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

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2019

☐ **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	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**ANIP**	**The NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act:
None

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ NO ☐

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	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 ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2019 was $657.7 million (based upon the last reported sale price of $82.20 per share on June 30, 2019, on The NASDAQ Global Market).

As of February 20, 2020, 12,096,556 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, 2019

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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 context requires otherwise, to ANI Pharmaceuticals, Inc., a Delaware c-corporation, and its consolidated subsidiaries. References to “named executive officers” refer to our current named executive officers, except where the context requires otherwise. References to the "Merger" refer to the merger of BioSante Pharmaceuticals, Inc. ("BioSante") and ANIP, completed on June 19, 2013, wherein ANI Merger Sub, Inc., a wholly owned subsidiary of BioSante, merged with and into ANIP with ANIP continuing as the surviving company and becoming a wholly owned subsidiary of BioSante. On July 17, 2013, BioSante changed its name to ANI Pharmaceuticals, Inc.

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.

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, 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 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. In December 2017, we entered into a five-year senior secured $125.0 million credit facility (the “Credit Agreement”) with Citizens Bank N.A. The Credit Agreement was 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 was a $118.0 million Delayed Draw Term Loan (the “DDTL”), which could only be drawn on in order to pay down the Company’s remaining 3.0% Notes, which matured in December 2019. The Credit Facility also extended the maturity of the $72.2 million secured 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. On November 29, 2019, we exercised our option to borrow $118.0 million pursuant to the DDTL feature under the existing Credit Facility and the proceeds were used to repay the outstanding Notes, which matured on December 1, 2019. As of December 31, 2019, we had not drawn on the Revolver.

With the additional funds resulting from borrowings and operating cash, we have acquired Abbreviated 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, 11 products in 2018, and six products in 2019 bringing our portfolio of products to 46 as of December 31, 2019. 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., 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 Pharmaceuticals Canada Inc. (“ANI Canada”).

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 2015, we have successfully:

- Increased prescription product sales through a combination of market share gains on existing products and new product launches.
- Filed one ANDA.
- Acquired the NDAs for and began marketing Atacand, Atacand HCT, Arimidex, Casodex, Lithobid, Vancocin, Inderal LA, Inderal XL, and InnoPran XL.
- Increased our product pipeline, through development, partnership, and acquisition, to 109 total products.
- Entered into a $265.2 million credit agreement with Citizens, Bank, N.A.
- Acquired WellSpring Pharma Services Inc. (“ANI Canada”)
- Launched 40 products.
- Acquired the NDAs for Cortrophin gel and Cortrophin-Zinc in January 2016; assembled a Cortrophin re-commercialization team of dedicated 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; executed a long-term commercial agreement with a Cortrophin gel fill/finish contract manufacturer; have validated all analytical methods used to release batches of corticotropin API and Cortrophin gel finished drug product; have manufactured a number of commercial scale batches of API including three registration batches and have completed process validation; have manufactured a number of commercial scale batches of Cortrophin gel finished drug product including three registration batches and have completed process validation; have completed viral clearance validation; have completed a 20-person human clinical study that demonstrated that our Cortrophin gel is effective for its intended use by demonstrating a blood level cortisol response that was consistent with cortisol levels produced by our drug product in the 1960s; remain on track to file our supplemental NDA in the first quarter 2020.

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, 2019, our products include both branded and generic pharmaceuticals, specifically:

Generic Products	Branded Products
Aspirin and Extended Release Dipyridamole	Arimidex
Bretylium Tosylate Injection, USP	Atacand
Candesartan Hydrochlorothiazide	Atacand HCT
Cholestyramine	Casodex
Desipramine Hydrochloride	Cortenema
Diphenoxylate Hydrochloride and Atropine Sulfate	Inderal LA
Erythromycin Ethylsuccinate	Inderal XL
Erythromycin Ethylsuccinate for Oral Suspension	InnoPran XL
Esterified Estrogen with Methyltestosterone	Lithobid
Etodolac	Reglan
Ezetimibe-Simvastatin	Vancocin
Felbamate	
Fenofibrate	
Flecainide	
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	
Vancomycin Hydrochloride for Oral Solution	

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

Aspirin and extended-release dipyridamole is indicated to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis.

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

Bretylium Tosylate Injection, USP is indicated in the prophylaxis and therapy of ventricular fibrillation. It is also indicated in the treatment of life-threatening ventricular arrhythmias, such as ventricular tachycardia that have failed to respond to adequate doses of a first-line antiarrhythmic agent, such as lidocaine.

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.

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.

Erythromycin Ethylsuccinate for Oral Solution is indicated in the treatment of infections caused by susceptible strains of 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.

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.

Vancomycin Hydrochloride for Oral Solution is used for the treatment of enterocolitis caused by staphylococcus aureus, including methicillin-resistant strains, and antibiotic-associated pseudomembranous colitis caused by clostridium difficile.

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 six Schedule II products currently on the market, our pipeline includes two ANDA's 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 13 complex formulation products currently on the market, our pipeline includes 13 extended-release products and eight 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 certain of our products deemed controlled substances, we must submit a request to the DEA for a quota to purchase the amount of API needed for manufacture. 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, 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, generic Vancomycin, and generic Vancomycin for Oral Solution 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 Aspirin and Extended Release Dipyridamole, Bretylium Tosylate Injection, USP, Cholestyramine, Desipramine Hydrochloride, Diphenoxylate Hydrochloride and Atropine Sulfate, Erythromycin Ethylsuccinate, Erythromycin Ethylsuccinate for Oral Suspension, 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 API needed to manufacture certain of our products deemed controlled substances. 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 our controlled substances at commercial level.

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 2019, we recorded $0.5 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.

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, Smith Drug Company, 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, 2019, approximately 80% of our net revenues were attributable to three wholesalers: McKesson Corporation 25%, AmerisourceBergen Corporation 32%, and Cardinal Health, Inc. 23%. For the years ended December 31, 2018 and 2017, McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Corporation, together accounted for approximately 81% and 78% 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, Smith Drug Company, 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 Anda, 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, The Premier Group, and Kaiser Permanente Purchasing Organization.

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.

Backlog

We define backlog as firm orders received prior to December 31, 2019 that have not been shipped as of December 31, 2019. We had a backlog of $8.1 million, $6.3 million, and $0.5 million at December 31, 2019, 2018, and 2017, respectively, relating to contract manufacturing purchase orders from customers.

Employees

As of December 31, 2019, we had 338 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 32%, 25%, and 23% of net revenues, respectively, during the year ended December 31, 2019. As of December 31, 2019, accounts receivable from these three customers was approximately 88% 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 or the loss of our relationship with one or more of these wholesalers, 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 10% of our total revenue in 2019, 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, 2019, 2018, and 2017, revenues for EEMT were 9%, 11%, and 13% of total revenue, respectively, and revenues from Opium Tincture were 1%, 1%, and 2% 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.

Additionally, our EEMT products are related to an outstanding Notice of Opportunity for Hearing on related to estrogen-androgen products. We can offer no assurances that FDA will not resolve this hearing nor take a contrary position in the future with regards to the marketing of EEMT products going forward.

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 dependent on imported API to make certain of our products. If the FDA detained or refused to allow the importation of such API, our revenues from certain of our products 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. Any prolonged disruption in the supply of imported API could materially affect our ability to manufacture and distribute our products, reduce or eliminate our revenues, 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. Additionally, because the FDA does not review and approve labeling for the products without approved NDAs or ANDAs, it would be difficult to make a claim for preemption due to the FDA's approval of the labeling and this 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 manufacture our controlled substances. An inability to obtain such approvals would reduce or eliminate our revenues for our controlled substances, 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 our controlled substances. 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 our controlled substances 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.

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 significantly reduce 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. 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.

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, 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.

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.

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.

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 NDAs for Cortrophin Gel, 40 units/mL and 80 units/mL and Cortrophin Zinc, 40 units/mL, along with certain documentation and trademark applications, from Merck for $75.0 million and a percentage of future net sales of the products under the NDAs. We have incurred and intend to continue to incur significant research and development expense with respect to development of the products. 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 manufacturing of the corticotropin API and have manufactured six different commercial scale batches, including registration and process validation batches. All commercial scale API batches have met specifications. We have also continued to advance to manufacturing of Cortrophin Gel and have manufactured four different commercial scale batches, including registration and process validation batches. All commercial scale Cortrophin Gel batches have met specifications. We must complete registration enabling stability studies, which are ongoing, and we are on track to submit our supplementary NDA to the FDA in first quarter 2020. 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 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, 2019. We purchased approximately 13% of our inventory from one supplier during the year ended December 31, 2018 and approximately 23% of our inventory from two suppliers during the year ended December 31, 2017. 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, 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 many of our products. We expect our reliance on third party manufacturers to continue to increase in the future as we receive approvals for new products to be manufactured through our collaborative arrangements, and as we seek additional growth opportunities outside of the capabilities of our current manufacturing facilities. If we are unable to secure third-party manufacturers for these products on commercially acceptable terms, we may not be able to market and distribute such products at a profit. Any delays or difficulties with third-party manufacturers could adversely affect the marketing and distribution of these products, 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 and subsequent sales of branded products and authorized generics of branded products, 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 and subsequent sales of branded products and authorized generics of branded products. 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, 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 growth and acquisitions. 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 growth and acquisitions. 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 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, 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.

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;
- we may be required to obtain specialized equipment in order to manufacture products on a commercial scale; and
- we may be subject to milestone payments to collaborative partners, the timing of which we may be unable to predict.

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.

We may become involved in legal proceedings from time to time which may result in substantial losses, government enforcement actions, damage to our business and reputation, and place a strain on our internal resources.

In the ordinary course of our business, we may become involved in legal proceedings, as a party or non-party witness, with both private parties and certain government agencies. We may incur substantial time and expenses participating in these types of lawsuits and investigations, which could also divert management's attention from ongoing business concerns and normal operations. In addition, these matters and any other substantial litigation may result in verdicts against us or government enforcement actions, which may include significant monetary awards, and preventing the manufacture, marketing and sale of our products. Any dispute resolved unfavorably, could have a material adverse effect on our business, financial position, and operating results. See Note 12. Commitments and Contingencies, in the notes to the consolidated financial statements in Part II - Item 8 of this Annual Report on Form 10-K.

We are susceptible to product liability claims that may not be covered by insurance, which, if successful, could require us to pay substantial sums.

Like all pharmaceutical companies, we face of the risk of loss resulting from, and the adverse publicity associated with, product liability lawsuits, whether or not such claims are valid. We likely cannot avoid such claims. Unanticipated side effects or unfavorable publicity concerning any of our products or product candidates would likely have an adverse effect on our ability to achieve acceptance by prescribing physicians, managed care providers, pharmacies and other retailers, customers, patients and clinical trial participants. Even unsuccessful product liability claims could require us to spend money on litigation, divert management's time, damage our reputation and impair the marketability of our products. In addition, although we believe that we have adequate product liability insurance coverage, we cannot be certain that our insurance will, in fact, be sufficient to cover such claims or that we will be able to obtain or maintain adequate insurance coverage in the future at acceptable prices. A successful product liability claim that is excluded from coverage or exceeds our policy limits could require us to pay substantial sums. Additionally, insurance coverage for product liability may become prohibitively expensive in the future or may not be available at all, and as a result, we may not be able to maintain adequate product liability insurance coverage to mitigate the risk of large claims, or we may be required to maintain a larger self-insured retention that we would otherwise choose.

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

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.

Failure to comply with applicable transfer pricing and similar regulations could have a material adverse effect on our financial position and operating results.

We are subject to complex transfer pricing and other tax regulations in the United States and Canada designed to ensure that appropriate levels of income are reported as earned and are taxed in the appropriate taxing jurisdictions. Although we believe that we are in substantial compliance with all applicable U.S and Canadian regulations and restrictions, we are subject to the risk that governmental authorities could audit our transfer pricing and related practices and assert that additional taxes are owed. In the event that the audits or assessments are concluded adversely against us, we may or may not be able to offset or mitigate the consolidated effect of any such assessments.

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 2019 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, product 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. We recorded an impairment charge of $75 thousand in the year ended December 31, 2019, in relation to our Ranitidine product right asset and there can be no assurances that our remaining intangible assets won't be impaired in the future. No impairment charge was recognized during the year ended December 31, 2018.

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 under our Senior Secured Credit Facility will continue to require a significant amount of cash.

Our ability to continue to make scheduled interest payments and to make future principal payments on our debt, including our secured term loan ("Term Loan") and Delayed Draw Term Loan ("DDTL"), depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not continue to generate cash flows from operations sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flows, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional equity capital on terms that may be onerous or highly dilutive.

Our 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.

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 24% of our outstanding capital stock entitled to vote as of December 31, 2019. 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, 2019, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 136 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

Our legal proceedings are discussed in Note 12. Commitments and Contingencies, in the notes to the consolidated financial statements in Part II. Item 8. of this Annual Report on Form 10-K.

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, 2020, there were approximately 110 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

None.

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

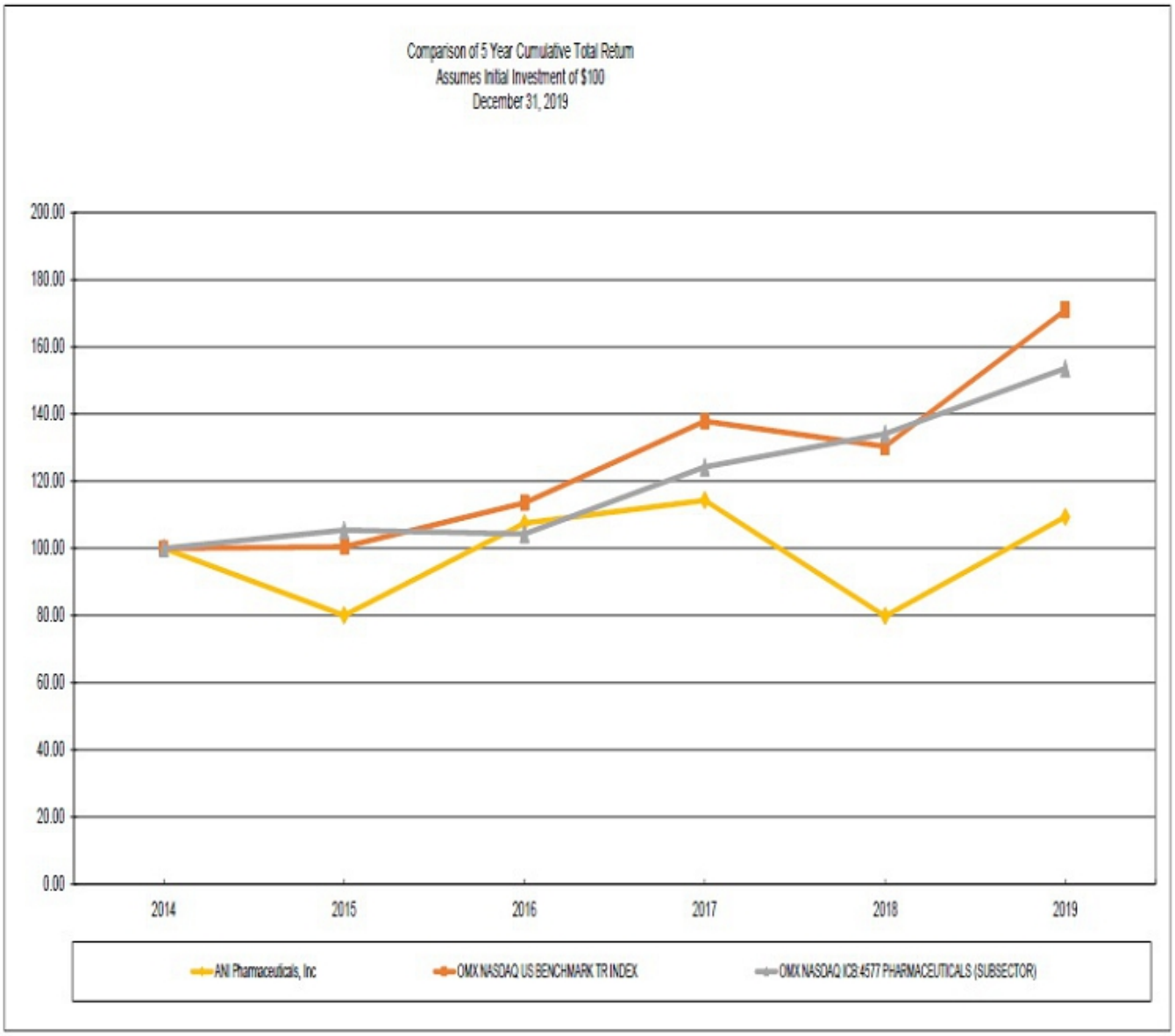
None.

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, 2014, with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance.



Item 6. Selected Consolidated Financial Data

The following table sets forth selected financial data as of and for the five years ended December 31, 2019. The information has been derived from our audited consolidated financial statements for each of the years ended December 31, 2019, 2018, 2017, 2016, and 2015. 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)	2019	2018[1]	2017[2]	2016	2015
Statement of Operations Data:					
Net revenues	$ 206,547	$ 201,576	$ 176,842	$ 128,622	$ 76,322
Total operating expenses	190,196	166,217	148,513	108,543	43,622
Operating income from continuing operations	16,351	35,359	28,329	20,079	32,700
Benefit/(provision) for income taxes	2,937	(4,557)	(17,425)	(4,744)	(6,358)
Net income/(loss) from continuing operations	$ 6,094	$ 15,494	$ (1,076)	$ 3,934	$ 15,375
Basic and diluted income/(loss) from continuing operations per share:					
Basic income/(loss) per share from continuing operations	$ 0.51	$ 1.31	$ (0.09)	$ 0.34	$ 1.34
Diluted income/(loss) per share from continuing operations	$ 0.50	$ 1.30	$ (0.09)	$ 0.34	$ 1.32
Balance Sheet Data:					
Total assets	$ 456,789	$ 430,604	$ 412,138	$ 322,864	$ 285,265
Total Convertible Notes, net of deferred financing costs	-	112,463	128,208	120,643	113,427
Non-current Term Loan and Delayed Draw Term Loan, net of deferred financing costs and current component	175,808	67,296	69,946	-	-
Total stockholder's equity	$ 212,791	$ 197,263	$ 174,756	$ 169,648	$ 160,082

[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.

This section of this Form 10-K generally discusses 2019 and 2018 items and year-to-year comparisons between 2019 and 2018. Discussions of 2017 items and year-to-year comparisons between 2018 and 2017 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 27, 2019.

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 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, 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 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 $125.0 million 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 was a $118.0 million Delayed Draw Term Loan (the "DDTL"), which could only be drawn on in order to pay down the Company's remaining 3.0% Convertible Senior Notes, which matured in December 2019. The Credit Facility also extended the maturity of the $72.2 million secured 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.

In 2019, we entered into an agreement with Teva Pharmaceutical Industries Ltd. to purchase a basket of ANDAs for 35 previously-marketed generic drug products. We also acquired from Coeptis Pharmaceuticals, Inc. seven development stage generic products. During the 2019 year, we launched six products.

Additionally, on November 29, 2019, we exercised our option to borrow $118.0 million pursuant to the DDTL feature under the existing Credit Facility and the proceeds were used to repay the outstanding 3% Convertible Senior Notes, which matured on December 1, 2019.

Fiscal 2019 Developments

Asset Acquisitions

In March 2019, we entered into an agreement with Teva Pharmaceutical Industries Ltd. to purchase a basket of ANDAs for 35 previously-marketed generic drug products for $2.5 million in cash. The transaction closed in March 2019 and we made the $2.5 million payment using cash on hand.

In June 2019, we acquired from Coeptis Pharmaceuticals, Inc. seven development stage generic products, as well as active pharmaceutical ingredient ("API") and reference-listed drug inventory related to certain of the products for a payment of $2.3 million. The entire payment, and $24 thousand of transaction costs directly related to the acquisition, was recorded as research and development expense because the potential generic products have significant remaining work required in order to commercialize the products and do not have an alternative future use. In addition, we could make up to $12.0 million in payments for certain development and commercial milestones.

Amendment to Teva Pharmaceuticals Asset Purchase Agreement

In January 2019, we entered into an amendment to three asset purchase agreements (the "Asset Purchase Agreement Amendment") with Teva Pharmaceuticals USA, Inc. ("Teva"). Under the terms of the Asset Purchase Agreement Amendment, all royalty obligations of the Company owed to Teva with respect to products associated with ten ANDAs under the original asset purchase agreements ceased being effective as of December 31, 2018. As consideration for the termination of such future royalty obligations, we paid Teva a sum of $16.0 million.

Product Launches

In March 2019, we launched two additional presentations of Erythromycin Ethylsuccinate for Oral Suspension. Erythromycin Ethylsuccinate is indicated in the treatment of infections caused by susceptible strains of selected diseases.

In September 2019, we launched Vancomycin Hydrochloride for Oral Solution, which is a prescription medication administered orally for treatment of enterocolitis caused by staphylococcus aureus, including methicillin-resistant strains, and antibiotic-associated pseudomembranous colitis caused by clostridium difficile.

In October 2019, we launched Aspirin and Extended Release Dipyridamole capsules, which are indicated to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis.

In December 2019, we launched Bretylium Tosylate Injection USP 50mg/ml. Bretylium Tosylate Injection USP is indicated in the prophylaxis and therapy of ventricular fibrillation. It is also indicated in the treatment of life-threatening ventricular arrhythmias, such as ventricular tachycardia that have failed to respond to adequate doses of a first-line antiarrhythmic agent, such as lidocaine.

Cortrophin Gel Re-commercialization Update

We continue to successfully progress our Cortrophin re-commercialization program. Significant accomplishments since the September 30, 2019 quarterly report on Form 10-Q filed on November 6, 2019 include:

- We successfully completed API process validation by completing the fourth commercial scale batch of Corticotropin API. We also completed manufacturing for a fifth commercial scale batch of Corticotropin API. All five commercial scale batches were analytically consistent with each other and met all API release specifications. We expect to have six months stability on all API registration batches prior to the supplementary NDA filing and by the end of first quarter 2020.

- We successfully completed drug product process validation in the fourth quarter of 2019. We also completed manufacturing of a fourth commercial scale batch of Cortrophin Gel. This batch was analytically consistent with previously manufactured batches and met all drug product release specifications. We have already completed manufacturing for three commercial scale registration stability batches of Cortrophin Gel and expect to have six months stability on each prior to the supplementary NDA filing and by the end of first quarter 2020.

We remain on track to file a supplemental NDA as planned by the end of the first quarter 2020.

General

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018.

	Years Ended December 31,	
(in thousands)	**2019**	**2018**
Net revenues	$ 206,547	$ 201,576
Operating expenses		
Cost of sales (excluding depreciation and amortization)	63,154	73,024
Research and development	19,806	15,388
Selling, general, and administrative	55,843	44,063
Depreciation and amortization	44,612	33,742
Cortrophin pre-launch charges	6,706	-
Intangible asset impairment charge	75	-
Operating income	16,351	35,359
Interest expense, net	(12,966)	(14,758)
Other expense, net	(228)	(550)
Income before benefit/(provision) for income taxes	3,157	20,051
Benefit/(provision) for income taxes	2,937	(4,557)
Net income	$ 6,094	$ 15,494

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,	
	2019	**2018**
Net revenues	100.0%	100.0%
Operating expenses		
Cost of sales (excluding depreciation and amortization)	30.6%	36.2%
Research and development	9.6%	7.6%
Selling, general, and administrative	27.0%	21.9%
Depreciation and amortization	21.6%	16.7%
Cortrophin pre-launch charges	3.2%	-%
Intangible asset impairment charge	-%	-%
Operating income	8.0%	17.6%
Interest expense, net	(6.3)%	(7.3)%
Other expense, net	(0.1)%	(0.3)%
Income before benefit/(provision) for income taxes	1.6%	10.0%
Benefit/(provision) for income taxes	1.4%	(2.3)%
Net income	3.0%	7.7%

Results of Operations for the Years Ended December 31, 2019 and 2018

Net Revenues

(in thousands)	Years Ended December 31, 2019	2018	Change	% Change
Generic pharmaceutical products	$ 128,729	$ 117,451	$ 11,278	9.6%
Branded pharmaceutical products	63,767	60,554	3,213	5.3%
Contract manufacturing	11,139	9,119	2,020	22.2%
Royalty and other income	2,912	14,452	(11,540)	(79.9)%
Total net revenues	$ 206,547	$ 201,576	$ 4,971	2.5%

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

Net revenues for the year ended December 31, 2019 were $206.5 million compared to $201.6 million for the same period in 2018, an increase of $5.0 million, or 2.5%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $128.7 million during the year ended December 31, 2019, an increase of 9.6% compared to $117.5 million for the same period in 2018. The primary reasons for the increase are the September 2019 launch of Vancomycin Oral Solution, annualization of the 2018 launches of Ezetimibe-Simvastatin and Candesartan, other products launched in 2019, as well as increased unit sales of Vancomycin tablets. These increases were tempered by decreases in sales of Esterified Estrogen with Methyltestosterone (“EEMT”), Diphenoxylate Hydrochloride and Atropine Sulfate, and Fenofibrate.

  As described in Item 1. Business – Government Regulations – Unapproved Products, we market EEMT and Opium Tincture without Food and Drug Administration (“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, 2019 and 2018 were $20.7 million and $24.9 million, respectively.

- Net revenues for branded pharmaceutical products were $63.8 million during the year ended December 31, 2019, an increase of 5.3% compared to $60.6 million for the same period in 2018. The primary reasons for the increase were a full year of sales on our Arimidex and Casodex products, which were launched under our label in July 2018, and Atacand, which was launched under our label in October 2018, all of which were previously included in Royalty and other, as well as increased sales of Inderal XL. These increases were tempered by lower unit sales of InnoPran XL, Lithobid, and Inderal LA.

- Contract manufacturing revenues were $11.1 million during the year ended December 31, 2019, an increase of 22.2% compared to $9.1 million for the same period in 2018, due primarily to a full year of contract manufacturing revenue in our ANI Canada subsidiary. 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, 2019 and 2018 were $3.1 million and $2.0 million, respectively.

- Royalty and other were $2.9 million during the year ended December 31, 2019, a decrease of $11.5 million from $14.5 million for the same period in 2018, due primarily to the launch of Atacand, Atacand HCT, Arimidex, and Casodex under our own label in 2018, all of which were included in Branded pharmaceutical product sales in 2019. During the year ended December 31, 2019, we recognized $0.5 million of royalty revenue related to a true-up from our former partner for sales of the authorized generic for Vancocin. Royalty and other also includes the impact of product development and laboratory services revenue from our ANI Canada subsidiary.

Cost of Sales (Excluding Depreciation and Amortization)

	Years Ended December 31,			
(in thousands)	2019	2018	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 63,154	$ 73,024	$ (9,870)	(13.5)%

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, 2019, cost of sales decreased to $63.2 million from $73.0 million for the same period in 2018, a decrease of $9.9 million or 13.5%. The year ended December 31, 2018 included $5.6 million of costs of sales related to the excess of fair value over cost on Inderal XL and InnoPran XL inventory and write-off of remaining inventory acquired as part of the acquisition when we re-launched the products under our own label. In addition, cost of sales for the year ended December 31, 2019 included lower sales of products subject to profit-sharing arrangements, as well as the impact of the January 2019 royalty buy out from the Asset Purchase Agreement Amendment with Teva. Decreases were tempered by the fourth quarter 2019 $4.6 million inventory reserve charge, primarily related to the exit from the market for Methylphenidate Extended Release. Cost of sales as a percentage of net revenues decreased to 30.6% during the year ended December 31, 2019, from 36.2% during same period in 2018, primarily due to the non-recurrence of $5.6 million net impact on cost of sales (2.8% as a percent of net revenues) of the excess of fair value over cost for Inderal XL and InnoPran XL inventory sold and written off during the period, as well as lower royalty expense recognized in the period, offset by the inventory reserve charges recognized in the fourth quarter 2019.

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, 2019, we purchased 13% of our inventory from one supplier. As of December 31, 2019, amounts payable to this supplier were $0.7 million. In the year ended December 31, 2018, we purchased 13% of our inventory from one supplier.

In order to manufacture certain of our products deemed controlled substances, we must submit a request to the Drug Enforcement Administration ("DEA") for a quota to purchase the amount of API needed for manufacture. 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 our controlled substances at commercial level.

Other Operating Expenses

(in thousands)	Years Ended December 31, 2019	2018	Change	% Change
Research and development	$ 19,806	$ 15,388	$ 4,418	28.7%
Selling, general, and administrative	55,843	44,063	11,780	26.7%
Depreciation and amortization	44,612	33,742	10,870	32.2%
Cortrophin pre-launch charges	6,706	-	6,706	NM(1)
Intangible asset impairment charge	75	-	75	NM(1)
Total other operating expenses	$ 127,042	$ 93,193	$ 33,849	36.3%

(1) Not Meaningful

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

For the year ended December 31, 2019, other operating expenses increased to $127.0 million from $93.2 million for the same period in 2018, an increase of $33.8 million, or 36.3%, primarily as a result of the following factors:

- Research and development expenses increased from $15.4 million to $19.8 million, an increase of 28.7%, due to $2.3 million of expense related to in-process research and development acquired in the acquisition from Coeptis, as well as 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), and $1.2 million in expense for development milestone payments earned under certain collaborative agreements. These increases were partially offset by the non-recurrence of $1.3 million of expense related to in-process research and development acquired in the asset purchase with Impax Laboratories, Inc. in the second quarter of 2018. We anticipate that research and development costs will be lower in 2020 as compared to 2019, as we anticipate the completion of our Cortrophin re-development efforts.

- Selling, general, and administrative expenses increased from $44.1 million to $55.8 million, an increase of 26.7%, driven by a full year of costs related to our ANI Canada subsidiary, increased U.S. based headcount and increased pharmacovigilance compliance costs in continued support of the expansion of our commercial portfolio, increased stock compensation expense, higher Generic Drug User Fee Amendments (“GDUFA”) and Prescription Drug User Fee Act (“PDUFA”) user fees paid to the U.S. FDA, higher legal fees, and increased sales and marketing related costs. We anticipate that selling, general, and administrative expenses will continue to be greater in 2020 than in 2019 as we support anticipated revenue growth and increased scope of our business.

- Depreciation and amortization increased from $33.7 million to $44.6 million, an increase of 32.2%, primarily due to the $6.8 million cumulative amortization expense recorded in relation to the January 2019 royalty buy out as well as the amortization of the ANDAs acquired in April 2018, May 2018, and March 2019. We anticipate that depreciation and amortization expense will continue to be greater in 2020 than in 2019.

- As discussed in Note 13. Cortrophin Pre-Launch Charges, in the notes to the consolidated financial statements in Part II. Item 8. of this Annual Report on Form 10-K, we recognized Cortrophin pre-launch charges of $6.7 million in the year ended December 31, 2019. No Cortrophin pre-launch charges were recognized in the year ended December 31, 2018.

- We recognized an impairment charge of $75 thousand in relation to our Ranitidine product right asset during the year ended December 31, 2019. No impairment charge was recognized during the year ended December 31, 2018.

Other Expense, net

(in thousands)	Years Ended December 31, 2019	2018	Change	% Change
Interest expense, net	$ (12,966)	$ (14,758)	$ 1,792	(12.1)%
Other expense, net	(228)	(550)	322	NM(1)
Total other expense, net	$ (13,194)	$ (15,308)	$ 2,114	(13.8)%

(1) Not Meaningful

For the year ended December 31, 2019, we recognized other expense of $13.2 million versus other expense of $15.3 million for the same period in 2018, a decrease of $2.1 million. Interest expense, net for 2019 and 2018 consists primarily of interest expense on our convertible debt and interest expense on borrowings under our Term Loan and DDTL. The decrease is primarily due to the December 2018 $25.0 million paydown and December 2019 maturity of the convertible debt, partially offset by interest expense on the DDTL, which was drawn upon on November 29, 2019. For the year ended December 31, 2019 and 2018, there was $0.2 million and $0.7 million of interest capitalized into construction in progress, respectively.

Benefit/(Provision) for Income Taxes

(in thousands)	Years Ended December 31, 2019	2018	Change	% Change
Benefit/(provision) for income taxes	$ 2,937	$ (4,557)	$ 7,494	(164.5)%

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. 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, 2019, we recognized an income tax benefit of $2.9 million, an effective benefit rate of 93.0% of consolidated pre-tax income reported in the period. Our effective tax rate for 2019 was impacted by the use of the research and experimental tax credit in the U.S., changes in state tax rates due to our changing presence in certain states, the release of ANI Canada’s net valuation allowance, application of our newly adopted transfer pricing policy to 2019 and to 2018, and the impact of current period awards of stock-based compensation, stock option exercises, disqualifying dispositions of incentive stock options, among other items.

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.

Liquidity and Capital Resources

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

	December 31,	
(in thousands)	2019	2018
Cash and cash equivalents	$ 62,332	$ 43,008
Accounts receivable, net	72,129	64,842
Inventories, net	48,163	40,503
Prepaid income taxes, net	1,076	-
Prepaid expenses and other current assets	3,995	4,524
Total current assets	$ 187,695	$ 152,877
Current component of Term Loan and Delayed Draw Term Loan, net of deferred financing costs	$ 9,941	$ 3,256
Convertible Notes, net of discount and deferred financing costs	-	112,463
Accounts payable	14,606	8,884
Accrued expenses and other	2,362	1,707
Accrued royalties	5,084	8,456
Accrued compensation and related expenses	3,736	3,524
Current income taxes payable, net	-	5,022
Accrued government rebates	8,901	8,974
Returned goods reserve	16,595	12,552
Deferred revenue	451	711
Total current liabilities	$ 61,676	$ 165,549

At December 31, 2019, we had $62.3 million in unrestricted cash and cash equivalents. At December 31, 2018, we had $43.0 million in unrestricted cash and cash equivalents. We generated $45.6 million of cash from operations in the year ended December 31, 2019. In June 2019, we acquired from Coeptis Pharmaceuticals, Inc. seven development stage generic products, as well as active pharmaceutical ingredient API and reference-listed drug inventory related to certain of the products for a payment of $2.3 million using cash on hand. In addition, we could make up to $12.0 million in payments for certain development and commercial milestones. In March 2019, we purchased from Teva Pharmaceutical Industries Ltd. a basket of ANDAs for 35 previously-marketed generic drug products for $2.5 million using cash on hand. In January 2019, we entered into the Asset Purchase Agreement Amendment, under which all royalty obligations the Company owed to Teva with respect to products associated with ten ANDAs under the original asset purchase agreements ceased being effective as of December 31, 2018. As consideration for the termination of such future royalty obligations, we paid Teva $16.0 million 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 was a $118.0 million Delayed Draw Term Loan (the "DDTL"), which could only be drawn on in order to pay down the Company's remaining 3.0% Convertible Senior Notes, which matured 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.

On November 29, 2019, we exercised our option to borrow $118.0 million pursuant to the DDTL feature under the existing Credit Facility and the proceeds were used to repay the outstanding 3% Convertible Senior Notes, which matured on December 1, 2019.

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

Our working capital ratio, defined as total current assets divided by total current liabilities, is 3.0 as of December 31, 2019. 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 and debt obligations 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 32%, 25%, and 23% of net revenues during the year ended December 31, 2019. As of December 31, 2019 accounts receivable from these three customers totaled approximately 88% of accounts receivable, net. As a result, negotiated payment terms with these customers have a material impact on our liquidity and working capital.

None of our products accounted for 10% or more of our net revenues in 2019. One of our pharmaceutical products, EEMT, accounted for approximately 11% of our net revenues in 2018. 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 was a $118.0 million DDTL, which could only be drawn on in order to pay down the Company’s remaining 3.0% Convertible Senior Notes, which matured 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 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. On November 29, 2019, we exercised our option to borrow $118.0 million pursuant to the DDTL feature under the existing Credit Facility and the proceeds were used to repay the outstanding 3% Convertible Senior Notes, which matured on December 1, 2019. As of December 31, 2019, we had a $187.5 million outstanding balance on the Credit Facility. As of December 31, 2019, we had not drawn on the Revolver.

