), a Canadian company that performs contract development and manufacturing of pharmaceutical products. In conjunction with the transaction, we acquired WellSpring’s pharmaceutical manufacturing facility, laboratory, and offices, its current book of commercial business, as well as an organized workforce. Following the consummation of the transaction, WellSpring was merged into ANI Canada with the resulting entity’s name being ANI Pharmaceuticals Canada Inc. In addition, we acquired the ANDAs for three previously-commercialized generic products, the approved ANDAs for two generic products that have yet to be commercialized, the development package for one generic product, a license, supply, and distribution agreement for a generic product with an ANDA that is pending approval, and certain manufacturing equipment required to manufacture one of the products. We also acquired the ANDAs for 23 previously-marketed generic products and API for four of the acquired products. During the 2018 year, we launched 11 products.

In addition, in December 2018, we refinanced our $125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the "Credit Facility") for up to $265.2 million. The principal new feature of the Credit Facility is a $118.0 million Delayed Draw Term Loan (the "DDTL"), which can only be drawn on in order to pay down the Company's remaining 3.0% Convertible Senior Notes, which will mature in December 2019. The Credit Facility also extended the maturity of the $72.2 million secured term loan balance to December 2023. In addition, the Credit Facility increased the previous $50.0 million line of credit (the "Revolver") to $75.0 million. As of December 31, 2018, we had not drawn on the Revolver or DDTL.

Recent Developments

Acquisition of WellSpring Pharma Services Inc.

On August 6, 2018, our subsidiary, ANI Canada, acquired all the issued and outstanding equity interests of WellSpring, a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Pursuant to these customary adjustments, the total purchase consideration was $16.7 million. The consideration was paid entirely from cash on hand. In conjunction with the transaction, we acquired WellSpring's pharmaceutical manufacturing facility, laboratory, and offices, its current book of commercial business, as well as an organized workforce. Following the consummation of the transaction, WellSpring was merged into ANI Canada with the resulting entity's name being ANI Pharmaceuticals Canada Inc.

We acquired WellSpring to provide an additional tech transfer site in order to accelerate the re-commercialization of the previously-approved ANDAs in our pipeline, to expand our contract manufacturing revenue base, and to broaden our manufacturing capabilities to three manufacturing facilities.

Asset Acquisitions

In April 2018, we entered into an agreement with Impax Laboratories, Inc. (now Amneal Pharmaceuticals, Inc., or "Amneal") to purchase the approved ANDAs for three previously-commercialized generic drug products, the approved ANDAs for two generic drug products that have not yet been commercialized, the development package for one generic drug product, a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval, and certain manufacturing equipment required to manufacture one of the products, for $2.3 million in cash up front. The transaction closed in May 2018 and we made the $2.3 million payment using cash on hand.

At the same time, we entered into a supply agreement with Amneal under which we may elect to purchase the finished goods for one of the products for up to 17 months beginning October 1, 2019, under certain conditions. If we do elect to purchase the finished goods from Amneal for this period, we may be required to pay a milestone payment of up to $10.0 million upon launch, depending on the number of competitors selling the product at the time of launch.

In April 2018, we entered into an agreement with IDT Australia, Limited to purchase the ANDAs for 23 previously-marketed generic drug products and active pharmaceutical ingredient ("API") of four of the acquired products for $2.7 million in cash and a single-digit royalty on net profits from sales of one of the products. The transaction closed in April 2018 and we made the $2.7 million payment using cash on hand.

Amendment to Teva Pharmaceuticals Asset Purchase Agreement

In January 2019, we entered into Amendment No. 4 to our Asset Purchase Agreement with Teva Pharmaceuticals USA, Inc. ("Teva"). Under the terms of the Purchase Agreement Amendment, all royalty obligations of the Company owed to Teva with respect to products associated with ten ANDAs under the Asset Purchase Agreement shall cease effective as of December 31, 2018. In consideration for the termination of such future royalty obligations, we paid Teva a sum of $16.0 million.

Product Launches

In October 2018, we launched Candesartan Hydrochlorothiazide Tablets, 16mg/12.5mg, 32mg/12.5mg, and 32mg/25mg, an authorized generic of Atacand HCT, for the treatment of hypertension.

In October 2018, we launched Terbutaline Sulfate Tablets USP, 2.5mg and 5mg, an authorized generic of Brethine®. Terbutaline sulfate is indicated for the prevention and reversal of bronchospasm in patients 12 years of age and older with asthma and reversible bronchospasm associated with bronchitis and emphysema.

In August 2018, we launched Morphine Sulfate Oral Solution 10mg/5mL, 20mg/5mL and 100mg/5mL. Morphine Sulfate Oral Solution is indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Morphine Sulfate Oral Solution 100 mg per 5 mL (20 mg/mL) is indicated for the relief of acute and chronic pain in opioid-tolerant patients.

In June 2018, we launched Cholestyramine for Oral Suspension. Cholestyramine for Oral Suspension USP is indicated as adjunctive therapy to diet for the reduction of elevated serum cholesterol in patients with primary hypercholesterolemia (elevated low-density lipoprotein “LDL” cholesterol) who do not respond adequately to diet. It is also indicated for the relief of pruritus associated with partial biliary obstruction.

Cortrophin Gel Re-commercialization Update

In the fourth quarter of 2018, we completed our first commercial scale batch of Corticotropin API, which met specifications and was analytically-consistent with commercial API batches from the legacy API commercial manufacturer. We continue to manufacture additional commercial scale batches of Corticotropin API and are on track to initiate API process validation and registration batch manufacturing in the first quarter of 2019. We have completed validation for some API analytical methods to be used for API batch release and stability testing and will validate the remaining API release methods in the first quarter of 2019, prior to initiation of process validation and registration batch manufacturing. Commercial scale registration batch manufacturing and process validation for Cortrophin Gel is scheduled to begin in the second quarter of 2019.

Vancocin Oral Solution Update

We are currently advancing a commercialization effort for Vancocin oral solution. We filed a prior approval supplement (“PAS”) for the product in September 2018. This product will be manufactured at our site in Baudette, Minnesota.

General

The following table summarizes our results of operations for the years ended December 31, 2018, 2017, and 2016.

	Years Ended December 31,		
(in thousands)	2018	2017	2016
Net revenues	$201,576	$176,842	$128,622
Operating expenses			
Cost of sales (excluding depreciation and amortization)	73,024	79,032	48,780
Research and development	15,388	9,070	2,906
Selling, general, and administrative	44,063	31,580	27,829
Depreciation and amortization	33,742	27,928	22,343
Intangible asset impairment charge	-	903	6,685
Operating income	35,359	28,329	20,079
Interest expense, net	(14,758)	(12,035)	(11,327)
Other (expense)/income, net	(550)	55	(74)
Income before provision for income taxes	20,051	16,349	8,678
Provision for income taxes	(4,557)	(17,425)	(4,744)
Net income/(loss)	$15,494	$(1,076)	$3,934

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

	Years Ended December 31,		
	2018	2017	2016
Net revenues	100.0%	100.0%	100.0%
Operating expenses			
Cost of sales (excluding depreciation and amortization)	36.2%	44.7%	37.9%
Research and development	7.6%	5.1%	2.3%
Selling, general, and administrative	21.9%	17.9%	21.6%
Depreciation and amortization	16.7%	15.8%	17.4%
Intangible asset impairment charge	-%	0.5%	5.2%
Operating income	17.6%	16.0%	15.6%
Interest expense, net	(7.3)%	(6.8)%	(8.8)%
Other (expense)/income, net	(0.3)%	-%	(0.1)%
Income before provision for income taxes	10.0%	9.2%	6.7%
Provision for income taxes	(2.3)%	(9.8)%	(3.7)%
Net income/(loss)	7.7%	(0.6)%	3.0%

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Results of Operations for the Years Ended December 31, 2018 and 2017

Net Revenues

	Years Ended December 31,				
(in thousands)	2018	2017	Change	% Change	
Generic pharmaceutical products	$ 117,451	$ 118,437	$(986)	(0.8)	%
Branded pharmaceutical products	60,554	50,919	9,635	18.9	%
Contract manufacturing	9,119	7,046	2,073	29.4	%
Royalty and other income	14,452	440	14,012	NM	(1)
Total net revenues	$ 201,576	$ 176,842	$24,734	14.0	%

(1) Not Meaningful

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, 2018 were $201.6 million compared to $176.8 million for the same period in 2017, an increase of $24.7 million, or 14.0%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $117.5 million during the year ended December 31, 2018, a slight decrease of 0.8% compared to $118.4 million for the same period in 2017. The primary reason for the decrease was volume decreases for Fenofibrate and Nilutamide, as well as sales decreases for Propranolol ER driven by price, tempered by the impact of the second quarter 2017 launch of Diphenoxylate Hydrochloride and Atropine Sulfate, the second quarter 2018 launch of Ezetimibe-Simvastatin, and other products launched in 2018. In 2019, we anticipate increases in generic pharmaceutical product revenues, primarily related to products we expect to launch in 2019.

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, 2018 and 2017 were $24.9 million and $27.6 million, respectively.

- Net revenues for branded pharmaceutical products were $60.6 million during the year ended December 31, 2018 an increase of 18.9% compared to the $50.9 million for the same period in 2017. The primary reason for the increase was sales of Arimidex and Casodex, which were launched under our label in July 2018, sales of Atacand and Atacand HCT, which were launched under our label in October 2018, and sales of Inderal XL and InnoPran XL, both of which were acquired in the first quarter of 2017, and which were re-launched under our label in the first quarter of 2018. These increases were tempered by lower unit sales of Inderal LA and Vancocin. In 2019, we anticipate increases in branded pharmaceutical product revenues related to a full year of sales of Atacand, Atacand HCT, Arimidex, and Casodex, all of which were launched under our label in 2018.

- Contract manufacturing revenues were $9.1 million during the year ended December 31, 2018, an increase of 29.4% compared to $7.0 million for the same period in 2017, due primarily to contract manufacturing revenue in our ANI Canada subsidiary, partially offset by timing of orders from contract manufacturing customers in the period. We acquired WellSpring in August 2018. 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 both the years ended December 31, 2018 and 2017 were $2.0 million. In 2019, we anticipate increases in contract manufacturing revenues, primarily related to a full year of contract manufacturing revenue in our ANI Canada subsidiary.

- Royalty and other income were $14.5 million during the year ended December 31, 2018, an increase of $14.0 million from $0.4 million for the same period in 2017, due primarily to royalties on sales of Atacand, Atacand HCT, Casodex, and Arimidex. We acquired the right, title, and interest in the NDAs and the U.S. right to market these products in December 2017. During the year ended December 31, 2018, we also recognized $1.8 million of royalties from a license for patent rights initially owned by Cell Genesys, Inc., which merged with BioSante in 2009. The royalties stem from sales and milestones related to the Yescarta® product. Royalty and other income also includes the impact of product development and laboratory services revenue from our ANI Canada subsidiary. Upon full transition of the products and upon launching the products under our own labels, we recognize revenue for the products as sales of generic or branded pharmaceutical products. In 2019, we anticipate a decrease in royalty and other income primarily related to the launch of Atacand, Atacand HCT, Arimidex, and Casodex under our own label in 2018.

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, 2018 and 2017.

Cost of Sales (Excluding Depreciation and Amortization)

	Years Ended December 31,			
(in thousands)	2018	2017	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 73,024	$ 79,032	$(6,008)	(7.6)%

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 operations.

For the year ended December 31, 2018, cost of sales decreased to $73.0 million from $79.0 million for the same period in 2017, a decrease of $6.0 million or 7.6%, primarily due to lower sales of products subject to profit-sharing arrangements, as well as the lack of $7.5 million of costs of sales related to the excess of fair value over cost on Inderal XL and InnoPran XL inventory, which impacted 2017. This decrease was tempered by $5.6 million of cost of sales related to the excess of fair value over costs on Inderal XL and InnoPran XL inventory and the write-off of remaining inventory acquired as part of the acquisition when we re-launched the products under our own label during the first quarter of 2018. Cost of sales as a percentage of net revenues decreased to 36.2% during the year ended December 31, 2018, from 44.7% during same period in 2017, primarily as a result of increased royalty income and a change in product mix towards higher-margin brand products and lower sales of products subject to profit-sharing arrangements. Cost of sales for the year ended December 31, 2017 also included $7.5 million net impact on cost of sales (5.9% as a percent of net revenues) of the excess of fair value over cost for Inderal XL and InnoPran XL inventory sold during the period.