We may at any time repay borrowings under the term loans, including the initial Term Loan and DDTL, and the Revolver without any premium or penalty, and we must repay all borrowings thereunder by December 27, 2023. We may use the proceeds of the Revolver for working capital and other general corporate purposes.

Amounts drawn under the Term Loan and 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. On the Revolver, we 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 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 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. 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 were 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 was $69.48 per share, with an underlying 1,709,002 common shares; 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, 2019.

Customer Payments

In addition to the financings in prior years, payments from customers are a significant source of cash in 2019, 2018, and 2017 and were our primary source of cash in 2019 and 2018.

Uses of Cash

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

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

In the first quarter of 2019, we entered into the Asset Purchase Agreement Amendment, under which all royalty obligations the Company owed to Teva with respect to products associated with ten ANDAs under the original asset purchase agreements ceased being effective as of December 31, 2018. As consideration for the termination of such future royalty obligations, we paid Teva $16.0 million using cash on hand. Also in the first quarter of 2019, we purchased from Teva Pharmaceutical Industries Ltd. a basket of ANDAs for 35 previously-marketed generic drug products for $2.5 million in cash using cash on hand. In the second quarter or 2019, we acquired from Coeptis Pharmaceuticals, Inc. seven development stage generic products, as well as active pharmaceutical ingredient API and reference-listed drug inventory related to certain of the products for a payment of $2.3 million using cash on hand. In addition, we could pay up to $12.0 million in payments for certain development and commercial milestones. In 2019, we had $6.6 million of capital expenditures.

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.

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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)	**2019**	**2018**
Operating Activities	$ 45,631	$ 67,074
Investing Activities	$ (27,549)	$ (27,379)
Financing Activities	$ 1,250	$ (27,816)

Net Cash Provided by Operating Activities

Net cash provided by operating activities was $45.6 million for the year ended December 31, 2019, compared to $67.1 million during the same period in 2018, a decrease of $21.4 million. This decrease was principally due to changes in working capital tempered by an increase in net sales.

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2019 was $27.5 million, principally due to the January 2019 Asset Purchase Agreement Amendment for $16.0 million, the March 2019 asset acquisition of ANDAs for $2.5 million, the June 2019 acquisition of in-process research and development related to seven development-stage products for $2.3 million, and $6.6 million of capital expenditures during the period.

Net Cash Provided by/(Used In) Financing Activities

Net cash provided by financing activities was $1.3 million for the year ended December 31, 2019, principally due to $5.7 million of proceeds from stock option exercises, partially offset by $2.7 million of payments on the Term Loan and $1.0 million of treasury stock purchased in relation to restricted stock vestings. Proceeds of $118.0 million from the borrowing on the DDTL were used to repay the outstanding $118.8 million 3% Convertible Senior Notes, which matured on December 1, 2019.

Contractual Obligations

The following table summarizes our long-term contractual obligations and commitments as of December 31, 2019.

	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]	$ 187,480	$ 10,412	$ 25,578	$ 151,490	$ -
Interest on long-term debt obligations [2]	26,156	6,969	13,373	5,814	-
Operating lease obligations	527	217	267	43	-
Purchase obligations [3]	18,269	16,754	1,510	5	-
Total	$ 232,432	$ 34,352	$ 40,728	$ 157,352	$ -

[1] Represents our $69.5 million Term Loan due December 27, 2023 and our $118.0 million Delayed Draw Term Loan due December 2023. (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 Delayed Draw Term Loan. Interest for the Term Loan is calculated based on our payment schedule as proscribed in the Senior Secured 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 the Delayed Draw Term Loan is calculated based on our payment schedule as proscribed in the Senior Secured Credit Facility and using an estimated interest rate of 3.97%, which is the estimated interest rate on the Delayed Draw Term Loan as fixed by our interest rate swap.

[3]Purchase obligations primarily includes contractual obligations for inventory/material 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

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 $192.5 million and $178.0 million of revenue related to sales of generic and branded pharmaceutical products in 2019 and 2018, 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. 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, 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 $26.1 million for the year ended December 31, 2019.

Government Rebates

As 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, 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 $1.8 million for the year ended December 31, 2019.

Returns

As 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, 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 $1.9 million for the year ended December 31, 2019.

Administrative Fees and Other Rebates

As 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, 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 $3.7 million for the year ended December 31, 2019.

Prompt Payment Discounts

As 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, 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 $1.1 million for the year ended December 31, 2019.

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 $11.1 million and $9.1 million of revenue related to sales of contract manufactured products in 2019 and 2018, 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 $0.8 million and $12.5 million of revenue related to royalties from licensing agreements in 2019 and 2018, respectively.

Product Development Services Revenue

We provide product development services to customers, which are performed over time. These services primarily relate to the technical 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 technical transfer projects is generally 18 months to three years. Deposits received from these customers are recorded as deferred revenue until revenue is earned and 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 $1.1 and $1.0 million of revenue related to product development services in 2019 and 2018, respectively.

Intangible Assets

As 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, our definite-lived intangible assets have a carrying value of $180.4 million as of December 31, 2019. 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 March 2018, we entered into an agreement with Appco Pharma, LLC (“Appco”), in which a potential generic product, Ranitidine, was to be developed and marketed. Per the agreement, we paid Appco a series of licensing fees in conjunction with certain development milestones. Ranitidine was launched in the third quarter of 2019, resulting in the final milestone payment of $80 thousand. The $80 thousand milestone payment was capitalized as an intangible asset and determined to have an estimated useful life of eight years. In September 2019, the FDA issued a public statement that some ranitidine medicines contain a nitrosamine impurity called N-nitrosdimethylamine (“NDMA”) at low levels. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests and the cause of the presence of this impurity in the ranitidine products is not yet fully understood at this time. During the fourth quarter 2019, testing of the API used in our ranitidine drug product, as well as testing of the drug product itself, indicated a level of NDMA above acceptable thresholds and Appco initiated a voluntary recall. The Company has elected to exit the market for Ranitidine and determined that the carrying value of the asset has been impaired. During the fourth quarter 2019, the Company recognized a full impairment of the remaining $75 thousand carrying value of the asset.

No events or circumstances arose in 2019 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. 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, 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, 2019 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"). 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 2016 Employee Stock Purchase Plan and included in our consolidated statements of operations:

	Years Ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Cost of sales	$ 119	$ 98	$ 92
Research and development	785	787	678
Selling, general, and administrative	8,313	5,897	5,320
	$ 9,217	$ 6,782	$ 6,090

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, and they are accounted for 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 Income before Benefit/(Provision) for Income Taxes would be affected by $0.9 million for the year ended December 31, 2019.

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.

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 Canada 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 gains and losses included in other comprehensive income and record intra-period tax allocations, when those effects are deemed material. Our effective income tax rate is also affected by changes in tax law, our level of earnings, and the results of tax audits.

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

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In November 2019, the Financial Accounting Standards Board (“FASB”) issued guidance simplifying the accounting for income taxes by removing the following exceptions: 1) exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income or a gain from other items, 2) exception requirement to recognize a deferred tax liability for equity method investments when a foreign subsidiary becomes and equity method investment, 3) exception to the ability not to recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary, and 4) exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss the year. The amendments also simplify accounting for income taxes by doing the following: 1) requiring that an entity recognize a franchise tax or similar tax that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax, 2) requiring that an entity evaluate when a step up in the tax basis of goodwill should be considered part of the business combination in which the book goodwill was originally recognized and when it should be considered a separate transaction, 3) specifying that an entity is not required to allocate the consolidated amount of current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements, 4) requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date, and 5) making minor Codification improvements for income taxes related to employee stock ownership plans and investments in qualified affordable housing projects accounted for using the equity method. The guidance is effective for reporting periods beginning after December 15, 2020, 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 November 2018, the FASB issued guidance clarifying that certain transactions between collaborative arrangement participants should be accounted for as 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 will adopt this guidance as of January 1, 2020. 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 amending 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 will adopt this guidance as of January 1, 2020. 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. In April 2019, the FASB further clarified the scope of the credit losses standard and addressed issues related to accrued interest receivable balances, recoveries, variable interest rates, and prepayment. In May 2019, the FASB issued further guidance to provide entities with an option to irrevocably elect the fair value option applied on an instrument-by-instrument basis for eligible financial instruments. In November 2019, the FASB issued further guidance on expected recoveries for purchased financial assets with credit deterioration, and transition refiled for troubled debt restructurings, disclosures related to accrued interest receivables, financial assets secured by collateral maintenance provisions. 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 may change the way we assess the collectability of our receivables and recoverability of other financial instruments. We will adopt this guidance as of January 1, 2020. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

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

Recently Adopted Accounting Pronouncements

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 swaps are designated in LIBOR. The guidance was effective for reporting periods beginning after December 15, 2018. We adopted this guidance as of January 1, 2019 on a prospective basis. The adoption of this guidance did not have a material impact on our consolidated financial statements.

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 was effective for the quarter that began after the effective date. The adoption of this guidance resulted in the inclusion of the statement of changes stockholder’s equity in our interim financial statement filings.

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 are measured at their grant date fair value. Upon transition, the existing nonemployee awards are measured at fair value as of the adoption date. The guidance was effective for reporting periods beginning after December 15, 2018, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2019. The adoption of this guidance did not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. 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 was effective for reporting periods beginning after December 15, 2018. We adopted this guidance on a modified retrospective basis effective January 1, 2019, using the following allowable practical expedients:

- We did not reassess if any expired or existing contracts are or contain leases;
- We did not reassess the classification of any expired or existing leases.

Additionally, we made ongoing accounting policy elections whereby we (i) do not recognize right-of-use assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combine lease and non-lease elements of our operating leases.

Upon adoption of the new guidance on January 1, 2019, we recognized a right-of-use asset of approximately $0.5 million, which was reduced by approximately $10 thousand of net prepaid rents at the date of adoption, along with a lease liability of approximately $0.5 million. We also recognized total deferred tax assets of approximately $0.1 million and deferred tax liabilities of approximately $0.1 million related to book-tax basis differences. The net effect of the adoption resulted in a cumulative effect adjustment to retained earnings on January 1, 2019 of approximately $2 thousand.

Off-Balance Sheet Arrangements

As of December 31, 2019, 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.

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 was a $118.0 million Delayed Draw Term Loan (the "DDTL"), which could only be drawn on in order to pay down the Company's remaining 3.0% Convertible Senior Notes, which matured in December 2019. The Credit Facility also extended the maturity of the $72.2 million secured Term Loan (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. On November 29, 2019, we exercised our option to borrow $118.0 million pursuant to the DDTL feature under the existing Credit Facility and the proceeds were used to repay the outstanding 3% Convertible Senior Notes, which matured on December 1, 2019. Amounts drawn on the Term Loan and 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. On the Revolver, we 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. As of December 31, 2019, we had a $187.5 million outstanding balance on the Credit Facility. As of December 31, 2019, we had not drawn on the Revolver.

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.

On February 7, 2019, we entered into an interest rate swap to manage our exposure to the variable interest rate on our DDTL. The interest rate swap hedges the variable cash flows associated with borrowings under the DDTL, effectively providing a fixed rate of interest throughout the life of the DDTL. 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, 2019 by approximately $50 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, 2019.

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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2019, 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, 2019, 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, 2020 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, 2020

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, 2019, 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, 2019, 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, 2019 and 2018, 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, 2019, and the related notes and our report dated February 27, 2020 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, 2020

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

	December 31, 2019	*December 31, 2018*
Assets		
Current Assets		
Cash and cash equivalents	$ 62,332	$ 43,008
Accounts receivable, net of $59,946 and $47,705 of adjustments for chargebacks and other allowances at December 31, 2019 and 2018, respectively	72,129	64,842
Inventories, net	48,163	40,503
Prepaid income taxes, net	1,076	-
Prepaid expenses and other current assets	3,995	4,524
Total Current Assets	187,695	152,877
Property and equipment, net	40,551	38,090
Restricted cash	5,029	5,021
Deferred tax assets, net of deferred tax liabilities and valuation allowance	38,326	27,964
Intangible assets, net	180,388	201,604
Goodwill	3,580	3,580
Other non-current assets	1,220	1,468
Total Assets	$ 456,789	$ 430,604
Liabilities and Stockholders' Equity		
Current Liabilities		
Current component of Term Loan and Delayed Draw Term Loan, net of deferred financing costs	$ 9,941	$ 3,256
Convertible Notes, net of discount and deferred financing costs	-	112,463
Accounts payable	14,606	8,884
Accrued expenses and other	2,362	1,707
Accrued royalties	5,084	8,456
Accrued compensation and related expenses	3,736	3,524
Current income taxes payable, net	-	5,022
Accrued government rebates	8,901	8,974
Returned goods reserve	16,595	12,552
Deferred revenue	451	711
Total Current Liabilities	61,676	165,549
Non-current Liabilities		
Term Loan and Delayed Draw Term Loan, net of deferred financing costs and current component	175,808	67,296
Other non-current liabilities	6,514	496
Total Liabilities	$ 243,998	$ 233,341
Commitments and Contingencies (Note 12)		
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 12,104,875 shares issued and 12,089,565 outstanding at December 31, 2019; 11,862,508 shares issued and 11,851,329 shares outstanding at December 31, 2018	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at December 31, 2019 and 2018, respectively	-	-
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at December 31, 2019 and 2018, respectively	-	-
Treasury stock, 15,310 shares of common stock, at cost, at December 31, 2019 and 11,179 shares of common stock, at cost, at December 31, 2018	(723)	(659)
Additional paid-in capital	200,800	186,812
Retained earnings	17,584	11,488
Accumulated other comprehensive loss, net of tax	(4,871)	(379)
Total Stockholders' Equity	212,791	197,263
Total Liabilities and Stockholders' Equity	$ 456,789	$ 430,604

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,		
	2019	*2018*	*2017*
Net Revenues	$ 206,547	$ 201,576	$ 176,842
Operating Expenses			
Cost of sales (excluding depreciation and amortization)	63,154	73,024	79,032
Research and development	19,806	15,388	9,070
Selling, general, and administrative	55,843	44,063	31,580
Depreciation and amortization	44,612	33,742	27,928
Cortrophin pre-launch charges	6,706	-	-
Intangible asset impairment charge	75	-	903
Total Operating Expenses	190,196	166,217	148,513
Operating Income	16,351	35,359	28,329
Other Expense, net			
Interest expense, net	(12,966)	(14,758)	(12,035)
Other (expense)/income, net	(228)	(550)	55
Income Before Benefit/(Provision) for Income Taxes	3,157	20,051	16,349
Benefit/(provision) for income taxes	2,937	(4,557)	(17,425)
Net Income/(Loss)	$ 6,094	$ 15,494	$ (1,076)
Basic and Diluted Earnings/(Loss) Per Share:			
Basic Earnings/(Loss) Per Share	$ 0.51	$ 1.31	$ (0.09)
Diluted Earnings/(Loss) Per Share	$ 0.50	$ 1.30	$ (0.09)
Basic Weighted-Average Shares Outstanding	11,841	11,677	11,547
Diluted Weighted-Average Shares Outstanding	12,040	11,772	11,547

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,		
	2019	*2018*	*2017*
Net income/(loss)	$ 6,094	$ 15,494	$ (1,076)
Other comprehensive income/(loss), net of tax:			
Change in fair value of interest rate swap, net of tax	(4,492)	(379)	-
Total other comprehensive loss, net of tax	(4,492)	(379)	-
Total comprehensive income/(loss), net of tax	$ 1,602	$ 15,115	$ (1,076)

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, 2019, 2018, and 2017
(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, 2016	$ 1	11,589	$ -	$ 172,563	-	$ -	$ -	$ (2,916)	$ 169,648
Cumulative Effect of Change in Accounting Principle	-	-	-	14	-	-	-	(14)	-
Balance, net of Cumulative-effect Adjustment	$ 1	11,589	$ -	$ 172,577	-	$ -	$ -	$ (2,930)	$ 169,648
Stock-based Compensation Expense	-	-	-	6,090	-	-	-	-	6,090
Changes in Treasury Stock Related to Stock-based Compensation Arrangements	-	-	-	-	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
Changes in Treasury Stock Related to Stock-based Compensation Arrangements	-	-	-	-	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
Cumulative Effect of Change in Accounting Principle	-	-	-	-	-	-	-	2	2
Stock-based Compensation Expense	-	-	-	9,217	-	-	-	-	9,217
Changes in Treasury Stock Related to Stock-based Compensation Arrangements	-	-	-	-	20	(1,031)	-	-	(1,031)
Issuance of Common Shares upon Stock Option and ESPP Exercise	-	136	-	5,738	-	-	-	-	5,738
Issuance of Restricted Stock Awards	-	106	-	(967)	(16)	967	-	-	-
Change in Fair Value of Interest Rate Swap, Net of Tax	-	-	-	-	-	-	(4,492)	-	(4,492)
Net Income	-	-	-	-	-	-	-	6,094	6,094
Balance, December 31, 2019	$ 1	12,105	$ -	$ 200,800	15	$ (723)	$ (4,871)	$ 17,584	$ 212,791

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,	*2019*	*2018*	*2017*
Cash Flows From Operating Activities			
Net income/(loss)	$ 6,094	$ 15,494	$ (1,076)
Adjustments to reconcile net income/(loss) to net cash and cash equivalents provided by operating activities:			
Stock-based compensation	9,217	6,782	6,090
Deferred taxes	(9,134)	(5,180)	3,560
Depreciation and amortization	44,612	33,742	27,928
Acquired in-process research and development ("IPR&D")	2,324	1,335	-
Non-cash interest relating to convertible notes and loan cost amortization	7,024	8,465	7,666
Loss on repurchase of Convertible notes	-	468	-
Intangible asset impairment charge	75	-	903
Changes in operating assets and liabilities:			
Accounts receivable, net	(7,287)	(4,743)	(12,893)
Inventories, net	(7,660)	(379)	5,356
Prepaid expenses and other current assets	403	(1,142)	(17)
Accounts payable	5,039	3,466	3
Accrued royalties	(3,372)	(3,708)	(417)
Current income taxes, net	(6,098)	6,184	(3,560)
Accrued government rebates	(73)	1,044	2,039
Returned goods reserve	4,043	4,278	2,518
Accrued expenses, accrued compensation, and other	424	968	1,319
Net Cash and Cash Equivalents Provided by Operating Activities	45,631	67,074	39,419
Cash Flows From Investing Activities			
Acquisition of WellSpring Pharma Services Inc., net of cash acquired	-	(16,467)	-
Acquisition of product rights, IPR&D, and other related assets	(20,914)	(5,169)	(97,624)
Acquisition of property and equipment, net	(6,635)	(5,743)	(10,369)
Net Cash and Cash Equivalents Used in Investing Activities	(27,549)	(27,379)	(107,993)
Cash Flows From Financing Activities			
Payment of debt issuance and convertible debt repurchase costs	-	(1,572)	(2,737)
Payments on Term Loan agreement	(2,707)	(2,813)	-
Borrowings under Term Loan agreement	-	-	75,000
Borrowings under Delayed Draw Term Loan agreement	118,000	-	-
Proceeds from stock option exercises and ESPP purchases	5,738	2,978	353
Repayment of Convertible Notes	(118,750)	(26,125)	-
Unwinding of portion of call option overlay, net	-	375	-
Treasury stock purchases for restricted stock vestings	(1,031)	(659)	(259)
Net Cash and Cash Equivalents Provided/(Used in) by Financing Activities	1,250	(27,816)	72,357
Net Change in Cash and Cash Equivalents	19,332	11,879	3,783
Cash and cash equivalents, beginning of period	48,029	36,150	32,367
Cash and cash equivalents, end of period	$ 67,361	$ 48,029	$ 36,150
Reconciliation of cash, cash equivalents, and restricted cash, beginning 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, beginning of period	48,029	36,150	32,367
Reconciliation of cash, cash equivalents, and restricted cash, end of period Cash and cash equivalents	62,332	43,008	31,144
Restricted cash	5,029	5,021	5,006
Cash, cash equivalents, and restricted cash, end of period	67,361	48,029	36,150
Supplemental disclosure for cash flow information:			
Cash paid for interest, net of amounts capitalized	$ 6,092	$ 6,285	$ 3,759
Cash paid for income taxes	$ 10,033	$ 6,397	$ 17,786
Supplemental non-cash investing and financing activities:			
Acquisition of marketing and distribution rights included in accounts payable	$ 500	$ -	$ -
Property and equipment purchased and included in accounts payable	$ 723	$ 521	$ 485

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

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries, ANIP Acquisition Company and ANI Pharmaceuticals Canada Inc. (together, "ANI," the "Company," "we," "us," or "our") is an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. ANI was organized as a Delaware corporation in April 2001. At our 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 or loss on transactions denominated in foreign currencies was immaterial for the years ended December 31, 2019, 2018, and 2017. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar.

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, determination of right-of-use assets and lease liabilities, 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.

Leases

At the inception of a contract we determine if the arrangement is, or contains, a lease. Right-of-use ("ROU") assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Rent expense is recognized on a straight-line basis over the lease term.

We have made certain accounting policy elections whereby we (i) do not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combine lease and non-lease elements of our operating leases. Operating lease ROU assets are included in other non-current assets and operating lease liabilities are included in accrued expenses and other and other non-current liabilities in our consolidated balance sheets. As of December 31, 2019, we did not have any finance leases.

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, 2019, three customers represented approximately 32%, 25%, and 23% of net revenues, respectively. As of December 31, 2019, accounts receivable from these customers totaled 88% of net accounts receivable. During the year ended December 31, 2018, three customers represented approximately 21%, 23%, and 33% of net revenues, respectively. During the year ended December 31, 2017, three customers represented approximately 29%, 29%, and 20% 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, 2019, we purchased approximately 13% of our inventory from one supplier. As of December 31, 2019, amounts payable to this supplier was $0.7 million. During the year ended December 31, 2018, we purchased approximately 13% of our inventory from one supplier. During the year ended December 31, 2017, we purchased approximately 23% of our inventory from two suppliers.

Revenue Recognition

On 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.

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.

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)	**2019**	**2018**	**2017**
Sales of generic pharmaceutical products	$ 128,729	$ 117,451	$ 118,437
Sales of branded pharmaceutical products	63,767	60,554	50,919
Sales of contract manufactured products	11,139	9,119	7,046
Royalties from licensing agreements	807	12,504	-
Product development services	1,125	1,019	-
Other[(1)]	980	929	440
Total net revenues	$ 206,547	$ 201,576	$ 176,842

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

Timing of Revenue Recognition	**Years Ended December 31,**		
(in thousands)	**2019**	**2018**	**2017**
Performance obligations transferred at a point in time	$ 205,422	$ 200,557	$ 176,842
Performance obligations transferred over time	1,125	1,019	-
Total	$ 206,547	$ 201,576	$ 176,842

During the year ended December 31, 2019, we did not incur, and therefore did not defer, any material incremental costs to obtain contracts. We recognized a decrease of $10.2 million of net revenue from performance obligations satisfied in prior periods during the year ended December 31, 2019, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales, partially offset by royalties from licensing agreements. We provide technical transfer services to customers, for which services are transferred over time. As a result, we had $0.1 million and $0.1 million of contract assets related to revenue recognized based on percentage of completion but not yet billed and $0.5 million and $0.7 million of deferred revenue at December 31, 2019 and 2018, respectively. We had no contract assets or deferred revenue at December 31, 2017. For the year ended December 31, 2019, we recognized $0.1 million of revenue that was included in deferred revenue as of December 31, 2018.

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.

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.

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, 2019, 2018, and 2017:

	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, 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
Accruals/Adjustments	260,771	17,549	19,105	36,874	10,789
Credits Taken Against Reserve	(249,896)	(17,622)	(15,062)	(35,946)	(10,249)
Balance at December 31, 2019	$ 49,882	$ 8,901	$ 16,595	$ 8,281	$ 2,549

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 contract manufactured products.

As of December 31, 2019, the value of our unsatisfied performance obligations (or backlog) was $8.1 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.

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.

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 technical transfer of product development to our facility in Oakville, Ontario. The duration of these technical transfer projects can be up 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 percentage of completion basis, which results in contract assets on our balance sheet. As of December 31, 2019, the value of our unsatisfied performance obligations for product development services contracts was $1.3 million. We expect to satisfy these performance obligations in the next 6 to 15 months.

Cash, Cash Equivalents, and Restricted Cash

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.

In April 2016, we purchased the rights, title, and interest in the NDA for Inderal LA, as well as certain documentation, trademark rights, and finished goods from Cranford Pharmaceuticals, LLC for $60.0 million in cash and milestone payments based on future gross profits from sales of products under the NDA. Additionally, we transferred $5.0 million to an escrow account as security for future milestone payments. This escrow account balance is included in restricted cash in our accompanying consolidated balance sheet as of December 31, 2019.

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. Our allowance for doubtful accounts was immaterial as of December 31, 2019 and 2018.

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. In the fourth quarter of 2019, we recognized inventory reserve charges of $4.6 million, primarily related to our exiting from the market of Methylphenidate Extended Release.

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, 2019, 2018, and 2017. 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, 2019 and 2018.

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

Intangible Assets

Intangible assets other than goodwill consist of acquired ANDAs for previously commercialized and marketed drug products, acquired approved ANDAs for generic products yet to be commercialized, an acquired development package for a generic drug product, a license, supply and distribution agreement for a generic drug product, acquired product rights for generic products, acquired NDAs and product rights for branded products, acquired marketing and distribution rights, and a non-compete agreement.

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. During the year ended December 31, 2019, we recognized an impairment charge of $75 thousand relating to our Ranitidine product right asset (Note 7). No impairment losses related to intangible assets were recognized in the year ended December 31, 2018. During the year ended December 31, 2017, we recognized impairment charges of $0.9 million in relation to our testosterone gel NDA asset (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, 2019, 2018, and 2017.

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.

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 $19.8 million, $15.4 million, and $9.1 million for the years ended December 31, 2019, 2018, and 2017, 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 and classified where the underlying salaries are classified. 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 $9.1 million, $6.7 million, and $6.1 million of non-cash, stock-based compensation cost for the years ended December 31, 2019, 2018, and 2017, respectively, and $147 thousand, $102 thousand, and $68 thousand of the 2019, 2018, and 2017 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.

During the second quarter of 2019, we adopted an intercompany transfer pricing policy that uses the "comparable profits method" for pricing intercompany services between ANI Pharmaceuticals, Inc. and ANI Canada. For U.S. and Canadian tax purposes, the policy was adopted in conjunction with the acquisition date of August 6, 2018.

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 have provided a valuation allowance against certain of our state net operating loss ("NOL") carryforwards that are not expected to be used during the carryforward periods. As of December 31, 2018, we had provided a valuation allowance against ANI Canada's net deferred tax assets of $1.9 million and against certain of our state net operating loss ("NOL") carryforwards that are not expected to be used during the carryforward periods of $0.3 million. As a result of the newly adopted transfer pricing policy, our assessment of the amount of ANI Canada's deferred tax assets that are more likely than not to be realized changed. As a result, during the second quarter 2019, we released ANI Canada's valuation allowance and, as a result, our valuation allowance at December 31, 2019 of $0.4 million relates solely to our state NOL carryforwards.

We have not provided for deferred taxes related to any difference between the tax basis in the shares of ANI Canada and the financial reporting basis in those shares since it has the intent and ability to indefinitely reinvest ANI Canada's earnings and not repatriate those earnings.

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 on the consolidated financial statements. 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, 2019, 2018, and 2017. We are subject to taxation in various U.S. jurisdictions and Canada and all of our income tax returns remain subject to examination by tax authorities due to the availability of NOL carryforwards.

We consider potential tax effects resulting from discontinued operations and for gains and losses in other comprehensive income and record intra-period tax allocations, when those effects are deemed material. In 2019 and 2018, we entered in an interest rate swap agreements (Note 4) that we designated as cash flow hedges designed to manage exposure to changes in LIBOR-based interest rate underlying our secured Term Loan (the "Term Loan") and Delayed Draw Term Loan ("DDTL") 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 elected a policy that the principal portion of our 3.0% Convertible Senior Notes that matured on December 1, 2019 (the "Notes," Note 3) was settled in cash. As such, the principal portion of the Notes had no effect on either the numerator or denominator when determining diluted earnings (loss) per share. Any conversion gain was assumed to be settled in shares and was incorporated in diluted earnings (loss) per share using the treasury method. This policy was consistent with our election for settlement of the Notes under the First Supplemental Indenture to the Notes. The warrants issued in conjunction with the issuance of the Notes were considered to be dilutive when they were in-the-money relative to our average stock price during the period; the bond hedge purchased in conjunction with the issuance of the Notes was always considered to be anti-dilutive.

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

The numerator for earnings per share for the years ended December 31, 2019, 2018, and 2017 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)	2019	2018	2017	2019	2018	2017
Net income/(loss)	$ 6,094	$ 15,494	$ (1,076)	$ 6,094	$ 15,494	$ (1,076)
Net income allocated to restricted stock	(97)	(154)	-	(97)	(154)	-
Net income/(loss) allocated to common shares	$ 5,997	$ 15,340	$ (1,076)	$ 5,997	$ 15,340	$ (1,076)
Basic Weighted-Average Shares Outstanding	11,841	11,677	11,547	11,841	11,677	11,547
Dilutive effect of stock options and ESPP				103	95	-
Dilutive effect of Notes				96	-	-
Diluted Weighted-Average Shares Outstanding				12,040	11,772	11,547
Earnings/(Loss) per share	$ 0.51	$ 1.31	$ (0.09)	$ 0.50	$ 1.30	$ (0.09)

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 3.0 million, 4.4 million, and 4.8 million for the years ended December 31, 2019, 2018, and 2017, 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

On 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, December 2018, and February 2019. See Note 4 for further details regarding the interest rate swap.

At times 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 non-current 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.

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. 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, we determined that we operate in one reportable segment. Our operations are located in the United States and Canada. The majority of the assets of the Company are located in the United States.

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

(in thousands)	Years Ended December 31,		
Location of Operations	**2019**	**2018**	**2017**
United States	$ 199,663	$ 196,886	$ 176,842
Canada	6,884	4,690	-
Total Revenue	$ 206,547	$ 201,576	$ 176,842

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

(in thousands)	December 31, 2019	December 31, 2018
United States	$ 26,708	$ 24,437
Canada	13,843	13,653
Total property and equipment, net	$ 40,551	$ 38,090

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

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In November 2019, the Financial Accounting Standards Board ("FASB") issued guidance simplifying the accounting for income taxes by removing the following exceptions: 1) exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income or a gain from other items, 2) exception requirement to recognize a deferred tax liability for equity method investments when a foreign subsidiary becomes and equity method investment, 3) exception to the ability not to recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary, and 4) exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss the year. The amendments also simplify accounting for income taxes by doing the following: 1) requiring that an entity recognize a franchise tax or similar tax that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax, 2) requiring that an entity evaluate when a step up in the tax basis of goodwill should be considered part of the business combination in which the book goodwill was originally recognized and when it should be considered a separate transaction, 3) specifying that an entity is not required to allocate the consolidated amount of current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements, 4) requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date, and 5) making minor Codification improvements for income taxes related to employee stock ownership plans and investments in qualified affordable housing projects accounted for using the equity method. The guidance is effective for reporting periods beginning after December 15, 2020, 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 November 2018, the FASB issued guidance clarifying that certain transactions between collaborative arrangement participants should be accounted for as 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 will adopt this guidance as of January 1, 2020. 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 amending 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 will adopt this guidance as of January 1, 2020. 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. In April 2019, the FASB further clarified the scope of the credit losses standard and addressed issues related to accrued interest receivable balances, recoveries, variable interest rates, and prepayment. In May 2019, the FASB issued further guidance to provide entities with an option to irrevocably elect the fair value option applied on an instrument-by-instrument basis for eligible financial instruments. In November 2019, the FASB issued further guidance on expected recoveries for purchased financial assets with credit deterioration, and transition refiled for troubled debt restructurings, disclosures related to accrued interest receivables, financial assets secured by collateral maintenance provisions. 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 may change the way we assess the collectability of our receivables and recoverability of other financial instruments. We will adopt this guidance as of January 1, 2020. The adoption of this guidance is not expected to have a material impact on our consolidated financial statements.

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

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 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 swaps are designated in LIBOR. The guidance was effective for reporting periods beginning after December 15, 2018. We adopted this guidance as of January 1, 2019 on a prospective basis. The adoption of this guidance did not have a material impact on our consolidated financial statements.

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 was effective for the quarter that began after the effective date. The adoption of this guidance resulted in the inclusion of the statement of changes stockholder's equity in our interim financial statement filings.

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 are measured at their grant date fair value. Upon transition, the existing nonemployee awards are measured at fair value as of the adoption date. The guidance was effective for reporting periods beginning after December 15, 2018, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2019. The adoption of this guidance did not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. 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 was effective for reporting periods beginning after December 15, 2018. We adopted this guidance on a modified retrospective basis effective January 1, 2019, using the following allowable practical expedients:

- We did not reassess if any expired or existing contracts are or contain leases;
- We did not reassess the classification of any expired or existing leases.

Additionally, we made ongoing accounting policy elections whereby we (i) do not recognize right-of-use assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combine lease and non-lease elements of our operating leases.

Upon adoption of the new guidance on January 1, 2019, we recognized a right-of-use asset of approximately $0.5 million, which was reduced by approximately $10 thousand of net prepaid rents at the date of adoption, along with a lease liability of approximately $0.5 million. We also recognized total deferred tax assets of approximately $0.1 million and deferred tax liabilities of approximately $0.1 million related to book-tax basis differences. The net effect of the adoption resulted in a cumulative effect adjustment to retained earnings on January 1, 2019 of approximately $2 thousand.

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 final allocation of the purchase price 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
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.

2. BUSINESS COMBINATION (Continued)

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 $6.9 million of revenue and recorded a net loss of $5.2 million for the year ended December 31, 2019.

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 loss for the year ended December 31, 2017 includes the impact to WellSpring of $4.4 million of related party debt forgiveness.

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 was a $118.0 million DDTL, which could only be drawn on in order to pay down the Company's remaining 3.0% Convertible Senior Notes, which matured on December 1, 2019. The Credit Facility (and specifically the DDTL) has a subjective acceleration clause in case of a material adverse event. The Credit Facility also extended the maturity of the $72.2 million 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, pursuant to which $4.5 million of the loan will be paid in quarterly installments during 2020. As of December 31, 2019, $4.5 million of the loan is recorded as current borrowings in the accompanying consolidated balance sheets. In February 2019, we entered into an interest rate swap arrangement to manage our exposure to changes in LIBOR-based interest rates underlying the DDTL once drawn upon (Note 4). On November 29, 2019, we exercised our option to borrow $118.0 million pursuant to the DDTL feature and the proceeds were used to repay the outstanding 3% Convertible Senior Notes, which matured on December 1, 2019. The DDTL matures in December 2023 and includes a repayment schedule, pursuant to which $5.9 million will be paid in quarterly installments during 2020. As of December 31, 2019, $5.9 million of the loan is recorded as current borrowings in the accompanying consolidated balance sheets. Amounts drawn on the Term Loan and 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. On the Revolver, we 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.