We source the raw materials for our products from both domestic and international suppliers, which we carefully select. 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 PAS by the FDA. The process of obtaining an approval of such a PAS can require between four and 18 months. While we also generally qualify a single source for non-API raw materials, the process required to qualify an alternative source of a non-API raw material is typically much less rigorous. If we were to change the supplier of a raw material for a product, the cost for the material could be greater than the amount we paid with the previous supplier. Changes in suppliers are rare, but could occur as a result of a supplier's business failing, an issue arising from an FDA inspection, or failure to maintain our required standards of quality. As a result, we select suppliers with great care, based on various factors including quality, reliability of supply, and long-term financial stability. 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. During the year ended December 31, 2018, we purchased 13% of our inventory from one supplier. As of December 31, 2018, amounts payable to this supplier was immaterial. In the year ended December 31, 2017, we purchased 23% of our inventory from two suppliers.

In order to manufacture Morphine Sulfate oral solution, Opium Tincture, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride capsules, we must submit a request to the Drug Enforcement Agency ("DEA") for a quota to purchase the amount of morphine sulfate, opium, and oxycodone hydrochloride 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 Morphine Sulfate oral solution, Opium Tincture, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride capsules.

Other Operating Expenses

	Years Ended December 31,				
(in thousands)	2018	2017	Change	% Change	
Research and development	$ 15,388	$ 9,070	$6,318	69.7	%
Selling, general, and administrative	44,063	31,580	12,483	39.5	%
Depreciation and amortization	33,742	27,928	5,814	20.8	%
Intangible asset impairment charge	-	903	(903)	(100.0)	%
Total other operating expenses	$ 93,193	$ 69,481	$23,712	34.1	%

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, 2018, other operating expenses increased to $93.2 million from $69.5 million for the same period in 2017, an increase of $23.7 million, or 34.1%, primarily as a result of the following factors:

- Research and development expenses increased from $9.1 million to $15.4 million, an increase of 69.7%, due to timing of work on development projects, primarily the Cortrophin gel re-commercialization project and work on the ANDAs acquired in the asset purchase agreement with Impax Laboratories, Inc. (now Amneal), as well as $1.3 million of expense related to in-process research and development acquired from Amneal in an asset purchase in May. We anticipate that research and development costs will continue to increase in 2019, in support of our strategy to expand our product portfolio and as we continue to focus on the development of our Cortrophin product.

- Selling, general, and administrative expenses increased from $31.6 million to $44.1 million, an increase of 39.5%, primarily due to increases in personnel and related costs and costs associated with the WellSpring acquisition. We anticipate that selling, general, and administrative expenses will continue to increase in 2019, as we support anticipated additional revenue growth.

- Depreciation and amortization increased from $27.9 million to $33.7 million, an increase of 20.8%, primarily due to the amortization of the rights, title, and interest in the NDAs for Atacand, Atacand HCT, Arimidex, and Casodex, which were acquired in December 2017. We anticipate that depreciation and amortization expense will continue to increase in 2019, as a result of a full year of depreciation recognized from the property, plant and equipment acquired in the WellSpring acquisition.

- As discussed under Intangible Assets in our Critical Accounting Estimates, we recognized an impairment charge of $0.9 million in relation to our testosterone gel NDA asset during the year ended December 31, 2017. No impairment charge was recognized during the year ended December 31, 2018.

Other Expense, net

	Years Ended December 31,			
(in thousands)	2018	2017	Change	% Change
Interest expense, net	$ (14,758)	$ (12,035)	$(2,723)	22.6 %
Other (expense)/income, net	(550)	55	(605)	NM (1)
Total other expense, net	$ (15,308)	$ (11,980)	$(3,328)	27.8 %

(1) Not Meaningful

For the year ended December 31, 2018, we recognized other expense, net of $15.3 million versus other expense, net of $12.0 million for the same period in 2017, an increase of $3.3 million. Interest expense, net in 2018 consisted primarily of interest expense on our convertible debt and interest expense on borrowings under our term loan. Interest expense, net in 2017 consisted primarily of interest expense on our convertible debt and interest expense on borrowings under our line of credit. For the year ended December 31, 2018, we also recorded a loss of $0.5 million on the repurchase of our Notes in other (expense)/income, net. For the years ended December 31, 2018 and 2017, there was $0.7 million and $0.6 million of interest capitalized into construction in progress, respectively.

Provision for Income Taxes

	Years Ended December 31,			
(in thousands)	2018	2017	Change	% Change
Provision for income taxes	$ (4,557)	$ (17,425)	$12,868	(73.8)%

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. The Tax Cuts and Jobs Act, which was enacted on December 22, 2017, included a number of changes to existing U.S. tax laws, most notably the reduction of the U.S. corporate income tax rate from 35% to 21%, which began in 2018. We measure our deferred tax assets and liabilities using the tax rates that we believe will apply in the years in which the temporary differences are expected to be recovered or paid. See Note 11. Income Taxes, in the notes to the consolidated financial statements in Part II. Item 8. of this Annual Report on Form 10-K for further information.

For the year ended December 31, 2018, we recognized income tax expense of $4.6 million, versus $17.4 million in the prior year period, a provision decrease of $12.9 million. The effective tax rate for the year ended December 31, 2018 was 22.7% of pre-tax income reported in the period. Our effective tax rate for the year ended December 31, 2018 was impacted primarily by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017 and lowered the U.S. corporate tax rate from 35% to 21%, which began in 2018. Our effective tax rate was also impacted by the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

The effective tax rate for the year ended December 31, 2017 was 106.6% of pre-tax income reported in the period. Our effective tax rate for the year ended December 31, 2017 was primarily impacted by the $13.4 million revaluation of our deferred tax assets and liabilities at the lower 21% U.S. corporate income tax rate. Our effective tax rate was also impacted by the Domestic Production Activities Deduction, as well as the impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

Results of Operations for the Years Ended December 31, 2017 and 2016

Net Revenues

	Years Ended December 31,				
(in thousands)	2017	2016	Change	% Change	
Generic pharmaceutical products	$ 118,437	$ 95,201	$23,236	24.4	%
Branded pharmaceutical products	50,919	26,443	24,476	92.6	%
Contract manufacturing	7,046	5,537	1,509	27.3	%
Royalty and other income	440	1,441	(1,001)	(69.5	)%
Total net revenues	$ 176,842	$ 128,622	$48,220	37.5	%

Net revenues for the year ended December 31, 2017 were $176.8 million compared to $128.6 million for the same period in 2016, an increase of $48.2 million, or 37.5%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $118.4 million during the year ended December 31, 2017, an increase of 24.4% compared to $95.2 million for the same period in 2016. The primary reason for the increase was the annualization of 2016 launches, notably Nilutamide, Erythromycin Ethylsuccinate, and Fenofibrate, the impact of the third quarter 2017 launch of Diphenoxylate Hydrochloride and Atropine Sulfate, and increased unit sales of Methazolamide and Flecainide. These increases were tempered by volume decreases in EEMT sales, driven by market contraction, and sales decreases for Propranolol ER driven by price.

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, 2017 and 2016 were $27.6 million and $34.3 million, respectively.

- Net revenues for branded pharmaceutical products were $50.9 million during the year ended December 31, 2017 an increase of 92.6% compared to the $26.4 million for the same period in 2016. The primary reason for the increase was sales of Inderal XL and InnoPran XL, both of which were launched in first quarter of 2017, as well as sales of Inderal LA, which was launched in the second quarter of 2016. These increases were partially offset by decreased unit sales for Vancocin. We experience periodic larger orders for our Vancocin product that relate to clinical trials. Such orders constituted $2.4 million of our branded pharmaceutical product revenue for the year ended December 31, 2016. We had no such orders in the year ended December 31, 2017.

- Contract manufacturing revenues were $7.0 million during the year ended December 31, 2017, an increase of 27.3% compared to $5.5 million for the same period in 2016, 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, 2017 and 2016 were $2.0 million and $1.5 million, respectively.

- Royalty and other income were $0.4 million during the year ended December 31, 2017, a decrease of 69.5% from $1.4 million for the same period in 2016, primarily because sales of Fenofibrate in the ANI label have replaced the royalties previously received on the product. We launched Fenofibrate under our own label in the second quarter of 2016.

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, 2017 and 2016.

Cost of Sales (Excluding Depreciation and Amortization)

	Years Ended December 31,			
(in thousands)	2017	2016	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 79,032	$ 48,780	$30,252	62.0 %

For the year ended December 31, 2017, cost of sales increased to $79.0 million from $48.8 million for the same period in 2016, an increase of $30.3 million or 62.0%, 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 XL and InnoPran XL inventory acquired during the first three months of 2017 through asset acquisition transactions and subsequently sold during the period. Cost of sales as a percentage of net revenues increased to 44.7% during the year ended December 31, 2017, from 37.9% during same period in 2016, primarily as a result of increased sales of products subject to profit-sharing arrangements and the $10.4 million net impact on cost of sales (5.9% as a percent of net revenues) of the excess of fair value over cost for Inderal XL and InnoPran XL inventory sold during the period. This trend continued until such time that the inventory acquired as components of the Inderal XL and InnoPran XL asset purchases were consumed. During the year ended December 31, 2016, cost of sales included $5.9 million (4.6% as a percent of net revenue) related to the excess of fair value over cost for Inderal LA and Propranolol ER inventory sold during the period. During the second quarter 2017, we completed sales of the Inderal LA inventory acquired as a component of the Inderal LA asset purchase.

During the year ended December 31, 2017, we purchased 23% of our inventory from two suppliers. As of December 31, 2017, amounts payable to these suppliers was $0.2 million. In the year ended December 31, 2016, we purchased 25% of our inventory from one supplier.

Other Operating Expenses

	Years Ended December 31,				
(in thousands)	2017	2016	Change	% Change	
Research and development	$ 9,070	$ 2,906	$6,164	212.1	%
Selling, general, and administrative	31,580	27,829	3,751	13.5	%
Depreciation and amortization	27,928	22,343	5,585	25.0	%
Intangible asset impairment charge	903	6,685	(5,782)	(86.5	)%
Total other operating expenses	$ 69,481	$ 59,763	$9,718	16.3	%

For the year ended December 31, 2017, other operating expenses increased to $69.5 million from $59.8 million for the same period in 2016, an increase of $9.7 million, or 16.3%, primarily as a result of the following factors:

- Research and development expenses increased from $2.9 million to $9.1 million, an increase of 212.1%, due to timing of work on development projects, primarily the Cortrophin gel re-commercialization project and the Vancocin oral solution project. Projects included work on the ANDAs purchased in 2014 and 2015.

- Selling, general, and administrative expenses increased from $27.8 million to $31.6 million, an increase of 13.5%, primarily due to increases in personnel and related costs and $0.5 million of expenses related to a proposed transaction that we ultimately decided not to pursue further. These increases were partially offset by the lack of the $1.3 million of expenses related to the transition of our CFO in the second quarter of 2016.

- Depreciation and amortization increased from $22.3 million to $27.9 million, an increase of 25.0%, due primarily to the amortization of the distribution license and trademark for Inderal XL, which were acquired in February 2017, the amortization of the product rights for InnoPran XL, which were acquired in February 2017, and the amortization of the rights, title, and interest in the NDA for Inderal LA, which were acquired in April 2016.

- As discussed under Intangible Assets in our Critical Accounting Estimates, we recognized an impairment charge of $0.9 million and $6.7 million in relation to our testosterone gel NDA asset during the years ended December 31, 2017 and 2016, respectively.

Other Expense, net

	Years Ended December 31,			
(in thousands)	2017	2016	Change	% Change
Interest expense, net	$ (12,035)	$ (11,327)	$ (708)	6.3 %
Other income/(expense), net	55	(74)	129	(174.3)%
Total other expense, net	$ (11,980)	$ (11,401)	$ (579)	5.1 %

For the year ended December 31, 2017, we recognized other expense, net of $12.0 million versus other expense, net of $11.4 million for the same period in 2016, an increase of $0.6 million. Interest expense, net for both periods consists primarily of interest expense on our convertible debt and, in 2017, included interest expense on borrowings under our line of credit. For the years ended December 31, 2017 and 2016, there was $0.6 million and $0.2 million of interest capitalized into construction in progress, respectively.

Provision for Income Taxes

	Years Ended December 31,			
(in thousands)	2017	2016	Change	% Change
Provision for income taxes	$ (17,425)	$ (4,744)	$(12,681)	267.3 %

For the year ended December 31, 2017, we recognized income tax expense of $17.4 million, versus $4.7 million in the prior year period, a provision increase of $12.7 million. The effective tax rate for the year ended December 31, 2017 was 106.6% of pre-tax income reported in the period. Our effective tax rate for the year ended December 31, 2017 was primarily impacted by the $13.4 million revaluation of our deferred tax assets and liabilities at the lower 21% U.S. corporate income tax rate. Our effective tax rate was also impacted by the Domestic Production Activities Deduction, as well as the impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

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 Cortrophin 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 discrete items. These discrete 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.

Liquidity and Capital Resources

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

	December 31,	
(in thousands)	2018	2017
Cash and cash equivalents	$43,008	$31,144
Accounts receivable, net	64,842	58,788
Inventories, net	40,503	37,727
Prepaid income taxes, net	-	1,162
Prepaid expenses and other current assets	4,524	2,784
Total current assets	$152,877	$131,605
Current component of long-term borrowing, net of deferred financing costs	$3,256	$3,353
Convertible notes, net of discount and deferred financing costs	112,463	-
Accounts payable	8,884	3,630
Accrued expenses and other	1,707	1,571
Accrued royalties	8,456	12,164
Accrued compensation and related expenses	3,524	2,306
Current income taxes payable, net	5,022	-
Accrued government rebates	8,974	7,930
Returned goods reserve	12,552	8,274
Deferred revenue	711	-
Total current liabilities	$165,549	$39,228

At December 31, 2018, we had $43.0 million in unrestricted cash and cash equivalents. At December 31, 2017, we had $31.1 million in unrestricted cash and cash equivalents. We generated $67.1 million of cash from operations in the year ended December 31, 2018. In August 2018, we acquired WellSpring, a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Pursuant to these customary adjustments, the total purchase consideration was $16.7 million. The consideration was paid entirely from cash on hand. As a result of the transaction, we acquired WellSpring's pharmaceutical manufacturing facility, laboratory, and offices, current book of commercial business, as well as an organized workforce. In April 2018, we purchased from IDT Australia, Limited the ANDAs for 23 previously-marketed generic drug products and API for four of the acquired products for $2.7 million in cash and a single-digit royalty on net profits from sales of one of the products. We made the $2.7 million payment using cash on hand. In May 2018, we purchased from Impax Laboratories, Inc. (now Amneal) the approved ANDAs for three previously-commercialized generic drug products, the approved ANDAs for two generic drug products that have not yet been commercialized, the development package for one generic drug product, a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval, and certain manufacturing equipment required to manufacture one of the products, for $2.3 million in cash. We made the $2.3 million payment using cash on hand.

In December 2018, we refinanced our $125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the "Credit Facility") for up to $265.2 million. The principal new feature of the Credit Facility is a $118.0 million Delayed Draw Term Loan (the "DDTL"), which can only be drawn on in order to pay down the Company's remaining 3.0% Convertible Senior Notes, which will mature in December 2019. The Credit Facility also extended the maturity of the $72.2 million secured term loan (the "Term Loan") balance to December 2023. In addition, the Credit Facility increased the previous $50.0 million line of credit (the "Revolver") to $75.0 million. In December 2018, we entered into separate, privately negotiated agreements with certain holders of our Notes and repurchased $25.0 million aggregate principal amount of Notes for a total of $26.1 million in cash, including accrued but unpaid interest up to but excluding the closing date for the transactions. At the same time, we unwound a corresponding portion of the bond hedge and warrant, which are described in further detail below under "- *Sources and Uses of Cash – Debt Financing*". As a result of unwinding this portion of the bond hedge and warrant, we received a net amount of $0.4 million.

In February 2017, we purchased from Cranford Pharmaceuticals, LLC a distribution license, trademark and certain finished goods inventory for Inderal XL for $20.2 million in cash. We made the $20.2 million cash payment using cash on hand. In February 2017, we purchased from Holmdel Pharmaceuticals, LP 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. We made the $30.6 million cash payment using $30.0 million of funds from our line of credit and $0.6 million of cash on hand. In December 2017, we purchased from AstraZeneca AB and AstraZeneca UK Limited the right, title, and interest in the NDAs and the U.S. rights to market Atacand, Atacand HCT, Arimidex, and Casodex, for $46.5 million in cash. We made the $46.5 million cash payment with funds from the $75.0 million five-year Term Loan we entered into with Citizens Bank N.A., which was refinanced as discussed above.

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 0.9 as of December 31, 2018. 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 21%, 23%, and 33% of net revenues during the year ended December 31, 2018. As of December 31, 2018, accounts receivable from these three customers totaled approximately 81% of accounts receivable, net. As a result, negotiated payment terms with these customers have a material impact on our liquidity and working capital.

One of our pharmaceutical products, EEMT, accounted for approximately 11% of our net revenues in 2018. Three of our pharmaceutical products, EEMT, Inderal LA, and Fenofibrate, accounted for approximately 40% of our net revenues in 2017. Three of our pharmaceutical products, EEMT, Inderal LA, and Propranolol ER, accounted for approximately 44% of our net revenues in 2016. 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 December 2018, we refinanced our $125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility for up to $265.2 million. The principal new feature of the Credit Facility is a $118.0 million DDTL, which can only be drawn on in order to pay down the Company's remaining 3.0% Convertible Senior Notes, which will mature in December 2019. The DDTL was accounted for as new debt. The Credit Facility also extended the maturity of the $72.2 million secured term loan balance to December 2023. In addition, the Credit Facility increased the previous $50.0 million line of credit to $75.0 million. The Term Loan and Revolver were accounted for as a modification of our existing term loan and line of credit, respectively. As of December 31, 2018, we had not drawn on the Revolver or DDTL.

We may at any time repay borrowings under the term loans, including the initial term loan and any delayed draw term loans, and the revolving credit facility without any premium or penalty, and so long as we meet certain conditions by August 30, 2019 relating to our total net leverage ratio and liquidity or to the repayment or refinancing of our outstanding Notes, we must repay all borrowings thereunder by December 27, 2023. We may use the proceeds of revolving loans for working capital and other general corporate purposes and may only use the proceeds from the delayed draw term loans, if borrowed, to refinance our outstanding Notes.

Amounts drawn bear an interest rate equal to, at our option, either a LIBOR rate plus 1.50% to 2.75% per annum, depending on our total leverage ratio or an alternative base rate plus an applicable base rate margin, which varies within a range of 0.50% to 1.75%, depending our total leverage ratio. We will incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. We will also incur a delayed draw ticking fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. We must comply with various customary financial and non-financial covenants under the Credit Facility. The primary financial covenants under the Credit Facility consist of a maximum total leverage ratio, which initially shall be no greater than 3.75 to 1.00 and a minimum fixed charge coverage ratio which shall be greater than or equal to 1.25 to 1.00. The primary non-financial covenants under the Credit Agreement limit, subject to various exceptions, the Company's ability to incur future indebtedness, to place liens on assets, to pay dividends or make other distributions on the Company's capital stock, to repurchase the Company's capital stock, to conduct acquisitions, to alter its capital structure and to dispose of assets.

In December 2017, we entered into a $125.0 million Credit Agreement with Citizens Bank, N.A, which was replaced by the $265.2 million Credit Facility described above. The Credit Agreement was comprised of a $75.0 million five-year term loan and a $50.0 million senior secured revolving credit facility and was secured by the assets of the Company. The funds from the Term Loan were used to pay down the $25.0 million balance on our existing Line of Credit, as well as to purchase the right, title, and interest in the NDAs and the U.S. rights to market Atacand, Atacand HCT, Arimidex, and Casodex, for $46.5 million in cash, as noted above.

In May 2016, we entered into a credit arrangement with Citizens Bank Capital, a division of Citizens Asset Finance, Inc. that provided for a $30.0 million asset-based revolving credit loan facility. In February 2017, we implemented the accordion feature and increased the Line of Credit to $40.0 million. In December 2017, we refinanced our $25.0 million outstanding on the line of credit into the $75.0 million term loan as noted above.

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. In December 2018, we repurchased $25.0 million of our outstanding Notes. At the same time, we unwound a corresponding portion of the bond hedge and warrant, which are described in further detail below. As a result of unwinding this portion of the bond hedge and warrant, we received a net amount of $0.4 million. The remaining Notes are convertible into 1,709,002 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 1,709,002 common shares remaining as of December 31, 2018; the exercise price of the warrant is $96.21 per share, also with an underlying 1,709,002 common shares remaining as of December 31, 2018.

Customer Payments

In addition to the financings in prior years, payments from customers are a significant source of cash in 2018, 2017, and 2016 and were our primary source of cash in 2018 and 2016.

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 second quarter of 2018, we purchased from IDT Australia, Limited the ANDAs for 23 previously-marketed generic drug products and API for four of the acquired products for $2.7 million in cash. In the second quarter 2018, we also purchased from Impax Laboratories, Inc. (now Amneal) the approved ANDAs for three previously-commercialized generic drug products, the approved ANDAs for two generic drug products that have not yet been commercialized, the development package for one generic drug product, a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval, and certain manufacturing equipment required to manufacture one of the products, for $2.3 million in cash. In the third quarter of 2018, we acquired WellSpring, a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Pursuant to these customary adjustments, the total purchase consideration was $16.7 million. The consideration was paid entirely from cash on hand. In December 2018, we entered into separate, privately negotiated agreements with certain holders of our Notes and repurchased $25.0 million of our outstanding Notes. At the same time, we unwound a corresponding portion of the bond hedge and warrant. As a result of unwinding this portion of the bond hedge and warrant, we received a net amount of $0.4 million. In 2018, we had $5.7 million of capital expenditures.

In the first quarter of 2017, we purchased from Cranford Pharmaceuticals, LLC a distribution license, trademark and certain finished goods inventory for Inderal XL for $20.2 million in cash. In the first quarter of 2017, we purchased from Holmdel Pharmaceuticals, LP 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. In the fourth quarter of 2017, we acquired the right, title, and interest in the NDAs and the U.S. rights to market Atacand, Atacand HCT, Arimidex, and Casodex for $46.5 million in cash. In 2017, we had $10.4 million of capital expenditures.

In the first quarter of 2016, we purchased from Merck Sharp & Dohme B.V. the NDAs and associated product rights and manufacturing licenses for Cortrophin gel and Cortrophin-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.

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:

	Years Ended December 31,		
(in thousands)	2018	2017	2016
Operating Activities	$67,074	$39,419	$27,472
Investing Activities	$(27,379)	$(107,993)	$(149,060)
Financing Activities	$(27,816)	$72,357	$(729)

Net Cash Provided by Operating Activities

Net cash provided by operating activities was $67.1 million for the year ended December 31, 2018, compared to $39.4 million during the same period in 2017, an increase of $27.7 million. This increase was principally due to changes in working capital, as well as increased sales volume and corresponding gross profit dollars.

Net cash provided by operating activities was $39.4 million for the year ended December 31, 2017, compared to $27.5 million during the same period in 2016, an increase of $11.9 million between the periods. This increase was principally due to 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, 2018 was $27.4 million, principally due to the payment of $16.5 million of consideration, net of cash acquired, to acquire WellSpring, the April and May 2018 asset acquisitions of ANDAs for $5.2 million, and $5.7 million of capital expenditures during the period.

Net cash used in investing activities for the year ended December 31, 2017 was $108.0 million, principally due to the February 2017 payment of $20.2 million for the asset acquisition of the product rights for Inderal XL, the February 2017 payment of $30.6 million for the asset acquisition of the NDAs for InnoPran XL, the December 2017 payment of $46.5 million for the asset acquisition of the product rights for Atacand, Atacand HCT, Arimidex, and Casodex, and $10.4 million of capital expenditures during the period, primarily related to new equipment to expand our

manufacturing capability.

Net cash used in investing activities for the year ended December 31, 2016 was $149.1 million, principally due to the January 2016 asset acquisition of the NDAs for Cortrophin gel and Cortrophin-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, and $4.6 million of capital expenditures during the period.

Net Cash (Used In)/Provided By Financing Activities

Net cash used in financing activities was $27.8 million for the year ended December 31, 2018, principally due to $26.1 million related to the repurchase of the Notes, $1.6 million relating to debt issuance and convertible debt repurchase costs, $2.8 million of payments on the term loan, and $0.7 million of treasury stock purchased in relation to restricted stock vestings, partially offset by $3.0 million of proceeds from stock option exercises.

Net cash provided by financing activities was $72.4 million for the year ended December 31, 2017, principally due to the cash inflows from establishing the $75.0 million Term Loan, partially offset by the $1.7 million of debt issuance fees allocated to the Term Loan and $1.0 million of debt issuance fees allocated to the Revolving Credit Facility.

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.

Contractual Obligations

The following table summarizes our long-term contractual obligations and commitments as of December 31, 2018.