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 is, as of December 31, 2019 no greater than 3.50 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 non-current components of the Term Loan and DDTL as of December 31, 2019 and 2018 are:

	Current	
(in thousands)	**2019**	**2018**
Current borrowing on secured Term Loan and Delayed Draw Term Loan	$ 10,412	$ 3,609
Deferred financing costs	(471)	(353)
Current component of Term Loan and Delayed Draw Term Loan, net of deferred financing costs	$ 9,941	$ 3,256

	Non-Current	
(in thousands)	**2019**	**2018**
Non-current borrowing on secured Term Loan and Delayed Draw Term Loan	$ 177,069	$ 68,578
Deferred financing costs	(1,261)	(1,282)
Term Loan and Delayed Draw Term Loan, net of deferred financing costs and current component	$ 175,808	$ 67,296

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, 2019, we had a $69.5 million balance on the Term Loan and $118.0 million balance on the DDTL. As of December 31, 2019, we had not drawn on the Revolving Credit Facility. Of the $1.0 million of deferred debt issuance costs allocated to the Revolving Credit Facility, $0.8 million is included in other non-current assets in the accompanying consolidated balance sheets and $0.2 million is included in prepaid expenses and other current assets in the accompanying consolidated balance sheets. Of the 0.5 million of deferred debt issuance costs allocated to the DDTL, $0.1 million is classified as a direct deduction to the current portion of the DDTL in the accompanying consolidated balance sheets and $0.4 million is classified as a direct reduction to the non-current portion of the DDTL in the accompanying consolidated balance sheets. Of the $1.3 million of deferred debt issuance costs allocated to the Term Loan, $0.4 million is classified as a direct deduction to the current portion of the Term Loan in the accompanying consolidated balance sheets and $0.9 million is classified as a direct deduction to the non-current portion of the Term Loan in the accompanying consolidated balance sheets.

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

(in thousands)	Term Loan	DDTL
2020	$ 4,512	$ 5,900
2021	5,414	5,900
2022	5,414	8,850
2023	54,141	97,350
Total	$ 69,481	$ 118,000

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 paid 3.0% interest semi-annually in arrears on June 1 and December 1 of each year, starting on June 1, 2015, and matured on 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 to additional paid-in capital (“APIC”) in the accompanying consolidated balance sheets. The remaining Notes were convertible into 1,709,002 shares of common stock, based on an initial conversion price of $69.48 per share.

The Notes were 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.

3. INDEBTEDNESS (Continued)

Upon conversion by the holders, we had the option 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 was 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 were 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, we 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 a “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 and the remaining warrant had an underlying 1,709,002 common shares.

On December 2, 2019 (December 1, 2019 was not a business day), we used the proceeds of the DDTL and operating cash on hand to repay the outstanding Notes. Holders of $50,000 of the Notes elected for conversion, which pursuant to the First Supplemental Indenture to the Notes, resulted in the holders’ receipt of cash for the principal portion of the Notes and 33 shares of our common stock. These shares were provided by our counterparty pursuant to the Call Option Overlay. As of December 31, 2019, the remaining warrant had an underlying 1,709,002 common shares.

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

(in thousands)	2019	2018
Principal amount	$ -	$ 118,750
Unamortized debt discount	-	(5,648)
Deferred financing costs	-	(639)
Net carrying value	$ -	$ 112,463

The effective interest rate on the Notes was 7.4% and 8.5%, on an annualized basis, as of December 31, 2019 and 2018, respectively.

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

(in thousands)	2019	2018	2017
Contractual coupon	$ 6,635	$ 7,170	$ 4,313
Amortization of debt discount	5,647	7,002	6,720
Amortization of finance fees	1,377	1,463	845
Capitalized interest	(191)	(724)	(554)
	$ 13,468	$ 14,911	$ 11,324

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 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.

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 decreases in line with our Term Loan. As of December 31, 2019, the notional amount of the interest rate swap was $69.5 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, 2019, the fair value of the interest rate swap liability was valued at $2.4 million and was recorded in other non-current liabilities in the accompanying consolidated balance sheets. As of December 31, 2019, $1.9 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, 2019, changes in the fair value of the interest rate swap of $1.5 million, net of tax, was recorded in accumulated other comprehensive (loss), net of tax in our consolidated statements of comprehensive income. Differences between the hedged LIBOR rate and the fixed rate are recorded as interest expense in the same period that the related interest is recorded for the Term Loan based on the LIBOR rate. In the year ended December 31, 2019, $0.2 million of interest expense was recognized in relation to the interest rate swap.

In February 2019, we entered into an interest rate swap with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our DDTL. As of December 31, 2019, the notional amount of the interest rate swap was $118.0 million and decreases in line with our DDTL. The interest rate swap provides an effective fixed rate of 2.47% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. The interest rate swap hedges the variable cash flows associated with the borrowings under our DDTL (Note 3), effectively providing a fixed rate of interest throughout the life of our DDTL. As of December 31, 2019, the fair value of the interest rate swap liability was valued at $3.8 million and was recorded in other non-current liabilities in the accompanying consolidated balance sheets. As of December 31, 2019, $3.0 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, 2019, changes in the fair value of the interest rate swap of $3.0 million, net of tax, were recorded in accumulated other comprehensive loss, net of tax in our consolidated statements of comprehensive income. Differences between the hedged LIBOR rate and the fixed rate are recorded as interest expense in the same period that the related interest is recorded for the DDTL based on the LIBOR rate. In the year ended December 31, 2019, $0.1 million of interest expense was recognized in relation to the February 2019 interest rate swap.

5. INVENTORIES

Inventories consist of the following as of December 31:

(in thousands)	2019	2018[1]
Raw materials	$ 34,881	$ 27,671
Packaging materials	2,902	2,563
Work-in-progress	361	1,210
Finished goods	16,750	10,620
	54,894	42,064
Reserve for excess/obsolete inventories	(6,731)	(1,561)
Inventories, net	$ 48,163	$ 40,503

(1) Includes inventory acquired in acquisition of WellSpring (Note 2).

During the fourth quarter 2019, we recognized a $4.6 million inventory reserve charge, primarily related to our exit from the market of Methylphenidate Extended Release.

6. PROPERTY, PLANT, AND EQUIPMENT

Property, plant, and equipment consist of the following as of December 31:

(in thousands)	2019	2018[1]
Land	$ 4,566	$ 4,558
Buildings	10,275	10,079
Machinery, furniture, and equipment	34,984	26,814
Construction in progress	3,496	5,040
	53,321	46,491
Less: accumulated depreciation	(12,770)	(8,401)
Property and equipment, net	$ 40,551	$ 38,090

(1) Includes property and equipment acquired in acquisition of WellSpring (Note 2).

Depreciation expense for the years ended December 31, 2019, 2018, and 2017 totaled $4.4 million, $2.1 million, and $1.2 million, respectively. During the years ended December 31, 2019 and 2018, there was $0.2 million and $0.7 million of interest capitalized into construction in progress, respectively.

7. INTANGIBLE ASSETS

Goodwill

As a result of the Merger we recorded goodwill of $1.8 million. As a result of our acquisition of WellSpring, we recorded additional goodwill of $1.7 million in 2018. We assess the recoverability of the carrying value of goodwill on an annual basis as of October 31 of each year, and whenever events occur or circumstances changes that would, more likely than not, reduce the fair value of our reporting unit below its carrying value.

Changes in the carrying amount of goodwill as of December 31 are as follows:

(in thousands)	2019	2018
Balance at beginning of year	$ 3,580	$ 1,838
Acquisition of WellSpring (Note 2)	-	1,742
Balance at end of year	$ 3,580	$ 3,580

For the goodwill impairment analyses performed at October 31, 2019 and 2018, we performed qualitative assessments to determine whether it was more likely than not that our goodwill asset was impaired in order to determine the necessity of performing a quantitative impairment test, under which management would calculate the asset's fair value. When performing the qualitative assessments, we evaluated events and circumstances that would affect the significant inputs used to determine the fair value of the goodwill. Events and circumstances evaluated include: macroeconomic conditions that could affect us, industry and market considerations for the pharmaceutical industry that could affect us, cost factors that could affect our performance, our financial performance (including share price), and consideration of any company-specific events that could negatively affect us, our business, or our fair value. Based on our assessments of the aforementioned factors, it was determined that it was more likely than not that the fair value of our one reporting unit is greater than its carrying amount as of October 31, 2019 and 2018, and therefore no quantitative testing for impairment was required.

In addition to the qualitative impairment analysis performed at October 31, 2019, there were no events or changes in circumstances that could have reduced the fair value of our reporting unit below its carrying value from October 31, 2019 to December 31, 2019. No impairment loss was recognized during the years ended December 31, 2019, 2018, and 2017, and the balance of goodwill was $3.6 million as of December 31, 2019 and 2018.

Definite-lived Intangible Assets

Acquisition of Abbreviated New Drug Applications

In March 2019, we entered into an agreement with Teva Pharmaceutical Industries Ltd. to purchase a basket of ANDAs for 35 previously-marketed generic drug products for $2.5 million in cash. We also capitalized $10 thousand of costs directly related to the transaction. We accounted for this transaction as an asset purchase. The $2.5 million of ANDAs are being amortized in full over their estimated useful lives of 10 years. Please see Note 8 for further details regarding the transaction.

In January 2019, we entered into an amendment to three asset purchase agreements (the "Asset Purchase Agreement Amendment") with Teva Pharmaceuticals USA, Inc. ("Teva"). Under the terms of the Asset Purchase Agreement Amendment, all royalty obligations of the Company owed to Teva with respect to products associated with ten ANDAs under the original asset purchase agreements ceased being effective as of December 31, 2018. As consideration for the termination of such future royalty obligations, we paid Teva a sum of $16.0 million. Upon the payment of $16.0 million, the purchase price of each basket of ANDAs was increased as if the payment had been made on the initial acquisition date. As a result, we recognized cumulative amortization expense of $6.8 million upon recording the transaction. Please see Note 8 for further details regarding the transaction.

7. INTANGIBLE ASSETS (Continued)

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. We also capitalized $0.1 million of costs directly related to the transaction. We accounted for this transaction as an asset purchase. The $1.0 million acquired ANDA intangible assets are being amortized in full over their estimated useful lives of 10 years. Please see Note 8 for further details regarding the transaction.

In April 2018, we entered into an agreement with IDT Australia, Limited to purchase 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 also capitalized $18 thousand of costs directly related to the transaction. We accounted for this transaction as an asset purchase. The $2.5 million acquired ANDA intangible assets are being amortized in full over their estimated useful lives of 10 years. Please see Note 8 for further details regarding the transaction.

Acquisition of New Drug Applications and Product Rights

In December 2017, we entered into an agreement with AstraZeneca AB and AstraZeneca UK Limited 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. We also entered into a license agreement for use of these trademarks in the U.S. We also capitalized $0.2 million of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $46.7 million product rights assets are being amortized in full over their estimated useful lives of 10 years. Please see Note 8 for further details regarding the transaction.

In February 2017, we entered into an agreement with Cranford Pharmaceuticals, LLC to purchase a distribution license, trademark, and certain finished goods inventory for Inderal XL for $20.2 million in cash. We accounted for this transaction as an asset purchase. We also capitalized $40 thousand of costs directly related to the transaction. The $15.1 million product rights intangible asset acquired in the asset purchase is being amortized in full over its estimated useful life of 10 years. Please see Note 8 for further details regarding the transaction.

In February 2017, we entered into an agreement with Holmdel Pharmaceuticals, LP to purchase the NDA, trademark, and certain finished goods inventory for InnoPran XL, including a license to an Orange Book listed patent, for $30.6 million in cash. We accounted for this transaction as an asset purchase. We also capitalized $0.1 million of costs directly related to the transaction. The $19.0 million product rights intangible asset acquired in the asset purchase is being amortized in full over its estimated useful life of 10 years. Please see Note 8 for further details regarding the transaction.

7. INTANGIBLE ASSETS (Continued)

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. In addition, the remaining $0.9 million asset was recorded as a short-term asset held for sale as of December 31, 2016 in the prepaid expenses and other assets caption in the accompanying consolidated balance sheets. 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.

Marketing and Distribution Rights

In April 2019, we entered into an agreement with Pharmaceutics International, Inc. ("PII") and BAS ANDA LLC ("BAS"), under which a previously-commercialized product will be developed and marketed. Per the agreement, we may pay PII a series of licensing fees in conjunction with the achievement of certain development and commercial milestones. In the fourth quarter of 2019, the product was launched, triggering a $0.5 million payment due to PII. The payment due as of December 31, 2019 was capitalized as an intangible asset and will be amortized in full over its useful life of 10 years.

In March 2018, we entered into an agreement with Appco Pharma, LLC ("Appco"), in which a potential generic product, Ranitidine, was to be developed and marketed. Per the agreement, we paid Appco a series of licensing fees in conjunction with certain development milestones. Ranitidine was launched in the third quarter of 2019, resulting in the final milestone payment of $80 thousand. The $80 thousand milestone payment was capitalized as an intangible asset and determined to have an estimated useful life of eight years. In September 2019, the Food and Drug Administration ("FDA") issued a public statement that some ranitidine medicines contain a nitrosamine impurity called N-nitrosdimethylamine ("NDMA") at low levels. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests and the cause of the presence of this impurity in the ranitidine products is not yet fully understood at this time. During the fourth quarter 2019, testing of the API used in our ranitidine drug product, as well as testing of the drug product itself, indicated a level of NDMA above acceptable thresholds and Appco initiated a voluntary recall. The Company has elected to exit the market for Ranitidine and determined that the carrying value of the asset has been impaired. During the fourth quarter 2019, the Company recognized a full impairment of the remaining $75 thousand carrying value of the asset.

7. INTANGIBLE ASSETS (Continued)

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

	December 31, 2019		December 31, 2018		Weighted Average
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	Amortization Period
Acquired ANDA intangible assets	$ 64,704	$ (30,169)	$ 46,194	$ (17,093)	10.0 years
NDAs and product rights	230,974	(87,352)	230,974	(62,222)	10.0 years
Marketing and distribution rights	10,923	(8,982)	10,423	(7,051)	4.7 years
Non-compete agreement	624	(334)	624	(245)	7.0 years
	$ 307,225	$ (126,837)	$ 288,215	$ (86,611)	10.0 years

Definite-lived intangible assets are stated at cost, net of amortization, generally using the straight-line method over the expected useful lives of the intangible assets. In the case of the Inderal XL and InnoPran XL asset purchases, because we anticipate that the acquired assets will provide a greater economic benefit in the earlier years, we are amortizing 80% of the value of the intangible assets over the first five years of useful lives of the assets and amortizing the remaining 20% of the value of the intangible assets over the second five years of useful lives of the assets. Amortization expense was $40.2 million, $31.7 million, and $26.7 million for the years ended December 31, 2019, 2018, and 2017, respectively.

We test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. We recognized an impairment of $75 thousand in the year ended December 31, 2019, in relation to the Ranitidine product right asset. No impairment losses related to intangible assets were recognized in the year ended December 31, 2018. We recognized an impairment of $0.9 million in the year ended December 31, 2017, in relation to the Testosterone Gel NDA. No events or circumstances arose in 2019, 2018, or 2017 that indicated that the carrying value of any of our other definite-lived intangible assets may not be recoverable.

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

(in thousands)	
2020	$ 33,180
2021	31,734
2022	28,329
2023	27,581
2024	24,604
2025 and thereafter	34,960
Total	$ 180,388

8. FAIR VALUE DISCLOSURES

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current liabilities) approximate their carrying values because of their short-term nature. The Term Loan and DDTL bear an interest rate that fluctuates with the changes in LIBOR and, because the variable interest rates approximate market borrowing rates available to us, we believe the $69.5 million and $118.0 million carrying value of the Term Loan and DDTL approximated their fair values at December 31, 2019.

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

Our contingent value rights (“CVRs”), which were granted coincident with our merger with BioSante and expire in June 2023, are considered to be contingent consideration and are classified as liabilities. As such, the CVRs were recorded as purchase consideration at their estimated fair value, using Level 3 inputs, and are marked to market each reporting period until settlement. The fair value of CVRs is estimated using the present value of management’s projection of the expected payments pursuant to the terms of the CVR agreement, which is the primary unobservable input. If our projection or expected payments were to increase substantially, the value of the CVRs could increase as a result. The present value of the liability was calculated using a discount rate of 15%. We determined that the fair value of the CVRs was immaterial as of December 31, 2019 and 2018. We also determined that the changes in such fair value were immaterial for the years ended December 31, 2019, 2018, and 2017.

In April 2018, we entered into an interest rate swap arrangement (Note 4), with Citizens Bank, N.A. to manage our exposure to the variable interest rate on our previous Term Loan. The notional amount of this interest rate swap was set to match the balance of our previous Term Loan. The fair value of our interest rate swap was estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. The model used to value the interest rate swap included inputs of readily observable market data, a Level 2 input.

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 to December 2023. At the same time, we closed out the original interest rate swap and entered into a new interest rate swap arrangement (Note 4) to manage our exposure to the variable interest rate on our Term Loan (Note 3). The notional amount of our interest rate swap is set to match the balance of our Term Loan. Both the notional amount of the interest rate swap and the balance of our Term Loan were $69.5 million as of December 31, 2019. The fair value of our interest rate swap is estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in detail in Note 4, the fair value of the interest rate swap was a $2.4 million liability at December 31, 2019.

In February 2019, we entered into an interest rate swap arrangement (Note 4), with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our DDTL (Note 3). The notional amount of our interest rate swap is set to match the balance of our DDTL. Both the notional amount of the interest rate swap and the balance of our DDTL were $118.0 million as of December 31, 2019. The fair value of our interest rate swap was estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. The model used to value the interest rate swap included inputs of readily observable market data, a Level 2 input. As described in detail in Note 4, the fair value of the interest rate swap was a $3.8 million liability at December 31, 2019.

8. FAIR VALUE DISCLOSURES (Continued)

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of December 31, 2019 and December 31, 2018, by level within the fair value hierarchy:

(in thousands)

Description	Fair Value at December 31, 2019	Level 1	Level 2	Level 3
Liabilities				
Interest rate swaps	$ 6,215	$ -	$ 6,215	$ -
CVRs	$ -	$ -	$ -	$ -

Description	Fair Value at December 31, 2018	Level 1	Level 2	Level 3
Liabilities				
Interest rate swaps	$ 496	$ -	$ 496	$ -
CVRs	$ -	$ -	$ -	$ -

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

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

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

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

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

We measure our long-lived assets, including property, plant and equipment, intangible assets and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. During the year ended December 31, 2019, we recognized a $75 thousand impairment charge related to our Ranitidine product right asset (Note 7). There were no other fair value impairments recognized in the year ended December 31, 2019.

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. See Note 2, Business Combination.

8. FAIR VALUE DISCLOSURES (Continued)

Acquired Non-Financial Assets Measured at Fair Value

In June 2019, we acquired from Coeptis Pharmaceuticals, Inc. seven development stage generic products, as well as API and reference-listed drug inventory related to certain of the products for a payment of $2.3 million. The entire payment, and $24 thousand of transaction costs directly related to the acquisition, was recorded as research and development expense because the potential generic products have significant remaining work required in order to commercialize the products and do not have an alternative future use. In addition, we could make up to $12.0 million in payments for certain development and commercial milestones. These milestones were determined to be contingent liabilities and will be accrued when they are both estimable and probable.

In April 2019, we entered into an agreement with PII and BAS, under which a previously-commercialized product will be developed and marketed. Per the agreement, we may pay PII a series of licensing fees in conjunction with the achievement of certain development and commercial milestones. In the fourth quarter of 2019, the product was launched, triggering a $0.5 million payment due to PII. The payment due as of December 31, 2019 was capitalized as an intangible asset and will be amortized in full over its useful life of 10 years.

In March 2019, we entered into an agreement with Teva Pharmaceutical Industries Ltd. to purchase a basket of ANDAs for 35 previously-marketed generic drug products for $2.5 million in cash (Note 7). We also capitalized $10 thousand of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $2.5 million of ANDAs were recorded at their relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible assets, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 15%. The ANDAs will be amortized in full over their 10-year useful lives and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2019 and therefore no impairment loss was recognized for the year ended 2019.

In January 2019, we entered into an amendment to asset purchase agreements with Teva related to three purchases of baskets of ANDAs. Under the terms of the Asset Purchase Agreement Amendment, all royalty obligations of the Company owed to Teva with respect to products associated with ten ANDAs under the original asset purchase agreements ceased being effective as of December 31, 2018. As consideration for the termination of such future royalty obligations, we paid Teva a sum of $16.0 million in cash (Note 7). Upon payment of $16.0 million, the purchase price of each basket of ANDAs was increased to reflect the subsequent payment as if that payment had been made on the initial acquisition date. As a result, in addition to increasing the carrying value of the acquired ANDA intangible assets by $9.2 million, we recognized cumulative amortization expense of $6.8 million. The payment was allocated to the three ANDA baskets based on the relative fair value of the ANDA baskets, which were determined using Level 3 unobservable inputs. In order to determine the fair value of the acquired ANDA intangible assets, we used the present value of the estimated cash flows related to the ANDAs, using a discount rate of 12%. The additional carrying value will be amortized over the remaining useful lives of the three ANDA baskets and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2019 and therefore no impairment loss was recognized for the year ended 2019.

8. FAIR VALUE DISCLOSURES (Continued)

In April 2018, we entered into an agreement with Impax Laboratories, Inc. (now 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 (Note 7). 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. This milestone payment was determined to be contingent consideration and will be recognized when the contingency is resolved. When one of the approved ANDAs that have not yet been commercialized is launched, we could be required to pay a milestone of $25.0 million to Teva Pharmaceuticals USA, Inc. (“Teva”), depending on the number of competitors selling the product at the time of launch. In addition, depending on the number of competitors selling the product one year after the launch date, we could be required to pay a second milestone of $15.0 million to Teva. These milestones are determined to be contingent liabilities and will be recognized if and when they are both estimable and probable. Because we believe that neither milestone is both estimable and probable, we did not record a contingent liability for the milestones. We also capitalized $0.1 million of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $1.0 million acquired ANDA intangible assets were recorded at their relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the acquired ANDA intangible assets, we used the present value of the estimated cash flows related to the approved ANDAs, using discount rates of 10 to 15%. The acquired ANDAs will be amortized in full over their 10-year useful lives, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. The $58 thousand of manufacturing equipment used to manufacture one of the products was recorded at its relative fair value, based on the estimated net book value of the equipment purchased. The equipment will be amortized in full over its 5-year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2019 and therefore no impairment loss was recognized for the years ended December 31, 2018 and 2019. The $1.3 million of in-process research and development related to products with significant further work required in order to commercialize the products, and for which there is no alternative future use. The in-process research and development was recorded at its relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the in-process research and development, we used the present value of the estimated cash flows related to the products, using a discount rate of 75%, reflective of the higher risk associated with these products. As the transaction was accounted for as an asset purchase, the $1.3 million of in-process research and development was immediately recognized as research and development expense.

In April 2018, we entered into an agreement with IDT Australia, Limited to purchase 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 (Note 7). We also capitalized $18 thousand of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $2.5 million acquired ANDA intangible assets were recorded at their relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible assets, we used the present value of the estimated cash flows related to the product rights, using discount rates of 10% to 15%. The acquired ANDA intangible assets will be amortized in full over their 10-year useful lives, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2019 and therefore no impairment loss was recognized for the years ended December 31, 2018 and 2019. We also recorded $0.2 million of raw materials inventory, measured at fair value. The fair value of the raw materials inventory was determined based on the estimated replacement cost.

8. FAIR VALUE DISCLOSURES (Continued)

In March 2018, we entered into an agreement with Appco, in which a potential generic product, Ranitidine, was to be developed and marketed. Per the agreement, we paid Appco a series of licensing fees in conjunction with certain development milestones. Ranitidine was launched in the third quarter of 2019, resulting in the final milestone payment of $80 thousand. The $80 thousand milestone payment was capitalized as an intangible asset and determined to have estimated useful life of eight years. In September 2019, the FDA issued a public statement that some ranitidine medicines contain a nitrosamine impurity referred to as NDMA at low levels. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests and the cause of the presence of this impurity in the ranitidine products is not yet fully understood at this time. During the fourth quarter of 2019, testing of the API used in our ranitidine drug product, as well as testing of the drug product itself, indicated a level of NDMA above acceptable thresholds and Appco initiated a voluntary recall. The Company has elected to exit the market for Ranitidine and determined that the carrying value of the asset has been impaired. During the fourth quarter of 2019, the Company recognized a full impairment of the remaining $75 thousand carrying value of the asset.

In December 2017, we entered into an agreement with AstraZeneca AB and AstraZeneca UK Limited to purchase the right, title, and interest in the NDAs and the U.S. right to market Atacand, Atacand HCT, Arimidex, and Casodex, for $46.5 million in cash (Note 7). We also licensed these trademarks for use in the U.S. We also capitalized $0.2 million of costs directly related to the asset purchase. The agreement included a $3.0 million contingent payment due in early 2023 if the annual net sales of the Atacand and Atacand HCT products equals or exceeds certain threshold amounts in 2020, 2021, and 2022. Because we believe that the likelihood of meeting or exceeding the threshold amounts is not probable, we did not record a contingent liability in relation to the agreement. We accounted for this transaction as an asset purchase. The $46.7 million product rights intangible assets were recorded at their relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible assets, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The product rights will be amortized in full over their 10-year useful lives, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2019 and therefore no impairment loss was recognized for the years ended December 31, 2017, 2018, and 2019.

In February 2017, we entered into an agreement with Cranford Pharmaceuticals, LLC to purchase a distribution license, trademark, and certain finished goods inventory for Inderal XL for $20.2 million in cash (Note 7). We also capitalized $40 thousand of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $15.1 million product rights intangible asset was recorded at its relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible asset, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The product rights will be amortized in full over its 10-year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2019 and therefore no impairment loss was recognized for the years ended December 31, 2019, 2018, and 2017. We also recorded $5.0 million of finished goods inventory. The fair value of the finished goods inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin.

In February 2017, we entered into an agreement with Holmdel Pharmaceuticals, LP to purchase the NDA, trademark, and certain finished goods inventory for InnoPran XL, including a license to an Orange Book listed patent, for $30.6 million in cash (Note 7). We also capitalized $0.1 million of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $19.0 million product rights intangible asset was recorded at its relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible asset, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The product rights will be amortized in full over its 10-year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2019 and therefore no impairment loss was recognized for the years ended December 31, 2017, 2018, and 2019. We also recorded $11.6 million of finished goods inventory. The fair value of the finished goods inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin.

9. STOCKHOLDERS' EQUITY

Authorized shares

We are authorized to issue up to 33.3 million shares of common stock with a par value of $0.0001 per share, 0.8 million shares of class C special stock with a par value of $0.0001 per share, and 1.7 million shares of undesignated preferred stock with a par value of $0.0001 per share at December 31, 2019.

There were 12.1 million and 11.9 million shares of common stock issued and outstanding as of December 31, 2019 and 2018, respectively.

There were 11 thousand shares of class C special stock issued and outstanding as of December 31, 2019 and 2018. Each share of class C special stock entitles its holder to one vote per share. Each share of class C special stock is exchangeable, at the option of the holder, for one share of our common stock, at an exchange price of $90.00 per share, subject to adjustment upon certain capitalization events. Holders of class C special stock are not entitled to receive dividends or to participate in the distribution of our assets if we were to liquidate, dissolve, or wind-up the company. The holders of class C special stock have no cumulative voting, preemptive, subscription, redemption, or sinking fund rights.

There were no shares of undesignated preferred stock outstanding as of December 31, 2019 and 2018.

Warrants

Warrants to purchase an aggregate of 1.7 million shares of our common stock were outstanding and exercisable as of December 31, 2019:

Issue Date	Number of Underlying Shares of Common Stock (in thousands)	Per Share Exercise Price	First Expiration Date
December 4, 2014	1,486	$ 96.21	March 1, 2020
December 5, 2014	223	$ 96.21	March 1, 2020

All outstanding warrants are classified as equity. No warrants were granted, exercised, or expired unexercised during the years ended December 31, 2019, 2018 and 2017. The warrants expire ratably over a 60 business day period beginning on March 1, 2020 and finishing on May 25, 2020.

10. STOCK-BASED COMPENSATION

Employee Stock Purchase Plan

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan, which was approved by shareholders in our May 25, 2016 annual shareholder meeting. The Board of Directors and shareholders approved a maximum of 0.2 million shares of common stock, which were reserved and made available for issuance under the ESPP. Under the ESPP, participants can purchase shares of our stock at a 15% discount. We issued six thousand, five thousand, and four thousand shares in the years ended December 31, 2019, 2018, and 2017, respectively.

The following table summarizes ESPP expense incurred under the 2016 Employee Stock Purchase Plan and included in our accompanying consolidated statements of operations:

	Years Ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Cost of sales	$ 18	$ 11	$ 6
Research and development	29	16	1
Selling, general, and administrative	100	75	61
	$ 147	$ 102	$ 68

Stock Incentive Plan

All equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the “2008 Plan”). As of December 31, 2019, 0.4 million shares of our common stock remained available for issuance under the 2008 Plan.

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

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)	**2019**	**2018**	**2017**
Cost of sales	$ 101	$ 87	$ 86
Research and development	756	771	677
Selling, general, and administrative	8,213	5,822	5,259
	$ 9,070	$ 6,680	$ 6,022

We recognized income tax benefits of $1.4 million, $1.2 million, and $0.6 million for stock-based compensation-related tax deductions in our 2019, 2018, and 2017 consolidated statements of operations, respectively.

10. STOCK-BASED COMPENSATION (Continued)

Stock Options

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

For 2019, 2018, and 2017, the fair value of each option grant was estimated using the Black-Scholes option-pricing model, using the following assumptions:

	Years Ended December 31,		
	2019	**2018**	**2017**
Expected option life (years)	5.50 - 6.25	5.48 - 6.25	5.33 - 7.00
Risk-free interest rate	1.91% - 2.58%	2.64% - 2.93%	1.93% - 2.33%
Expected stock price volatility	63.1% - 66.7%	55.1% - 60.6%	50.3% - 57.4%
Dividend yield	—	—	—

We use the simplified method to estimate the life of options. The risk-free interest rate used is the yield on a U.S. Treasury note as of the grant date with a maturity equal to the estimated life of the option. We calculated an estimated volatility rate based on the closing prices of several competitors that manufacture similar products. We have not issued a cash dividend in the past nor do we have any current plans to do so in the future; therefore, an expected dividend yield of zero was used.

In 2017, we granted options to two consultants. We used the Black-Scholes option-pricing model to determine the fair value of the option grants and the valuation of the grants were marked to market through December 31, 2018. In June 2018, the FASB issued guidance simplifying the accounting for nonemployee stock-based compensation awards (Note 1). We adopted this guidance as of January 1, 2019, therefore the nonemployee awards are measured at fair value as of the adoption date, and no longer marked to market.

10. STOCK-BASED COMPENSATION (Continued)

A summary of stock option activity under the 2008 Plan during the years ended December 31, 2019, 2018, and 2017 is presented below:

(in thousands, except per share and remaining term data)	Option Shares	Weighted Average Exercise Price	Weighted Average Grant-date Fair Value	Weighted Average Remaining Term (years)	Aggregate Intrinsic Value
Outstanding December 31, 2016	578	$ 39.28		8.2	$ 12,928
Granted	207	51.66	$ 27.04		
Exercised	(13)	15.92			542
Forfeited	(5)	53.29			
Expired	-	-			
Outstanding December 31, 2017	767	$ 42.93		7.8	$ 16,785
Granted	156	57.60	$ 31.76		
Exercised	(142)	19.47			5,863
Forfeited	(18)	60.17			
Expired	(4)	74.53			
Outstanding at December 31, 2018	759	$ 49.74		7.6	$ 2,221
Granted	160	65.97	$ 40.14		
Exercised	(130)	41.99			3,335
Forfeited	(31)	56.66			
Expired	(1)	54.36			
Outstanding at December 31, 2019	757	$ 54.21		7.2	$ 6,761
Exercisable at December 31, 2019	366	$ 50.47		6.2	$ 4,469

As of December 31, 2019, there was $8.9 million of total unrecognized compensation cost related to non-vested stock options granted under the 2008 Plan. The cost is expected to be recognized over a weighted-average period of 2.5 years. During the year ended December 31, 2019, we received $5.5 million in cash from the exercise of stock options and recorded a $0.7 million tax benefit related to these exercises. During the year ended December 31, 2018, we received $2.8 million in cash from the exercise of stock options and recorded a $0.6 million tax benefit related to these exercises. During the year ended December 31, 2017, we received $0.2 million in cash from the exercise of stock options and recorded a $0.2 million tax benefit related to these exercises.

10. STOCK-BASED COMPENSATION (Continued)

Restricted Stock Awards

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

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

A summary of RSA activity under the Plan during the years ended December 31, 2019, 2018, and 2017 is presented below:

(in thousands, except per share and remaining term data)	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Term (years)
Unvested at December 31, 2016	63	$ 45.72	2.2
Granted	50	49.51	
Vested	(28)	44.49	
Forfeited	-	-	
Unvested at December 31, 2017	85	$ 48.34	2.6
Granted	65	58.11	
Vested	(33)	47.34	
Forfeited	-	-	
Unvested at December 31, 2018	117	$ 54.04	2.1
Granted	122	66.39	
Vested	(42)	54.77	
Forfeited	(5)	62.63	
Unvested at December 31, 2019	192	$ 61.46	2.6

As of December 31, 2019, there was $8.6 million of total unrecognized compensation cost related to non-vested RSAs granted under the Plan, which is expected to be recognized over a weighted-average period of 2.6 years.

11. INCOME TAXES

On August 6, 2018, ANI Canada acquired all the issued and outstanding equity interests of WellSpring in a non-taxable transaction (Note 2). Following the consummation of the transaction, WellSpring was merged into ANI Canada. For U.S. Federal and state income tax purposes, ANI Canada is not part of ANI's consolidated group; rather, ANI Canada is subject to income taxes only in Canada and solely based on its stand-alone operations. The foreign current and foreign deferred provisions (benefits) below represent ANI Canada's tax provision (benefit) from the Canadian taxing jurisdictions.

We are required to establish a valuation allowance for deferred tax assets if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. We consider the projected future taxable income and tax planning strategies in making this assessment. As of December 31, 2018, we had provided a valuation allowance against our consolidated net deferred tax assets of $2.2 million.

As part of purchase accounting, as of the August 6, 2018 acquisition date the Company established net deferred tax assets relating to differences in the book bases (determined based on fair value purchase accounting) and tax bases (determined based on the carryover nature of the nontaxable transaction) of ANI Canada's assets and liabilities of approximately $1.9 million, offset by a full valuation allowance due to our determination that it was more likely than not that all of the deferred tax assets will not be realized. During the second quarter 2019, we adopted an intercompany transfer pricing policy that uses the "comparable profits method" for pricing intercompany services between ANI Pharmaceuticals, Inc. and ANI Canada. For U.S. and Canadian tax purposes, the policy was adopted in conjunction with the acquisition date of August 6, 2018. As a result of the newly adopted transfer pricing policy, our assessment of the amount of ANI Canada's deferred tax assets that are more likely than not to be realized changed and, as a result, during the second quarter 2019, we released the remaining net valuation allowance related to ANI Canada's deferred tax assets.

As of December 31, 2019, our consolidated valuation allowance was $0.4 million, related solely to deferred tax assets for net operating loss carryforwards in certain U.S. state jurisdictions.

Our total provision for income taxes consists of the following for the years ended December 31, 2019, 2018, and 2017:

(in thousands)	2019	2018	2017
Current income tax provision:			
Federal	$ 4,985	$ 7,985	$ 13,175
State	1,212	1,751	690
Total	6,197	9,736	13,865
Deferred income tax (benefit)/provision:			
Federal	(6,274)	(4,630)	4,065
State	(2,027)	(556)	(556)
Foreign	1,000	(214)	-
Total	(7,301)	(5,400)	3,509
Change in valuation allowance	(1,833)	221	51
Total (benefit)/provision for income taxes	$ (2,937)	$ 4,557	$ 17,425

11. INCOME TAXES (Continued)

The difference between our expected income tax provision from applying U.S. Federal statutory tax rates to the pre-tax income and actual income tax provision relates primarily to the effect of the following:

	As of December 31,		
	2019	**2018**	**2017**
US Federal statutory rate	21.0%	21.0%	35.0%
State taxes, net of Federal benefit	3.2%	2.4%	2.0%
Foreign taxes	0.4%	26.5%	-%
Impact of Tax Cuts and Jobs Act	-%	-%	81.9%
Domestic production activities deduction	-%	-%	(8.8)%
Change in valuation allowance	(58.1)%	(26.5)%	-%
Stock-based compensation	(6.7)%	(1.8)%	0.8%
Non-deductible costs	9.1%	-%	0.5%
Change in state apportionment factors, state and foreign rates	(28.1)%	-%	-%
Research and experimentation and charitable credits	(33.5)%	-%	(2.5)%
Transfer pricing and other	(0.2)%	1.1%	(2.3)%
Total income tax (benefit)/provision	(93.0)%	22.7%	106.6%

In 2017 our effective tax rate was impacted by the revaluation of our deferred tax assets and liabilities at the lower 21% U.S. corporate tax rate, as proscribed by the Tax Cuts and Jobs Act, which was enacted on December 22, 2017 and lowered the U.S. corporate 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. 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 net $13.4 million increase in income tax expense for the year ended December 31, 2017.