	Payments Due by Period				
(in thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-term debt obligations [1]	$190,937	$ 122,359	$ 9,023	$ 59,555	$ -
Interest on long-term debt obligations [2]	16,274	6,496	5,338	4,440	-
Operating lease obligations	525	159	282	84	-
Purchase obligations [3]	12,848	10,947	1,839	62	-
Total	$220,584	$ 139,961	$ 16,482	$ 64,141	$ -

[1] Represents our $72.2 million Term Loan due December 27, 2023 and our $118.8 million remaining Convertible Senior Notes due December 2019. (Note 3, Indebtedness, in the notes to the consolidated financial statements in Part II. Item 8. of this Annual Report on Form 10-K.)

[2] Represents interest due on our Term Loan and our Convertible Senior Notes. Interest for the Term Loan is calculated based on our payment schedule as proscribed in the Credit Facility and using an estimated interest rate of 4.10%, which is the estimated interest rate on the Term Loan as fixed by our interest rate swap. Interest for our Convertible Senior Notes is calculated based on 3.0% interest due semi-annually and assumes all interest is paid and the remaining 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

As of January 1, 2018, we adopted guidance for revenue recognition for contracts, using the modified retrospective method. The adoption of the new guidance impacted the way we analyze, document, and disclose revenue recognition under customer contracts and resulted in additional disclosures in our financial statements. The implementation of the guidance had no material impact on the measurement or recognition of revenue from customer contracts of prior periods and did not have a material impact on our net revenues. For our revenue recognition policies prior to adopting the guidance for revenue recognition for contracts, please see Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2017.

Upon adoption of this new guidance, we recognize revenue using the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price, including the identification and estimation of variable consideration;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when we satisfy a performance obligation.

We derive our revenues primarily from sales of generic and branded pharmaceutical products. Revenue is recognized when our obligations under the terms of our contracts with customers are satisfied, which generally occurs when control of the products we sell is transferred to the customer. We estimate variable consideration after considering applicable information that is reasonably available. We generally do not have incremental costs to obtain contracts that would otherwise not have been incurred. We do not adjust revenue for the promised amount of consideration for the effects of a significant financing component because our customers generally pay us within 100 days.

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. In addition, for our product development services revenue, we recognize revenue on a percentage of completion basis, which requires judgments related to how much work has been completed on various components our projects.

Revenue from Sales of Generic and Branded Pharmaceutical Products

Product sales consist of sales of our generic and brand pharmaceutical products. Our sole performance obligation in our contracts is to provide pharmaceutical products to customers. Our products are sold at pre-determined standalone selling prices and our performance obligation is considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer upon delivery of the product to the customer, as our pharmaceutical products are sold on an FOB destination basis and because inventory risk and risk of ownership passes to the customer upon delivery. Payment terms for these sales are generally less than 100 days. We recognized $178.0 million, $169.4 million, and $121.6 million of revenue related to sales of generic and branded pharmaceutical products in 2018, 2017, and 2016, respectively.

Revenue from Distribution Agreements

From time to time, 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. We have assessed and determined that we control the products sold under these marketing and distribution agreements and therefore are the principal for sales under each of these marketing and distribution agreements. As a result, we recognize revenue on a gross basis when control has passed to the customer and we have satisfied our performance obligation. 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 operations and are accrued in accrued royalties in our consolidated balance sheets until payment has occurred.

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").

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 $23.0 million for the year ended December 31, 2018.

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 anticipate that we will have further increases in our quarterly Medicaid rebate amounts related to sales of our recently acquired branded and authorized generic products and increases in our quarterly Medicare rebates related to sales of our Fenofibrate, Inderal LA, InnoPran XL, and Vancomycin 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 $1.1 million for the year ended December 31, 2018.

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.

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 $1.4 million for the year ended December 31, 2018.

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.

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 $3.3 million for the year ended December 31, 2018.

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.

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 $0.9 million for the year ended December 31, 2018.

Contract Manufacturing Product Sales Revenue

Contract manufacturing arrangements consist of agreements in which we manufacture a pharmaceutical product on behalf of third party. Our performance obligation is to manufacture and provide pharmaceutical products to customers, typically pharmaceutical companies. The contract manufactured products are sold at pre-determined standalone selling prices and our performance obligations are considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer when the product leaves our dock to be shipped to the customer, as our pharmaceutical products are sold on an FOB shipping point basis and the inventory risk and risk of ownership passes to the customer at that time. Payment terms for these sales are generally less than two months. We estimate returns based on historical experience. Historically, we have not had material returns for contract manufactured products. We recognized $9.1 million, $7.0 million, and $5.5 million of revenue related to sales of contract manufactured products in 2018, 2017, and 2016, respectively.

Royalties from Licensing Agreements

From time to time, we enter into transition agreements with the sellers of products we acquire, under which we license to the seller the right to sell the acquired products. Therefore, we recognize the revenue associated with sales of the underlying products as royalties. Because these royalties are sales-based, we recognize the revenue when the underlying sales occur, based on sales and gross profit information received from the sellers. In addition, we receive royalties from a license for patent rights initially owned by Cell Genesys, Inc., which merged with BioSante in 2009. The royalties are the results of sales and milestones related to the Yescarta® product. We recognize revenue for sales-based royalties when the underlying sales occur. We estimate variable consideration related to milestones, which requires significant judgment. We recognized $12.5 million of revenue related to royalties from licensing agreements in 2018. We did not recognize revenue for royalties from licensing agreements in 2017 and 2016.

Product Development Services Revenue

We provide product development services to customers, which are performed over time. These services primarily relate to the technology transfer of products to our facility in Oakville, Ontario. Technology transfer refers to the process required to move the manufacture of a product to a new manufacturing site and may include performance obligations such as formulation development, production of small-scale batches, process development, and analytical

method development and validation. The duration of these technology transfer projects is generally 18 months to three years. Deposits received from these customers are recorded as deferred revenue until revenue is recognized. For contracts with no deposits and for the remainder of contracts with deposits, we invoice customers as our performance obligations are satisfied. We recognize revenue on a proportional basis, which results in contract assets on our balance sheet. We recognized $1.0 million of revenue related to product development services in 2018. We did not recognize revenue for product development services in 2017 and 2016.

Intangible Assets

As discussed in Note 1 of Item 8. Consolidated Financial Statements, our definite-lived intangible assets have a carrying value of $201.6 million as of December 31, 2018. 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 four 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 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. Throughout 2017, we continued to attempt to sell the Testosterone Gel NDA and were unable to complete a sale. As a result, in the fourth quarter of 2017, we determined that the asset could be impaired. After performing an impairment assessment, which indicated that the fair value of the asset was lower than the carrying value, we recorded an additional impairment of $0.9 million in the year ended December 31, 2017, writing off the asset in its entirety.

No events or circumstances arose in 2018 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

As discussed in Note 1 of Item 8. Consolidated Financial statements, our goodwill balance relates to the Merger and the acquisition of WellSpring 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, 2018 was $3.6 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 2018, the stock-based compensation expense related to the ESPP was $102 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 operations:

	Years Ended December 31,		
(in thousands)	2018	2017	2016
Cost of sales	$ 87	$ 86	$ 60
Research and development	771	677	112
Selling, general, and administrative	5,822	5,259	5,870
	$ 6,680	$ 6,022	$ 6,042

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 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 and dividend yields. Changes in these assumptions can affect the fair value estimate.

Through December 31, 2016, we estimated the awards that would ultimately vest, using judgment for the amounts that would be forfeited due to failure to fulfill service conditions. To the extent actual results or updated estimates differed from current estimates, such amounts were recorded as a cumulative adjustment in the period estimates were revised. As of January 1, 2017, in accordance with new guidance from the FASB, we no longer estimate forfeitures, instead we 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 for Income Taxes would be affected by $0.7 million for the year ended December 31, 2018.

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 Tax Cuts and Jobs Act, which was enacted on December 22, 2017, includes a number of changes to existing U.S. tax laws, most notably the reduction of the U.S. corporate income tax rate from 35% to 21%, which began in 2018. We measure our deferred tax assets and liabilities using the enacted tax rates that we believe will apply in the years in which the temporary differences are expected to be recovered or paid. As a result,

we remeasured our deferred tax assets and deferred tax liabilities to reflect the reduction in the enacted U.S. corporate income tax rate, resulting in a $13.4 million increase in income tax expense for the year ended December 31, 2017. 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. Our effective tax rate decreased as a result of the change in U.S. corporate income tax rate from the Tax Cuts and Jobs Act.

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**.**

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In November 2018, the Financial Accounting Standards Board ("FASB") issued guidance clarifying that certain transactions between collaborative arrangement participants should be accounted for revenue under Accounting Standards Codification Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The guidance is effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

In October 2018, the FASB issued guidance for accounting for derivatives and hedging. The guidance provides for the inclusion of the Secured Overnight Financing Rate ("SOFR") Overnight Index swap rate as a benchmark interest rate for hedge accounting purposes. In July 2017, the Financial Conduct Authority in the United Kingdom announced that it would phase out London Interbank Offered Rate ("LIBOR") as a benchmark by the end of 2021. As a result, the U.S. Federal Reserve identified the SOFR as its preferred alternative reference rate, calculated with a broad set of short-term repurchase agreements backed by treasury securities. Amounts drawn under our five-year senior secured credit facility bear interest rates in relation to LIBOR, and our interest rate swap is designated in LIBOR. 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 will adopt this guidance as of January 1, 2019. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In August 2018, the FASB issued guidance aligning the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance is effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted, including adoption in an interim period. We will adopt this guidance as of January 1, 2019 on a prospective basis. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In August 2018, the FASB issued guidance modifying the disclosure requirements on fair value measurements. The amendments add, modify, and eliminate certain disclosure requirements on fair value measurements. The guidance is effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

In June 2018, the FASB issued guidance simplifying the accounting for nonemployee stock-based compensation awards. The guidance aligns the measurement and classification for employee stock-based compensation awards to nonemployee stock-based compensation awards. Under the guidance, nonemployee awards will be measured at their grant date fair value. Upon transition, the existing nonemployee awards will be measured at fair value as of the adoption date. The guidance is effective for reporting periods beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, including adoption in an interim period. We will adopt this guidance as of January 1, 2019. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

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 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. In July 2018, the FASB issued additional guidance, which offers a transition option to entities adopting the new lease standards. Under the transition option, entities can elect to apply the new guidance using a modified retrospective approach at the beginning of the year in which the new lease standard is adopted, rather than to the earliest comparative period presented in their financial statements. 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 will elect to use the transition option, as well as the package of practical expedients when we adopt the guidance using the modified retrospective approach as of January 1, 2019. As a result of adoption of this guidance, we anticipate that we will record right-of-use assets and lease liabilities totaling approximately $450 thousand to $500 thousand primarily related to our long-term office operating leases. We also expect that the adoption of this guidance will result in additional lease-related disclosures in the footnotes to 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 operations, comprehensive income, balance sheets, or cash flows.

Recently Adopted Accounting Pronouncements

In August 2018, the Securities and Exchange Commission (“SEC”) adopted the final rule amending certain disclosure requirements that have become redundant, duplicative, overlapping, outdated, or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The rule was effective on November 5, 2018 and will be effective for the quarter that begins after the effective date. The adoption of this guidance will result in the inclusion of the statement of stockholder’s equity in our interim financial statement filings, as well as the removal of certain redundant disclosures in this Annual Report on Form 10-K for the year ending December 31, 2018.

In August 2017, the FASB issued guidance improving accounting for hedging activities. The guidance is intended to simplify hedge accounting by better aligning how an entity’s risk management activities and hedging relationships are presented in its financial statements. The guidance also simplifies the application of hedge accounting guidance in certain situations. The guidance is effective for the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption was permitted, including adoption in an interim period. The guidance with respect to the cash flow and net investment hedge relationships existing on the date of adoption must be applied on a modified retrospective basis and the new disclosure requirements must be applied on a prospective basis. We adopted this guidance as of January 1, 2018. The adoption of this guidance did not have a material impact on our consolidated financial statements. However, the adoption of this guidance did impact how we accounted for the interest rate swap we entered into in April 2018. See Note 4 of Item 8. Consolidated Financial Statements for further

details regarding the interest rate swap.

In May 2017, the FASB issued guidance clarifying when modification accounting should be used for changes to the terms or conditions of a share-based payment award. The guidance does not change the accounting for modifications, but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The guidance is effective for the fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption was permitted, including adoption in an interim period. We adopted this guidance as of January 1, 2018 on a prospective basis. The adoption of this guidance did not have a material impact on our consolidated financial statements.

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. In September 2017, the FASB issued guidance amending and rescinding prior SEC staff announcements and observer comments related to revenue recognition, pursuant to the SEC Staff Announcement at the July 20, 2017 Emerging Issues Task Force meeting.

We performed a comprehensive review of our existing revenue arrangements as of January 1, 2018 following the five-step model. Our analysis indicated that there were no significant changes to how the amount and timing of revenue is recognized under the new guidance as compared to existing guidance. Additionally, our analysis indicated that there were no significant changes to how costs to obtain and fulfill our customer contracts are recognized under the new guidance as compared to existing guidance. We adopted this guidance as of January 1, 2018 using the modified retrospective method and the impact of adoption on our consolidated balance sheet, statement of operations, and statement of cash flows was not material. The adoption of the new guidance impacted the way we analyze, document, and disclose revenue recognition under customer contracts beginning on January 1, 2018 and resulted in additional disclosures in our financial statements. ANI Canada adopted this guidance as of the acquisition date, August 6, 2018. The adoption of this guidance did not have a material impact on our consolidated financial statements.

Off-Balance Sheet Arrangements

As of December 31, 2018, 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, equity risk, and foreign currency exchange rate risk could have a significant impact on our results of operations.

As of December 31, 2018, our largest 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 shares of our common stock at a strike price of $96.21. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock exceeds the strike price of the warrants. In addition, non-performance by the counterparties under the hedge transactions would potentially expose us to dilution of our common stock to the extent our stock price exceeds the conversion price.

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

On December 27, 2018, we refinanced our $125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the “Credit Facility”) for up to $265.2 million. The principal new feature of the Credit Facility is a $118.0 million Delayed Draw Term Loan (the “DDTL”), which can only be drawn on in order to pay down the Company’s remaining 3.0% Convertible Senior Notes, which will mature in December 2019. The Credit Facility also extended the maturity of the $72.2 million secured term loan balance (the “Term Loan”) to December 2023. In addition, the Credit Facility increased the previous $50.0 million line of credit (the “Revolver”) to $75.0 million. Amounts drawn bear an interest rate equal to, at our option, either a LIBOR rate plus 1.50% to 2.75% per annum, depending on our total leverage ratio or an alternative base rate plus an applicable base rate margin, which varies within a range of 0.50% to 1.75%, depending our total leverage ratio. We will incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. We will also incur a delayed draw ticking fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. As of December 31, 2018, we had a $72.2 million outstanding balance on the Credit Facility. As of December 31, 2018, we had not drawn on the Revolver or DDTL.

On December 27, 2018, we entered into an interest rate swap to manage our exposure to the variable interest rate on our refinanced secured Term Loan. The interest rate swap hedges the variable cash flows associated with the secured Term Loan borrowings under the secured Term Loan, effectively providing a fixed rate of interest throughout the life of the secured Term Loan. As a result of the interest rate swap, our exposure to interest rate volatility is minimized.

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, 2018 by approximately $15 thousand.

We are exposed to risks associated with foreign currency exchange rate risks as we remeasure certain Canadian dollar-denominated transactions from our ANI Pharmaceuticals Canada Inc. subsidiary from the Canadian dollar to the U.S. dollar. Changes in exchange rates can positively or negatively impact our revenue, income, assets, liabilities, and equity. Currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity during the year ended December 31, 2018.

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ANI Pharmaceuticals, Inc. and Subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2018, 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) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (*2013*) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated February 27, 2019 expressed an unqualified opinion.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2013.

EISNERAMPER LLP

Iselin, New Jersey

February 27, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

ANI Pharmaceuticals, Inc. and Subsidiaries

Opinion on Internal Control over Financial Reporting

We have audited ANI Pharmaceuticals, Inc. and Subsidiaries' (the "Company") internal control over financial reporting as of December 31, 2018, based on criteria established in the *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in the *Internal Control - Integrated Framework* (*2013*) issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of ANI Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes and our report dated February 27, 2019 expressed an unqualified opinion.

Basis for Opinion

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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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 of internal control over financial reporting 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.

Definition and Limitations of Internal Control over Financial Reporting

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 entity; (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.

/s/ EisnerAmper LLP

EISNERAMPER LLP

Iselin, New Jersey

February 27, 2019

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

	December 31, 2018	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	$ 43,008	$ 31,144
Accounts receivable, net of $47,705 and $34,686 of adjustments for chargebacks and other allowances at December 31, 2018 and 2017, respectively	64,842	58,788
Inventories, net	40,503	37,727
Prepaid income taxes, net	-	1,162
Prepaid expenses and other current assets	4,524	2,784
Total Current Assets	152,877	131,605
Property and equipment, net	38,090	20,403
Restricted cash	5,021	5,006
Deferred tax assets, net of deferred tax liabilities and valuation allowance	27,964	22,667
Intangible assets, net	201,604	229,790
Goodwill	3,580	1,838
Other long-term assets	1,468	829
Total Assets	$ 430,604	$ 412,138
Liabilities and Stockholders' Equity		
Current Liabilities		
Current component of long-term borrowing, net of deferred financing costs	$ 3,256	$ 3,353
Convertible notes, net of discount and deferred financing costs	112,463	-
Accounts payable	8,884	3,630
Accrued expenses and other	1,707	1,571
Accrued royalties	8,456	12,164
Accrued compensation and related expenses	3,524	2,306
Current income taxes payable, net	5,022	-
Accrued government rebates	8,974	7,930
Returned goods reserve	12,552	8,274
Deferred revenue	711	-
Total Current Liabilities	165,549	39,228
Long-term Liabilities		
Long-term borrowing, net of deferred financing costs and current borrowing component	67,296	69,946
Convertible notes, net of discount and deferred financing costs	-	128,208

Other long-term liabilities	496	-
Total Liabilities	$ 233,341	$ 237,382
Commitments and Contingencies (Note 12)		
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 11,862,508 shares issued and 11,851,329 outstanding at December 31, 2018; 11,655,768 shares issued and 11,650,565 shares outstanding at December 31, 2017	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at December 31, 2018 and 2017, respectively	-	-
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at December 31, 2018 and 2017, respectively	-	-
Treasury stock, 11,179 shares of common stock, at cost, at December 31, 2018 and 5,203 shares of common stock, at cost, at December 31, 2017	(659)	(259)
Additional paid-in capital	186,812	179,020
Retained earnings/(accumulated deficit)	11,488	(4,006)
Accumulated other comprehensive loss, net of tax	(379)	-
Total Stockholders' Equity	197,263	174,756
Total Liabilities and Stockholders' Equity	$ 430,604	$ 412,138

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

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

	Years Ended December 31,		
	2018	**2017**	**2016**
Net Revenues	$201,576	$176,842	$128,622
Operating Expenses			
Cost of sales (excluding depreciation and amortization)	73,024	79,032	48,780
Research and development	15,388	9,070	2,906
Selling, general, and administrative	44,063	31,580	27,829
Depreciation and amortization	33,742	27,928	22,343
Intangible asset impairment charge	-	903	6,685
Total Operating Expenses	166,217	148,513	108,543
Operating Income	35,359	28,329	20,079
Other Expense, net			
Interest expense, net	(14,758)	(12,035)	(11,327)
Other (expense)/income, net	(550)	55	(74)
Income Before Provision for Income Taxes	20,051	16,349	8,678
Provision for income taxes	(4,557)	(17,425)	(4,744)
Net Income/(Loss)	$15,494	$(1,076)	$3,934
Basic and Diluted Earnings/(Loss) Per Share:			
Basic Earnings/(Loss) Per Share	$1.31	$(0.09)	$0.34
Diluted Earnings/(Loss) Per Share	$1.30	$(0.09)	$0.34
Basic Weighted-Average Shares Outstanding	11,677	11,547	11,445
Diluted Weighted-Average Shares Outstanding	11,772	11,547	11,573

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Comprehensive Income
(in thousands)

	Years Ended December 31,		
	2018	2017	2016
Net income/(loss)	$15,494	$(1,076)	$3,934
Other comprehensive income/(loss), net of tax:			
Change in fair value of interest rate swap, net of tax	(379)	-	-
Total other comprehensive loss, net of tax	(379)	-	-
Total comprehensive income/(loss), net of tax	$15,115	$(1,076)	$3,934

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, 2018, 2017, and 2016
(in thousands)

	Common Stock Par Value	Common Stock Shares	Class C Special Stock	Additional Paid-in Capital	Treasury Stock Shares	Treasury Stock	Accumulated Other Comprehensive Loss, Net of Tax	(Accumulated Deficit)/ Retained Earnings	Total
Balance, December 31, 2015	$ 1	11,498	$ -	$ 164,431	-	$ -	$ -	$ (4,350)	$ 160,082
Stock-based Compensation Expense	-	-	-	6,067	-	-	-	-	6,067
Treasury Stock purchases for restricted stock vestings	-	-	-	-	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
Stock Option Forfeiture Cumulative-effect Adjustment	-	-	-	14	-	-	-	(14)	-
Balance, net of Cumulative-effectAdjustment	$ 1	11,589	$ -	$ 172,577	-	$ -	$ -	$ (2,930)	$ 169,648
Stock-based Compensation Expense	-	-	-	6,090	-	-	-	-	6,090
Treasury Stock purchases for restricted stock vestings	-	-	-	-	5	(259)	-	-	(259)
Issuance of Common Shares upon Stock Option and ESPP Exercise	-	17	-	353	-	-	-	-	353
Issuance of Restricted Stock Awards	-	50	-	-	-	-	-	-	-
Net Loss	-	-	-	-	-	-	-	(1,076)	(1,076)
Balance, December 31, 2017	$ 1	11,656	$ -	$ 179,020	5	$ (259)	$ -	$ (4,006)	$ 174,756

Stock-based Compensation Expense	-	-	-	6,782	-	-	-	-	6,782
Treasury Stock purchases for restricted stock vestings	-	-	-	-	11	(659)	-	-	(659)
Issuance of Common Shares upon Stock Option and ESPP Exercise	-	142	-	2,719	(5)	259	-	-	2,978
Issuance of Restricted Stock Awards	-	65	-	-	-	-	-	-	-
Change in fair value of interest rate swap, net of tax	-	-	-	-	-	-	(379)	-	(379)
Repurchase of Convertible notes and unwind of call option overlay	-	-	-	(1,709)	-	-	-	-	(1,709)
Net Income	-	-	-	-	-	-	-	15,494	15,494
Balance, December 31, 2018	$ 1	11,863	$ -	$186,812	11	$(659)	$ (379)	$ 11,488	$197,263

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,	**2018**	**2017**	**2016**
Cash Flows From Operating Activities			
Net income/(loss)	$15,494	$(1,076)	$3,934
Adjustments to reconcile net income/(loss) to net cash and cash equivalents provided by operating activities:			
Stock-based compensation	6,782	6,090	6,067
Deferred taxes	(5,180)	3,560	(8,911)
Depreciation and amortization	33,742	27,928	22,343
Acquired in-process research and development ("IPR&D")	1,335	-	-
Non-cash interest relating to convertible notes and loan cost amortization	8,465	7,666	7,281
Loss on repurchase of Convertible notes	468	-	-
Intangible asset impairment charge	-	903	6,685
Changes in operating assets and liabilities:			
Accounts receivable, net	(4,743)	(12,893)	(23,963)
Inventories, net	(379)	5,356	(1,938)
Prepaid expenses and other current assets	(1,142)	(17)	(647)
Accounts payable	3,466	3	1,076
Accrued royalties	(3,708)	(417)	6,269
Current income taxes, net	6,184	(3,560)	3,525
Accrued government rebates	1,044	2,039	1,260
Returned goods reserve	4,278	2,518	3,108
Accrued expenses, accrued compensation, and other	968	1,319	1,383
Net Cash and Cash Equivalents Provided by Operating Activities	67,074	39,419	27,472
Cash Flows From Investing Activities			
Acquisiton of WellSpring Pharma Services Inc., net of cash acquired	(16,467)	-	-
Acquisition of product rights, IPR&D, and other related assets	(5,169)	(97,624)	(144,494)
Acquisition of property and equipment, net	(5,743)	(10,369)	(4,566)
Net Cash and Cash Equivalents Used in Investing Activities	(27,379)	(107,993)	(149,060)
Cash Flows From Financing Activities			
Payment of debt issuance and convertible debt repurchase costs	(1,572)	(2,737)	(294)
Payments on term loan agreement	(2,813)	-	-
Borrowings under term loan agreement	-	75,000	-
Proceeds from stock option exercises	2,978	353	1,570
Excess tax benefit from share-based compensation awards	-	-	617
Repurchase of common stock under the stock repurchase program	-	-	(2,500)
Repurchase of Convertible notes	(26,125)	-	-
Unwinding of portion of call option overlay, net	375	-	-

Treasury stock purchases for restricted stock vestings	(659)	(259)	(122)
Net Cash and Cash Equivalents (Used in)/Provided by Financing Activities	(27,816)	72,357	(729)
Net Change in Cash and Cash Equivalents	11,879	3,783	(122,317)
Cash and cash equivalents, beginning of period	36,150	32,367	154,684
Cash and cash equivalents, end of period	$48,029	$36,150	$32,367
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period			
Cash and cash equivalents	31,144	27,365	154,684
Restricted cash	5,006	5,002	-
Cash, cash equivalents, and restricted cash, beginning of period	36,150	32,367	154,684
Reconciliation of cash, cash equivalents, and restricted cash, end of period			
Cash and cash equivalents	43,008	31,144	27,365
Restricted cash	5,021	5,006	5,002
Cash, cash equivalents, and restricted cash, end of period	48,029	36,150	32,367
Supplemental disclosure for cash flow information:			
Cash paid for interest, net of amounts capitalized	$6,285	$3,759	$4,078
Cash paid for income taxes	$6,397	$17,786	$9,537
Supplemental non-cash investing and financing activities:			
Accrued royalties related to asset purchase	$-	$-	$3,882
Property and equipment purchased and included in accounts payable	$521	$485	$247

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

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries, ANIP Acquisition Company and ANI Pharmaceuticals Canada Inc. (together, "ANI," the "Company," "we," "us," or "our") is an integrated specialty pharmaceutical company focuse 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 three facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, Ontario, we manufacture oral solid dose products, as well as semi-solids, 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.