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

	As of December 31,	
(in thousands)	**2019**	**2018**
Deferred tax assets:		
Accruals and advances	$ 8,586	$ 7,748
Stock-based compensation	3,750	-
Bond hedge	-	3,019
Accruals for chargebacks and returns	7,603	7,132
Inventory	4,720	1,228
Intangible asset	14,923	9,393
Net operating loss carryforwards	4,767	5,604
Other	1,459	4,682
Total deferred tax assets	$ 45,808	$ 38,806
Deferred tax liabilities:		
Depreciation	$ (6,029)	$ (4,437)
Debt discount	-	(1,316)
Intangible assets	(13)	(11)
Other	(1,008)	(2,813)
Total deferred tax liabilities	$ (7,050)	$ (8,577)
Valuation allowance	(432)	(2,265)
Deferred tax assets, net of deferred tax liabilities and valuation allowance	$ 38,326	$ 27,964

11. INCOME TAXES (Continued)

As of December 31, 2019, we had U.S. federal net operating loss carryforwards of approximately $11.3 million, all of which arose as a result of the Merger and, if not used, expire in annual increments through 2033. The utilization of the net operating loss carryforwards are limited in future years as prescribed by Section 382 of the U.S. Internal Revenue Code; our current annual limitation of the federal net operating loss is approximately $0.8 million per year. Additionally, as of December 31, 2019 we have total net operating losses in Canada of $7.9 million that begin expiring in 2035.

We are subject to income taxes in numerous jurisdictions in the U.S. and in Canada. Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. We establish liabilities for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. These liabilities are established when we believe that certain positions might be challenged despite our belief that our tax return positions are fully supportable. We adjust these liabilities in light of changing facts and circumstances, such as the outcome of a tax audit. The provision for income taxes includes the impact of changes to the liability that is considered appropriate. We identified no material uncertain tax positions as of December 31, 2019 and 2018.

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

12. COMMITMENTS AND CONTINGENCIES

Operating Leases

All our existing leases as of December 31, 2019 are classified as operating leases. As of December 31, 2019, we have twelve material operating leases for facilities and office equipment with remaining terms expiring from 2021 through 2024 and a weighted average remaining lease term of 2.4 years. Many of our existing leases have fair value renewal options, none of which are considered certain of being exercised or included in the minimum lease term. Discount rates used in the calculation of our lease liability ranged between 4.02% and 8.95%.

Rent expense for the year ended December 31, 2019 consisted of the following:

(in thousands)	
Operating lease costs	$ 190
Variable lease costs	60
Total lease costs	$ 250

A maturity analysis of our operating leases follows:

(in thousands)	
Future payments:	
2020	$ 214
2021	152
2022	111
2023	40
2024	3
Total	$ 520
Discount	(31)
Lease liability	489
Current lease liability	(197)
Non-current lease liability	$ 292

Future minimum lease payments under non-cancelable operating leases as of December 31, 2018 were approximately $0.1 million per year from 2019 through 2022.

Vendor Purchase Minimums

We have supply agreements with four vendors that include purchase minimums. Pursuant to these agreements, we will be required to purchase a total of $15.2 million of API from these four vendors during the year ended December 31, 2020.

Government Regulation

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

Unapproved Products

Two of our products, Esterified Estrogen with Methyltestosterone (“EEMT”) and Opium Tincture, are marketed without approved NDAs or ANDAs. During the years ended December 31, 2019, 2018, and 2017, net revenues for these products totaled $20.7 million, $24.9 million, and $27.6 million, respectively.

The FDA's policy with respect to the continued marketing of unapproved products is stated in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled “Marketed New Drugs without Approved NDAs or ANDAs.” Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those marketed as unapproved drugs with potential safety risks or that lack evidence of effectiveness. We believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy. There can be no assurance, however, that the FDA will continue this policy or not take a contrary position with any individual product or group of products. If the FDA were to take a contrary position, we may be required to seek FDA approval for these products or withdraw such products from the market. If we decide to withdraw the products from the market, our net revenues for generic pharmaceutical products would decline materially, and if we decide to seek FDA approval, we would face increased expenses and might need to suspend sales of the products until such approval was obtained, and there are no assurances that we would receive such approval.

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the years ended December 31, 2019, 2018, and 2017 were $3.1 million, $2.0 million, and $2.0 million, respectively.

12. COMMITMENTS AND CONTINGENCIES (Continued)

Legal proceedings

We are involved, and from time to time may become involved, in various disputes, governmental and/or regulatory inquiries, investigations, and litigation matters, some of which could result in losses, including damages, fines, and/or civil or criminal penalties against us. These matters are often complex and have outcomes that we are unable to predict.

We intend to vigorously defend ourselves in these matters and believe that we have strong defenses regarding the claims currently asserted against us. However, from time to time, we may settle or otherwise resolve these matters on terms and conditions that we believe are in our best interests. Resolution of any or all claims, investigations, and legal proceedings, individually or in the aggregate, could have a material adverse effect on our results of operations and/or cash flows in any given accounting period or on our overall financial condition.

Some of these matters with which we are involved are described below, and unless otherwise disclosed, we are unable to predict the outcome of the matter or to provide an estimate of the range of reasonably possible material losses. We record accruals for loss contingencies to the extent we conclude it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. From time to time, we are also involved in other pending proceedings for which, in our opinion based upon facts and circumstances known at the time, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to our results. If and when any reasonably possible losses associated with the resolution of such other pending proceedings, in our opinion, become material, we will disclose such matters.

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. Discovery in this action closed on March 31, 2019. Trial is expected to be scheduled for October 2020. We continue 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 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 ("legacy claims"). All these original legacy claims were settled or closed out, including a series of claims in California that were resolved by coordinated proceeding and settlement. At the end of March 2019, we were served with a lawsuit in the Superior Court of California, County of Riverside, adding us as a defendant in a complaint filed in July 2017 that is alleged not to have been part of the original settled legacy claims. This new claim as well as the impact of the prior settlements on this claim is currently being evaluated by the Company, its insurers, and its legal counsel.

At the present time, we are unable to assess the likely outcome of the case. Our insurance company had assumed the defense of the legacy claims and paid all losses in settlement of the California cases. We cannot provide assurances that the outcome of this new matter 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 27th, 1978. We purchased the EES ANDA from Teva on July 10, 2015. 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 our 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 September 27, 2016. 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 reserved our legal right to an internal Agency appeal. 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 with no FDA objection to our prior actions.

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.

13. CORTROPHIN PRE-LAUNCH CHARGES

In January 2016, we acquired the right, title and interest in the NDAs for Cortrophin Gel and Cortrophin-Zinc. Subsequently, we have 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 API, executed a long-term supply agreement with an API manufacturer, with whom we have advanced the manufacture of corticotropin API via manufacture of commercial-scale batches, and executed a long-term commercial supply agreement with a current good manufacturing practice ("cGMP") aseptic fill contract manufacturer.

Prior to the third and fourth quarter 2019, all purchases of material, including pig pituitary glands and API, related to the re-commercialization efforts have been consumed in research and development activities and recognized as research and development expense in the period in which they were incurred. In the third quarter of 2019, we began purchasing materials that are intended to be used commercially in anticipation of FDA approval of Cortrophin Gel and the resultant product launch. Under U.S. GAAP, we cannot capitalize these pre-launch purchases of materials as inventory prior to FDA approval, and accordingly, they are charged to expense in the period in which they are incurred. We expect these pre-launch purchases of material to increase significantly in the future as we build raw materials, API and finished goods for the expected launch of this product. During the year ended December 31, 2019, we incurred related charges for the purchase of materials of $6.7 million. We currently project expense related to this activity to be approximately $11.0-$12.0 million for 2020. In the future, we also expect to incur other charges directly related to the Cortrophin pre-launch commercialization efforts, including, but not limited to, sales and marketing and consulting expenses, which will vary in frequency and impact on our results of operations.

14. SUBSEQUENT EVENTS

On January 8, 2020 we acquired the U.S. portfolio of 23 generic products from Amerigen Pharmaceuticals, Ltd. for $52.5 million in cash at close and up to $25.0 million in contingent profit share payments over the next four years. The contingent payments will be earned when annual gross profit exceeds a minimum threshold and will be earned on a subset of the acquired products. The acquired portfolio includes ten commercial products, three approved products with launches pending, four filed products, and four in-development products as well as a license to commercialize two approved products. We also made a $4.0 million cash payment to Amerigen to acquire certain commercial and development inventory and materials. The transaction was funded from cash on hand.

On January 17, 2020, ANI Pharmaceuticals, Inc. (the "Company") entered into employment agreements with its (i) President and Chief Executive Officer, Arthur S. Przybyl, (ii) Vice President of Finance and Chief Financial Officer, Stephen P. Carey, (iii) Senior Vice President of Business Development and Specialty Sales, Robert Schrepfer and (iv) Senior Vice President of Operations and Product Development, James G. Marken.

15. QUARTERLY FINANCIAL DATA (unaudited)

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

	2019 Quarters (unaudited)			
(in thousands, except per share data)	First	Second	Third	Fourth[1]
Net revenues	$ 52,887	$ 54,357	$ 51,337	$ 47,966
Total operating expenses	48,485	45,065	44,009	52,637
Operating income/(expense)	4,402	9,292	7,328	(4,671)
(Provision)/benefit for income taxes	(469)	653	(64)	2,817
Net income/(loss)	$ 449	$ 6,585	$ 3,895	$ (4,835)
Basic and diluted earnings/(loss) per share:				
Basic earnings/(loss) per share	$ 0.04	$ 0.55	$ 0.32	$ (0.41)
Diluted earnings/(loss) per share	$ 0.04	$ 0.53	$ 0.32	$ (0.41)

[1] During the fourth quarter 2019, we recognized a $4.6 million inventory reserve charge, primarily related to our exit from the market of Methylphenidate Extended Release. We also recognized Cortrophin pre-launch charges of $6.5 million.

	2018 Quarters (unaudited)			
(in thousands, except per share data)	First	Second	Third	Fourth
Net revenues	$ 46,483	$ 47,268	$ 50,703	$ 57,122
Total operating expenses	39,946	40,005	40,589	45,677
Operating income	6,537	7,263	10,114	11,445
Provision for income taxes	(592)	(726)	(1,329)	(1,910)
Net income	$ 2,250	$ 2,777	$ 5,037	$ 5,430
Basic and diluted earnings per share:				
Basic earnings per share	$ 0.19	$ 0.24	$ 0.43	$ 0.46
Diluted earnings per share	$ 0.19	$ 0.23	$ 0.42	$ 0.46

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of December 31, 2019. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Management's Annual Report on Internal Control over Financial Reporting

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

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

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

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

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

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control — Integrated Framework (2013).

Based on this assessment, our management has concluded that, as of December 31, 2019, our internal control over financial reporting is effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by EisnerAmper LLP, an independent registered public accounting firm, as stated in their attestation report, which is included herein.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except as noted below.

Item 9B. Other Information

None.

PART III

Item 10. Directors and Executive Officers of the Registrant

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

Information required by this item with respect to our directors will be set forth under the caption "Election of Directors" in our definitive proxy statement for our 2020 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Information required by this item with respect to our executive officers will be set forth under the caption "Executive Officers of the Company" in our definitive proxy statement for our 2019 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Information required by this item with respect to compliance with Section 16(a) of the Exchange Act will be set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for our 2020 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Information required by this item with respect to our audit committee, our audit committee financial expert, and any material changes to the way in which our security holders may recommend nominees to our Board of Directors will be set forth under the caption "Corporate Governance" in our definitive proxy statement for our 2020 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Item 11. Executive Compensation

Information required by this item with respect to executive compensation will be set forth under the caption "Executive Compensation" in our definitive proxy statement for our 2020 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

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

Information required by this item with respect to security ownership of certain beneficial owners and management will be set forth under the captions "Security Ownership of Certain Beneficial Owners" and "Security Ownership of Directors and Executive Officers" in our definitive proxy statement for our 2020 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

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

Information required by this item with respect to certain relationships and related transactions and director independence will be set forth under the captions "Certain Relationships and Related Transactions" and "Corporate Governance" in our definitive proxy statement for our 2020 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

Information required by this item with respect to principal accounting fees and services will be set forth under the caption "Ratification of Selection of Independent Registered Public Accountants" in our definitive proxy statement for our 2020 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

PART IV.

Item 15. Exhibits, Financial Statement Schedules

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

(a) Financial Statements:

The consolidated balance sheets of the Registrant as of December 31, 2019 and 2018, the related consolidated statements of operations, statements of comprehensive income, changes in stockholders' equity, and cash flows for each of the years ended December 31, 2019, 2018, and 2017, the footnotes thereto, and the reports of EisnerAmper LLP, independent registered public accounting firm, are filed herewith.

(b) Financial Statement Schedules:

All schedules have been omitted because they are not applicable or the required information is included in the consolidated financial statements or notes thereto.

(c) Exhibits

Exhibits included or incorporated by reference herein: see Exhibit Index on page 112.

ANI PHARMACEUTICALS, INC.
EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2019

Exhibit No.	Exhibit	Method of Filing
2.1	Amended and Restated Agreement and Plan of Merger, dated as of April 12, 2013, by and among BioSante Pharmaceuticals, Inc., ANI Merger Sub, Inc. and ANIP Acquisition Company (1)	Incorporated by reference to Exhibit 2.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013 (File No. 001-31812)
2.2	Asset Purchase Agreement, dated as of December 26, 2013, by and between ANI Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. (2)	Incorporated by reference to Exhibit 2.2 to ANI's Annual Report on Form 10-K as filed for the fiscal year ended December 31, 2013 (File No. 001-31812)
3.1	Certificate of Amendment of the Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc., dated as of July 17, 2013, Certificate of Amendment of the Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc., dated as of June 1, 2012, and Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013 (File No. 001-31812)
3.2	Amended and Restated Bylaws of ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on February 16, 2017 (File No. 001-31812)
4.1	Indenture, dated December 10, 2014, between ANI Pharmaceuticals, Inc. and The Bank of New York Mellon	Incorporated by reference to Exhibit 4.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 10, 2014 (File No. 001-31812)
4.2	First Supplemental Indenture, dated December 10, 2014, between ANI Pharmaceuticals, Inc. and The Bank of New York Mellon (including the form of the 3.00% Convertible Senior Note due 2019)	Incorporated by reference to Exhibit 4.2 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 10, 2014 (File No. 001-31812)
4.3	Form of Note	Incorporated by reference to Exhibit 4.2 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 10, 2014 (File No. 001-31812)
10.1*	ANI Pharmaceuticals, Inc. Fifth Amended and Restated 2008 Stock Incentive Plan	Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement on Schedule 14A as filed with the Securities and Exchange Commission on April 6, 2017 (File No. 001-31812)

Exhibit No.	Exhibit	Method of Filing
10.2*	Form of Incentive Stock Option Agreement under the ANI Pharmaceuticals, Inc. Fifth Amended and Restated 2008 Stock Incentive Plan (included in Exhibit 10.1)	Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement on Schedule 14A as filed with the Securities and Exchange Commission on April 6, 2017 (File No. 001-31812)
10.3*	Form of Non-Statutory Option Agreement under the ANI Pharmaceuticals, Inc. Fifth Amended and Restated 2008 Stock Incentive Plan (included in Exhibit 10.1)	Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement on Schedule 14A as filed with the Securities and Exchange Commission on April 6, 2017 (File No. 001-31812)
10.4	Generic Wholesale Service Agreement, dated as of May 1, 2006, between ANI Pharmaceuticals, Inc. and Cardinal Health, First Amendment to Generic Wholesale Service Agreement, dated as of July 10, 2008, Letter Agreement, dated as of July 10, 2008, regarding assignment of the Generic Wholesale Service Agreement to ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., Letter from Cardinal Health, dated December 22, 2008 Regarding Increase in Base Service Fee, and Second Amendment to Generic Wholesale Service Agreement, dated May 7, 2012 (2)	Incorporated by reference to Exhibit 10.59 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.5*	Employment Agreement, entered into by the Company and Arthur S. Przybyl	Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K filed January 22. 2020 (File No. 001-31812)
10.6*	Employment Agreement, entered into by the Company and Robert Schrepfer	Incorporated by reference to Exhibit 10.3 to ANI's Current Report on Form 8-K filed January 22. 2020 (File No. 001-31812)
10.7*	Employment Agreement, entered into by the Company and James G. Marken	Incorporated by reference to Exhibit 10.4 to ANI's Current Report on Form 8-K filed January 22. 2020 (File No. 001-31812)
10.8	Convertible note hedge transaction confirmation, dated December 4, 2014, by and between Nomura Global Financial Products Inc. and ANI	Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 8, 2014 (File No. 001-31812)
10.9	Warrant transaction confirmation, dated December 4, 2014, by and between Nomura Global Financial Products Inc. and ANI	Incorporated by reference to Exhibit 10.2 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 8, 2014 (File No. 001-31812)

Exhibit No.	Exhibit	Method of Filing
10.10	Additional convertible note hedge transaction confirmation, dated December 5, 2014, by and between Nomura Global Financial Products Inc. and ANI	Incorporated by reference to Exhibit 10.3 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 10, 2014 (File No. 001-31812)
10.11	Additional warrant transaction confirmation, dated December 5, 2014, by and between Nomura Global Financial Products Inc. and ANI	Incorporated by reference to Exhibit 10.4 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 10, 2014 (File No. 001-31812)
10.12	Amendment No. 2 to Asset Purchase Agreement, dated as of July 10, 2015, between Teva Pharmaceuticals, Inc. and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2015 (File No. 001-31812)
10.13	Asset Purchase Agreement, dated as of September 18, 2015, between Merck Sharp & Dohme B.V. and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2015 (File No. 001-31812)
10.14*	ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan	Incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement on Schedule 14A filed with the Commission on April 14, 2016
10.15	Asset Purchase Agreement between H2-Pharma, LLC and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2016 (File No. 001-31812)
10.16	Asset Purchase Agreement between Cranford Pharmaceuticals, LLC and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2016 (File No. 001-31812)
10.17*	Employment Agreement, entered into by the Company and Stephen P. Carey	Incorporated by reference to Exhibit 10.2 to ANI's Current Report on Form 8-K filed January 22. 2020 (File No. 001-31812)
10.18	Asset Purchase Agreement between Cranford Pharmaceuticals, LLC and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017 (File No. 001-31812)

Exhibit No.	Exhibit	Method of Filing
10.19	Asset Purchase Agreement between Holmdel Pharmaceuticals, LP and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017 (File No. 001-31812)
10.20	Asset Purchase Agreement between AstraZeneca AB, AstraZeneca UK Limited, and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.25 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (File No. 001-31812)
10.21	Stock Purchase Agreement by and among WellSpring Pharma Services Inc., WSP Pharma Holdings, LLC, ANI Pharmaceuticals Canada Inc., and ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2018 (File No. 001-31812)
10.22	Amended and Restated Credit Agreement between Citizens Bank, N.A. and ANI Pharmaceuticals, Inc. (3)	Incorporated by reference to Exhibit 10.22 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (File No. 001-31812)
10.23	Amendment No. 4 to Asset Purchase Agreement between ANI Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2019 (File No. 001-31812)
10.24*	Asset Purchase Agreement between Amerigen Pharmaceuticals LTD. and ANI Pharmaceuticals, Inc.	Filed herewith
10.25	Form of Restricted Stock Grant Agreement	Filed herewith
10.26	Form of Incentive Option Agreement	Filed herewith
10.27	Form of Non- Statutory Stock Option Agreement	Filed herewith
21	List of subsidiaries	Filed herewith
23.1	Consent of EisnerAmper LLP	Filed herewith
31.1	Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14	Filed herewith

Exhibit No.	Exhibit	Method of Filing
32.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
101	The following materials from ANI Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) the audited consolidated Balance Sheets, (ii) the audited consolidated Statements of Operations, (iii) the audited consolidated Statements of Comprehensive Income, (iv) the audited consolidated Statements of Stockholders' Equity; (v) the audited consolidated Statements of Cash Flows, and (vi) Notes to consolidated Financial Statements.	Filed herewith

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

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

(3) Confidential treatment has been requested with respect to redacted portions of this document.

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

Item 16. 10-K Summary

None.

SIGNATURES

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

ANI PHARMACEUTICALS, INC.

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

Date: February 27, 2020

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

Date: February 27, 2020

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

Name	Capacity	Date
/s/ Arthur S. Przybyl Arthur S. Przybyl	Director, President, and Chief Executive Officer	February 27, 2020
/s/ Robert E. Brown, Jr. Robert E. Brown, Jr.	Director and Chairman of the Board of Directors	February 27, 2020
/s/ Thomas J. Haughey Thomas J. Haughey	Director	February 27, 2020
/s/ David B. Nash, M.D., M.B.A. David B. Nash, M.D., M.B.A.	Director	February 27, 2020
/s/ Thomas A. Penn Thomas A. Penn	Director	February 27, 2020
/s/ Patrick D. Walsh Patrick D. Walsh	Director	February 27, 2020

Exhibit 10.24

Confidential materials have been omitted pursuant to Rule 601 under the Securities Act of 1933, as amended. Such information is both not material and would likely cause competitive harm to ANI Pharmaceuticals, Inc. if publically disclosed. Confidential portions are marked: [***]

EXECUTION VERSION

ASSET PURCHASE AGREEMENT

by and between

AMERIGEN PHARMACEUTICALS LTD.

and

ANI PHARMACEUTICALS, INC.

dated as of January 8, 2020

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This **ASSET PURCHASE AGREEMENT**, dated as of January 8, 2020 (this "Agreement"), is by and between Amerigen Pharmaceuticals Ltd., a Cayman Islands exempt company ("Seller") and ANI Pharmaceuticals, Inc., a Delaware corporation ("Purchaser"). Capitalized terms are defined on the pages of this Agreement set forth opposite the capitalized terms listed in the Index of Defined Terms.

WHEREAS, Seller desires to sell (and to cause the other members of Seller Group to sell) to Purchaser, and Purchaser desires to purchase, acquire and accept from Seller Group, the Transferred Assets and assume the Assumed Liabilities, in each case, upon the terms and subject to the conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises, the mutual covenants, promises, and agreements set forth in this Agreement, the mutual benefits to be gained by the performance thereof, and for other good and valuable consideration, the receipt and sufficiency of which is acknowledged and accepted, the parties, intending to be legally bound, agree as follows:

ARTICLE I
PURCHASE AND SALE OF TRANSFERRED ASSETS

Section 1.01. Purchase and Sale. Upon the terms and subject to the conditions of this Agreement, at the Closing, Seller agrees to, and agrees to cause the other members of Seller Group to, sell, transfer, assign and deliver to Purchaser, and Purchaser agrees to purchase, acquire and accept from Seller Group, the Transferred Assets for (a) an aggregate purchase price equal to the Purchase Price and (b) the assumption, as of the Closing, by Purchaser from Seller Group of the Assumed Liabilities. The purchase and sale of the Transferred Assets and the assumption of the Assumed Liabilities are collectively referred to in this Agreement as the "Acquisition."

Section 1.02. Transferred Assets and Excluded Assets.

(a) The term "Transferred Assets" means all of Seller Group's right, title and interest in, to and under all of the following assets, properties, privileges, claims, and rights of the Seller Group as they exist as of the Closing:

(i) the Transferred Product ANDAs (expressly excluding all Transition Product ANDAs);

(ii) all Transferred Product FDA Materials;

(iii) all Product Scientific and Regulatory Materials;

(iv) all Product Technology;

(v) Seller's labeler code of 43975 (the "Labeler Code")

(vi) the Transferred Contracts; and

(vii) Transferred Inventory.

(b) Seller Group shall not sell, transfer, assign or deliver to Purchaser, and Purchaser shall not purchase, acquire or accept from Seller Group, any Excluded Assets. The term "Excluded Assets" means all assets and right, title and interest of Seller Group (or any member thereof), other than the assets and right, title and interest expressly identified in Section 1.02(a), including:

(i) any cash or cash equivalents of Seller Group (or any member thereof);

(ii) any accounts receivable of Seller Group (or any member thereof);

(iii) any Inventory other than the Transferred Inventory (the "Excluded Inventory");

(iv) any refunds or credits, or rights to receive refunds or credits, from any Taxing Authority with respect to Taxes arising out of, relating to, resulting from or in connection with the Transferred Assets for Pre-Closing Tax Periods;

(v) any records (including accounting records) related to Taxes paid or payable by any member of Seller Group or any affiliate thereof and any financial and Tax records relating to the Transferred Assets that form part of the general ledger of any member of Seller Group or any affiliate thereof;

(vi) all books, documents, records and files prepared in connection with or relating to the transactions contemplated under this Agreement, including any strategic, valuation, financial and/or Tax analyses relating to the divestiture of the Transferred Assets and the Assumed Liabilities;

(vii) all corporate seals and all of the minute books and stock transfer books of any member of the Seller Group;

(viii) all Seller Benefit Plans and assets (including any related insurance proceeds) of, and any rights of any member of the Seller Group in, any Seller Benefit Plan and any contracts that constitute (or provide for services under) such benefit plans;

(ix) all insurance policies; and

(x) any attorney work product, attorney-client communications and other items protected by established legal privilege.

Section 1.03. Assumed Liabilities and Retained Liabilities.

(a) The term "Assumed Liabilities" means, subject to Section 1.03(b), all obligations, liabilities and commitments of any nature, whether known or unknown, express or implied, primary or secondary, direct or indirect, liquidated or unliquidated, absolute or contingent, accrued or unaccrued or due or to become due (collectively, "Liabilities"), arising out of, relating to, resulting from or in connection with (x) the development, manufacturing, marketing, commercialization, distribution or sale of the Products, and/or (y) the ownership or use of the Transferred Assets, in the case of each of clauses (x) and (y) by Purchaser Group from and after the Closing Date, including:

(i) all Liabilities arising out of, relating to, resulting from or in connection with the performance by Purchaser Group under the Transferred Contracts from and after the Closing Date;

(ii) all Liabilities for patent infringement, product liability, breach of warranty and similar claims (including all Proceedings in respect of such Liabilities) arising out of, relating to, resulting from or in connection with any Products manufactured, marketed, commercialized, distributed or sold by Purchaser Group from and after the Closing Date;

(iii) all Liabilities arising out of, relating to, resulting from or in connection with any returns, rebates or chargebacks (including the processing thereof) that occur after the Closing Date to the extent attributable to Products distributed or sold by Purchaser Group from and after the Closing Date;

(iv) all Liabilities arising out of, relating to, resulting from or in connection with any recalls or market withdrawals (whether voluntary or involuntary) that occur after the Closing Date to the extent attributable to Products distributed or sold by Purchaser Group from and after the Closing Date;

(v) all Taxes arising out of, relating to, resulting from or in connection with the Transferred Assets (other than Excluded Taxes);

(vi) the portion of Transfer Taxes for which Purchaser is responsible pursuant to Section 9.01(d); and

(vii) the portion of Government Rebates for which Purchaser is responsible pursuant to Section 2.04(d).

(b) Purchaser shall not assume any Retained Liabilities and Seller shall pay, perform and discharge all Retained Liabilities when due by Seller and each member of Seller Group. The term "Retained Liabilities" means all Liabilities of Seller Group (including Excluded Taxes) other than the Assumed Liabilities.

Section 1.04. Consents to Certain Assignments.

(a) Notwithstanding anything in this Agreement to the contrary, this Agreement shall not constitute an agreement to assign any Transferred Asset if an attempted assignment thereof, without the consent of a third party, would constitute a violation of any Applicable Law or Judgment or a breach, default, violation or other contravention of the rights of such third party. If any assignment by any member of Seller Group to, or any assumption by Purchaser of, any interest in, or Liability under, any Transferred Asset requires the consent of a third party, then such assignment or assumption shall be made subject to such consent being obtained. Except for Seller's obligations to obtain such consents under Section 5.04 and Section 1.04(b), Purchaser agrees that no member of Seller Group shall have any Liability whatsoever to Purchaser relating to the failure to obtain any such consent that may be required in connection with the transactions contemplated by this Agreement or any circumstances resulting therefrom. Purchaser further agrees that no representation, warranty, covenant or agreement of Seller herein shall be breached or deemed breached, and no condition shall be deemed not satisfied, as a result of (A) the failure to obtain any such consent, or (B) any suit, action or proceeding (a "Proceeding") or investigation commenced or threatened by or on behalf of any person relating to the failure to obtain any such consent or any circumstances resulting therefrom.

(b) If any such consent is not obtained prior to the Closing, the Closing shall nonetheless take place on the terms set forth in this Agreement and, thereafter, Purchaser and Seller shall use their respective commercially reasonable efforts to secure such consent as promptly as practicable after the Closing and, if and to the extent that any such Consent is not so obtained, Seller shall cooperate in any lawful and commercially reasonable arrangement proposed by Purchaser under which (A) Purchaser shall obtain (without payment of any additional consideration therefor to Purchaser and without infringing upon the legal rights of such third party or violating any Applicable Law or Judgment) the economic claims, rights and benefits under the Transferred Asset with respect to which the consent has not been obtained in accordance with this Agreement and (B) Purchaser shall assume any related economic burden with respect to such Transferred Asset.

ARTICLE II
CLOSING; CLOSING CONSIDERATION; PURCHASE PRICE ADJUSTMENT

Section 2.01. Closing. The closing of the Acquisition (the "Closing") shall occur concurrently with the execution of this Agreement and take place remotely by electronic exchange of documents or at such other place as may be agreed by Seller and Purchaser. The date on which the Closing occurs is referred to in this Agreement as the "Closing Date". The Closing shall be deemed to be effective as of 12:00:01 a.m. eastern time on the Closing Date.

Section 2.02. Closing Consideration. At the Closing, Purchaser shall pay (a) the Closing Consideration to Seller by wire transfer of immediately available funds to an account or accounts designated in writing by Seller to Purchaser prior to the Closing, and (b) $30,703,341.43 to Wilmington Trust, National Association, which amount represents the total outstanding amount of debt due and payable by Seller under the Marathon Agreement (the "Closing Debt"), by wire transfer of immediately available funds to an account designated in writing by Seller to Purchaser prior to the Closing. The term "Closing Consideration" means (a) $52,500,000, *plus* (b) the Estimated Closing Inventory, *less* (c) the Estimated Closing Trade Deductions, *less* (d) the Escrow Amounts, *less* (e) the Closing Debt.

Section 2.03. Transactions to be Effected at the Closing.

(a) Concurrently with the execution of this Agreement, Seller shall deliver or cause to be delivered to:

(i) Purchaser duly executed counterparts of the Transfer Documents and the other Ancillary Agreements.

(ii) Purchaser a payoff letter executed by Wilmington Trust, National Association, together with any and all applicable UCC termination statements and other documentation required to evidence the termination and repayment of the Closing Debt and the release of all Liens related thereto, which payoff letter shall provide for, among other things, the repayment of all such Closing Debt.

(iii) each counterparty listed on Schedule X in respect of the corresponding Transferred Contract listed on such Schedule X, a notice in the form attached as Exhibit J.

(b) Concurrently with the execution of this Agreement, Purchaser shall deliver or cause to be delivered to Seller (i) duly executed counterparts of the Transfer Documents and the other Ancillary Agreements and (ii) the Closing Consideration in accordance with Section 2.02.

(c) Concurrently with the execution of this Agreement, Purchaser shall pay the Escrow Amounts to the Escrow Agent by wire transfer of immediately available funds in accordance with the terms and conditions of the Escrow Agreement.

Section 2.04. Purchase Price Adjustments.

(a) Transferred Inventory.

(i) Estimated Closing Inventory. Seller has prepared and delivered to Purchaser the statement attached as Exhibit K (the "Estimated Closing Inventory Statement"), setting forth Seller's reasonable, good faith estimate of the book value of the Transferred Inventory as of 12:00:01 a.m. eastern time on the Closing Date ("Estimated Closing Inventory") calculated in accordance with the principles set forth on Schedule I-1 (the "Inventory Principles").

(ii) Final Closing Inventory Statement. Within 60 days after the Closing Date, Purchaser shall prepare and deliver to Seller a statement (the "Final Closing Inventory Statement"), setting forth Purchaser's determination of book value of the Transferred Inventory as of 12:00:01 a.m. eastern time on the Closing Date ("Closing Inventory") calculated in accordance with the Inventory Principles. During such 60-day period, Seller shall, and shall cause the other members of Seller Group to, afford to Purchaser and its accountants, counsel and other representatives reasonable access, upon reasonable prior written notice during normal business hours during the period prior to the Closing, to the books and records, Contracts and other properties and assets of Seller Group to the extent relating to the Estimated Closing Inventory and the Inventory Principles, if such access does not unreasonably disrupt the normal operations of Seller Group.

(b) Trade Deductions.

(i) Estimated Closing Trade Deductions. Seller has prepared and delivered to Purchaser the statement attached as Exhibit L (the "Estimated Closing Trade Deductions Statement"), setting forth Seller's reasonable, good faith estimate of the book value of the Trade Deductions ("Estimated Closing Trade Deductions") calculated in accordance with the principles set forth on Schedule I-2 (the "Trade Deductions Principles").

(ii) Final Trade Deductions Statement. Within one hundred and fifty (150) days after the Closing Date, Purchaser shall prepare and deliver to Seller a statement (the "Final Closing Trade Deductions Statement"), setting forth Purchaser's determination of book value of the Trade Deductions calculated in accordance with the Trade Deductions Principles (the "Closing Trade Deductions"). During such 150-day period, Seller shall, and shall cause the other members of Seller Group to, afford to Purchaser and its accountants, counsel and other representatives reasonable access, upon reasonable prior written notice during normal business hours, to the books and records, Contracts and other properties and assets of Seller Group to the extent relating to the Estimated Closing Trade Deductions and the Trade Deductions Principles, if such access does not unreasonably disrupt the normal operations of Seller Group.

(c) Returns. For each calendar quarter during the period beginning on the Closing Date and ending thirty six (36) months after the Closing Date (the "Return Period"), Purchaser shall prepare and deliver to Seller, no later than sixty (60) days after the end of each calendar quarter during the Return Period, a statement (each, a "Quarterly Returns Statement"), setting forth Purchaser's reasonable, good faith calculation of the book value of the Product returns during such calendar quarter then ended (each such determination, the "Quarterly Returns"), in each case, calculated in accordance with the principles set forth on Schedule I-3 (the "Returns Principles"). During the 30-day period following Purchaser's delivery of a Quarterly Returns Statement, Purchaser shall afford Seller and its accountants, counsel and other representatives reasonable access, upon reasonable prior written notice during normal business hours, to the books and records of Purchaser solely to the extent relating to the Quarterly Returns and the Returns Principles, if such access does not unreasonably disrupt the normal operations of Purchaser.

(d) Government Rebates.