On August 6, 2018, our subsidiary, ANI Pharmaceuticals Canada Inc. ("ANI Canada"), acquired all the issued and outstanding equity interests of WellSpring Pharma Services Inc. ("WellSpring"), a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Pursuant to these customary adjustments, the total purchase consideration was $16.7 million. The consideration was paid entirely from cash on hand. In conjunction with the transaction, we acquired WellSpring's pharmaceutical manufacturing facility, laboratory, and offices, its current book of commercial business, as well as an organized workforce. Following the consummation of the transaction, WellSpring was merged into ANI Canada with the resulting entity's name being ANI Pharmaceuticals Canada Inc.

Our operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, dependence on significant customers, 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

We have a subsidiary located in Canada. The subsidiary conducts its transactions in U.S. dollars and Canadian dollars, but its functional currency is the U.S. dollar. The results of any non-U.S. dollar transactions are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income. Our gain on transactions determined in foreign currencies was immaterial for the year ended December 31, 2018. Unless otherwise noted, all references to “$” or “dollar” refer to the U.S. dollar.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, revenue recognition, allowance for doubtful accounts, variable consideration determined based on 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, income tax provision, 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 may differ from those estimates. Management periodically evaluates estimates used in the preparation of the financial statements for reasonableness.

Comprehensive Income

Comprehensive income, which is reported in the statement of comprehensive income, consists of net income, changes in fair value of our interest rate swap, and other comprehensive income, net of tax.

Credit Concentration

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

During the year ended December 31, 2018, three customers represented approximately 21%, 23%, and 33% of net revenues, respectively. As of December 31, 2018, accounts receivable from these customers totaled 81% of net accounts receivable. During the year ended December 31, 2017, three customers represented approximately 29%, 29%, and 20% of net revenues, respectively. During the year ended December 31, 2016, three customers represented approximately 28%, 22%, and 18% 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, 2018, we purchased approximately 13% of our inventory from one supplier. As of December 31, 2018, amounts payable to this supplier was immaterial. During the year ended December 31, 2017, we purchased approximately 23% of our inventory from two suppliers. During the year ended December 31, 2016, we purchased approximately 25% of our inventory from one supplier.

Revenue Recognition

As of January 1, 2018, we adopted guidance for revenue recognition for contracts, using the modified retrospective method. The implementation of the guidance had no material impact on the measurement or recognition of revenue from customer contracts of prior periods. For our revenue recognition policies prior to adopting the guidance for revenue recognition for contracts, please see Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2017.

Upon adoption of this new guidance, we recognize revenue using the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price, including the identification and estimation of variable consideration;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when we satisfy a performance obligation.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

We derive our revenues primarily from sales of generic and branded pharmaceutical products. Revenue is recognized when our obligations under the terms of our contracts with customers are satisfied, which generally occurs when control of the products we sell is transferred to the customer. We estimate variable consideration after considering applicable information that is reasonably available. We generally do not have incremental costs to obtain contracts that would otherwise not have been incurred. We do not adjust revenue for the promised amount of consideration for the effects of a significant financing component because our customers generally pay us within 100 days.

All revenue recognized in our consolidated statements of operations is considered to be revenue from contracts with customers. The following table depicts the disaggregation of revenue:

Products and Services	**Years Ended December 31,**		
(in thousands)	**2018**	**2017**	**2016**
Sales of generic pharmaceutical products	$117,451	$118,437	$95,201
Sales of branded pharmaceutical products	60,554	50,919	26,443
Sales of contract manufactured products	9,119	7,046	5,537
Royalties from licensing agreements	12,504	-	-
Product development services	1,019	-	-
Other[(1)]	929	440	1,441
Total net revenues	$201,576	$176,842	$128,622

[(1)]Primarily includes laboratory services and royalties on sales of contract manufactured products

Timing of Revenue Recognition	**Years Ended December 31,**		
(in thousands)	**2018**	**2017**	**2016**
Performance obligations transferred at a point in time	$200,557	$176,842	$128,622
Performance obligations transferred over time	1,019	-	-
Total	$201,576	$176,842	$128,622

During the year ended December 31, 2018, we did not incur, and therefore did not defer, any material incremental costs to obtain contracts. We recognized $5.3 million of net revenue from performance obligations satisfied in prior periods during the year ended December 31, 2018, consisting primarily of royalties from licensing agreements and revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. In August 2018, we acquired WellSpring (see Note 3), a contract manufacturing company that also provides technical transfer services to customers, for which services are transferred over time. As a result, we had $0.1 million of contract assets related to revenue recognized based on percentage of completion but not yet billed and $0.7 million of deferred revenue at December 31, 2018. We had no contract assets or deferred revenue at December 31, 2017 and 2016.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

Revenue from Sales of Generic and Branded Pharmaceutical Products

Product sales consists of sales of our generic and brand pharmaceutical products. Our sole performance obligation in our contracts is to provide pharmaceutical products to customers. Our products are sold at pre-determined standalone selling prices and our performance obligation is considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer upon delivery of the product to the customer, as our pharmaceutical products are sold on an FOB destination basis and because inventory risk and risk of ownership passes to the customer upon delivery. Payment terms for these sales are generally less than 100 days.

Revenue from Distribution Agreements

From time to time, we enter into 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. These products are sold under our own label. We have assessed and determined that we control the products sold under these marketing and distribution agreements and therefore are the principal for sales under each of these marketing and distribution agreements. As a result, we recognize revenue on a gross basis when control has passed to the customer and we have satisfied our performance obligation. 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 operations and are accrued in accrued royalties in our consolidated balance sheets until payment has occurred.

Sales of our pharmaceutical products are subject to variable consideration due to chargebacks, government rebates, returns, administrative and other rebates, and cash discounts. Estimates for these elements of variable consideration require significant judgment.

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.

The difference between ASP and WAC is recorded as a reduction in both gross revenues in the consolidated statements of operations 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.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

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 operations 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 operations and as an increase to the return goods reserve in the consolidated balance sheets.

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 operations and accounts receivable in the consolidated balance sheets.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

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 operations 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, 2018, 2017, and 2016:

	Accruals for Chargebacks, Returns, and Other Allowances				
(in thousands)	Chargebacks	Government Rebates	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
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
Accruals/Adjustments	179,297	12,237	12,184	24,037	8,126
Credits Taken Against Reserve	(177,852)	(10,198)	(9,666)	(22,361)	(7,846)
Balance at December 31, 2017	$ 28,230	$ 7,930	$ 8,274	$ 5,226	$ 1,834
Accruals/Adjustments	229,813	11,383	14,243	33,167	9,371
Credits Taken Against Reserve	(219,036)	(10,339)	(9,965)	(31,040)	(9,196)
Balance at December 31, 2018	$ 39,007	$ 8,974	$ 12,552	$ 7,353	$ 2,009

Contract Manufacturing Product Sales Revenue

Contract manufacturing arrangements consists of agreements in which we manufacture a pharmaceutical product on behalf of third party. Our performance obligation is to manufacture and provide pharmaceutical products to customers, typically pharmaceutical companies. The contract manufactured products are sold at pre-determined standalone selling prices and our performance obligations are considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer when the product leaves our dock to be shipped to the customer, as our pharmaceutical products are sold on an FOB shipping point basis and the inventory risk and risk of ownership passes to the customer at that time. Payment terms for these sales are generally less than two months. We estimate returns based on historical experience. Historically, we have not had material returns for

As of December 31, 2018, the value of our unsatisfied performance obligations (or backlog) was $6.3 million, which consists of firm orders for contract manufactured products, for which our performance obligations remain unsatisfied and for which the related revenue has yet to be recognized. We anticipate satisfying these performance obligations within six months.

Royalties from Licensing Agreements

From time to time, we enter into transition agreements with the sellers of products we acquire, under which we license to the seller the right to sell the acquired products. Therefore, we recognize the revenue associated with sales of the underlying products as royalties. Because these royalties are sales-based, we recognize the revenue when the underlying sales occur, based on sales and gross profit information received from the sellers. Upon full transition of the products and upon launching the products under our own labels, we recognize revenue for the products as sales of generic or branded pharmaceutical products, as described above.

In addition, we receive royalties from a license for patent rights initially owned by Cell Genesys, Inc., which merged with BioSante in 2009. The royalties are the results of sales and milestones related to the Yescarta® product. We recognize revenue for sales-based royalties when the underlying sales occur and when related milestones occur, which requires significant judgment.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

Product Development Services Revenue

We provide product development services to customers, which are performed over time. These services primarily relate to the technology transfer of products to our facility in Oakville, Ontario. Technology transfer refers to the process required to move the manufacture of a product to a new manufacturing site and may include performance obligations such as formulation development, production of small-scale batches, process development, and analytical method development and validation. The duration of these technology transfer projects is generally 18 months to three years. Deposits received from these customers are recorded as deferred revenue until revenue is recognized. For contracts with no deposits and for the remainder of contracts with deposits, we invoice customers as our performance obligations are satisfied. We recognize revenue on a proportional basis, which results in contract assets on our balance sheet. As of December 31, 2018, the value of our unsatisfied performance obligations for product development services contracts was $2.0 million. We expect to satisfy these performance obligations in the next 6 to 15 months.

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, 2018 and 2017.

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.

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	1 - 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, 2018, 2017, and 2016. 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, 2018 and 2017.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

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, ANDAs for three previously-commercialized generic drug products, the approved ANDAs for two generic drug products that have yet to be commercialized, the development package for one generic drug product, a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval, ANDAs for 23 previously-marketed generic products we acquired in 2018, NDAs and product rights for our branded products Atacand, Atacand HCT, Arimidex, Casodex, Lithobid, Vancocin, Inderal LA, Inderal XL, InnoPran XL, and Cortrophin, 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 four 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. No impairment losses related to intangible assets were recognized in the year ended December 31, 2018. During the years ended December 31, 2017 and 2016 we recognized impairment charges of $0.9 million and $6.7 million in relation to our testosterone gel NDA asset, respectively (Note 7).

Goodwill

Goodwill relates to the Merger and the acquisition of WellSpring 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 for impairment

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.

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 were to exceed its fair value, we would recognize an impairment charge for the amount by which the carrying amount exceeded the reporting unit’s fair value. The loss recognized would not exceed the total amount of goodwill allocated to that reporting unit. No impairment loss related to goodwill was recognized in the years ended December 31, 2018, 2017, and 2016.

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 operations 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.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

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 operations 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 $15.4 million, $9.1 million, and $2.9 million for the years ended December 31, 2018, 2017, and 2016, 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 is recognized as expense on a straight-line basis over the employee’s requisite service period. We also account for forfeitures as they occur rather than using an estimated forfeiture rate. We recognize excess tax benefits or tax deficiencies as a component of our current period provision for income taxes.

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 $6.7 million, $6.1 million, and $6.1 million of non-cash, stock-based compensation cost for the years ended December 31, 2018, 2017, and 2016, respectively, of which $102 thousand, $68 thousand, and $25 thousand of the 2018, 2017, and 2016 expense related to the ESPP, respectively.

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 and dividend yields. Changes in these assumptions can affect the fair value estimate.

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 Tax Cuts and Jobs Act, which was enacted on December 22, 2017, includes a number of changes to existing U.S. tax laws, most notably the reduction of the U.S. corporate income tax rate from 35% to 21%, which began in 2018. We measure our deferred tax assets and liabilities using the enacted tax rates that we believe will apply in the years in which the temporary differences are expected to be recovered or paid. As a result, we remeasured our deferred tax assets and deferred tax liabilities to reflect the reduction in the enacted U.S. corporate income tax rate, resulting in a $13.4 million increase in income tax expense for the year ended December 31, 2017 (Note 11). Beginning with our acquisition of ANI Canada in August 2018, our Canadian operations are subject to corporate taxes at a foreign statutory rate of 26.5%.

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. As of December 31, 2018 and 2017, we maintained a valuation allowance against certain state net operating loss carryforwards that we believe may not be realizable within the individual state statutory carry forward periods. Additionally, as of December 31, 2018 we maintained a valuation against all of our net deferred tax assets at ANI Canada based on our assessment of the eventual realization of those assets.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

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 are subject to taxation in Canada and remain subject to examination by taxing jurisdictions for a period of four years.

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, 2018, 2017, and 2016.

We consider potential tax effects resulting from discontinued operations and record intra-period tax allocations, when those effects are deemed material. In 2018, we entered in an interest rate swap agreement (Note 4) that we designated as a cash flow hedge designed to manage exposure to changes in LIBOR-based interest rate underlying our Term Loan with Citizen’s Bank., N.A. Due to the effective nature of the hedge, the initial fair value of the hedge and subsequent changes in the fair value of the hedge are recognized in accumulated other comprehensive loss, net of tax in the accompanying consolidated balance sheets. Income taxes are allocated to the hedge component of accumulated other comprehensive income based on appropriate intra-period tax allocations when those effects are deemed material.

Earnings (Loss) per Share

Basic earnings (loss) 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 (loss) 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 because the impact of all dilutive potential common shares is anti-dilutive.

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 (loss) 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 (loss) 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 3) 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 (loss) per share. Any conversion gain is assumed to be settled in shares and is incorporated in diluted earnings (loss) 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.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

The numerator for earnings per share for the years ended December 31, 2018, 2017, and 2016 are calculated for basic and diluted earnings (loss) per share as follows:

	Basic			Diluted		
	Years Ended December 31,			Years Ended December 31,		
(in thousands, except per share amounts)	**2018**	**2017**	**2016**	**2018**	**2017**	**2016**
Net income/(loss)	$15,494	$(1,076)	$3,934	$15,494	$(1,076)	$3,934
Net income allocated to restricted stock	(154)	-	(21)	(154)	-	(21)
Net income/(loss) allocated to common shares	$15,340	$(1,076)	$3,913	$15,340	$(1,076)	$3,913
Basic Weighted-Average Shares Outstanding	11,677	11,547	11,445	11,677	11,547	11,445
Dilutive effect of stock options and ESPP				95	-	128
Diluted Weighted-Average Shares Outstanding				11,772	11,547	11,573
Earnings/(Loss) per share	$1.31	$(0.09)	$0.34	$1.30	$(0.09)	$0.34

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share, including the shares underlying the Notes, were 4.4 million, 4.8 million, and 4.5 million for the years ended December 31, 2018, 2017, and 2016, respectively. Due to the net loss in the year ended December 31, 2017, all dilutive potential common shares were also excluded from the diluted loss per share calculation, as the impact of those potential common shares is anti-dilutive in the case of a net loss. 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.

Hedge Accounting

As of January 1, 2018, we adopted guidance intended to simplify hedge accounting by better aligning how an entity's risk management activities and hedging relationships are presented in its financial statements. The guidance also simplified the application of hedge accounting guidance in certain situations. The adoption of this guidance did not have a material impact on our consolidated financial statements. However, the adoption of this guidance did impact how we accounted for the interest rate swaps we entered into in April 2018 and December 2018. See Note 4 for further details regarding the interest rate swap.

We use derivative financial instruments to hedge our exposure to interest rate risks. All derivative financial instruments are recognized as either assets or liabilities at fair value on the consolidated balance sheet and are classified as current or long-term based on the scheduled maturity of the instrument.

When we enter into a hedge arrangement and intend to apply hedge accounting, we formally document the hedge relationship and designate the instrument for financial reporting purposes as a fair value hedge, a cash flow hedge, or a net investment hedge. When we determine that a derivative financial instrument qualifies as a cash flow hedge and is effective, the changes in fair value of the instrument are recorded in accumulated other comprehensive income/(loss), net of tax in our consolidated balance sheets and will be reclassified to earnings when the hedged item affects earnings.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

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 8 for additional information regarding fair value.

Geographic Information

Based on the distinct nature of our operations, our internal management structure, and the financial information that is evaluated regularly by our Chief Operating Decision Maker ("CODM"), we determined that we operate in one reportable segment. Our operations are located in the United States and Canada.

The following table depicts the Company's revenue by geographic operations during the following periods:

(in thousands)	Years Ended December 31,		
Location of Operations	**2018**	**2017**	**2016**
United States	$196,886	$176,842	$128,622
Canada	4,690	-	-
Total Revenue	$201,576	$176,842	$128,622

The following table depicts the Company's property and equipment, net according to geographic location as of:

(in thousands)	December 31, 2018	December 31, 2017
United States	$ 24,437	$ 20,403
Canada	13,653	-
Total property and equipment, net	$ 38,090	$ 20,403

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In November 2018, the Financial Accounting Standards Board ("FASB") issued guidance clarifying that certain transactions between collaborative arrangement participants should be accounted for revenue under Accounting Standards Codification Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The guidance is effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

In October 2018, the FASB issued guidance for accounting for derivatives and hedging. The guidance provides for the inclusion of the Secured Overnight Financing Rate ("SOFR") Overnight Index swap rate as a benchmark interest rate for hedge accounting purposes. In July 2017, the Financial Conduct Authority in the United Kingdom announced that it would phase out London Interbank Offered Rate ("LIBOR") as a benchmark by the end of 2021. As a result, the U.S. Federal Reserve identified the SOFR as its preferred alternative reference rate, calculated with a broad set of short-term repurchase agreements backed by treasury securities. Amounts drawn under our five-year senior secured credit facility bear interest rates in relation to LIBOR, and our interest rate swap is designated in LIBOR. 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 will adopt this guidance as of January 1, 2019. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In August 2018, the FASB issued guidance aligning the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance is effective for reporting periods beginning after December 15,

2019, including interim periods within that fiscal year. Early adoption is permitted, including adoption in an interim period. We will adopt this guidance as of January 1, 2019 on a prospective basis. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

In August 2018, the FASB issued guidance modifying the disclosure requirements on fair value measurements. The amendments add, modify, and eliminate certain disclosure requirements on fair value measurements. The guidance is effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

In June 2018, the FASB issued guidance simplifying the accounting for nonemployee stock-based compensation awards. The guidance aligns the measurement and classification for employee stock-based compensation awards to nonemployee stock-based compensation awards. Under the guidance, nonemployee awards will be measured at their grant date fair value. Upon transition, the existing nonemployee awards will be measured at fair value as of the adoption date. The guidance is effective for reporting periods beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, including adoption in an interim period. We will adopt this guidance as of January 1, 2019. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

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.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

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. In July 2018, the FASB issued additional guidance, which offers a transition option to entities adopting the new lease standards. Under the transition option, entities can elect to apply the new guidance using a modified retrospective approach at the beginning of the year in which the new lease standard is adopted, rather than to the earliest comparative period presented in their financial statements. 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 will elect to use the transition option, as well as the package of practical expedients when we adopt the guidance using the modified retrospective approach as of January 1, 2019. As a result of this guidance, we anticipate that we will record right-of-use assets and lease liabilities totaling approximately $450 thousand to $500 thousand primarily related to our long-term office operating leases. We also expect that the adoption of this guidance will result in additional lease-related disclosures in the footnotes to 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 operations, comprehensive income, balance sheets, or cash flows.

Recently Adopted Accounting Pronouncements

In August 2018, the Securities and Exchange Commission (“SEC”) adopted the final rule amending certain disclosure requirements that have become redundant, duplicative, overlapping, outdated, or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The rule was effective on November 5, 2018 and will be effective for the quarter that begins after the effective date. The adoption of this guidance will result in the inclusion of the statement of stockholder’s equity in our interim financial statement filings, as well as the removal of certain redundant disclosures in this Annual Report on Form 10-K for the year ending December 31, 2018.

In August 2017, the FASB issued guidance improving accounting for hedging activities. The guidance is intended to simplify hedge accounting by better aligning how an entity's risk management activities and hedging relationships are presented in its financial statements. The guidance also simplifies the application of hedge accounting guidance in certain situations. The guidance is effective for the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption was permitted, including adoption in an interim period. The guidance with respect to the cash flow and net investment hedge relationships existing on the date of adoption must be applied on a modified retrospective basis and the new disclosure requirements must be applied on a prospective basis. We adopted this guidance as of January 1, 2018. The adoption of this guidance did not have a material impact on our consolidated financial statements. However, the adoption of this guidance did impact how we accounted for the interest rate swap we entered into in April 2018. See Note 4 for further details regarding the interest rate swap.

In May 2017, the FASB issued guidance clarifying when modification accounting should be used for changes to the terms or conditions of a share-based payment award. The guidance does not change the accounting for modifications, but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The guidance is effective for the fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption was permitted, including adoption in an interim period. We adopted this guidance as of January 1, 2018 on a prospective basis. The adoption of this guidance did not have a material impact on our consolidated financial statements.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

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

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. In September 2017, the FASB issued guidance amending and rescinding prior SEC staff announcements and observer comments related to revenue recognition, pursuant to the SEC Staff Announcement at the July 20, 2017 Emerging Issues Task Force meeting.

We performed a comprehensive review of our existing revenue arrangements as of January 1, 2018 following the five-step model. Our analysis indicated that there were no significant changes to how the amount and timing of revenue is recognized under the new guidance as compared to existing guidance. Additionally, our analysis indicated that there were no significant changes to how costs to obtain and fulfill our customer contracts are recognized under the new guidance as compared to existing guidance. We adopted this guidance as of January 1, 2018 using the modified retrospective method and the impact of adoption on our consolidated balance sheet, statement of operations, and statement of cash flows was not material. The adoption of the new guidance impacted the way we analyze, document, and disclose revenue recognition under customer contracts beginning on January 1, 2018 and resulted in additional disclosures in our financial statements. ANI Canada adopted this guidance as of the acquisition date, August 6, 2018. The adoption of this guidance did not have a material impact on our consolidated financial statements.

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ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

2. BUSINESS COMBINATION

Summary

On August 6, 2018, our subsidiary, ANI Canada, acquired all the issued and outstanding equity interests of WellSpring, a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Pursuant to these customary adjustments, the total purchase consideration was $16.7 million. The consideration was paid entirely from cash on hand. In conjunction with the transaction, we acquired WellSpring's pharmaceutical manufacturing facility, laboratory, and offices, its current book of commercial business, as well as an organized workforce. Following the consummation of the transaction, WellSpring was merged into ANI Canada with the resulting entity's name being ANI Pharmaceuticals Canada Inc.

We acquired WellSpring to provide an additional tech transfer site in order to accelerate the re-commercialization of the previously-approved ANDAs in our pipeline, to expand our contract manufacturing revenue base, and to broaden our manufacturing capabilities to three manufacturing facilities.

Transaction Costs

In conjunction with the acquisition, we incurred approximately $1.1 million in transaction costs, all of which were expensed in 2018.

Purchase Consideration and Net Assets Acquired

The business combination was accounted for using the acquisition method of accounting, with ANI as the accounting acquirer of WellSpring. The acquisition method requires that acquired assets and assumed liabilities be recorded at their fair values as of the acquisition date.

The following presents the preliminary allocation of the purchase price, which has been updated to reflect the December 2018 net working capital adjustment of $0.6 million, resulting in a $0.6 million decrease to goodwill, to the assets acquired and liabilities assumed on August 6, 2018:

	(in thousands)
Total Purchase Consideration	$ 16,687
Cash and cash equivalents	220
Accounts receivable	1,311
Inventories	2,197
Prepaid expenses and other current assets	361
Property and equipment	13,935
Deferred tax assets, net	-
Goodwill	1,742
Total assets acquired	19,766
Accounts payable and other current liabilities	2,413
Deferred revenue	666
Total liabilties assumed	3,079
Net assets acquired	$ 16,687

The net assets were recorded at their estimated fair value. In valuing acquired assets and liabilities, fair value estimates were based primarily on future expected cash flows, market rate assumptions for contractual obligations, and appropriate discount rates.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

2. BUSINESS COMBINATION (Continued)

The above allocation of the purchase price is based upon certain preliminary valuations and other analyses that have not been finalized as of the date of this filing. Any changes in the estimated fair values of the net assets recorded for this business combination upon the finalization of more detailed analyses of the facts and circumstances that existed at the date of the transaction may change the allocation of the purchase price. As such, the purchase price allocations for this transaction are preliminary estimates, which may be subject to change within the measurement period.