(i) Purchaser and Seller shall (A) cooperate reasonably in the analysis of dispensing data relating to rebates pursuant to any government rebate programs with respect to state or federal government claims for Approved Products sold on or prior to the Closing Date ("Government Rebates"), and (B) agree upon a reasonable allocation to assist the parties in calculating rebates in accordance with this Section 2.04(d)(i). Purchaser and Seller agree that the responsibility for Government Rebates shall be allocated between Purchaser and Seller as follows: (I) Seller shall be responsible for payment of (A) 100% of the amount of Government Rebates invoiced by the applicable Governmental Rebate Authority, where such invoice relates to Approved Product reimbursements paid by the Governmental Rebate Authority during the period ending March 30, 2020 and all prior calendar quarters, and (B) 8.8% of the amount of Government Rebates invoiced by the applicable Governmental Rebate Authority, where such invoice relates to Approved Product reimbursements paid by the Governmental Rebate Authority during the period beginning on April 1, 2020 and ending on June 30, 2020 (Seller's aggregate responsibility, the "Seller Rebate Amount") and (II) Purchaser shall be responsible for the remaining amount of Government Rebates not otherwise covered under clause (I) of this sentence. With respect to Government Rebates, Purchaser shall have the right to request through Seller any claims level data (dispensing data) contained in any report from a Government Rebate program which shall be used for purposes of determining the date of such claim or for state rebate dispute purposes. In the event Purchaser determines an invoice or claim for a Government Rebate should be disputed, Seller shall reasonably cooperate with Purchaser to dispute such claim or invoice.

(ii) Purchaser shall prepare and deliver to Seller, no later than September 30, 2020 (a "Government Rebates Statement", and the Government Rebates Statement, together with the Final Closing Inventory Statement, the Final Closing Trade Deductions Statement, and each Quarterly Returns Statements, a "Final Closing Statement"), setting forth Purchaser's reasonable, good faith calculation of (A) the amount of the Government Rebates for the calendar quarter ending March 31, 2020 and the calendar quarter ending June 30, 2020, and (B) the Seller Rebate Amount. During the 30-day period following Purchaser's delivery of the Government Rebates Statement, Purchaser shall afford Seller and its accountants, counsel and other representatives reasonable access, upon reasonable prior written notice during normal business hours, to the books and records of Purchaser solely to the extent relating to the Government Rebates Statement, if such access does not unreasonably disrupt the normal operations of Purchaser.

(e) Objections; Resolution of Disputes.

(i) Unless Seller notifies Purchaser in writing (A) within 30 days after Seller's receipt of (I) the Final Closing Inventory Statement of any objection to the computation of Closing Inventory set forth therein, or (II) the Final Closing Trade Deduction Statement of any objection to the computation of Closing Trade Deductions set forth therein, or (B) within 15 days after Seller's receipt of (I) a Quarterly Returns Statement of any objection to the computation of Quarterly Returns set forth therein, or (II) the Government Rebates Statement of any objection to the computation of the Seller Rebate Amount (in each case, as applicable, (x) a "Notice of Objection", (y) such 30-day or 15-day period, the "Objection Period"), and (z) as the context so requires, the party sending the Notice of Objection, the "Objecting Party", and the party receiving the Notice of Objection, the "Receiving Party"), the applicable Final Closing Statement shall become final and binding at the end of such Objection Period. During such Objection Period, the Objecting Party and its representatives shall be permitted to review the working papers of the Receiving Party relating to the applicable Final Closing Statement. Any Notice of Objection shall specify in reasonable detail the basis for the objections set forth therein and shall be executed by a duly authorized officer of the Objecting Party.

(ii) If the Objecting Party provides the applicable Notice of Objection to the Receiving Party during the applicable Objection Period, Purchaser and Seller shall, during the 30-day period following the Receiving Party's receipt of the Notice of Objection, attempt in good faith to resolve the Objecting Party's objections. During such 30-day period, the Receiving Party and its representatives shall be permitted to review the working papers of the Objecting Party and its accountants relating to the Notice of Objection and the basis therefor. If Seller and Purchaser are unable to resolve all such objections with respect to the disputed matters within such 30 day period, the matters remaining in dispute shall be submitted to Ernst & Young (or, if such firm declines to act, to another nationally recognized public accounting firm mutually agreed upon by Purchaser and Seller and, if Purchaser and Seller are unable to so agree within 10 days after the end of such 30 day period, then Purchaser and Seller shall each select such a firm and such firms shall jointly select a third nationally recognized firm (such selected firm being the "Independent Expert")) to resolve such disputed matters.

(iii) Within 25 days of the submission of the dispute to the Independent Expert, Purchaser and Seller shall each provide the Independent Expert and each other with a written report detailing such party's position with respect to the disputed matters. The parties shall instruct the Independent Expert to render its reasoned written decision as promptly as practicable but in no event later than 30 days after its engagement, and to render such decision based on the written submissions of the parties and the terms set forth in this Agreement and not upon independent review. The Independent Expert will determine each disputed matter (the amount of which may not be more favorable to the Receiving Party than the related amount reflected in the applicable Final Closing Statement or more favorable to the Objecting Party than the related amount set forth in the applicable Notice of Objection). The resolution of disputed items by the Independent Expert shall be final and binding, and the determination of the Independent Expert shall constitute an arbitral award that is final, binding and non-appealable and upon which a Judgment may be entered by a court having jurisdiction thereover. The fees and expenses of the Independent Expert shall be borne equally by Purchaser and Seller. After any Final Closing Statement shall have become final and binding, no party shall have any further rights to make any claims against the other party in respect of (i) any element that such party raised, or could have raised, in its Notice of Objection or (ii) any payment made hereunder with respect to the applicable Purchase Price adjustments under this Section 2.04.

(f) Payments.

(i) Final Closing Inventory.

(A) For purposes of this agreement, the "Final Closing Inventory" shall be an amount equal to Closing Inventory as finally determined pursuant to Sections 2.04(a) and (e).

(B) If the Final Closing Inventory is less than the Estimated Closing Inventory (such shortfall amount, the "Inventory Shortfall Amount"), Seller shall pay the Inventory Shortfall Amount to Purchaser.

(C) If the Final Closing Inventory is greater than the Estimated Closing Inventory (such excess amount, the "Inventory Surplus Amount"), Purchaser shall pay the Inventory Surplus Amount to Seller.

(D) If the Final Closing Inventory equals the Estimated Closing Inventory, neither any Inventory Shortfall Amount nor any Inventory Surplus Amount shall be paid.

(ii) Final Closing Trade Deductions.

(A) For purposes of this agreement, the "Final Closing Trade Deductions" shall be an amount equal to Closing Trade Deductions as finally determined pursuant to Sections 2.04(b) and (e).

(B) If the Final Closing Trade Deductions is less than the Estimated Closing Trade Deductions (such shortfall amount, the "Trade Deductions Shortfall Amount"), then (I) Purchaser shall pay the Trade Deductions Shortfall Amount to Seller, and (II) within five (5) business days after such determination, Purchaser, on the one hand, and Seller, on the other hand, shall jointly instruct the Escrow Agent to pay to Seller the balance of the Trade Deductions Escrow Account.

(C) If the Final Closing Trade Deductions is greater than the Estimated Closing Trade Deductions (such excess amount, the "Trade Deductions Surplus Amount"), then payments shall be made subject to the following, to be satisfied exclusively from and asserted against, in order:

(I) first, if the Trade Deductions Escrow Account has not been exhausted or released, then, to the extent of the Trade Deductions Escrow Account, within five (5) business days after such determination, Purchaser, on the one hand, and Seller, on the other hand, shall jointly instruct the Escrow Agent to pay (x) to Purchaser, from the Trade Deductions Escrow Account, an amount equal to the Trade Deductions Surplus Amount, and (y) to Seller, from the Trade Deductions Escrow Account, an amount, if any, equal to the balance of the Trade Deductions Escrow Account after payment pursuant to the preceding clause (x);

(II) second, if (x) the Trade Deductions Surplus Amount exceeds the amount satisfied in accordance with Section 2.04(f)(ii)(C)(I)(x), and (y) the Returns Escrow Account has not been exhausted or released, then, to the extent of the Returns Escrow Account, within five (5) business days after such determination, Purchaser, on the one hand, and Seller, on the other hand, shall jointly instruct the Escrow Agent to pay to Purchaser, from the Returns Escrow Account, an amount equal to such excess; and

(III) third, if the Trade Deductions Surplus Amount exceeds the amount satisfied in accordance with Section 2.04(f)(ii)(C)(I)(x) and Section 2.04(f)(ii)(C)(II), then, at Purchaser's option, Purchaser shall either (x) withhold and set off such excess against any amount of any Earn-Out Payment otherwise due to be paid under Section 2.05, or (y) recover directly against Seller an amount equal to such excess.

(D) If the Final Closing Trade Deductions equals the Estimated Closing Trade Deductions, then (I) neither any Trade Deductions Shortfall Amount nor any Trade Deductions Surplus Amount shall be paid, and (II) within five (5) business days, Purchaser, on the one hand, and Seller, on the other hand, shall jointly instruct the Escrow Agent to pay to Seller the balance of the Trade Deductions Escrow Account.

(iii) Final Quarterly Returns.

(A) For purposes of this agreement, "Final Quarterly Returns" for any calendar quarter then ended during the Return Period shall be an amount equal to the Quarterly Returns for such calendar quarter, in each case as finally determined pursuant to Sections 2.04(c) and (e).

(B) For each calendar quarter during the Return Period, within five (5) business days after determining the corresponding Final Quarterly Returns, (I) Purchaser, on the one hand, and Seller, on the other hand, shall jointly instruct the Escrow Agent to pay to Purchaser, from the Returns Escrow Account, an amount equal to the Final Quarterly Returns for such calendar quarter then ended, and (II) if the amount of such Final Quarterly Returns for such calendar quarter then ended exceeds the amount satisfied in accordance with Section 2.04(f)(iii)(B)(I), then, at Purchaser's option, Purchaser shall either (x) withhold and set off such excess against any amount of any Earn-Out Payment otherwise due to be paid under Section 2.05, or (y) recover directly against Seller an amount equal to such excess.

(C) Within five (5) business days after the determination of the Final Quarterly Return for the final calendar quarter during the Return Period, after giving effect to all payments to Purchaser from the Returns Escrow Account under the preceding clause (B), solely to the extent there is any remaining balance in the Returns Escrow Account, then Purchaser, on the one hand, and Seller, on the other hand, shall jointly instruct the Escrow Agent to pay to Seller the balance of the Returns Escrow Account.

(iv) Final Seller Rebate Amount.

(A) For purposes of this agreement, the "Final Seller Rebate Amount" shall be an amount equal to (I) the Seller Rebate Amount as finally determined pursuant to Sections 2.04(d) and (e), *plus* (II) any Losses to the extent arising or resulting from (x) any Prior Quarter Adjustments (PQAs), or (y) any pricing audit by any Governmental Rebate Authority, in each case, as clause (x) or (y) relates to any Government Rebates invoiced by the applicable Governmental Rebate Authority for which Seller is responsible for payment of under clause (I) of the second sentence of Section 2.04(d).

(B) Within five (5) business days after determining the Final Seller Rebate Amount, payments shall be made subject to the following, to be satisfied exclusively from and asserted against, in order:

(I) first, to the extent of the Government Rebates Escrow Account, Purchaser, on the one hand, and Seller, on the other hand, shall jointly instruct the Escrow Agent to pay (x) to Purchaser, from the Government Rebates Escrow Account, an amount equal to the Final Seller Rebate Amount, and (y) to Seller, from the Government Rebates Escrow Account, an amount, if any, equal to the balance of the Government Rebates Escrow Account after payment pursuant to the preceding clause (x);

(II) second, if (x) the Final Seller Rebate Amount exceeds the amount satisfied in accordance with Section 2.04(f)(iv)(B)(I)(x), and (y) the Returns Escrow Account has not been exhausted or released, then, to the extent of the Returns Escrow Account, Purchaser, on the one hand, and Seller, on the other hand, shall jointly instruct the Escrow Agent to pay to Purchaser, from the Returns Escrow Account, an amount equal to such excess; and

(III) third, if (x) the amount of such Final Seller Rebate Amount exceeds the amount satisfied in accordance with Section 2.04(f)(iv)(B)(II), and (y) such excess amount solely is attributable to Losses arising or resulting from any pricing audit by any Governmental Rebate Authority for any period prior to the Closing Date, then, at Purchaser's option, Purchaser shall either (1) withhold and set off such excess against any amount of any Earn-Out Payment otherwise due to be paid under Section 2.05, or (2) recover directly against Seller an amount equal to such excess.

(v) Payments. Payment of any amounts due under this Section 2.04, if any, shall be made by wire transfer of immediately available funds within five (5) business days of the date on which the final amount due and payable is finally determined.

(g) Post-Closing Books and Records. Following the Closing, Purchaser shall maintain the accounting books and records on which the Final Closing Inventory Statement is to be based consistent with the Inventory Principles.

Section 2.05. Earn-Out Payments.

(a) Estimated Earn-Out Statement. During the period beginning with Purchaser's fiscal year ending December 31, 2020 and ending with Purchaser's fiscal year ending December 31, 2023 (each such fiscal year, a "Fiscal Year", and such entire period, the "Earn-Out Period"), with respect to each Fiscal Year, within 30 calendar days after the date on which Purchaser's audited annual financial statements are filed, published, or otherwise generally made available to Purchaser's investors for such Fiscal Year (but no later than 90 calendar days following the end of the applicable Fiscal Year), Purchaser shall prepare and deliver to Seller a written statement (the "Earn-Out Statement") setting forth Purchaser's reasonable, good faith calculation of such preceding Fiscal Year's Net Profits and Earn-Out Amount, each as calculated in accordance with GAAP. For purposes of this Agreement:

(i) "Net Profits" means, with respect to each Fiscal Year during the Earn-Out Period, (A) Net Revenues minus (B) Costs, in each case, with respect to such applicable Fiscal Year.

(ii) "Net Revenues" means an amount equal to (A) the gross amount invoiced by or on behalf of Purchaser (or any other member of the Purchaser Group) or any licensee thereof for sales of the Earn-Out Products minus (B) the Permitted Deductions. For clarity, Net Revenues shall not include the sale of Earn-Out Products between or among Purchaser, any of its subsidiaries, and/or their licensees for resale purposes, provided such resale is included in Net Revenues.

(iii) "Permitted Deductions" means the sum of (A) all chargebacks, rebates, quantity and cash discounts, and other customary discounts to customers, wholesalers, resellers, or distributors, (B) all costs and expenses incurred by Purchaser that are reasonably related to recalls of the Earn-Out Products (less any amounts recovered by Purchaser from any third-party in connection with any such recall), (C) allowances and credits for spoiled, damaged, outdated, rejected, or returned Earn-Out Products or price adjustments, billing errors, failure to supply payments, retroactive price reductions, or shelf stock adjustments, (D) uncollectible amounts on prior commercial sales, and (E) nonrefundable, unreimbursed or un-reimbursable taxes, duties, surcharges, tariffs, or other government charges (including, for the avoidance of doubt, government rebates and other amounts due to Governmental Entities) directly related to the commercial sale of Earn-Out Products.

(iv) "Costs" mean the sum of all direct manufacturing costs associated with generating such Net Revenues, including (A) cost of materials, components, supplies, and other resources consumed, (B) labor, including salaries, wages, and employee benefits but excluding equity-based or deferred compensation, (C) net cost or credit of unreimbursed or un-reimbursable value-added taxes or duties actually paid or utilized, (D) out-of-pocket expenses paid to third parties for the manufacture of Earn-Out Products, and (E) manufacturing variances to the extent in line with reasonable industry standards and incurred in the manufacture of Earn-Out Products, excluding any manufacturing variances attributable to negligence or misconduct. For the avoidance of doubt, "Costs" excludes any general or administrative costs or expenses or other indirect costs or expenses not generally included under GAAP.

(v) "Earn-Out Products" means the Products set forth on Schedule II.

(b) Objections; Resolution of Disputes.

(i) Unless Seller notifies Purchaser in writing within 45 days after Seller's receipt of the Earn-Out Statement of any objection to the computation of such preceding Fiscal Year's Net Profits and Earn-Out Amount set forth therein (the "Earn-Out Notice of Objection"), such Earn-Out Statement shall become final and binding at the end of such 45-day period. During such 45-day period, Seller and its representatives shall be permitted to review the working papers (and other applicable books and records) of Purchaser and, to the extent applicable, its subsidiaries, in each case, relating to the Earn-Out Statement (and the components thereof). Any Earn-Out Notice of Objection shall specify in reasonable detail the basis for the objections set forth therein and shall be executed by a duly authorized officer of Seller.

(ii) If Seller provides the Earn-Out Notice of Objection to Purchaser within such 45-day period, Seller and Purchaser shall, during the 30-day period following Purchaser's receipt of the Earn-Out Notice of Objection, attempt in good faith to resolve Seller's objections. During such 30-day period, Purchaser and its representatives shall be permitted to review the working papers (and other applicable books and records) of Seller relating to the Earn-Out Notice of Objection and the basis therefor. If Purchaser and Seller are unable to resolve all such objections with respect to the disputed matters within such 30-day period, the matters remaining in dispute shall be submitted to the Independent Expert to resolve such disputed matters.

(iii) Within 30 days of the submission of the dispute to the Independent Expert, Purchaser and Seller shall each provide the Independent Expert and each other with a written report detailing such party's position with respect to the disputed matters. The parties shall instruct the Independent Expert to render its reasoned written decision as promptly as practicable but in no event later than 30 days after its engagement, and to render such decision based on the written submissions of the parties and the terms set forth in this Agreement and not upon independent review. The Independent Expert will determine each disputed matter (the amount of which may not be more favorable to Seller than the related amount reflected in such Earn-Out Notice of Objection or more favorable to Purchaser than the related amount set forth in such Earn-Out Statement). With respect to such Fiscal Year and its corresponding Earn-Out Payment (if any), the resolution of disputed items by the Independent Expert for such Fiscal Year shall be final and binding, and the determination of the Independent Expert shall constitute an arbitral award that is final, binding and non-appealable and upon which a Judgment may be entered by a court having jurisdiction thereover. The fees and expenses of the Independent Expert shall be borne equally by Purchaser and Seller. After the Earn-Out Statement for any individual Fiscal Year shall have become final and binding, Seller shall have no further right to make any claims against Purchaser in respect of any element of such Earn-Out Payment or payment of such Earn-Out Payment (if any).

(c) Payments.

(i) Subject to Section 2.05(c)(iv), for each Fiscal Year during the Earn-Out Period, if the Net Profits for such Fiscal Year exceed such Fiscal Year's Earn-Out Threshold, Purchaser shall pay to Seller the Earn-Out Payment for such Fiscal Year.

(ii) For purposes this Agreement, the "Earn-Out Threshold" means the following for each individual Fiscal Year during the Earn-Out Period:

(A) $16,000,000 for the Fiscal Year ending December 31, 2020;

(B) $14,000,000 for the Fiscal Year ending December 31, 2021;

(C) $12,000,000 for the Fiscal Year ending December 31, 2022; and

(D) $11,000,000 for the Fiscal Year ending December 31, 2023.

(iii) "Earn-Out Payment" means, with respect to each individual Fiscal Year during the Earn-Out Period, an amount equal to the product of (A) 50%, *multiplied by* (B) the amount by which the Net Profits for such Fiscal Year exceed such Fiscal Year's Earn-Out Threshold; provided, however, that notwithstanding the foregoing, (x) the maximum aggregate amount of all Earn-Out Payments for all Fiscal Years during the Earn-Out Period to be paid by Purchaser to Seller shall not exceed $25,000,000, and (y) all Earn-Out Payments shall be subject to Section 2.05(c)(iv). For the avoidance of doubt, in no event shall an Earn-Out Payment for an individual, preceding Fiscal Year be due and payable to Seller if the Net Profits for any such Fiscal Year do not exceed the corresponding Earn-Out Threshold for such Fiscal Year.

(iv) Seller acknowledges and agrees that (A) Purchaser shall pay the first $670,000 of the aggregate amount of all Earn-Out Payments to be paid under this Section 2.05 to the Escrow Agent for deposit into the Returns Escrow Account, (B) Purchaser shall make each such payment within five (5) business days of the date on which such applicable amounts are finally determined pursuant to Section 2.05(b), and (C) the payment of such $670,000 by Purchaser to the Escrow Agent shall constitute Earn-Out Payments due and payable by Purchaser to Seller under this Section 2.05.

(d) Except as set forth in Section 2.05(c)(iv), payment of any Earn-Out Payment, if any, shall be made by wire transfer (in accordance with wire transfer instructions to be provided by Seller at least two (2) business days prior to the applicable payment date) of immediately available funds within five (5) business days of the date on which such amount is finally determined pursuant to Section 2.05(b); provided that, if the parties are unable to resolve a disputed matter set forth in the Earn-Out Notice of Objection in the 30-day period described in Section 2.05(b)(ii), Purchaser will pay to Seller all undisputed amounts of the Earn-Out Payment by wire transfer (in accordance with wire transfer instructions to be provided by Seller at least two (2) business days prior to the applicable payment date) of immediately available funds within five (5) business days of the end of such 30-day period, and Purchaser will pay to Seller any remaining amounts determined by the Independent Expert in accordance with Section 2.05(b)(iii) within five (5) business days of receipt of the Independent Expert's final written decision.

(e) Notwithstanding anything contained herein to the contrary, Purchaser agrees that it will, and will cause its subsidiaries to, (i) use commercially reasonable efforts to sell the Earn-Out Products during the Earn-Out Period, and (ii) not take any action (or omit to take any action) with the intent or purpose of reducing or avoiding any Earn-Out Payment. Without limiting the generality of the foregoing, Seller acknowledges and agrees that Purchaser presently intends to base its decisions regarding the operations of Purchaser's businesses, including the pricing of services and the investment and allocation of resources (including as relates to the Earn-Out Products), on the basis of strategic objectives of Purchaser and its Subsidiaries and their respective affiliates, and certain situations could arise where such decisions taken without the intent or purpose of reducing or avoiding any Earn-Out Payment may nevertheless adversely affect the Earn-Out Payments.

(f) Notwithstanding anything contained herein to the contrary, except as provided below in this subsection 2.05(f), neither Purchaser nor any of its subsidiaries may transfer, sell, license or assign, to any Person who is not an affiliate of Purchaser, all or substantially all of the rights pertaining to the Earn-Out Products (including as a part of a sale that includes all or substantially all of the assets of Purchaser or all or substantially all of the equity interests of Purchaser, including by way of a merger or consolidation), unless the transferee, licensee or assignee, as applicable, of such transfer, sale, license or assignment (i) expressly assumes in writing the obligations of Purchaser under this Section 2.05, including payment of the Earn-Out Payments (except to the extent previously paid), and (ii) (A) has the capabilities to commercialize products that are substantially similar to the Earn-Out Products, or (B) Purchaser remains responsible for the obligations under this Section 2.05; provided that this subsection 2.05(f)(ii) shall not apply in the event of a sale of Purchaser, including all or substantially all of the assets of Purchaser or all or substantially all of the equity interests of Purchaser, including by way of merger or consolidation.

(g) Seller understands and agrees that the right to receive the Earn-Out Payments (i) is solely a contractual right and will not be evidenced by a certificate or other instrument, (ii) may not be sold, assigned, transferred, pledged, encumbered, or in any other manner transferred or disposed of, in whole or in part, and (iii) does not give Seller any dividend rights or voting rights and does not represent any equity or ownership interest in (A) Purchaser or in any constituent company to this Agreement or any of their respective affiliates, or (B) the Transferred Assets.

Section 2.06. Withholding. Purchaser shall be entitled to deduct and withhold from any consideration otherwise payable or deliverable to Seller such amounts as may be required to be deducted or withheld therefrom under the Code or other applicable Law; provided, however that if Purchaser becomes aware of any such required deduction or withholding, Purchaser shall give advance notice to and consult with Seller prior to any such deduction or withholding and shall provide Seller with an opportunity to furnish any form, certification, or information that would reduce or eliminate such deduction or withholding or to update or supplement any form, certification, or information previously provided. To the extent such amounts are so deducted or withheld, such amounts shall be treated for all purposes as having been paid to the Person to whom such amounts would otherwise have been paid absent such deduction or withholding.

ARTICLE III
REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the Disclosure Letter, Seller hereby represents and warrants to Purchaser as follows (and, solely for purposes of this Article III, the Transition Product ANDAs shall be deemed to constitute Transferred Assets):

Section 3.01. Organization and Standing. Seller is an exempted limited liability company incorporated and validly existing under the laws of the Cayman Islands and has full corporate power and authority to enable it to own, lease or otherwise hold the Transferred Assets owned, leased or otherwise held by it and to conduct its business as presently conducted by it. Except as would not reasonably be expected to have a Seller Material Adverse Effect, each of Seller Subsidiaries is validly existing under the laws of its jurisdiction of organization and has full corporate or other power and authority to enable it to own, lease or otherwise hold the Transferred Assets owned, leased or otherwise held by it and to conduct its business as presently conducted by it.

Section 3.02. Authority, Execution and Delivery; Enforceability. Seller has full corporate power and authority to execute this Agreement and the Ancillary Agreements to which it is, or is specified to be, a party and to consummate the transactions contemplated to be consummated by it by this Agreement and such Ancillary Agreements. Each of Seller Subsidiaries has or, prior to the Closing, will have full corporate or other power and authority to execute the Ancillary Agreements to which it is, or is specified to be, a party and to consummate the transactions contemplated to be consummated by it by such Ancillary Agreements. Seller has taken all corporate action required by its Articles of Association to authorize the execution and delivery of this Agreement and the Ancillary Agreements to which it is, or is specified to be, a party and to authorize the consummation of the transactions contemplated to be consummated by it by this Agreement and such Ancillary Agreements. Each of Seller Subsidiaries has or, prior to the Closing, will have taken all corporate or other action required by its organizational documents to authorize the execution and delivery of the Ancillary Agreements to which it is, or is specified to be, a party and to authorize the consummation of the transactions contemplated to be consummated by it by such Ancillary Agreements. Seller has duly executed and delivered this Agreement and prior to the Closing will have duly executed and delivered each Ancillary Agreement to which it is, or is specified to be, a party and, assuming due authorization, execution and delivery by the members of Purchaser Group party thereto, this Agreement constitutes, and each Ancillary Agreement to which it is, or is specified to be, a party will after the Closing constitute, its legal, valid and binding obligation, enforceable against it in accordance with its terms subject, as to enforcement, to applicable bankruptcy, insolvency, moratorium, reorganization or similar laws affecting creditors' rights generally and to general equitable principles. Each of Seller Subsidiaries prior to the Closing will have duly executed and delivered each Ancillary Agreement to which it is, or is specified to be, a party, and, assuming due authorization, execution and delivery by the members of Purchaser Group party thereto, each Ancillary Agreement to which it is, or is specified to be, a party will after the Closing constitute its legal, valid and binding obligation, enforceable against it in accordance with its terms subject, as to enforcement, to applicable bankruptcy, insolvency, moratorium, reorganization or similar laws affecting creditors' rights generally and to general equitable principles.

Section 3.03. No Conflicts or Violations, No Consents or Approvals Required. The execution and delivery by Seller of this Agreement do not and the consummation of the transactions contemplated to be consummated by it by this Agreement will not, and the execution and delivery by each member of Seller Group of each Ancillary Agreement to which it is, or is specified to be, a party will not and the consummation of the transactions contemplated to be consummated by it by such Ancillary Agreement will not, conflict with, or result in any breach of or constitute a default under, or result in the creation of any Lien (other than Permitted Liens or Liens caused by Purchaser Group) upon any of the Transferred Assets under, any provision of (a) in the case of Seller, its Articles of Association and, in the case of each of the other members of Seller Group, its organizational documents, (b) any Transferred Contract to which any member of Seller Group is a party or by which any of the Transferred Assets is bound, (c) any contract, agreement, commitment, indenture, mortgage, lease, pledge, note, bond, license, permit, or other instrument or obligation of any member of the Seller Group or any of the Transferred Assets, (d) any judgment, order or decree of a Governmental Entity ("Judgment") or Law applicable to any member of Seller Group or any of the Transferred Assets ("Applicable Law"), other than, in the case of clauses (b), (c) and (d) above, any such conflicts, breaches, defaults or Liens that would not reasonably be expected to have a Seller Material Adverse Effect. No consent, approval or authorization ("Consent") of, or registration, declaration or filing with, any Federal, state, local or foreign court or arbitral body of competent jurisdiction, governmental agency, authority, commission, instrumentality or regulatory body (each, a "Governmental Entity") is required to be obtained or made by or with respect to any member of Seller Group in connection with the execution, delivery and performance of this Agreement or the consummation of the transactions contemplated to be consummated by it by this Agreement.

Section 3.04. Good and Valid Title. A member of Seller Group has, and as of the Closing will have, good and valid title to each of the Transferred Assets, in each case, free and clear of all Liens (other than Permitted Liens).

Section 3.05. Intellectual Property. The marketing, commercialization, distribution and sale of the Approved Products and the development and manufacturing of the Products in the Territory in the manner conducted by Seller Group immediately prior to the Closing Date, does not, in any material respect, conflict with, infringe upon or otherwise misappropriate any Intellectual Property Rights of any person. Except as set forth in the Disclosure Letter, all Transferred Product Technology is solely owned by either Seller or another member of Seller Group, and no license fees in respect of any Transferred Product Technology are paid or payable to any third parties for the use by Seller or another member of Seller Group of the Transferred Product Technology.

Section 3.06. Contracts. Each Transferred Contract is valid, binding, and in full force and effect, and is enforceable by the applicable member of Seller Group in accordance with its terms subject, as to enforcement, to applicable bankruptcy, insolvency, moratorium, reorganization or similar laws affecting creditors' rights generally. The applicable member of Seller Group has performed all obligations, in all material respects, required to be performed by it under each Transferred Contract, and such member of Seller Group is not in material breach or default thereunder and, to the knowledge of Seller, no other party to such Transferred Contract is in material breach or default thereunder. As of the date of this Agreement, no counterparty to any Transferred Contract has notified the Company that such counterparty (a) ceased, or intends to cease after the Closing Date, its goods or services under such Transferred Contract, or (b) terminated or materially reduced, or intends to terminate or materially reduce after the Closing Date, its relationship with the Company under such Transferred Contract (including by sending a notice of a right of first refusal or similar correspondence regarding a reduction in price or quantity of the Products under such Transferred Contract).

Section 3.07. Regulatory Matters.

(a) Since January 1, 2017, (i) no member of Seller Group has received (A) any FDA Form 483 Notice of Observation with respect to any Product or any facility in which any Product is manufactured, (B) any FDA Notice of Adverse Finding with respect to any Product or (C) any "warning letter" or similar written correspondence from the FDA with respect to any Product and (ii) there has not been a recall or market withdrawal of any Product by any member of Seller Group, whether voluntary or involuntary. No recall or market withdrawal of any Product by any member of Seller Group is pending or, to the knowledge of Seller, threatened in connection with any Product.

(b) All Transferred Product ANDAs and Transferred Product FDA Materials filed with the FDA were, at the time of filing, true and complete in all material respects. To the knowledge of Seller, since January 1, 2017, no member of Seller Group or officer, employee or agent thereof has (i) made an untrue statement of a material fact to the FDA with respect to any Product, (ii) failed to disclose a material fact required to be disclosed to the FDA with respect to any Product or (iii) committed an act with respect to any Product that would reasonably be expected to provide a basis for the FDA to invoke its policy in respect of "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191, as amended. Seller has made available to Purchaser true and complete copies of all material correspondence with the FDA in Seller's possession or control with respect to the Transferred Product ANDA.

(c) Except as would not reasonably be expected to be material to the Transferred Assets, the Transferred Product ANDAs are valid and in full force and effect and not subject to any Proceeding for suspension or revocation.

Section 3.08. Proceedings. There is no (a) outstanding Judgment against any member of Seller Group, (b) Proceeding pending or, to the knowledge of Seller, threatened against any member of Seller Group or (c) investigation by any Governmental Entity pending or, to the knowledge of Seller, threatened against any member of Seller Group, in the case of each of clauses (a), (b) and (c), in respect of the Products or the Transferred Assets, including, without limitation, any Proceeding to place a clinical hold order on, or otherwise terminate, delay, or suspend, any proposed or ongoing pre-clinical or clinical studies, trials, investigational new drug applications, or investigations conducted or proposed to be conducted in connection with the Transferred Assets.

Section 3.09. Compliance with Applicable Law.

(a) The development, manufacturing, marketing, commercialization, distribution and sale of the Products by Seller Group, to the knowledge of Seller, is in material compliance with, and since January 1, 2017, has been in material compliance with, all Applicable Law.

(b) Since January 1, 2017, no member of Seller Group has received any written notice from any Governmental Entity alleging any failure of the development, manufacturing, marketing, commercialization, distribution and sale of the Products to comply with any Applicable Law.

(c) Anti-Bribery. Within the past six (6) years, no member of the Seller Group or any of their directors, officers, or to the knowledge of Seller, any employees, agents or consultants, or any other Person acting for, or on behalf of, the Seller Group, directly or indirectly:

(i) has violated or is in violation of the U.S. Foreign Corrupt Practices Act (the "FCPA") or any other laws regarding corruption or illegal payments applicable to the Seller Group (collectively with the FCPA, the "Improper Payment Laws");

(ii) has made, undertaken, offered to make, promised to make or authorized the payment or giving of any bribe, rebate, payoff, influence payment, kickback or other payment, gift or other transfer of money or anything of value (including meals or entertainment) to (A) any officer, employee or ceremonial office holder of any government, instrumentality thereof, government-controlled legal entity or supra-national organization (such as the United Nations), (B) any political party, (C) any political candidate, or (D) any royal family member, that is prohibited under any Improper Payment Law or otherwise for the purpose of influencing any act or decision of such payee in his or her official capacity, inducing such payee to do or omit to do any act in violation of his or her lawful duty, securing any improper advantage or inducing such payee to use his or her influence with a government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality in violation of his or her lawful duty (any of the foregoing a "Prohibited Payment");

(iii) has used funds or other assets, or made any promise or undertaking, for establishment or maintenance of a secret, unrecorded or improperly recorded fund (a "Prohibited Fund"); or

(iv) has made any false or fictitious entries in any books or records of the Seller Group relating to any Prohibited Payment or Prohibited Fund.

Section 3.10. Transferred Assets. The Transferred Assets comprise all of the assets of Seller Group (excluding all employees, independent contractors, real estate and general administrative overhead assets) that are necessary and useful to develop, manufacture, market, commercialize, distribute and/or sell, as applicable, the Products in a manner substantially consistent with the manner in which the Products were developed, manufactured, marketed, commercialized, distributed and/or sold, as applicable, by Seller Group immediately prior to the Closing Date. Upon the Closing, no member of the Seller Group will hold any assets that are of the same kind of assets as the Transferred Assets that are reasonably necessary to enable Purchaser to develop, manufacture, market, commercialize, distribute and/or sell the Products in a manner substantially consistent with the manner in which the Products were developed, manufactured, marketed, commercialized, distributed and/or sold by the Seller Group immediately prior to the Closing Date.

Section 3.11. Transferred Inventory. The Transferred Inventory will be of quality and quantity usable and saleable in the ordinary course of business consistent with past practice, except in each case for excess, obsolete items and items of below-standard quality in the Estimated Closing Inventory (which, for the avoidance of doubt, are deemed Excluded Assets). Since December 31, 2018, Seller has sold Products in quantities that are materially consistent with the demand and ordinary shipment and sales practices of Seller, and Seller has not engaged in "channel stuffing" of any of the Products.

Section 3.12. Brokers or Finders. Except as set forth in the Disclosure Letter, no member of Seller Group has entered into any Contract pursuant to which any agent, broker, investment banker or other firm or person is or will be entitled to any broker's or finder's fee or any other commission or similar fee in connection with any of the transactions contemplated by this Agreement.

Section 3.13. Profit and Loss Statement. Attached to Section 3.13 of the Disclosure Letter is a true and complete copy of the profit and loss statements of the Transferred Assets for the eleven-month period ended November 30, 2019 (the "Financial Statement"). The Financial Statement (i) was derived from and are in accordance with the books and records of the Seller Group, and (ii) fairly presents the results of operations of the Transferred Assets as of the date thereof and for the period indicated.

Section 3.14. Taxes.

(a) All Tax Returns required to be filed by Seller or otherwise related to the Transferred Assets have been duly and timely filed. All such Tax Returns are true and complete in all respects.

(b) No claim has been made by a Taxing Authority in a jurisdiction where Seller does not file a Tax Return such that Seller may have been subject to taxation in that jurisdiction.

(c) All Taxes owed by Seller or otherwise related to the Transferred Assets that are or have become due have been timely paid in full.

(d) There are no Liens other than Permitted Liens on any of the Transferred Assets related to any Taxes.

(e) All Taxes which Seller is (or was) required by Law to withhold, collect, or deposit in connection with amounts paid or owing to any employee, independent contractor, creditor, stockholder, or other third party have been duly withheld, collected, deposited, or paid over to the proper Taxing Authority.

(f) Seller has not been the subject of any audits, inquiries, or other proceedings with respect to Taxes, and there are no pending or active audits or legal proceedings involving Tax matters or, to knowledge of Seller, threatened audits, inquiries or proposed deficiencies or other claims for unpaid Taxes of Seller or Taxes otherwise relating to the Transferred Assets.

(g) Purchaser will not be held liable for any Taxes that are or have become due on or prior to the Closing Date as a successor or transferee, by statute, contract or otherwise, as a result of the transfer of any Transferred Assets under this Agreement.

(h) Seller has not (i) granted a power-of-attorney relating to Tax matters in connection with the Transferred Assets to any person, or (ii) applied for and/or received a ruling or determination from a Taxing Authority regarding a past or prospective transaction relating to the Transferred Assets.

(i) Seller has not participated in a reportable transaction (as defined in U.S. Treasury Regulations Section 1.6011-4(b)), or a transaction without economic substance (within the meaning of Section 7701(o) of the Code).

(j) There are no outstanding agreements extending or waiving the statutory period of limitation applicable to any claim for, or the period for the collection or assessment of Taxes with respect to the Transferred Assets.

(k) None of the Transferred Assets is subject to any tax partnership agreement or is otherwise treated, or required to be treated, as held in an arrangement requiring a partnership income Tax Return to be filed under Subchapter K of Chapter 1 of Subtitle A of the Code.

(l) Each of the representations and warranties set forth in this Section 3.14 are made with respect to any predecessors of Seller.

Section 3.15. Employment and Employee Benefits. Neither Seller nor any other member of the Seller Group is a party to a collective bargaining or other labor agreement and, to the knowledge of Seller, no organizational activities by a union or other labor representative have occurred during the prior 12 month period with respect to employees of Seller or any member of the Seller Group. Neither Seller nor any member of the Seller Group maintains or contributes to, or has any obligation to contribute to or otherwise has any liability with respect to, any Seller Benefit Plan. Seller and each member of the Seller Group has complied in all material respects with the requirements of Section 4980B with respect to continuation of health benefits. Neither Seller nor any member of the Seller Group has any liability under WARN.

ARTICLE IV
REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser hereby represents and warrants to Seller as follows:

Section 4.01. Organization and Standing. Purchaser is a validly existing corporation and in good standing under the laws of the State of Delaware and has full corporate power and authority to enable it to conduct its business as presently conducted by it. Except as would not reasonably be expected to have a Purchaser Material Adverse Effect, each of Purchaser's subsidiaries is validly existing under the laws of its jurisdiction of organization and has full corporate or other power and authority to enable it to conduct its business as presently conducted by it.

Section 4.02. Authority; Execution and Delivery, Enforceability. Purchaser has full corporate power and authority to execute this Agreement and the Ancillary Agreements to which it is, or is specified to be, a party and to consummate the transactions contemplated to be consummated by it by this Agreement and such Ancillary Agreements. Each of Purchaser's subsidiaries has or, prior to the Closing, will have full corporate or other power and authority to execute the Ancillary Agreements to which it is, or is specified to be, a party and to consummate the transactions contemplated to be consummated by it by such Ancillary Agreements. Purchaser has taken all corporate action required by its organizational documents to authorize the execution and delivery of this Agreement and the Ancillary Agreements to which it is, or is specified to be, a party and to authorize the consummation of the transactions contemplated to be consummated by it by this Agreement and such Ancillary Agreements. Each of Purchaser's subsidiaries has or, prior to the Closing, will have taken all corporate or other action required by its organizational documents to authorize the execution and delivery of the Ancillary Agreements to which it is, or is specified to be, a party and to authorize the consummation of the transactions contemplated to be consummated by it by such Ancillary Agreements. Purchaser has duly executed and delivered this Agreement and prior to the Closing will have duly executed and delivered each Ancillary Agreement to which it is, or is specified to be, a party and, assuming due authorization, execution and delivery by the members of Seller Group party thereto, this Agreement constitutes, and each Ancillary Agreement to which it is, or is specified to be, a party will after the Closing constitute, its legal, valid and binding obligation, enforceable against it in accordance with its terms subject, as to enforcement, to applicable bankruptcy, insolvency, moratorium, reorganization or similar laws affecting creditors' rights generally and to general equitable principles. Each of Purchaser's subsidiaries prior to the Closing will have duly executed and delivered each Ancillary Agreement to which it is, or is specified to be, a party, if any, and, assuming due authorization, execution and delivery by the members of Seller Group party thereto, each Ancillary Agreement to which it is, or is specified to be, a party will after the Closing constitute its legal, valid and binding obligation, enforceable against it in accordance with its terms subject, as to enforcement, to applicable bankruptcy, insolvency, moratorium, reorganization or similar laws affecting creditors' rights generally and to general equitable principles.

Section 4.03. No Conflicts or Violations, No Consents or Approvals Required. The execution and delivery by Purchaser of this Agreement do not and the consummation of the transactions contemplated to be consummated by it by this Agreement will not, and the execution and delivery by each member of Purchaser Group of each Ancillary Agreement to which it is, or is specified to be, a party will not and the consummation of the transactions contemplated to be consummated by it by such Ancillary Agreement will not, conflict with, or result in any breach of or constitute a default under, or result in the creation of any Lien upon any of the properties or assets of any member of Purchaser Group under, any provision of (a) the organizational documents of any member of Purchaser Group, (b) any Contract to which any member of Purchaser Group is a party or by which any of their respective properties or assets is bound, (c) any contract, agreement, commitment, indenture, mortgage, lease, pledge, note, bond, license, permit, or other instrument or obligation of any member of the Purchaser Group, or (d) any Judgment or Applicable Law applicable to any member of Purchaser Group or any of their respective properties or assets, other than, in the case of clauses (b), (c) and (d) above, any such conflicts, breaches, defaults or Liens that would not reasonably be expected to have a Purchaser Material Adverse Effect. No Consent of, or registration, declaration or filing with, any Governmental Entity is required to be obtained or made by or with respect to any member of Purchaser Group in connection with the execution, delivery and performance of this Agreement or the consummation of the transactions contemplated to be consummated by it by this Agreement.

Section 4.04. Proceedings. There is no (a) outstanding Judgment against any member of Purchaser Group, (b) Proceeding pending or, to the knowledge of Purchaser, threatened against any member of Purchaser Group or (c) investigation by any Governmental Entity pending or, to the knowledge of Purchaser, threatened against any member of Purchaser Group that, in the case of each of clauses (a), (b) and (c), would reasonably be expected to have a Purchaser Material Adverse Effect.

Section 4.05. Availability of Funds. Purchaser has, and at the Closing will have, available cash and capacity under existing borrowing facilities which together are sufficient to enable it to consummate the Acquisition and the other transactions contemplated by this Agreement and the Ancillary Agreements.

Section 4.06. Brokers or Finders. No member of Purchaser Group has entered into any Contract pursuant to which any agent, broker, investment banker or other firm or person is or will be entitled to any broker's or finder's fee or any other commission or similar fee in connection with any of the transactions contemplated by this Agreement.

ARTICLE V
RESERVED

ARTICLE VI
RESERVED

ARTICLE VII
RESERVED

ARTICLE VIII
INDEMNIFICATION

Section 8.01. Survival of Representations, Warranties and Covenants. All representations, warranties and covenants contained in this Agreement or any Ancillary Agreement shall survive the Closing and remain in full force and effect as follows: (a) for a period of 15 months following the Closing Date, with respect to all representations and warranties, other than with respect to (i) Seller Fundamental Representations and Purchaser Fundamental Representations which shall survive the Closing and remain in full force and effect for a period of 24 months following the Closing Date, and (ii) the representations and warranties of Seller set forth in Section 3.14 (Taxes) and the covenant to indemnify for any Excluded Tax that is a Retained Liability pursuant to Section 8.02(c), which shall survive for a period of sixty (60) days following the expiration of the applicable statute of limitations (including any extensions thereof), or (b) with respect to each other covenant or agreement contained in this Agreement or any Ancillary Agreement, for a period following the Closing in accordance with its terms (the respective expiration dates for the survival of the representations and warranties and covenants and agreements shall be referred to herein as the "Expiration Date"), except that any representation, warranty, covenant or agreement that would otherwise terminate in accordance with clause (a) or (b) will continue to survive if a Claim Notice shall have been timely given to the Indemnifying Party by the Indemnified Party on or prior to such applicable Expiration Date, until the related claim for indemnification has been satisfied or otherwise resolved as provided in this Article VIII.

Section 8.02. Indemnification by Seller. Subject to the limitations set forth in Section 8.05, from and after the Closing, Seller shall indemnify, defend and hold harmless each member of Purchaser Group and each of their respective officers, directors, employees, stockholders, agents and representatives (the "Purchaser Indemnitees") from and against any and all claims, losses, damages, liabilities, obligations or expenses, including reasonable third party legal fees and expenses (collectively, "Losses"), to the extent arising or resulting from any of the following:

(a) any inaccuracy or breach as of the date of this Agreement and as of the Closing Date of any representation or warranty of Seller contained in this Agreement;

(b) any breach of or failure to perform any covenant or agreement of Seller contained in this Agreement;

(c) any Retained Liability; and

(d) any items specifically excluded from coverage under the R&W Policy and set forth on Schedule XI attached hereto.

Section 8.03. Indemnification by Purchaser. Subject to the limitations set forth in Section 8.05, from and after the Closing, Purchaser shall indemnify, defend and hold harmless each member of Seller Group and each of their respective officers, directors, employees, stockholders, agents and representatives (the "Seller Indemnitees") from and against any and all Losses, to the extent arising or resulting from any of the following:

(a) any inaccuracy or breach as of the date of this Agreement and as of the Closing Date of any representation or warranty of Purchaser contained in this Agreement;

(b) any breach of or failure to perform any covenant or agreement of Purchaser contained in this Agreement; and

(c) any Assumed Liability.

Section 8.04. Indemnification Procedures.

(a) Procedures Relating to Indemnification of Third Party Claims. If any Purchaser Indemnitee or Seller Indemnitee, as applicable (the "Indemnified Party"), receives written notice of the commencement of any Proceeding or the assertion of any claim by a third party or the imposition of any penalty or assessment for which indemnity may be sought under Section 8.02 or 8.03 (a "Third Party Claim"), and such Indemnified Party intends to seek indemnity pursuant to this Article VIII, the Indemnified Party shall promptly provide Purchaser (if a Seller Indemnitee is the Indemnified Party) or Seller (if a Purchaser Indemnitee is the Indemnified Party), as applicable (the "Indemnifying Party"), with written notice of such Third Party Claim, stating the nature, basis and the amount thereof, to the extent known, along with copies of the relevant documents evidencing such Third Party Claim and the basis for indemnification sought. Failure of the Indemnified Party to give such notice will not relieve the Indemnifying Party from liability on account of this indemnification, except if and to the extent that the Indemnifying Party is actually materially prejudiced thereby. The Indemnifying Party will have 30 days from receipt of any such notice of a Third Party Claim to give notice to assume the defense thereof. If notice to the effect set forth in the immediately preceding sentence is given by the Indemnifying Party, the Indemnifying Party will have the right to assume the defense of the Indemnified Party against the Third Party Claim with counsel of its choice. So long as the Indemnifying Party has assumed the defense of the Third Party Claim in accordance herewith, (i) the Indemnified Party may retain separate co-counsel at its sole cost and expense and participate in the defense of the Third Party Claim, and (ii) the Indemnifying Party will not consent to the entry of any Judgment or enter into any settlement with respect to the Third Party Claim unless (A) the Indemnified Party has consented in writing (such prior written consent not to be unreasonably withheld or delayed) or (B) (i) the Indemnifying Party pays the full amount of the Liability in connection with such Third Party Claim, (ii) there is an unconditional release of all Indemnified Parties from all Liability arising out of such Third Party Claim or Action, and (iii) no Indemnified Party admits to any wrongdoing. The parties will cooperate in good faith in responding to, defending against, or settling Third Party Claims; provided that the foregoing will not require any person to take any action that would violate Law. Whether or not the Indemnifying Party has assumed the defense of a Third Party Claim, the Indemnifying Party will not be obligated to indemnify the Indemnified Party hereunder for any settlement entered into or any Judgment consented to with respect to such Third Party Claim without the Indemnifying Party's prior written consent (such written consent will not be unreasonably withheld or delayed).

(b) Procedures for Non-Third Party Claims. Upon the discovery of any matter giving rise to a claim of indemnity under Section 8.02 or 8.03 (but not involving a Third Party Claim), the Indemnified Party shall promptly provide the Indemnifying Party with written notice of such claim, stating the nature, basis and the amount thereof, if known, along with copies of the relevant documents evidencing such claim and the basis for indemnification sought. Failure of the Indemnified Party to give such notice will not relieve the Indemnifying Party from liability on account of this indemnification, except to the extent that the Indemnifying Party is actually materially prejudiced thereby. The Indemnifying Party will have 30 days from receipt of any such notice to dispute a claim of the Indemnified Party. If the Indemnifying Party has timely disputed such a claim, the Indemnified Party and the Indemnifying Party shall attempt to resolve in good faith such dispute within 30 days of the Indemnifying Party providing notice to the Indemnified Party of the dispute of such claim (it being understood that such good faith attempt shall not require either party to submit the dispute to arbitration). If such dispute is not so resolved within such 30-day period, then either party may initiate a lawsuit with respect to the subject matter of such dispute in accordance with, and subject to the limitations of, Article XI.

(c) Cooperation. The parties shall reasonably cooperate in resolving any claim of indemnity under Section 8.02 or 8.03 (including any Third Party Claim). Such cooperation will include, upon reasonable advance written notice, during normal business hours and so long as it does not unreasonably disrupt the normal operations of the business, providing reasonable access to and copies of information, records and documents relating to such claim and furnishing employees to assist in the investigation, defense and resolution of such claim. Notwithstanding the immediately foregoing sentence, this Section 8.04(c) shall not obligate the providing party to (a) adversely affect the ability of such party to assert attorney-client or attorney work product privilege or a similar privilege, (b) furnish information, documents, or records if the parties are in an adversarial relationship in litigation or arbitration, in which case the applicable rules relating to discovery shall govern, (c) violate any Applicable Law or Judgment, or (d) breach any duty of confidentiality owed to any person whether such duty arises contractually, statutorily or otherwise.

Section 8.05. Limits on Indemnification.

(a) Notwithstanding anything contained herein to the contrary:

(i) Seller Limits:

(A) Seller shall not be liable, pursuant to Section 8.02(a) and Section 8.02(d) for any Losses suffered by any Purchaser Indemnitee unless the aggregate amount of all such Losses suffered by Purchaser Indemnitees exceeds, on a cumulative basis, an amount equal to $262,500, and then only to the extent that such Losses exceed such amount; provided, that, the foregoing indemnification limitations shall not apply to indemnity claims made by Purchaser Indemnitees pursuant to Section 8.02(a) and Section 8.02(d) with respect to Seller Fundamental Representations, the representations and warranties set forth in Section 3.14 (Taxes), or fraud;

(B) except in the case of fraud, the R&W Policy and the Indemnity Escrow Account shall be the sole and exclusive recourse for claims made by Purchaser Indemnitees pursuant to Section 8.02(a);

(C) except in the case of fraud, the aggregate liability of Seller for Losses pursuant to Section 8.02(d) shall in no event exceed $7,875,000; and

(D) the aggregate liability of Seller hereunder shall in no event exceed the Purchase Price received by Seller under this Agreement.

(ii) Purchaser Limits:

(A) Purchaser shall not be liable, pursuant to Section 8.03(a) for any Losses suffered by any Seller Indemnitee unless the aggregate amount of all such Losses suffered by Seller Indemnitees exceeds, on a cumulative basis, an amount equal to $262,500, and then only to the extent that such Losses exceed such amount; provided, that, the foregoing indemnification limitations shall not apply to indemnity claims made by Seller Indemnitees pursuant to Section 8.03(a) with respect to Purchaser Fundamental Representations or fraud;

(B) the aggregate liability of Purchaser for any Losses pursuant to Section 8.03(a) shall, in no event, exceed $7,875,000; provided, that, the foregoing indemnification limitations shall not apply to indemnity claims made by Seller Indemnitees pursuant to Section 8.03(a) with respect to Purchaser Fundamental Representations or fraud; and

(C) the aggregate liability of Purchaser hereunder shall in no event exceed the Purchase Price payable to Seller under this Agreement.

(b) Order of Recovery; Set-Off Against Earn-Out Payments. Notwithstanding anything contained herein to the contrary, Purchaser Indemnitees' right to indemnification for Losses under Section 8.02 that are finally determined to be owed in accordance with Section 8.04 shall be subject to the following, to be satisfied exclusively from and asserted against, in order, in each case, subject to the terms, conditions and limitations of this Agreement:

(i) first, if the Indemnity Escrow Account has not been exhausted or released, to the extent of the remaining funds in the Indemnity Escrow Account, then Purchaser, on the one hand, and Seller, on the other hand, shall jointly instruct the Escrow Agent to disburse from the Escrow Account to such Purchaser Indemnitees an amount equal to the lesser of (A) the amount of Losses to which such Purchaser Indemnitees is entitled to be indemnified, and (B) the then remaining balance of the Indemnity Escrow Account;

(ii) second, if the amount of Losses to which such Purchaser Indemnitee is entitled to be indemnified exceeds the amounts satisfied under Section 8.05(b)(i), and solely in the case of claims made by Purchaser Indemnitees pursuant to Section 8.02(a), against the R&W Policy, to the extent then available and Losses are recoverable thereunder; and

(iii) third, if the amount of Losses to which such Purchaser Indemnitee is entitled to be indemnified exceeds the amount satisfied in accordance with Section 8.05(b)(i) and (ii), either, at Purchaser's option, (A) by withholding and setting off against any amount of an Earn-Out Payment otherwise due to be paid under Section 2.05 or (B) directly against Seller.

(c) Neither party hereto shall be liable hereunder to the other party hereto for any indirect, special, incidental, consequential or punitive damages (whether for loss of current or future revenues or profits, loss in value or otherwise) and no "multiple of revenues" or "multiple of profits" or similar valuation methodology shall be used in calculating the amount of any Losses.

(d) The amount of any Loss for which indemnification is provided under this Article VIII shall be determined after deducting therefrom any amounts actually recovered by the Indemnified Party from any third party (including insurance proceeds) as a result of the facts or circumstances giving rise to the Losses.

(e) Each Indemnified Party shall mitigate any Losses for which it is entitled to indemnification under this Article VIII, including by using its commercially reasonable efforts to pursue recovering any proceeds reasonably available under insurance policies; provided that no such Indemnified Party shall be required to take any action or refrain from taking any action that is contrary to any applicable Contract or Applicable Laws binding on such Indemnified Party or any affiliate thereof.

(f) For the purposes of determining the amount of any Losses arising out of, relating to or resulting from any inaccuracy or breach of any representation or warranty to be true and correct, and for purposes of determining whether or not such inaccuracy or breach has occurred, such representations and warranties shall be considered without giving effect to any limitation or qualifications as to "materiality," "Seller Material Adverse Effect", "Purchaser Material Adverse Effect" or any other derivation of the word "material."

(g) Purchaser acknowledges that it and its representatives have received or been afforded the opportunity to review prior to the date of this Agreement all written materials which Seller Group was required to make available to Purchaser pursuant to this Agreement on or prior to the date of this Agreement. Purchaser acknowledges that it and its representatives (i) have been permitted access to the books and records, Contracts and other properties and assets of Seller Group to the extent relating to the Products, the Transferred Assets or the Assumed Liabilities and (ii) have had an opportunity to discuss with employees of Seller Group the Products, the Transferred Assets and the Assumed Liabilities, in the case of each clauses (i) and (ii) that Purchaser and its representatives have desired or requested to see, review or discuss, as applicable. Purchaser further acknowledges and agrees that (A) other than the representations and warranties of Seller specifically contained in Article III, no member of Seller Group or any other person has made or makes any representation or warranty either expressed or implied (1) with respect to the Products, the Transferred Assets, the Assumed Liabilities or the transactions contemplated by this Agreement or the Ancillary Agreements or (2) as to the accuracy or completeness of any information regarding the Products, the Transferred Assets, the Assumed Liabilities or the transactions contemplated by this Agreement or by the Ancillary Agreements made available to Purchaser and its representatives and (B) Purchaser Indemnitees shall have no claim or right to indemnification pursuant to this Article VIII and no member of Seller Group or any other person shall have or be subject to any liability to any Purchaser Indemnitee or any other person with respect to any information, documents or materials made available by Seller Group or any of its representatives to Purchaser and its representatives, including any information, documents or materials made available to Purchaser and its representatives in any "data room" (whether electronic or otherwise) or in any other form (it being understood that this clause (B) does not supersede or otherwise affect the representations and warranties of Seller specifically contained in Article III). Without limiting the generality of the foregoing, except as provided under this Agreement, Purchaser acknowledges and agrees that no member of Seller Group or any other person has made or makes any representation or warranty relating to the maintenance, repair, condition, design, performance or marketability of any Transferred Asset, including merchantability or fitness for a particular purpose.

Section 8.06. Tax Treatment of Indemnification. For all Tax purposes, Purchaser and Seller agree to treat (and shall cause each other member of Purchaser Group or Seller Group, respectively, to treat) any indemnity payment under this Agreement as an adjustment to the Purchase Price unless otherwise required by a final determination by the IRS or other applicable Taxing Authority (which shall include, in the case of the IRS, the execution of an IRS Form 870-AD or successor form), a final judgment of a court of competent jurisdiction, or a change in Applicable Law occurring after the date hereof.

Section 8.07. Exclusive Remedy. Except for fraud or any non-monetary equitable relief to which any party hereto may be entitled from and after the Closing, the indemnification provisions contained in this Article VIII are intended to provide the sole and exclusive remedy following the Closing as to all Losses any party hereto (and any other Seller Indemnitee or Purchaser Indemnitee) may incur arising from or relating to the Agreement and the Ancillary Agreements and the transactions contemplated hereunder and thereunder, and each party hereby waives, to the full extent they may do so, any other rights or remedies that may arise under any applicable statute, rule or regulation.

ARTICLE IX
TAX MATTERS

Section 9.01. Tax Matters.

(a) Allocation of Taxes. In the case of any Straddle Period, (i) income Taxes, sales and use Taxes, value added Taxes and withholding Taxes shall be computed as if such taxable period ended on (and included) the Closing Date and (ii) all other Taxes (including Property Taxes) for the Pre-Closing Tax Period shall be equal to the amount of such Taxes for the entire Straddle Period multiplied by a fraction, the numerator of which is the number of days during the Straddle Period that are in the Pre-Closing Tax Period and the denominator of which is the number of days in the entire Straddle Period.

(b) Filing of Tax Returns and Payment and Refunds of Taxes. The party required by Applicable Law to file any Tax Return with respect to any Taxes applicable to the Transferred Assets for any Straddle Period shall timely file such Tax Return and pay such Taxes to the applicable Taxing Authority. To the extent Purchaser so pays any Taxes that are Retained Liabilities or Seller so pays any Taxes that are Assumed Liabilities, Seller or Purchaser (as applicable) shall reimburse the other party for the amount of such Taxes. To the extent Purchaser receives a refund of any such Taxes that are Retained Liabilities or Seller receives a refund of any such Taxes that are Assumed Liabilities, Purchaser or Seller (as applicable) shall pay over to the other party the amount of such refund, net of any reasonable out-of-pocket costs and expenses.

(c) Purchase Price Allocation.

(i) No later than 90 days after the Closing Date, Seller shall deliver to Purchaser a statement (the "Allocation Statement") allocating the Purchase Price (increased by the Assumed Liabilities and any other items to the extent properly taken into account under Section 1060 of the Code) among the Transferred Assets and any other assets to the extent properly treated as acquired for Tax purposes pursuant to this Agreement in accordance with Section 1060 of the Code. If, within 30 days after the delivery of the Allocation Statement, Purchaser has not notified Seller in writing that Purchaser objects to the allocation set forth in the Allocation Statement, the Allocation Statement shall become final and binding on the parties. If, within such 30-day period, Purchaser has so notified Seller, Purchaser and Seller shall use commercially reasonable efforts to resolve such dispute within 30 days. In the event that Purchaser and Seller are able to resolve such dispute within such 30-day period, the allocation reflected on the Allocation Statement shall be adjusted to reflect such resolution and the Allocation Statement (as so adjusted) shall become final and binding on the parties. In the event that Purchaser and Seller are unable to resolve such dispute within such 30-day period, the parties shall (A) refer the matter to the Independent Expert and (B) instruct Independent Expert to, no later than 30 days after its acceptance of the matter, resolve the dispute in a manner consistent with the principles set forth in this Section 9.01(c)(i) and furnish to each party notice of such resolution. The Allocation Statement shall then be adjusted to reflect such resolution and the Allocation Statement (as so adjusted) shall become final and binding on the parties. All fees and expenses of the Independent Expert shall be shared equally by the parties.

(ii) Once the Allocation Statement becomes final and binding pursuant to Section 9.01(c)(i), the parties agree to (A) be bound by the Allocation Statement for all Tax purposes and (B) act in accordance with the Allocation Statement in the preparation, filing and audit of any Tax Return, in each case, unless otherwise required by a closing agreement with an applicable Taxing Authority or a final judgment of a court of competent jurisdiction.

(d) Transfer Taxes.

(i) All Transfer Taxes shall be borne fifty percent (50%) by Seller and fifty percent (50%) by Purchaser. If either Seller or Purchaser receives any refund, credit or recovery of any Transfer Tax that was borne by both parties, the party receiving such refund, credit or recovery shall promptly pay to the other party fifty percent (50%) of the amount of such refund, credit or recovery, net of any reasonable out-of-pocket costs and expenses.

(ii) Each member of Seller Group, on the one hand, and Purchaser and its affiliates, on the other hand, shall use commercially reasonable efforts to obtain any available exemption from any Transfer Taxes and shall cooperate with the other parties in providing any information and documentation that may be necessary to obtain any such exemption, including any applicable resale or exemption certificate.

(iii) Seller and Purchaser shall file all Tax Returns and other documentation required to be filed with respect to all Transfer Taxes and, if required by Applicable Law, Seller and Purchaser will, and will cause the other members of Seller Group or Purchaser Group, respectively, to, join in the execution of any such Tax Returns and other documentation.

(e) Purchaser and Seller agree to provide each other with such information and assistance as is reasonably necessary, including access to records and personnel, for the preparation of any Tax Return or for the defense of any Tax claim or assessment related to the Transferred Assets or the Assumed Liabilities, whether in connection with an audit or otherwise.

(f) Seller shall deliver to Purchaser at the Closing certificates, duly executed and acknowledged, certifying that any payments made pursuant to this Agreement are exempt from withholding pursuant to Section 1445 of the Code.

ARTICLE X
ADDITIONAL AGREEMENTS

Section 10.01. Publicity; Confidentiality; Non-Compete.

(a) Publicity. No public release or announcement concerning the transactions contemplated by this Agreement or the Ancillary Agreements shall be issued by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld or delayed), except as such release or announcement may be required by Applicable Law or the rules or regulations of any United States or foreign securities exchange, in which case the party required to make such release or announcement shall allow the other party reasonable time to comment on such release or announcement in advance of such issuance.

(b) Confidentiality.

(i) Each of Purchaser and Seller acknowledges that the information provided to it in connection with the Acquisition and the other transactions contemplated by this Agreement and the Ancillary Agreements is subject to the terms of the confidentiality agreement between Purchaser and Seller (the "Confidentiality Agreement"). The terms of the Confidentiality Agreement are incorporated herein by reference. Effective upon, and only upon, the Closing, the Confidentiality Agreement shall terminate with respect to information relating solely to the Products and the Transferred Assets (other than information relating to the Excluded Assets and the personnel of Seller Group). For the avoidance of doubt, Purchaser acknowledges that any and all other information provided to it by Seller Group or any of its representatives concerning Seller Group shall remain subject to the terms and conditions of the Confidentiality Agreement from and after the Closing.

(ii) Seller recognizes that it possesses information of a confidential or secret nature in both written and unwritten form, which has unique commercial value as related to the Transferred Assets (hereinafter referred to as "Confidential Information"). For purposes of this Agreement, the foregoing, "Confidential Information":

(A) shall include each of the following, to the extent constituting a Transferred Asset: (I) any pre-clinical, clinical, pharmaceutical development, prescription, or sales and marketing data for a Product; (II) trade secrets, processes, methods, data, know-how, prototypes, improvements, inventions, techniques, product plans, strategies and forecasts, including any development plans for the use of a Product; (III) forms, Contracts or promotional materials created for or used solely in relation to a Product; (IV) any correspondence, memoranda or files related solely to a Product which contain Confidential Information; and (V) any information, knowledge and data solely related to the Transferred Assets; and

(B) shall not include (I) any information which is or becomes generally available to and known by the general public (other than as a result of a disclosure through the actions of Seller Group or any of its representatives in violation of this Section or any other obligation of confidentiality owed to Purchaser or any of Purchaser's subsidiaries), or (II) any information, forms, Contracts or other items relating to the Excluded Assets.

(iii) Seller agrees that, following the Closing, all Confidential Information shall be the sole property of Purchaser Group and its assigns.

(iv) Through the expiration of the Earn-Out Period, Seller will, and will cause Seller Subsidiaries and representatives to, keep in strict confidence all Confidential Information and will not use or disclose any Confidential Information or anything relating to it, in whole or in part, or permit others to use or disclose Confidential Information in any way, without the prior written consent of Purchaser. Seller agrees to inform Purchaser as promptly as practicable in writing in the event of any breach of this obligation of confidentiality that becomes known to Seller.

(v) Notwithstanding anything contained in this Agreement to the contrary, Seller is permitted to disclose the Confidential Information pursuant to a Judgment; provided that, in each instance, Seller (A) promptly notifies Purchaser of the Judgment after Seller becomes aware of the Judgment, (B) cooperates with Purchaser in seeking a protective order or similar relief to protect the confidentiality of the information to be disclosed, and (C) limits the disclosure to what is requested by the Judgment.

(vi) Notwithstanding anything contained in this Agreement to the contrary, for the avoidance of doubt, Seller shall expressly have the right to disclose and use Confidential Information relating to the Transition Product ANDAs for the sole purpose of, and to the extent reasonably necessary for, obtaining marketing approval for the applicable Transition Reference Products in China.

(c) Non-Compete.

(i) If the Closing occurs, for a period of 48 months beginning on the Closing Date, Seller will not (and will cause the other members of the Seller Group not to), directly or indirectly, engage or participate in, or render services to (whether as an owner, operator, member, shareholder, trustee, manager, consultant, strategic partner, employee or otherwise, with or without compensation) any Restricted Business (as defined below) in the Territory. For the purposes of the foregoing, Seller will not be in breach of this Section 10.01(c): (A) by reason of its (and/or any other member(s) of the Seller Group's) beneficial ownership, of two percent (2%) or less of the equity of a person that engages in any Restricted Business so long as Seller and the other members of the Seller Group do not control the operation or management of such person that engages in any Restricted Business or (B) for exercising its rights with respect to the Transition Product ANDAs and the Transition Reference Products in accordance with the terms and conditions hereunder.

(ii) The parties acknowledge and agree that the restrictions contained in this Section are a reasonable and necessary protection of the immediate interests of Purchaser, and any violation of these restrictions would cause substantial harm to Purchaser and that Purchaser would not have entered into this Agreement and the other Ancillary Agreements without receiving the additional consideration offered by Seller in binding itself to these restrictions. In the event of a breach or a threatened breach by Seller or any Seller Subsidiaries of these restrictions, Purchaser may be entitled to an injunction restraining Seller or Seller Subsidiaries, as applicable, from such breach or threatened breach (without the necessity of proving the inadequacy as a remedy of money damages or the posting of a bond); provided, however, that the right to injunctive relief will not be construed as prohibiting Purchaser from pursuing any other available remedies, whether at Law or in equity, for such breach or threatened breach.

(iii) The term "Restricted Business" means the development, manufacturing, marketing, commercialization, distribution and sale of a pharmaceutical generic product that has the same indication as (x) any approved indication for the Approved Products, (y) any filed indication for the Pending Products and (z) any targeted indication for the Development Products, in each case, (x), (y) and (z), as of the Closing.

Section 10.02. Bulk Transfer Laws. Purchaser hereby waives compliance by Seller Group with the provisions of any so-called "bulk transfer laws" of any jurisdiction in connection with the sale of the Transferred Assets to Purchaser.

Section 10.03. Post-Closing Information.

(a) For a period of two years following the Closing, Purchaser shall, and shall cause the other members of Purchaser Group to, afford to Seller and its accountants, counsel and other representatives reasonable access, upon reasonable prior written notice during normal business hours, to the books and records, Contracts and other properties and assets of Purchaser Group solely to the extent relating to the Products, the Transferred Assets or the Assumed Liabilities for any reasonable business purpose in respect of Proceedings that are not adversarial to the Purchaser Group, insurance matters and financial reporting of Seller Group, if such access does not unreasonably disrupt the normal operations of Purchaser Group. Notwithstanding the immediately foregoing sentence, this Section 10.03(a) shall not obligate any member of Purchaser Group to (a) adversely affect the ability of any member of Purchaser Group to assert attorney-client or attorney work product privilege or a similar privilege, (b) furnish information, documents, or records if the parties are in an adversarial relationship in litigation or arbitration, in which case the applicable rules relating to discovery shall govern, (c) violate any Applicable Law or Judgment, or (d) breach any duty of confidentiality owed to any person whether such duty arises contractually, statutorily or otherwise.

(b) For a period of two years following the Closing, Seller shall, and shall cause the other members of Seller Group to, afford to Purchaser and its accountants, counsel and other representatives reasonable access, upon reasonable prior written notice during normal business hours, to the books and records, Contracts and other properties and assets of Seller Group solely to the extent relating to the Products, the Transferred Assets or the Assumed Liabilities for any reasonable business purpose in respect of Proceedings that are not adversarial to the Seller Group, insurance matters and financial reporting of Purchaser Group, if such access does not unreasonably disrupt the normal operations of Seller Group. Notwithstanding the immediately foregoing sentence, this Section 10.03(b) shall not obligate any member of Seller Group to (a) adversely affect the ability of any member of Seller Group to assert attorney-client or attorney work product privilege or a similar privilege, (b) furnish information, documents, or records if the parties are in an adversarial relationship in litigation or arbitration, in which case the applicable rules relating to discovery shall govern, (c) violate any Applicable Law or Judgment or (d) breach any duty of confidentiality owed to any person whether such duty arises contractually, statutorily or otherwise.

Section 10.04. Technology Transfer; FDA Approval.

(a) Seller and Purchaser shall use commercially reasonable efforts to effect an orderly transfer of the Product Scientific and Regulatory Material and the Product Technology from Seller Group to Purchaser Group pursuant to the terms of this Agreement as promptly as practicable after the Closing.