Goodwill is considered an indefinite-lived asset and relates primarily to intangible assets that do not qualify for separate recognition, such as the assembled workforce and synergies between the entities. Goodwill established as a result of the acquisition is not tax deductible in any taxing jurisdiction. There was no value ascribed to any separately identifiable intangible assets.

Legacy WellSpring operations generated $4.7 million of revenue and recorded a net loss of $1.1 million from the acquisition date through December 31, 2018.

Pro Forma Condensed Combined Financial Information (unaudited)

The following unaudited pro forma condensed combined financial information summarizes the results of operations for the periods indicated as if the WellSpring acquisition had been completed as of January 1, 2017.

	Years Ended December 31,	
(in thousands)	**2018**	**2017[1]**
Net revenues	$ 208,213	$ 188,758
Net income/(loss)	$ 13,287	$ (3,102)

(1) Net income for the year ended December 31, 2017 includes the impact to WellSpring of $4.4 million of related party debt forgiveness.

The pro forma amounts are not necessarily indicative of the results that would have been obtained if the transaction had occurred as of January 1, 2017 or that may be obtained in the future. The unaudited pro forma condensed consolidated financial information includes pro forma adjustments primarily relating to the following non-recurring items directly attributable to the business combination:

- Elimination of amortization expense related to the acquiree's historical intangible assets;
- Elimination of transaction costs;
- Elimination of profit on sales from WellSpring to ANI in the periods; and
- Tax impacts of the adjustments to the acquirer's net income, calculated as 23% in 2018 and 37% in 2017. As the acquiree has a loss in both years, there is no tax impact to adjustments to the acquiree's net income.

The pro forma financial information does not include the effects of any expected operational efficiencies or synergies resulting from the acquisition.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

3. INDEBTEDNESS

Credit Facility

On December 27, 2018, we refinanced our $125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the "Credit Facility") for up to $265.2 million. The principal new feature of the Credit Facility is a $118.0 million Delayed Draw Term Loan (the "DDTL"), which can only be drawn on in order to pay down the Company's remaining 3.0% Convertible Senior Notes, which will mature in December 2019. The Credit Facility (and specifically the DDTL) has a subjective acceleration clause in case of a material adverse event. As a result, the remaining 3% Convertible Senior Notes are classified as current in the accompanying consolidated balance sheets. The Credit Facility also extended the maturity of the $72.2 million secured term loan balance (the "Term Loan") to December 2023. In addition, the Credit Facility increased the previous $50.0 million line of credit (the "Revolver") to $75.0 million. Also on December 27, 2018, we entered into an interest rate swap arrangement to manage our exposure to changes in LIBOR-based interest rates underlying our refinanced Term Loan (Note 4). The Term Loan includes a repayment schedule, subsequent to which $3.6 million of the loan will be paid in quarterly installments during 2019. As a result, $3.6 million of the loan is recorded in current component of long-term borrowing, net of deferred financing in the accompanying consolidated balance sheets. Amounts drawn on the Term Loan and, if drawn upon, the DDTL, bear an interest rate equal to, at our option, either a LIBOR rate plus 1.50% to 2.75% per annum, depending on our total leverage ratio or an alternative base rate plus an applicable base rate margin, which varies within a range of 0.50% to 1.75%, depending our total leverage ratio. We will incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. We will also incur a delayed draw ticking fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio.

The Credit Facility is secured by a lien on substantially all of ANI Pharmaceuticals, Inc.'s and its principal domestic subsidiary's assets and any future domestic subsidiary guarantors' assets. The Credit Facility imposes financial covenants consisting of a maximum total leverage ratio, which initially shall be no greater than 3.75 to 1.00 and a minimum fixed charge coverage ratio, which shall be greater than or equal to 1.25 to 1.00. The primary non-financial covenants under the Credit Facility limit, subject to various exceptions, our ability to incur future indebtedness, to place liens on assets, to pay dividends or make other distributions on our capital stock, to repurchase our capital stock, to conduct acquisitions, to alter our capital structure, and to dispose of assets.

The carrying value of the current and long-term components of the Term Loan as of December 31, 2018 and 2017 are:

	Current	
(in thousands)	2018	2017
Current borrowing on secured term loan	$3,609	$3,750
Deferred financing costs	(353)	(397)
Current component of long-term borrowing, net of deferred financing costs	$3,256	$3,353

	Long-Term	
(in thousands)	2018	2017
Long-term borrowing on secured term loan	$ 68,578	$ 71,250
Deferred financing costs	(1,282)	(1,304)
Long-term borrowing, net of deferred financing costs and current borrowing component	$ 67,296	$ 69,946

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

3. INDEBTEDNESS (Continued)

The refinancing of the Term Loan was accounted for as a modification of our previous term loan and consequently, the remaining balance of the deferred issuance costs related to the previous term loan are included with the lenders fees associated with the refinance of the Term Loan and amortized as interest expense over the life of the Term Loan using the effective interest method. Fees to third parties associated with the refinance of the Term Loan were recognized as other (expense)/income, net in the accompanying consolidated statements of operations. The refinancing of the Revolver was accounted for as a modification of our previous revolving credit facility and consequently, the remaining balance of the deferred issuance costs related to the previous revolving credit facility are included with the lenders fees and fees to third parties associated with the refinance of the Revolver and amortized as interest expense on a straight-line basis over the life of the Revolver. All issuance costs allocated to the DDTL were deferred and will be amortized as interest expense on a straight-line basis over the five-year term of the DDTL.

As of December 31, 2018, we had a $72.2 million balance on the Term Loan. As of December 31, 2018, we had not drawn on the Revolving Credit Facility or DDTL. Of the $1.3 million of deferred debt issuance costs allocated to the Revolving Credit Facility, $1.0 million is included in other long-term assets in the accompanying consolidated balance sheets and $0.3 million is included in prepaid expenses and other current assets in the accompanying consolidated balance sheets. Of the $0.6 million of deferred debt issuance costs allocated to the DDTL, $0.5 million is included in other long-term assets in the accompanying consolidated balance sheets and $0.1 million is included in prepaid expenses and other current assets in the accompanying consolidated balance sheets. Of the $1.6 million of deferred debt issuance costs allocated to the Term Loan, $0.3 million is classified as a direct deduction to the current portion of the Term Loan and is included in current component of long-term borrowing, net of deferred financing costs in the accompanying consolidated balance sheets and $1.3 million is classified as a direct deduction to the long-term portion of the Term Loan and is included in long-term borrowing, net of deferred financing costs and current borrowing component in the accompanying consolidated balance sheets.

The contractual maturity for our Term Loan is as follows for the years ending December 31:

	(in thousands)
2019	$3,609
2020	3,609

2021	5,414
2022	5,414
2023	54,141
Total	$72,187

Previous Credit Agreement

In December 2017, we entered into a five-year senior secured credit facility (the “Credit Agreement”) with Citizens Bank, N.A. as a lender and administrative agent. As contemplated in the initial agreement, the Credit Agreement was syndicated to five additional lenders on February 5, 2018. The Credit Agreement was comprised of a $75.0 million five-year term loan (the “previous Term Loan”) and a $50.0 million senior secured revolving credit facility (the “Revolving Credit Facility”), with availability subject to a borrowing base consisting of eligible accounts receivable and inventory and the satisfaction of conditions precedent specified in the agreement.

The proceeds of the $75.0 million previous Term Loan were used to finance our acquisition of the four NDAs acquired for $46.5 million in cash and to refinance the existing indebtedness of $25.0 million that was outstanding on our now retired asset-based revolving credit facility with Citizens Business Capital, a division of Citizens Asset Finance, Inc. We deferred $2.7 million of total debt issuance costs related to the Credit Agreement, of which $1.7 million was allocated to the previous Term Loan and $1.0 million was allocated to the undrawn Revolving Credit Facility.

The Term Loan was accounted for as a modification of our existing Line of Credit and consequently, the remaining balance of the deferred issuance costs related to the Line of Credit are included with the previous Term Loan issuance costs and amortized as interest expense over the life of the previous Term Loan using the effective interest method. The issuance costs allocated to the Revolving Credit Facility will be deferred and amortized as interest expense on a straight-line basis over the term of the Revolving Credit Facility. During the year ended December 31, 2018, we recorded $2.7 million of interest expense related to the original Credit Agreement.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

3. INDEBTEDNESS (Continued)

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. In December 2018, we entered into separate, privately negotiated agreements with certain holders of our Notes and repurchased $25.0 million of our outstanding Notes. We accounted for the repurchase as an extinguishment of the portion of the Notes and recognized a loss on extinguishment of $0.5 million, which was recorded in other (expense)/income, net in the accompanying consolidated statements of operations. At the same time, we unwound a corresponding portion of the bond hedge and warrant, which are described in further detail below. As a result of unwinding this portion of the bond hedge and warrant, we received a net amount of $0.4 million. The repurchase of the notes and the unwinding of the bond hedge and warrant resulted in a $1.7 million net reduction in additional paid-in capital (“APIC”) in the accompanying consolidated balance sheets. The remaining Notes are convertible into 1,709,002 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.

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 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 8); 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 and the exercise price of the warrant is $96.21 per share of our common stock. 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. After the repurchase of $25.0 million of our outstanding Notes and the unwinding of the corresponding portion of the bond hedge and warrant, our remaining bond hedge had an underlying 1,709,002 common shares as of December 31, 2018 and the remaining warrant had an underlying 1,709,002 common shares as of December 31, 2018.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

3. INDEBTEDNESS (Continued)

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

(in thousands)	**2018**	**2017**
Principal amount	$118,750	$143,750
Unamortized debt discount	(5,648)	(13,924)
Deferred financing costs	(639)	(1,618)
Net carrying value	$112,463	$128,208

The effective interest rate on the Notes was 7.8% and 7.9%, on an annualized basis, as of December 31, 2018 and 2017, respectively.

The following table sets forth the components of total interest expense related to the Notes and Term Loan recognized in our consolidated statements of operations for the year ended December 31:

(in thousands)	**2018**	**2017**	**2016**
Contractual coupon	$7,170	$4,313	$4,312
Amortization of debt discount	7,002	6,720	6,372
Amortization of finance fees	1,463	845	844
Capitalized interest	(724)	(554)	(234)
	$14,911	$11,324	$11,294

4. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY

In April 2018, we entered into an interest rate swap arrangement, which was considered a derivative financial instrument, with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our previous Term Loan. The interest rate swap hedged the variable cash flows associated with the borrowings under our previous Term Loan (Note 3), effectively providing a fixed rate of interest throughout the life of the previous Term Loan.

In December 2018, we refinanced our previous Credit Agreement and, as part of that refinancing, extended the maturity of our $72.2 million secured term loan balance to December 2023. At the same time, we closed out the original interest rate swap and entered into a new interest rate swap arrangement, which is also considered a derivative financial instrument, with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our Term Loan. We accounted for the close-out of the original interest rate swap as a termination of the interest rate swap and wrote the interest rate swap liability and accumulated other comprehensive loss balance off as of the date of termination. As there were no excluded components, there was no net impact to the consolidated statement of operations. The interest rate swap hedges the variable cash flows associated with the borrowings under our Term Loan (Note 3), effectively providing a fixed rate of interest throughout the life of our Term Loan.

ANI Pharmaceuticals, Inc. and Subsidiaries

Notes to the Consolidated Financial Statements

For the years ended December 31, 2018, 2017, and 2016

4. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY (Continued)

The interest rate swap arrangement with Citizens Bank, N.A became effective on December 27, 2018, with a maturity date of December 27, 2023. The notional amount of the swap agreement at inception was $72.2 million and will decrease in line with our Term Loan. As of December 31, 2018, the notional amount of the interest rate swap was $72.2 million. The interest rate swap has a weighted average fixed rate of 2.60% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As of December 31, 2018, the fair value of the interest rate swap liability was valued at $0.5 million and was recorded in other long-term liabilities in the accompanying consolidated balance sheets. As of December 31, 2018, $0.4 million, the fair value of the interest rate swap net of tax, was recorded in accumulated other comprehensive loss, net of tax in the accompanying consolidated balance sheets. During the year ended December 31, 2018, changes in the fair value of the interest rate swap of $0.4 million, net of tax, was recorded in accumulated other comprehensive (loss), net of tax