(b) Seller and Purchaser shall cooperate in good faith to prepare and submit on or after the Closing Date all required notices to the FDA regarding the transfer of the Transferred Product ANDAs (expressly excluding all Transition Product ANDAs) from Seller Group to Purchaser Group. In connection with, and without limiting, the foregoing:

(i) within five (5) business days of the Closing Date, Seller shall deliver one or more flash drives to Purchaser containing one eCTD sequence for each Transferred Product ANDA and each Transition Product ANDA;

(ii) within ten (10) business days of the Closing Date, (A) with respect to each Transferred Product ANDA, Seller shall deliver, or cause to be delivered, to the FDA a Seller FDA Letter, and (B) with respect to each Transition Product ANDA, Seller shall deliver, or cause to be delivered, to the FDA a US Agent Appointment Letter;

(iii) within fifteen (15) business days of the Closing Date, (A) with respect to each Transferred Product ANDA and each Transition Product ANDA, Seller shall deliver one or more flash drives to Purchaser containing all applicable electronic RA files (except in the case of the Transferred Product ANDA for Indapamide, which files shall be delivered in both electronic/eCTD and paper files), and (B) with respect to each Transferred Product ANDA, Purchaser shall deliver, or cause to be delivered, to the FDA a Purchaser FDA Letters; provided, that any and all flash drives required to be delivered to Purchaser pursuant to Section 10.04(i) and (iii) shall be delivered to the following recipient at the physical address listed below, and Seller shall provide tracking numbers for such deliveries to the email account listed below:

Justin Uthup, Associate Director Regulatory Affairs
ANI Pharmaceuticals, Inc.
3757 Willow Stone Lane, Wake Forest, NC 27587
Phone: 919-647-9794
Email: justin.uthup@anipharmaceuticals.com

(iv) following the Closing, Seller will notify Purchaser of any FDA communications related to the Transferred Product ANDAs and the Transition Product ANDAs within one (1) business day;

(v) if, following the Closing, Seller is unable to update or recertify drug listings for any of the Transferred Product ANDAs or the Transition Product ANDAs that exist in Seller's labels, Purchaser shall have authority to update or recertify such drug listings on Seller's behalf for the purposes of maintaining FDA compliance;

(vi) Seller shall provide Medwatch forms for all individual adverse event cases to Purchaser received on or prior to the Closing Date relating to Products with applicable reporting periods closing in January or February of 2020, in each case to be provided to Purchaser no later than January 15, 2020;

(vii) Seller shall process and submit to the FDA all adverse drug experience cases related to the Products, to the extent received by Seller on or prior to the Closing Date, in compliance with FDA regulations (for the avoidance of doubt, such obligation may require Seller to continue to process and submit such cases after the Closing Date);

(viii) Seller shall forward all adverse drug experience cases related to the Products that are received by Seller (whether by phone, email, or other communication) following the Closing Date, within one Business Day of such receipt, to Purchaser at the following contact: phone: 1-800-308-6755, email: PVsupport@safetycall.com;

(ix) Within sixty (60) days following the Closing Date, Seller shall migrate its electronic safety database, including all historical adverse drug experience cases related to the Products prior to the Closing Date, to Purchaser's electronic safety database; and

(x) within fifteen (15) business days of the Closing Date, Seller shall notify Purchaser that the annual report for the Product Indapamide has been properly submitted to the FDA.

(c) Seller shall take all actions necessary to transition the website https://www.penicillaminesavings.com to Purchaser's webmaster within five (5) business days of the Closing Date.

(d) In connection with activities undertaken pursuant to this Section 10.04, Seller shall bear the costs incurred by Seller Group and Purchaser shall bear the costs incurred by Purchaser Group.

Section 10.05. Insurance. At all times from the Closing Date through the date which is three (3) years after the Closing Date, Purchaser shall maintain product liability and other insurance for Purchaser Group that is reasonable and customary in the pharmaceutical industry in the Territory for companies of comparable size. Purchaser shall provide Seller with written proof of such product liability and other insurance upon reasonable advance written request by Seller.

Section 10.06. Adverse Experience and Field Alert Reporting; Recalls and Withdrawals.

(a) Prior to the Closing Date, Seller Group shall be responsible for adverse experience and field alert reporting to the FDA in respect of the Products. From and after the Closing Date, Purchaser Group shall be responsible for adverse experience and field alert reporting to the FDA in respect of the Products. For the avoidance of doubt, Purchaser Group shall be responsible for adverse experience and field alert reporting to the FDA in respect of the Transition Reference Products in accordance with Section 10.09 of this Agreement. From and after the Closing Date, Seller shall promptly notify Purchaser of any adverse drug experience information (including any new adverse experience reports or any follow-up adverse experience reports per Section 10.04(b)(viii)) received by Seller or any field alert reportable events that become known to Seller, in each case in respect of the Products.

(b) Prior to the Closing Date, Seller Group shall be responsible for investigating and managing any recall or market withdrawal (whether voluntary or involuntary) of any Product. From and after the Closing Date, (i) Purchaser Group shall be responsible for investigating and managing any recall or market withdrawal (whether voluntary or involuntary) of any Product, and (ii) Seller shall provide assistance as Purchaser may reasonably request in connection with any such recall or market withdrawal.

Section 10.07. Misdirected Payments. From and after the Closing Date, if any member of Seller Group receives any amount which is a Transferred Asset or is otherwise properly due and owing to Purchaser Group in accordance with the terms of this Agreement (including in respect of any Products sold by Purchaser Group from and after the Closing Date), Seller promptly shall remit, or shall cause to be remitted, such amount (net of any Taxes) to Purchaser at the address set forth in Section 11.10. From and after the Closing Date, if any member of Purchaser Group receives any amount which is an Excluded Asset or is otherwise properly due and owing to Seller Group in accordance with the terms of this Agreement (including in respect of any Products sold by Seller Group prior to the Closing Date), Purchaser promptly shall remit, or shall cause to be remitted, such amount (net of any Taxes) to Seller at the address set forth in Section 11.10. In the event of any conflict between this Section 10.07 and Article VIII, Article VIII shall prevail.

Section 10.08. Cross License; Excluded Inventory.

(a) Seller grants to Purchaser an irrevocable, exclusive, royalty-free, fully paid-up, sublicensable, transferrable license under Seller's rights in any labeler code, imprints, logos, debossings, and other names or marks made on the Transferred Inventory and on any open or future orders of Products, to sell, distribute and otherwise commercialize or exploit such Transferred Inventory and Products in the Territory.

(b) Purchaser hereby agrees to, as applicable, sublicense or partially assign to Seller the Transferred Contracts listed on Schedule IX, solely to the extent permitted under such Transferred Contracts and necessary for Seller to commercialize or otherwise exploit the Transition Reference Products outside of the Territory. Purchaser agrees to use commercially reasonable efforts to execute and deliver such other documents and to cooperate with Seller, in each case at Seller's expense and request, to effect the terms of the preceding sentence.

(c) Concurrently with the execution of this Agreement, Seller shall deliver a notice of destruction to EVERSANA in the form attached as Exhibit A.

Section 10.09. Agreements Regarding Transition Product ANDAs; Transition Reference Products; and GDUFA Escrow Account.

(a) General. With respect to each Transition Product ANDA, during the applicable Transition Period, Seller will continue to hold, and be the "in-name-only" owner, of the Transition Product ANDA for the sole purpose of obtaining marketing approval for the applicable Transition Reference Product in China.

(b) Exclusive License. With respect to each Transition Product ANDA, during the applicable Transition Period, Seller hereby grants to Purchaser an irrevocable, exclusive, royalty-free, fully paid-up, sublicensable, transferrable license under Seller's rights in the applicable Transition Product ANDA to sell, distribute and otherwise commercialize or exploit the applicable Transition Reference Product in the Territory. For the avoidance of doubt, following the Closing, Purchaser will (i) have full and exclusive rights to commercialize the Transition Reference Products for sale in the Territory and (ii) retain all profits with respect thereto, subject to its obligations to Seller with respect to the Earn-out Payments.

(c) Transfer. Seller and Purchaser shall take all actions necessary for Seller to transfer full right and ownership of such applicable Transition Product ANDA to Purchaser at no cost and to terminate the applicable license from Section 10.09(b), including, without limitation, the delivery of a (i) Seller FDA Letter by Seller to the FDA with respect to the applicable Transition Product ANDA within five (5) business days following the Transition End Date for each Transition Product ANDA, and (ii) Purchaser FDA Letter by Purchaser to the FDA with respect to the applicable Transition Product ANDA within ten (10) business days following delivery of such Seller FDA Letter by Seller under clause (i) above.

(d) Other.

(i) With respect to each Transition Reference Product, during the Transition Period for such Transition Reference Product, Purchaser agrees and covenants to market, sell, and distribute the applicable Transition Reference Product under Seller's name as the manufacturer of such Transition Reference Product. For clarity, Purchaser may indicate that such Transition Reference Product is distributed by Purchaser on the label or promotional materials therefor.

(ii) With respect to each Transition Product ANDA, during the applicable Transition Period, Seller hereby delegates all other rights, liabilities, obligations, and regulatory responsibilities with respect to such Transition Product ANDA (*e.g.*, recall rights, adverse event reporting obligations, annual reporting obligations, interacting with the FDA, etc.) to Purchaser, and Purchaser hereby assumes all such rights and responsibilities. Purchaser shall perform and satisfy such rights and responsibilities on behalf of Seller and in compliance with all applicable Laws, including those Laws enforced by the FDA; provided, that Seller shall be responsible, and promptly reimburse Purchaser, for all reasonable and documented fees, costs, and expenses incurred by Purchaser or its affiliates in connection with assisting Seller or Seller's affiliates to obtain regulatory approval for any Transition Reference Products in China. For the avoidance of doubt, except for the rights expressly retained by Seller pursuant to this Section 10.09, all other rights, liabilities, and obligations associated with the Transition Product ANDAs shall be transferred to Purchaser at the Closing. With respect to each Transition Product ANDA, during the applicable Transition Period, Seller shall designate one official (the "Seller Regulatory Contact") to serve as the primary point of contact for Purchaser and the FDA for all regulatory matters concerning the Transition Product ANDAs. The initial Seller Regulatory Contact shall be Tamara Elder, whose contact information is as follows: email: telder@amerigenpharma.com, telephone number 951-966-5749. Seller may replace the Seller Regulatory Contract at anytime subject to the prior written consent of Purchaser, not to be unreasonably delayed, conditioned, or withheld. In the event a Governmental Entity inquiry, investigation, or similar process arises in connection with a Transition Product, or the signature, consent, or approval of an authorized representative of Seller is required for reporting or compliance purposes in connection with a Transition Product, Seller shall cause the Seller Regulatory Contact to be made available to the FDA and Purchaser during normal business hours, and to take, on behalf of Seller, all actions reasonably necessary to cause the Transition Product ANDAs, and Purchaser's commercialization thereof, to be in compliance with all applicable Laws, including those Laws enforced by the FDA.

(iii) Purchaser shall not be required to receive prior authorization or approval from Seller for any changes, variations, supplemental filings, or any other regulatory changes to the extent required to be made to the Transition Product ANDAs; provided, that Purchaser shall communicate all changes that have received regulatory approval to Seller upon approval (for changes that require specific approval) or otherwise at the end of the applicable annual report period for each of the Transition Product ANDAs within 60 calendar days after the close of such applicable annual report period.

(e) GDUFA Fees; GDUFA Escrow Account.

(i) In accordance with Section 2.03(c), at the Closing, Purchaser will deposit an amount equal to the GDUFA Escrow Amount with the Escrow Agent.

(ii) To the extent (A) the Transition Period ends on or prior to September 1, 2020, and (B) Seller and Purchaser have taken all actions necessary for Seller to transfer full right and ownership of the Transition Product ANDAs to Purchaser in accordance with Section 10.09(c) on or prior to September 1, 2020, then, promptly following the Transition Period, and in any event within five (5) business days thereafter, Purchaser, on the one hand, and Seller, on the other hand, shall jointly instruct the Escrow Agent to pay to Seller, from the GDUFA Escrow Account, an amount equal to the balance of the GDUFA Escrow Account.

(iii) To the extent the (A) the Transition Period ends after September 1, 2020, or (B) Seller and Purchaser have not taken all actions necessary for Seller to transfer full right and ownership of the Transition Product ANDAs to Purchaser in accordance with Section 10.09(c) on or prior to September 1, 2020, then, promptly following September 1, 2020, and in any event within five (5) business days thereafter, Purchaser, on the one hand, and Seller, on the other hand, shall jointly instruct the Escrow Agent to pay (x) to Purchaser, from the GDUFA Escrow Account, an amount equal to the GDUFA Fee, and (y) to Seller, from the GDUFA Escrow Account, an amount equal to the balance of the GDUFA Escrow Account after payment pursuant to clause (x).

Section 10.10. Government Rebates.

(a) Government Programs Transition Period.

(i) Seller and Purchaser shall use commercially reasonable efforts to terminate Seller's ownership of the Labeler Code with CMS on or before June 30, 2020 and to effect Purchaser as the registered owner of the Labeler Code with an effective date as promptly as practicable but in no event later than July 1, 2020.

(ii) Within thirty (30) days following the Closing Date, Seller shall submit a Medicaid National Drug Rebate Agreement ("NDRA") with the appropriate Governmental Rebate Authorities (the period beginning on the Closing Date and ending on the effective date of the NDRA codifying Purchaser's ownership of the Labeler Code, the "Government Programs Transition Period").

(iii) As promptly as administratively possible following Seller's submission to CMS of all applicable data required for each of the month of December 2019 and the fourth calendar quarter of 2019, but in no event later than January 31, 2020, Seller shall submit to CMS a Medicaid Drug Rebate Agreement Form 367(d) appointing Sharon Feldman (email: sharon.feldman@anipharmaceuticals.com; phone: (218) 634-3568; fax: (218) 634-3606) as the Technical Contact for the Labeler Code.

(iv) As promptly as practicable following Seller's receipt of all Government Rebate invoices relating to Product reimbursements paid by the applicable Governmental Rebate Authorities during the calendar quarter ending December 31, 2019, Seller and Purchaser shall cooperate in good faith to register Purchaser as the designated party to be invoiced by the applicable Governmental Rebate Authorities, including by preparing and submitting as promptly as administratively possible following the Closing Date (but no later than April 1, 2020) the Medicaid Drug Rebate Agreement Form 367(d) appointing Sharon Feldman (email: sharon.feldman@anipharmaceuticals.com; phone: phone: (218) 634-3568; fax: (218) 634-3606) as the Invoice Contact for the Labeler Code.

(v) As promptly as administratively possible following the Closing Date, Seller shall make all notifications and submissions necessary under each of Seller's hrsa.gov (Health Resources & Services Administration) and sam.gov (System for Award Management) registrations, in each case, to notify the applicable administrative authority of the Transaction and the date the Transaction was consummated, to transfer such website registrations to Purchaser, and to appoint Sharon Feldman (email: sharon.feldman@anipharmaceuticals.com; phone: phone: (218) 634-3568; fax: (218) 634-3606) as the authorized official and primary contact of each such registration.

(vi) Seller will continue to list the Products on all agreements with Governmental Rebate Authorities after the Closing Date. With respect to the Medicaid program, Purchaser will discuss its acquisition of the Labeler Code with CMS promptly following the Closing Date. Seller will coordinate termination of its NDRA for the Labeler Code with Purchaser to ensure there is no disruption in Medicaid coverage for the Products under state Medicaid programs. During the Government Programs Transition Period, Purchaser will calculate AMP and Best Price and submit to Seller to submit and certify to CMS in the Medicaid Drug Data Reporting System.

(vii) During the Government Programs Transition Period, (A) Mike Fortier and Forrest Lamm shall serve as the primary point of contact for Purchaser, CMS, and all other relevant government pricing authorities for all regulatory matters concerning this Section 10.10(a), and (B) Seller shall use commercially reasonable efforts to preserve substantially intact its relationships with EVERSANA to the extent related to, or necessary for Seller to comply with, the post-Closing obligations of Seller under this Agreement ..

(b) Certain Operational Matters.

(i) Price Reporting Information. Seller will deliver to Purchaser the following government price reporting information for Products sold in the Territory within ten (10) business days of the Closing Date, transactional detail for the period beginning October 1, 2018 through the Closing Date that is necessary to perform post-Closing government price calculations such as the "Average Manufacturer Price" or "AMP" (as defined in 42 U.S.C. § 1396r-8(k)(1) and 42 C.F.R. § 447.500 et seq., as may be amended from time to time), "Average Selling Price" or "ASP" (as defined in 42 U.S.C. 1395w–3a(c), as may be amended from time to time), "Best Price" (as defined in 42 U.S.C. § 1396r-8(c)(1)(C) (relating to the definition of Best Price) and 42 C.F.R. § 447.500 et seq., as may be amended from time to time), the "Non-Federal Average Manufacturer Price" or "Non-FAMP" and "Federal Ceiling Price" or "FCP" (as such terms are defined in 38 U.S.C. § 8126(h)(5) and any applicable agreement between a pharmaceutical manufacturer and the U.S. Department of Veterans Affairs to implement the provisions of the Veterans Health Care Act of 1992, 38 U.S.C. § 8126, or the "VA Master Agreement"), including:

(A) with respect to AMP, ASP, and Best Price, (I) calendar quarter in which baseline AMP was established, (II) baseline AMP, (III) all other baseline Product information submitted by Seller to the CMS in connection with the Medicaid drug rebate program (including units per package size, market start date, etc.), and (IV) transactional data reasonably necessary for Purchaser to calculate AMP, ASP, and Best Price for the quarters and months (as applicable) beginning with the AMP, ASP, and Best Price submissions due on or after the Closing Date;

(B) with respect to the U.S. Public Health Service 340B Drug Pricing Program created under Section 340B of the Public Health Service Act and Section 602 of the Veterans Health Care Act of 1992 (the "PHS Program"), the PHS Program price for the calendar quarter in which the Closing Date occurs and one subsequent calendar quarter; and

(C) with respect to the Veterans Health Care Act of 1992, (I) the applicable "Federal Ceiling Price" or "FCP" (as such figure is calculated pursuant to 38 U.S.C. § 8126(a) and the VA Master Agreement), (II) the Non-FAMP calculations for each calendar quarter of 2019, (III) any commercial sales data reasonably necessary to perform quarterly and annual Non-FAMP calculations, and (IV) any price lists applicable for purposes of sales under any applicable contract with the U.S. Department of Veterans Affairs under Federal Supply Schedule 65IB for Drugs, Pharmaceuticals, & Hematology Related Products.

(ii) During the Government Programs Transition Period:

(A) if Seller receives a request for an agreement proposal or a similar rebate agreement proposal from any Governmental Rebate Authority assistance program relating to any Product, Seller will provide Purchaser with such request or proposal. Purchaser may request that Seller propose a rebate with respect to such Product bearing Seller's NDC Number on financial terms specified by Purchaser; provided, however, that (I) any such proposal will be accompanied by a statement to the Governmental Rebate Authority assistance program explaining Purchaser's ownership of or license to (as applicable) and responsibility for the Product, (II) Purchaser will submit a comparable proposal with respect to the Product bearing Purchaser's NDC Number, and (III) Seller will retain the discretion to terminate any such agreement in accordance with its terms.

(B) Seller will process and pay all undisputed Government Rebates received after the Closing Date that are payable pursuant to the Governmental Rebate Authority assistance programs for all Products bearing Seller's NDC Number. Seller will provide Purchaser with data detailing all disputed and undisputed Government Rebates invoiced by such programs relating to periods following the Closing Date, and Purchaser may reasonably request that Seller dispute additional utilization on such invoices for a calendar quarter as designated by Purchaser, including through use of a CMS Form 304.

(C) Seller will provide Purchaser with quarterly corresponding utilization summaries and payment reports within one hundred twenty (120) days after the end of the applicable calendar quarter that describe the requested Government Rebate payments in reasonable detail.

(D) with respect to the Products sold by or on behalf of Purchaser on or after the Closing Date that bear Seller's NDC Number, Seller will continue to be responsible for reporting pricing information required under the applicable statutes, rules, and regulatory guidance relating to programs of the applicable Governmental Rebate Authorities, including the Medicaid Rebate Program, the PHS 340B Program, any program administered by the Veterans' Administration and the like until Seller has formally completed the ownership transfer and received confirmation from the applicable programs that the ownership transfer has been completed; provided, however, that Purchaser will be responsible for reporting such pricing information required under the VA Master Agreement and the Federal Supply Schedule contract as of the date of the addition of the Products to Purchaser's VA contracts.

(iii) Purchaser Information. Until such time as Seller no longer has any reporting obligations with respect to the Products, Purchaser will deliver to Seller by the twenty fourth (24th) day following the applicable month and quarter end (A) the monthly and quarterly AMP and ASP, as applicable, (B) the quarterly Best Price, and (C) any other government price reporting information for the Products necessary for Seller to satisfy its federal and state reporting obligations (the "Purchaser Information"). All Purchaser Information provided by Purchaser to Seller will, to Purchaser's knowledge, be complete and accurate at the time of submission, prepared in accordance with Purchaser's good faith reasonable efforts, and consistent with Purchaser's reasonable assumptions interpreting applicable laws, assuming that all information provided by Seller to Purchaser and used in providing such Purchaser Information to Seller, to Purchaser's knowledge, is complete and accurate. Purchaser will provide Seller with a certification at the time of each delivery of Purchaser Information by Purchaser to Seller as to the completeness and accuracy of such Purchaser Information in a form reasonably acceptable to Seller. Purchaser will deliver to Seller a report of all recalculations of Purchaser Information including those due to corrections of errors or other routine corrections, such as Best Price true-ups, made by Purchaser or any other related information as soon as practicable after determination by Purchaser and in any case no later than five (5) business days prior to any applicable timelines required by the relevant governmental pricing laws and guidance. When providing such additional information, Purchaser will certify the completeness and accuracy of such information in a form reasonably acceptable to Seller. Purchaser will indemnify and hold harmless Seller, its affiliates, and their respective representatives, successors, and assigns for and against any and all Losses resulting from, based on, or arising out of the provision of incomplete or inaccurate Purchaser Information or Purchaser Information provided in an untimely manner or not in accordance with the timeframes set forth in this Agreement, except to the extent that such incomplete or inaccurate Purchaser Information is incomplete or inaccurate as a result of inaccurate or incomplete information provided by Seller to Purchaser.

(iv) Seller shall submit, in a timely manner, all government price reporting filings (including AMP, ASP, Best Price, non-FAMP, and FCP) to the Governmental Rebate Authorities for any Product.

(v) For the month ending January 31, 2020, within ten (10) days of the last day of such month, for Product bearing Seller's NDC Number, Seller will provide to Purchaser, Best Price, sales at nominal prices as defined in 42 U.S.C. § 1396r-8, customary prompt pay discounts, and pricing data necessary to calculate AMP and ASP on a monthly and quarterly basis. Seller will deliver to Purchaser within fifteen (15) days following its receipt of such report the applicable AMP, ASP, Best Price, PHS 340B Program price, nonFAMP, and any adjustments to Federal Supply Schedule prices, determined in accordance with Seller's applicable methodologies and procedures.

(vi) For so long as Medicaid price reporting is required under healthcare laws relating to Governmental Rebate Authority programs for any Product manufactured under the Labeler Code (the "Labeler Code Reporting Period"), no later than the twenty-four (24th) day following the applicable month, beginning with the first month of the Government Programs Transition Period, Purchaser shall calculate and submit to Seller the Monthly Drug Data Reporting ("DDR") Submission with respect to each Product, in the format required for submission into the CMS DDR system until such time as Seller updates the technical contact in the CMS DDR system to Sharon Feldman in accordance with Section 10.10(a)(ii).

(vii) No later than ten (10) business days prior to the applicable CMS reporting deadline, beginning with the first month following the Closing Date, Seller shall, with respect to each Product, delegate signing authority to Purchaser for purposes of DDR submissions, (the "Medicaid Delegation of Signature Authority for Certification").

(viii) Upon the timely receipt of a monthly DDR submission, a quarterly DDR submission or a revision thereto, in each case as described above, Seller shall enter the information contained in the submission into the CMS DDR system by the deadline specified under applicable healthcare Laws until such time as Seller updates the technical contact in the CMS DDR system to Sharon Feldman in accordance with Section 10.10(a)(ii).

(ix) TriCare Rebate Program.

(A) Purchaser will work with Seller to coordinate the addition of the Products to Purchaser's Federal Supply Schedule contract and TriCare Rebate Program agreement to coincide with Seller removing the Products from their Federal Supply Schedule contracts and TriCare Rebate Program agreements, as applicable. As promptly as administratively possible following the Closing Date, Seller shall submit the form attached as Exhibit M via email to UFVARR_Requests@mail.mil. Seller and Purchaser will coordinate the addition and removal of the Products from the Federal Supply Schedule contracts and TriCare Rebate Program agreements, as applicable, such that the transition occurs as close to the Closing Date as possible, in conjunction with applicable regulations. Purchaser agrees to submit a Request For Modification to the VA National Acquisition Center to add the Products to Purchaser's Federal Supply Schedule contract within thirty (30) days following the Closing Date.

(I) Seller shall process and pay (with ultimate financial responsibility being determined as set forth in clause (II) below) all Government Rebates under the TriCare Rebate Program owed based on TriCare retail pharmacy dispensing data of all Products bearing an NDC Number of Seller for which utilization data are available or have been made available electronically or in writing on or prior to the Closing Date and until the Products have been deleted from Seller's Pricing Agreement with TriCare and added to Purchaser's Pricing Agreement with TriCare (even if the due date for rebate payment falls after the Closing Date). Purchaser shall process and pay (with financial responsibility being determined as set forth in clause (II) below) any and all Government Rebates under the TriCare Rebate Program relating to the Products for which utilization data are first made available electronically or in writing after the Closing Date, provided the Products have been added to Purchaser's Pricing Agreement with TriCare.

(II) Seller shall be financially responsible for Government Rebates under the TriCare Retail Pharmacy Rebate Program owed based on TriCare retail pharmacy dispensing data of Products bearing an NDC Number of Seller as set forth in Section 2.04(d)(i).

(c) Revisions of Reported Information.

(i) To the extent Seller calculates, submits, and certifies to CMS any necessary revisions of monthly DDR submissions or quarterly DDR submissions previously calculated by Seller relating to periods prior to and including the Closing Date, provided that in each case as soon as reasonably practicable after Seller determines that submission of such revisions is necessary but in any event not later than ten (10) Business Days prior to any submission by Seller to CMS of any restatement of AMP, ASP, or Base Price, Seller shall (A) notify Purchaser of its intention to revise any such submissions, and (B) provide Purchaser with its calculations supporting such restatement.

(ii) Purchaser shall calculate, submit, and certify to Seller any necessary revisions of monthly DDR submissions or quarterly DDR submissions previously submitted by Purchaser to Seller in each case as soon as reasonably practicable after Purchaser determines that submission of such revisions is necessary.

(iii) Upon and after the Closing Date, with respect to the parties' reporting responsibilities designated in this Section, the parties agree to cooperate and use commercially reasonable efforts to provide on a timely basis all such documentation as may reasonably be requested by each party of the other to report required pricing information.

(iv) The parties agree to cooperate and provide any other data and documentation as each party may reasonably request from time to time to assist in the matters described in this Section.

(v) Each party may use all information provided to it pursuant to this Section in reporting to CMS and other Governmental Rebate Authorities. The parties further agree that all data, including Medicaid Rebate Program pricing data, and data to be used for the programs described in this Section that are included in any report to the other party provided pursuant to this Section, will be calculated utilizing systems, processes, policies, practices, and pricing methodologies that comply with the requirements of such programs.

(vi) Each party shall treat the information received from the other party under this Section as Confidential Information of the other party and agrees that such disclosure is solely for the purpose of enabling such party to comply with its regulatory reporting obligations relating to Governmental Rebate Authority programs. Each party agrees to use commercially reasonable efforts to limit access to such information to employees, officers, or directors of such party responsible for reporting such information to Governmental Rebate Authority programs or who otherwise have a need to know such information.

(d) Additional Matters.

(i) Unless otherwise stated, all payments under this Section will be due thirty (30) calendar days after the date that the party obligated to make such payment receives the invoice for such payment.

(ii) Each party will:

(A) following the Closing Date, maintain accurate books and records related to the performance of its obligations to process Government Rebates (the "Relevant Records") under this Section until such books and records are no longer required to be maintained under Applicable Law;

(B) maintain such Relevant Records in sufficient detail to enable the calculation of the amounts for which reimbursements are required under this Section;

(C) be entitled, once a year, to hire at its own expense the Independent Expert to examine the relevant books and records of the other party for the purpose of verifying the accuracy of the reimbursement calculations under this Section ("Records Review"). Such review will be conducted upon reasonable prior written notice to such other party and the other party will permit the Independent Expert to conduct such Records Review. The Independent Expert shall provide a report regarding the reimbursement calculations and any amounts payable under this Section, and such report will, absent a clear error, be final and binding on the parties. If a Records Review uncovers an overpayment or underpayment has been made under this Section, then the full amount of such overpayment or underpayment will be paid by the party who incorrectly benefited from such underpayment or overpayment; and

(D) reasonably cooperate with the other party in processing Government Rebates and use commercially reasonable efforts to minimize the Government Rebates for which it seeks reimbursement.

Section 10.11. WARN; COBRA.

(a) WARN. Seller and the Seller Group shall have sole liability, if any, and Purchaser shall not have any liability, under WARN with respect to termination of employment of any employees of Seller or any member of the Seller Group, including without limitation any employee of Seller or any member of the Seller Group whose termination occurs on or prior to the Closing Date. Purchaser shall not take action with respect to former employees of Seller or any member of the Seller Group that would result in imposition of WARN liability on Seller or any such member.

(b) COBRA. Seller shall, or shall cause the members of the Seller Group, to take all actions necessary so that a group health plan of Seller, a member of the Seller Group or any of their affiliates continues to provide group health benefits to all employees and former employees of Seller or members of the Seller Group and their "qualified beneficiaries" (within the meaning of Section 4980B of the Code) for a period of time such that neither Purchaser nor any of Purchaser's affiliates has any liability under, or any obligation to comply with the requirements of, Section 4980B of the Code with respect to such individuals for any "qualifying event" that occurs in connection with the Acquisition.

Section 10.12. Customer Letters. It is acknowledged and agreed that one or more of Seller and Purchaser have delivered or intend to deliver a joint instruction letter to Seller's existing customers of the Products and that such letter may contain instructions or other terms that conflict with the terms of this Agreement. Each of the parties agrees that in the event of any such conflict between the terms or instructions set forth in any correspondence by the parties with their customers and this Agreement, as between the parties, the terms of this Agreement shall supersede such correspondence and govern the course of conduct, rights, and obligations of the parties.

Section 10.13. Services. Seller shall use commercially reasonable efforts (a) to retain the services (as employees or consultants) of (i) John Lowry or such other qualified replacement that is agreed to by Purchaser in writing, until March 31, 2020, (ii) Forrest Lamm or such other qualified replacement that is agreed to by Purchaser in writing, until May 31, 2020, and (iii) and Tamara Elder or such other qualified replacement that is agreed to by Purchaser in writing, until the latest Transition End Date for the Transition Product ANDAs, and, in each case, to cause the applicable person in clauses (i), (ii), and (iii) to reasonably cooperate with Purchaser to satisfy Seller's applicable obligations under this Agreement, and (b) upon any such individual in clause (i) no longer being retained, to designate (and promptly notify Purchaser of such designation) an individual or entity (which may be a shareholder of Seller or an affiliate thereof) to reasonably cooperate with Purchaser to satisfy Seller's applicable obligations under this Agreement.

Section 10.14. Further Assurances. Each party agrees (a) to furnish upon request to each other party such further information, (b) to execute and deliver to each other party such other documents and (c) to do such other acts and things, all as another party may reasonably request for the purpose of carrying out the intent of this Agreement and the other Ancillary Agreements and the Acquisition.

ARTICLE XI
MISCELLANEOUS

Section 11.01. Certain Definitions. For all purposes of this Agreement, the following defined terms shall have the following meanings:

(a) "affiliate" of any party means any person or entity controlling, controlled by or under common control with such party.

(b) "Ancillary Agreements" means, collectively, the Transfer Documents, the Escrow Agreement, and the Supply Agreement.

(c) "ANDA" means an Abbreviated New Drug Application (including any amendments and supplements thereto) filed with the FDA in accordance with Section 505(j) of the Federal Food, Drug and Cosmetic Act of 1938, as amended.

(d) "Approved Products" mean each and every generic drug product set forth on Schedule III for which the ANDA under the drug application number set forth on Schedule III has been submitted to and filed by the FDA and for which approval has been given by the FDA to manufacture, package, ship and sell such product in the Territory.

(e) "Articles of Association" means the Third Amended and Restated Articles of Association of Seller.

(f) "business day" means a day, other than a Saturday or a Sunday, on which commercial banks are not required or authorized to close in New York City, New York.

(g) "Claim Notice" means a notice provided by the Indemnified Party to the Indemnifying Party pursuant to Section 8.04(a) or (b).

(h) "Code" means the U.S. Internal Revenue Code of 1986, as amended.

(i) "Contracts" means all written or oral contracts, leases, subleases, licenses, indentures, agreements, commitments and other legally binding instruments.

(j) "Development Products" means each and every generic drug product set forth on Schedule III for which an ANDA has not been filed with the FDA.

(k) "Disclosure Letter" means the disclosure letter in respect of this Agreement delivered by Seller to Purchaser concurrently with the execution and delivery of this Agreement.

(l) "ERISA" means the Employee Retirement Income Security Act of 1974, as amended.

(m) "Escrow Account" means, collectively, the Indemnity Escrow Account, the GDUFA Escrow Account, the Trade Deductions Escrow Account, the Returns Escrow Account, and the Government Rebates Escrow Account.

(n) "Escrow Agent" means Citibank, N.A.

(o) "Escrow Agreement" means the Escrow Agreement, by and among Seller, Purchaser, and the Escrow Agent, in the form attached as Exhibit B hereto.

(p) "Escrow Amounts" means, collectively, the Indemnity Escrow Amount, the GDUFA Escrow Amount, the Trade Deductions Escrow Amount, the Returns Escrow Amount, and the Government Rebates Escrow Amount.

(q) "Excluded Taxes" means, without duplication, the following: (i) Taxes imposed by any Applicable Law on Seller, Seller Group, or any combined, unitary, or consolidated group of which any of the foregoing is or was a member, (ii) Taxes imposed on or with respect to the ownership or operation of the Excluded Assets or Retained Liabilities, (iii) Taxes imposed on or with respect to the acquisition, ownership or operation of the Transferred Assets for any Pre-Closing Tax Period, (iv) withholding Taxes attributable to the Transactions contemplated by this Agreement, (v) Taxes of any Person imposed on Purchaser or any of its affiliates as a transferee or successor, by contract or pursuant to any Law, which Taxes relate to (A) the Transferred Assets, and (B) an event or transaction occurring before the Closing, and (vi) the portion of Transfer Taxes for which Seller is responsible pursuant to Section 9.01(d).

(r) "FDA" means the United States Food and Drug Administration.

(s) "GAAP" means United States generally accepted accounting principles.

(t) "GDUFA Escrow Account" means the "GDUFA Escrow Account" as defined in the Escrow Agreement.

(u) "GDUFA Escrow Amount" means [***].

(v) "GDUFA Fee" means the Generic Drug Applicant Program Fee - small company fee (by definition owning 5 or fewer approved ANDAs) payable by Seller under the Generic Drug User Fee Amendments Act of 2017 (GDUFA II) in respect of the Transition Product ANDAs during the period beginning on October 1, 2020 and ending on September 30, 2021.

(w) "Governmental Rebate Authorities" includes, but is not limited to, (i) the Centers for Medicare and Medicaid Services ("CMS") and the Health Resources and Services Administration ("HRSA"), each within the United States Department of Health and Human Services, or any successor organization or agency, (ii) the Veterans' Administration ("VA") within the United States Department of Defense, or any successor organization or agency, and (iii) state pharmacy assistance programs.

(x) "Government Rebates Escrow Account" means the "Government Rebates Escrow Account" as defined in the Escrow Agreement.

(y) "Government Rebates Escrow Amount" means [***].

(z) "Indemnity Escrow Account" means the "Indemnity Escrow Account" as defined in the Escrow Agreement.

(aa) "Indemnity Escrow Amount" means [***].

(bb) "Intellectual Property Rights" means all issued patents and patent applications, all trademarks, tradenames, business names, and service marks and applications, registrations and renewals with respect thereto and goodwill associated therewith, all domain names and URLs, all copyrights and applications, registrations, and renewals with respect thereto, and all trade secrets, in each case, to the extent protectable under applicable law.

(cc) "Inventory" means all inventories of Seller Group of any Product that, as of the Closing, exists and is not already sold to a third party, including all drug substances, drug product, clinical inventory lots, reference standards, reserve samples, patient samples, inventories of active pharmaceutical ingredients, intermediates, raw materials, components, consumables, work-in- process, finished goods, supplies, parts, labels, and packaging materials (including rights and interests in goods in transit, consigned inventory, inventory sold on approval, and rental inventory).

(dd) "knowledge of Purchaser" means the actual knowledge of the individuals set forth on Schedule IV, after reasonable due inquiry.

(ee) "knowledge of Seller" means the actual knowledge of the individuals set forth on Schedule V, after reasonable due inquiry.

(ff) "Law" means U.S. or foreign statute, law, ordinance, rule or regulation.

(gg) "Liens" means all mortgages, liens, charges, claims, pledges or other encumbrances of any kind.

(hh) "Licensed Products" mean each and every generic and authorized generic drug product set forth on Schedule III for which Seller has rights to manufacture, package, ship and sell such product in the Territory.

(ii) "Marathon Agreement" has the meaning set forth in the Disclosure Letter.

(jj) "Pending Products" means each and every generic drug product set forth on Schedule III for which the ANDA under the drug application number set forth on Schedule III has been submitted to and filed by the FDA, and is pending authorization and approval to manufacture, package, ship and sell such product in the Territory.

(kk) "Permitted Liens" means (i) mechanics', carriers', workmen's, repairmen's or other similar Liens arising or incurred in the ordinary course of business, (ii) Liens arising under original purchase price conditional sales agreements or other similar Contracts entered into in the ordinary course of business, and (iii) Liens for Taxes and other governmental charges that are not due and payable, or that are being contested in good faith through appropriate proceedings.

(ll) "person" means any individual, firm, corporation, partnership, limited liability company, trust, joint venture, Governmental Entity or other entity.

(mm) "Pre-Closing Tax Period" means any taxable period (or portion thereof) ending on or before the Closing Date.

(nn) "Product Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and clinical trial material and information (including adverse drug experience information) owned by and in the possession or control of Seller Group, that is necessary to market, commercialize, distribute, sell, develop and manufacture the Products in accordance with the Transferred Product ANDAs.

(oo) "Product Technology" means all technology, trade secrets, know-how and proprietary information that is necessary to manufacture the Products in accordance with the Transferred Product ANDAs, including processes, specifications, test methods, instructions, master formulas, validation reports, stability data, analytical methods, records of complaints and annual product reviews, owned by and in the possession or control of Seller Group.

(pp) "Products" means, collectively, the Approved Products, the Licensed Products, the Pending Products and the Development Products.

(qq) "Property Taxes" means real, personal and intangible property Taxes.

(rr) "Purchase Price" means (i) the Closing Consideration, *plus* (ii) any Escrow Amounts paid to Seller, *plus* (iii) any Inventory Surplus Amount paid to Seller, *plus* (iv) any Trade Deductions Shortfall Amount paid to Seller, *plus* (v) any Earn-Out Payments paid to Seller.

(ss) "Purchaser FDA Letter" means a letter substantially in the form attached as Exhibit C hereto.

(tt) "Purchaser Fundamental Representations" means each of the following representations and warranties made by Purchaser: Section 4.02 (Authority, Execution and Delivery; Enforceability), Section 4.05 (Availability of Funds) and Section 4.06 (Brokers or Finders).

(uu) "Purchaser Group" means, collectively, Purchaser and Purchaser's subsidiaries.

(vv) "Purchaser Material Adverse Effect" means a change, event or effect that is or is reasonably likely to, individually or in the aggregate, have a material adverse effect on the ability of Purchaser to consummate the transactions contemplated by this Agreement.

(ww) "Reference Product" means, for each Product, the reference listed drug product for such Product.

(xx) "Returns Escrow Account" means the "Returns Escrow Account" as defined in the Escrow Agreement.

(yy) "Returns Escrow Amount" means [***].

(zz) "R&W Policy" means the representations and warranties insurance policy set forth on Exhibit D.

(aaa) "Seller Benefit Plan" means any employee benefit plan subject to Title IV of ERISA that is maintained by Seller or any member of the Seller Group, or with respect to which Seller or any member of the Seller Group contributes or has an obligation to contribute or has any liability.

(bbb) "Seller FDA Letter" means a letter substantially in the form attached as Exhibit E hereto.

(ccc) "Seller Fundamental Representations" means each of the following representations and warranties made by Seller: Section 3.02 (Authority, Execution and Delivery; Enforceability), Section 3.04 (Good and Valid Title), and Section 3.12 (Brokers or Finders).

(ddd) "Seller Group" means, collectively, Seller and Seller Subsidiaries.

(eee) "Seller Material Adverse Effect" means a change, event or effect that is or is reasonably likely to, individually or in the aggregate, have a material adverse effect on (i) on the Transferred Assets, taken as a whole, or (ii) the ability of Seller (or any member of Seller Group) to consummate the transactions contemplated by this Agreement, in either case, other than any effect arising out of, relating to, resulting from or in connection with (A) any change in the United States or foreign economies in general or securities or financial markets in general (to the extent that such change does not have a materially disproportionate effect on the Transferred Assets as compared to other similar assets), (B) any change that affects the generic pharmaceutical industry (to the extent that such change does not have a materially disproportionate effect on the Transferred Assets as compared to other similar assets), (C) any natural disaster or act of nature or any hostility, act of war, sabotage, terrorism, military action or any escalation or worsening thereof, (D) any action taken by Purchaser with respect to the Acquisition, (E) any change in Applicable Law or accounting rules or the interpretation thereof, (F) the failure of the Products to meet any projections (it being understood that the underlying causes of such failure may, if they are not otherwise excluded from the definition of Seller Material Adverse Effect, be taken into account in determining whether a Seller Material Adverse Effect has occurred), (G) the compliance with the terms of, or the taking any action required by, this Agreement or (H) the public announcement of this Agreement and the Ancillary Agreements or the consummation of the transactions contemplated by this Agreement and the Ancillary Agreements.

(fff) "Seller Subsidiaries" means the applicable subsidiaries of Seller who own the Transferred Assets, each of which subsidiaries is listed on Schedule VI.

(ggg) "Straddle Period" means any taxable period beginning on or prior to and ending after the Closing Date.

(hhh) "subsidiary" of any person means another person, an amount of the voting securities, other voting ownership or voting partnership interests of which sufficient to elect at least a majority of its board of directors or other governing body (or, if there are no such voting interests, 50% or more of the equity interests of which) is owned, directly or indirectly, by such first person.

(iii) "Supply Agreement" means the Supply Agreement, by and between Suzhou Amerigen Pharmaceuticals Co., Ltd. and Purchaser in the form attached as Exhibit F hereto.

(jjj) "Tax Return" means any return, declaration, statement, disclosure, report, form, estimate or information return relating to Taxes, including any amendments thereto and any related or supporting information, required or permitted to be filed with any Taxing Authority.

(kkk) "Taxes" means (i) any and all federal, state, local and foreign taxes, assessments and other governmental charges, duties, impositions, levies, customs, tariffs and fees in the nature of a tax, including taxes based upon or measured by gross receipts, income, profits, gain, sales, use and occupation, and value added, ad valorem, transfer, franchise, withholding, payroll, employment, alternative minimum, estimated, stamp, excise and property taxes as well as public imposts, fees and social security charges (including health, unemployment, workers' compensation and pension insurance), together with all interest, penalties and additions imposed with respect to such amounts or such interest, penalties, or additions, and (ii) any liability for the payment of any amounts of the type described in clause (i) as a result of any express or implied obligation to indemnify any other person or as a result of any obligation under any agreement or arrangement to make any payment determined by reference to the Tax liability of a third party.

(lll) "Taxing Authority" means any federal, state, local or foreign government, any subdivision, agency, commission or authority thereof or any quasi-governmental body exercising Tax regulatory authority or otherwise responsible for the imposition, collection or administration of any Tax.

(mmm) "Territory" means the United States.

(nnn) "Trade Deductions" means all chargebacks (including the processing thereof), rebates, per unit rebates, shelf-stock adjustments related to pricing actions taken before the Closing Date, and any other customary deductions that customers take or report in the ordinary course of business after the Closing Date related to sales of Approved Products that occurred prior to or on the Closing Date, in each case as calculated in accordance with the Trade Deductions Principles.

(ooo) "Trade Deductions Escrow Account" means the "Trade Deductions Escrow Account" as defined in the Escrow Agreement.

(ppp) "Trade Deductions Escrow Amount" means [***].

(qqq) "Transfer Documents" means (i) a bill of sale providing for the transfer of the Transferred Assets in substantially the form attached hereto as Exhibit G and (ii) an assignment and assumption agreement for the assumption of the Assumed Liabilities in substantially the form attached hereto as Exhibit H.

(rrr) "Transfer Taxes" means all sales (including bulk sales and VAT), use, transfer, recording, ad valorem, privilege, documentary, gross receipts, registration, conveyance, excise, license, stamp or similar Taxes and fees arising out of, in connection with or attributable to the transactions effectuated pursuant to this Agreement.

(sss) "Transferred Contracts" means the Contracts set forth on Schedule VII-A.

(ttt) "Transferred Current Inventory" means all Inventory exclusively with respect to the Products, in each case, owned by and in the possession or control of Seller Group as of the Closing set forth on Schedule VIII-2.

(uuu) "Transferred Future Inventory" means all Inventory exclusively with respect to the Products, in each case, to be delivered to Seller Group in connection with any open orders set forth on Schedule VIII-3.

(vvv) "Transferred Inventory" means all Transferred Current Inventory and all Transferred Future Inventory. For the avoidance of doubt, Transferred Inventory shall expressly exclude the Excluded Inventory.

(www) "Transferred Product ANDA" means, for each Approved Product and Pending Product, the ANDA under the applicable drug application number on Schedule III.

(xxx) "Transferred Product FDA Materials" means all reports filed with and submissions to, and all other written correspondence with, the FDA primarily related to the Products, in each case, owned by and in the possession or control of Seller Group, including, without limitation, the materials set forth on Schedule VII-B, to the extent necessary to sell and manufacture the Products in accordance with the Transferred Product ANDAs.

(yyy) "Transition Period" means, with respect to the Transition Product ANDAs, the period from the Closing Date until the earlier of (A) September 30, 2021 or (B) the date that all Transition Reference Products obtain marketing approval in China (such end date, the "Transition End Date").

(zzz) "Transition Product ANDA" means, for each Transition Reference Product, the applicable ANDA under the drug application number set forth on Schedule III.

(aaaa) "Transition Reference Products" means, collectively, Miglustat, Nebivolol, and Temozolomide, and each, a "Transition Reference Product."

(bbbb) "US Agent Appointment Letter" means a letter substantially in the form attached as Exhibit I hereto.

(cccc) "WARN" means the Worker Adjustment and Retraining Notification Act of 1988, and any similar state statute.

Section 11.02. Assignment. Neither this Agreement nor any of the rights and obligations of the parties hereunder may be assigned by either party hereto without the prior written consent of the other party hereto, except that (a) Purchaser may assign this Agreement and its rights and obligations hereunder to any successor-in-interest to Purchaser or Purchaser's business by way of merger, acquisition, consolidation or similar transaction, (b) Purchaser may assign its right to purchase the Transferred Assets hereunder to any of its wholly owned subsidiaries or affiliates, without the prior written consent of Seller (so long as Purchaser remains liable for all obligations of Purchaser arising hereunder), (c) Seller may assign this Agreement and its rights and obligations hereunder to any successor-in-interest to Seller or Seller's business by way of merger, acquisition, consolidation or similar transaction and (d) Seller may assign this Agreement and its rights and obligations hereunder to any affiliate so long as Seller remains liable for all obligations of Seller arising hereunder. Subject to the first sentence of this Section 11.02, this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns. Any attempted assignment or transfer in violation of this Section 11.02 shall be void.

Section 11.03. Amendments. This Agreement may be amended, modified, superseded or canceled only by an instrument in writing signed by an officer of each of the parties hereto and any of the representations, warranties, covenants, agreements, conditions or other terms hereof may be waived only by an instrument in writing signed by an officer of the party waiving compliance.

Section 11.04. No Third-Party Beneficiaries. Except as provided in Article VIII, this Agreement is for the sole benefit of the parties hereto and nothing herein expressed or implied shall give or be construed to give to any person, other than the parties hereto, any legal or equitable rights hereunder.

Section 11.05. Expenses. Whether or not the transactions contemplated by this Agreement and the Ancillary Agreements are consummated, except as otherwise expressly provided herein or therein, each of the parties hereto shall be responsible for the payment of its own respective costs and expenses incurred in connection with the negotiations leading up to and the performance of its respective obligations pursuant to this Agreement and the Ancillary Agreements, including the fees of any attorneys, accountants, brokers or advisors employed or retained by or on behalf of such party. Purchaser shall reimburse Seller for any reasonable costs and expenses incurred by Seller in connection with the matters set forth on Schedule XII attached hereto.

Section 11.06. Governing Law. This Agreement and any disputes relating hereto shall be governed and construed in accordance with the laws of the State of New York, without reference to the conflicts of law principles thereunder (other than Section 5-1401 of the General Obligations Law of the State of New York).

Section 11.07. Jurisdiction. Each party irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the courts of the State of New York located in the City of New York for any Proceeding arising out of, under or in connection with this Agreement, the transactions contemplated hereby or any disputes relating hereto (and such party agrees not to commence any such Proceeding except in such courts). Each party further agrees that service of any process, summons, notice or document pursuant to Section 11.10 shall be effective service of process for any such Proceeding brought against such party in any such court. Each party irrevocably and unconditionally waives any objection to the laying of venue of any such Proceeding in the courts of the State of New York located in the City of New York and further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such Proceeding brought in any such court has been brought in an inconvenient forum.

Section 11.08. Waiver of Jury Trial. Each party waives to the fullest extent permitted by Applicable Law, any right it may have to a trial by jury in respect of any Proceeding arising out of, under or in connection with this Agreement, the transactions contemplated hereby or any disputes relating hereto. Each party (a) certifies that no representative, agent or attorney of the other party has represented, expressly or otherwise, that such other party would not, in the event of any Proceeding, seek to enforce the foregoing waiver and (b) acknowledges that it and the other party have been induced to enter into this Agreement by, among other things, the mutual waiver and certifications in this Section 11.08.

Section 11.09. Specific Performance. Each party agrees that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that each party shall be entitled to an injunction or other equitable relief (without the proof of actual damages) to prevent breaches of this Agreement and to enforce specifically the provisions of this Agreement, this being in addition to any other remedy to which such party is entitled at law or in equity. Neither party shall oppose the granting of any such injunction or other equitable relief on the basis that (a) there is an adequate remedy at law or (b) an award of specific performance is not an appropriate remedy for any reason at law or in equity. Each party shall waive any requirement for the posting of any bond or the provision of any other security in connection with any such injunction or other equitable relief. If, prior to the End Date, either party brings any Proceeding to prevent breaches of this Agreement and to enforce specifically the provisions of the Agreement, the End Date shall automatically be extended by such time period established by the court presiding over such Proceeding.

Section 11.10. Notices. All notices, requests, permissions, waivers and other communications hereunder shall be in writing and shall be deemed to have been duly given (a) when received, if sent via overnight delivery via a national courier service or by registered or certified mail, postage prepaid, (b) when sent, if sent by facsimile with automatic confirmation or (c) when delivered, if delivered personally, in each case addressed to the applicable party at the following address for such party:

(a) if to Seller,

Amerigen Pharmaceuticals, Ltd.
c/o Amerigen Pharmaceuticals, Inc.
9 Polito Ave #900
Lyndhurst, NJ 07071
Attention: John Lowry – Chief Executive Officer

with a copy to (which shall not constitute notice):

Wilson Sonsini Goodrich & Rosati
Professional Corporation
12235 El Camino Real
San Diego, California 92103-3002
Attention: Martin Waters and Jason Skolnik
Facsimile: (858) 350-2399

(b) if to Purchaser,

ANI Pharmaceuticals, Inc.
210 W Main St
Baudette, MN 56623
Facsimile: (218) 634-3540
Email:stephen.carey@anipharmaceuticals.com, rob.schrepfer@anipharmaceuticals.com
Attention: Stephen Carey and Rob Schrepfer

with a copy to (which shall not constitute notice):

Orrick, Herrington and Sutcliffe LLP
51 West 52nd Street
New York, NY 10019-6142
Facsimile: (212) 506-5151
Email: kmilling@orrick.com, dschwartz@orrick.com
Attention: R. King Milling and David Schwartz

or to such other address(es) as shall be furnished in writing by any such party to the other party to this Agreement in accordance with the provisions of this Section 11.10.

Section 11.11. Headings; Interpretation.

(a) The descriptive headings of the several Articles and Sections of this Agreement and the Table of Contents to this Agreement are inserted for convenience only, do not constitute a part of this Agreement and shall not affect in any way the meaning or interpretation of this Agreement. All references herein to "Articles", "Sections", "Exhibits" or "Schedules" shall be deemed to be references to Articles or Sections hereof or Exhibits or Schedules hereto unless otherwise indicated.

(b) Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation". The words "hereof", "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The word "will" shall be construed to have the same meaning as the word "shall". The word "extent" in the phrase "to the extent" shall mean the degree to which a subject or thing extends, and such phrase shall not mean simply "if". The word "or" shall not be exclusive. The definitions in this Agreement are applicable to the singular as well as the plural of such terms and to the masculine as well as to the feminine and neuter genders of such terms, and a defined term has its defined meaning throughout this Agreement, regardless of whether it appears before or after the place in this Agreement where it is defined, including in any Schedule or Exhibit. Unless otherwise specifically indicated, references to any Contract or statute are to such Contract or statute as from time to time amended, modified or supplemented, including (in the case of Contracts) by waiver or consent and (in the case of statutes) by succession of comparable successor statutes. All references to "dollars" and "$" shall be deemed to be references to the lawful money of the United States.

Section 11.12. Counterparts. This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same agreement, and shall become effective when one or more counterparts have been signed by each of the parties hereto and delivered, in person or by facsimile or electronic image scan, receipt acknowledged in each case, to the other party to this Agreement.

Section 11.13. Integrated Contract, Schedules, Exhibits and Disclosure Letter.

(a) This Agreement (including any Schedules and Exhibits hereto), the Disclosure Letter, the Confidentiality Agreement and the Ancillary Agreements (including the schedules and exhibits thereto) constitute the entire agreement between the parties with respect to the subject matter hereof and thereof and supersede any previous agreements and understandings between the parties with respect to such matters. Any term used in any Schedule or Exhibit or the Disclosure Letter but not defined therein shall have the meaning assigned to it in this Agreement.

(b) The items contained in the Disclosure Letter are intended to qualify the representations, warranties, covenants and agreements of Seller contained in this Agreement and shall not be construed to broaden in any way the scope or effect of any such representations, warranties, covenants or agreements. The items contained in the Disclosure Letter are qualified in their entirety by reference to the specific provisions of this Agreement and are not intended to constitute, and shall not be construed as constituting, any representation, warranty, covenant or agreement of Seller. Any item contained in a particular section or subsection of the Disclosure Letter shall be deemed to be an exception to, response to or disclosure for purposes of (in each case, as applicable) (i) the representations, warranties, covenants and agreements of Seller that are contained in the corresponding Section or subsection of this Agreement and (ii) any other representations, warranties, covenants and agreements of Seller that are contained in this Agreement to the extent the relevance of such item as an exception to, response to or disclosure for purposes of (in each case, as applicable) such other representations, warranties, covenants and agreements is reasonably apparent on its face. Inclusion of an item in the Disclosure Letter shall not be deemed or construed (A) as an admission that such item represents a material fact, event or circumstance or a material exception to, response to or disclosure for purposes of (in each case, as applicable) a representation, warranty, covenant or agreement of Seller or that such item would reasonably be expected to have a Seller Material Adverse Effect or (B) to establish any standard of materiality or Seller Material Adverse Effect. No item in the Disclosure Letter relating to any possible breach or violation of any Contract, Applicable Law or Judgment shall be construed as an admission or indication that any such breach or violation exists, has occurred, is likely to occur or is possible to occur. Nothing in the Disclosure Letter shall be deemed by any person to be (1) an admission of liability of any person (including any member of Seller Group), (2) an admission of the existence of an obligation of any person (including any member of Seller Group) to any other person or (3) an admission against the interests of any person (including any member of Seller Group). Items reflected in the Disclosure Letter are not necessarily limited to items required by this Agreement to be reflected in the Disclosure Letter. Such additional items are set forth in the Disclosure Letter for information purposes and do not necessarily include other items of a similar nature. In disclosing the items in the Disclosure Letter, no member of Seller Group waives any attorney-client or attorney work product privilege or a similar privilege. The items contained in the Disclosure Letter are in all events subject to the Confidentiality Agreement.

Section 11.14. Severability; Enforcement. The invalidity of any portion of this Agreement shall not affect the validity, force or effect of the remaining portions hereof. If it is ever held that any restriction hereunder is too broad to permit enforcement of such restriction to its fullest extent, each party agrees that a court of competent jurisdiction may enforce such restriction to the maximum extent permitted by Applicable Law, and each party hereby consents and agrees that such scope may be judicially modified accordingly in any Proceeding brought to enforce such restriction.

Section 11.15. Mutual Drafting. The parties hereto are sophisticated and have been represented by counsel who have carefully negotiated the provisions hereof. As a consequence, the parties do not intend that the presumptions of any laws or other rules relating to the interpretation of contracts against the drafter of any particular clause should be applied to this Agreement and therefore waive their effects.

Section 11.16. Time of Essence. Time is of the essence with regard to all dates and time periods set forth or referred to in this Agreement.

[*Remainder of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, Seller and Purchaser have duly executed this Agreement as of the date first written above.

AMERIGEN PHARMACEUTICALS LTD.

By: /s/ John Walter Lowry III
Name: John Walter Lowry III
Title: Chief Executive Officer

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen Carey
Name: Stephen Carey
Title: Vice President & Chief Financial Officer

Exhibit 10.25

RESTRICTED STOCK GRANT AGREEMENT

THIS RESTRICTED STOCK GRANT AGREEMENT (this "**Agreement**") is entered into as of [●], by and between ANI Pharmaceuticals, Inc., a Delaware corporation (the "**Company**") and [●] ("**Recipient**"). The parties hereby agree as follows:

1. GRANT OF SHARES. The Company hereby grants to Recipient [●] ([●]) shares (the "**Shares**") of the Company's Common Stock, $0.0001 par value. Upon the Recipient's execution of this Agreement (or as soon thereafter as practicable), the Company shall deliver a certificate or certificates in Recipient's name representing the Shares to Recipient. Each certificate issued pursuant to this Section 1 shall bear the legends described in Section 9 below and shall be held by the Company for the Recipient. The Recipient agrees to sign and deliver to the Company a stock power, in the form attached hereto as Exhibit A, relating to the Shares. Upon vesting of any of the Shares hereunder in accordance with Section 3(b) below, the Company shall cancel the stock power with respect to such vested Shares and the Company shall return the certificate representing the Shares to its transfer agent and direct the transfer agent to deliver a certificate to (i) the Recipient for the number of Shares then vested and (ii) the Company for the number of Shares that remain subject to the Repurchase Option (as defined below).

2. GRANT OF SHARES. The grant of Shares contemplated hereby is made pursuant to the Company's Fifth Amended and Restated 2008 Stock Incentive Plan (the "**Plan**"), which Plan is incorporated herein by reference. This Agreement constitutes a "Restricted Stock Award" within the meaning of the Plan. Capitalized terms used herein and not otherwise defined have the meanings set forth in the Plan.

3. REPURCHASE OPTION.

(a) Upon the termination of Recipient's employment with the Company and all Subsidiaries for any reason (including, subject to Section 3(b), as a result of Recipient's death or disability), the Company or its assignee shall have an irrevocable option (the "**Repurchase Option**") to repurchase any and all unvested Shares from Recipient, at a price of $0.01 per share (the "**Option Price**"), as more particularly set forth in this Section 3; provided, however, that if such termination is (i) by the Company or any Subsidiary for any reason other than "cause" (as defined in the Recipient's employment agreement with the Company) or (ii) by the Recipient for "good reason" (as defined in such Recipient's employment agreement with the Company), then all of the Shares shall be deemed to be vested and not subject to the Repurchase Option.

(b) On the first anniversary of the date hereof 25% of the Shares shall vest and be released from the Repurchase Option, on the second anniversary of the date hereof an additional 25% of the Shares shall vest and be released from the Repurchase Option, on the third anniversary of the date hereof an additional 25% of the Shares shall vest and be released from the Repurchase Option and on the fourth anniversary of the date hereof all of the remaining Shares shall vest and be released from the Repurchase Option (each such anniversary of the date hereof, a "**Vesting Date**"); provided, however, that (i) if a Change in Control (as defined in the Plan) of the Company occurs, all the Shares shall immediately vest and be released from the Repurchase Option and (ii) upon the termination of Recipient's employment with the Company and all Subsidiaries as a result of the Recipient's death or disability, any Shares scheduled to vest on the first Vesting Date following such termination shall immediately vest and be released from the Repurchase Option.

(c) The Repurchase Option shall be exercised by written notice signed by an officer of the Company or by any assignee or assignees of the Company and delivered in accordance with Section 13(a). Such notice shall identify the number of Shares to be purchased and shall notify Recipient of the time, place and date for settlement of such purchase. The Company shall be entitled to pay for any Shares purchased pursuant to its Repurchase Option at the Company's option in cash or by offset against any indebtedness owing to the Company by Recipient, or by a combination of both. Upon delivery of such notice and payment of the purchase price in any of the ways described above, the Company shall become the legal and beneficial owner of the Shares being repurchased and all rights and interest therein or related thereto, and the Company shall have the right to transfer to its own name the Shares being repurchased by the Company, without further action by Recipient.

4. **Adjustments to the Shares**. If, from time to time, during the term of the Repurchase Option there is any change affecting the Company's outstanding Common Stock as a class that is effected without the receipt of consideration by the Company (through merger, consolidation, reorganization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, change in corporation structure or other transaction not involving the receipt of consideration by the Company), then any and all new, substituted or additional securities or other property to which Recipient is entitled by reason of Recipient's ownership of the Shares shall be immediately subject to the Repurchase Option and be included in the word "Shares" for all purposes of the Repurchase Option with the same force and effect as the Shares presently subject to the Repurchase Option, but only to the extent the Shares are covered, at the time, by such Repurchase Option. While the total Option Price shall remain the same after each such event, the Option Price per share of the Shares upon exercise of the Repurchase Option shall be appropriately adjusted.

5. **Breach of Consulting, Confidentiality or Non-Compete Agreements.** Notwithstanding anything in this Agreement to the contrary and in addition to the rights of the Committee under Section 12.4 of the Plan, in the event that the Recipient materially breaches the terms of any employment, consulting, confidentiality or non-compete agreement entered into with the Company or any Subsidiary (including an employment, consulting, confidentiality or non-compete agreement made in connection with the grant of the Shares), whether such breach occurs before or after termination of the Recipient's employment with the Company or any Subsidiary, the Committee in its sole discretion may require the Recipient to surrender shares of Common Stock received, and to disgorge any profits (however defined by the Committee), made or realized by the Recipient in connection with this Agreement or the Shares granted hereunder.

6. **Termination of Repurchase Option**. Sections 3 and 4 of this Agreement shall terminate upon the exercise in full or expiration of the Repurchase Option, whichever occurs first.

7. **Rights of Recipient**. Subject to the provisions of this Agreement, Recipient (but not any unapproved transferee) shall, during the term of this Agreement, exercise all rights and privileges of a stockholder of the Company with respect to the Shares. Recipient shall be deemed to be the holder for purposes of receiving any dividends that may be paid with respect to such Shares and for the purpose of exercising any voting rights relating to such Shares, even if some or all of such Shares have not yet vested and been released from the Repurchase Option.

8. **Limitations on Transfer**. In addition to any other limitation on transfer created by applicable securities laws, Recipient shall not assign, hypothecate, donate, encumber or otherwise dispose of any interest in any of the Shares that remain subject to the Repurchase Option. After the Shares have been released from the Repurchase Option, Recipient shall not assign, hypothecate, donate, encumber or otherwise dispose of any interest in such Shares unless and until:

(a) There is then in effect a registration statement under the Securities Act of 1933, as amended (the "**Act**"), covering such proposed disposition and such disposition is made in accordance with said registration statement; or

(b) Recipient shall have notified the Company of the proposed disposition and shall have furnished the Company with a detailed statement of the circumstances surrounding the proposed disposition, and, if requested by the Company, the Recipient shall have furnished the Company with an opinion of his own counsel, reasonably acceptable to the Company, to the effect that such disposition will not require registration of such shares under the Act.

9. **Restrictive Legends**. All certificates representing Shares that have not yet been released from the Repurchase Option shall have endorsed thereon a legend in substantially the following form:

> **"The shares represented by this certificate are subject to a repurchase option set forth in an agreement between the Company and the registered holder, or such holder's predecessor in interest, a copy of which is on file at the principal office of the Company. Any transfer or attempted transfer of any shares subject to such repurchase option is void without the prior express written consent of the Company."**

10. **Section 83(b) Election**. Recipient understands that Section 83(a) of the Internal Revenue Code of 1986, as amended (the "**Code**"), taxes as ordinary income the difference between the amount paid for the Shares and the fair market value of the Shares as of the date any restrictions on the Shares lapse. In this context, "restriction" includes the right of the Company to buy back the Shares pursuant to the Repurchase Option set forth in Section 3(a) above. Recipient understands that Recipient may elect to be taxed at the time the Shares are awarded, rather than when and as the Repurchase Option expires, by filing an election under Section 83(b) of the Code (an "**83(b) Election**") with the Internal Revenue Service within thirty (30) days from the date of purchase. A copy of the 83(b) Election form is attached hereto as Exhibit B. Even if the fair market value of the Shares at the time of the execution of this Agreement equals the amount paid for the Shares, the 83(b) Election must be made to avoid income under Section 83(a) in the future. Recipient understands that failure to file such an 83(b) Election in a timely manner may result in adverse tax consequences for Recipient. Recipient further understands that an additional copy of such 83(b) Election is required to be filed with his or her federal income tax return for the calendar year in which the date of this Agreement falls. **Recipient further acknowledges and understands that it is Recipient's sole obligation and responsibility to timely file such 83(b) Election, and neither the Company nor the Company's legal or financial advisors shall have any obligation or responsibility with respect to such filing.** Recipient acknowledges that the foregoing is only a summary of the effect of United States federal income taxation with respect to purchase of the Shares hereunder, and does not purport to be complete. Recipient further acknowledges that the Company has directed Recipient to seek independent advice regarding the applicable provisions of the Code, the income tax laws of any municipality, state or foreign country in which Recipient may reside, and the tax consequences of Recipient's death. Recipient assumes all responsibility for filing an 83(b) Election and paying all taxes resulting from such election or the lapse of the restrictions on the Shares.

11. **Refusal to Transfer**. The Company or its transfer agent shall not be required (a) to transfer on its books any Shares that shall have been transferred in violation of any of the provisions set forth in this Agreement or (b) to treat as owner of such shares or to accord the right to vote as such owner or to pay dividends to any transferee to whom such Shares shall have been so transferred.

12. **No Employment Rights**. This Agreement is not an employment contract and nothing in this Agreement shall affect in any manner whatsoever the right or power of the Company (or any parent or subsidiary of the Company) to terminate Recipient's relationship with the Company for any reason at any time, with or without cause and with or without notice.

13. **Miscellaneous.**

(a) **Notices.** Any notice or other communication required or permitted to be delivered to any party under this Agreement shall be in writing and shall be deemed properly delivered, given and received when delivered (by hand, by registered mail, or by courier or express delivery service) to the address or facsimile number set forth beneath the name of such party on the signature page hereto (or to such other address or facsimile number as such party shall have specified in a written notice given to the other parties hereto).

(b) **Successors and Assigns.** This Agreement shall bind and inure to the benefit of the successors and assigns of the Company and, subject to the restrictions on transfer herein set forth, inure to the benefit of and be binding upon Recipient and Recipient's heirs, executors, administrators, successors, and assigns. Without limiting the generality of the foregoing, the Repurchase Option of the Company hereunder shall be assignable by the Company at any time or from time to time, in whole or in part.

(c) **Attorneys' Fees; Specific Performance.** It is the intention of the parties that the Company, upon exercise of the Repurchase Option and payment of the Option Price, pursuant to the terms of this Agreement, shall be entitled to receive the Shares, in specie, in order to have such Shares available for future issuance without dilution of the holdings of other shareholders. Furthermore, it is expressly agreed between the parties that money damages are inadequate to compensate for the Shares and that (i) the Company shall, upon proper exercise of the Repurchase Option, be entitled to specific enforcement of its rights to purchase and receive said Shares, and (ii) Recipient shall, upon release of any of the Shares from the Repurchase Option, be entitled to specific enforcement of its rights to receive said Shares.

(d) **Governing Law.** This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware.

(e) **Further Assurances.** The parties agree to execute all such further instruments and to take all such further action as may reasonably be necessary to carry out the intent of this Agreement.

(f) **Amendment.** This Agreement may not be amended, modified or revoked, in whole or in part, except by an agreement in writing signed by each of the parties hereto.

(g) **Severability.** In the event that any provision of this Agreement, or the application of any such provision to any person or set of circumstances, shall be determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, shall not be impaired or otherwise affected and shall continue to be valid and enforceable to the fullest extent permitted by law.

(h) **Counterparts.** This Agreement may be executed in two or more counterparts and signature pages may be delivered via facsimile, each of which shall be deemed an original and all of which together shall constitute one instrument.

In Witness Whereof, the parties hereto have executed this Agreement as of the date first above written.

Company: **ANI PHARMACEUTICALS, INC.**

By: _____

Name:

Title:

Recipient: _____

Name:

Address: _____

_____

SIGNATURE PAGE TO RESTRICTED STOCK GRANT AGREEMENT

EXHIBIT A

STOCK POWER

FOR VALUE RECEIVED and pursuant to that certain Restricted Stock Grant Agreement between ANI Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and _____ (the "Recipient") dated as of March 28, 2019, and the Company's Fifth Amended and Restated 2008 Stock Incentive Plan (the "Plan"), the Recipient hereby sells, assigns and transfers to the Company, an aggregate _____ shares of Common Stock of the Company, standing in the Recipient's name on the books of the Company and represented by stock certificate number(s) _____ to which this instrument is attached, and hereby irrevocably constitutes and appoints _____ as his or her attorney in fact and agent to transfer such shares on the books of the Corporation, with full power of substitution in the premises.

Dated _____, 2019

_____
Signature

_____
Print Name

(Instruction: Please do not fill in any blanks other than the signature line. The purpose of the assignment is to enable the Company to exercise certain rights set forth in the Restricted Stock Grant Agreement and the Plan without requiring additional signatures on the part of the Recipient.)

Exhibit 10.26

FORM OF INCENTIVE STOCK OPTION AGREEMENT[1]

THIS INCENTIVE STOCK OPTION AGREEMENT is entered into and effective as of this day of _____, 20___ ("Date of Grant"), by and between ANI Pharmaceuticals, Inc. (the "Company") and (the "Optionee").

A. The Company has adopted the ANI Pharmaceuticals, Inc. Fourth Amended and Restated 2008 Stock Incentive Plan (the "Plan") authorizing the Board of Directors (the "Board") of the Company, or a committee as provided for in the Plan (the Board or such a committee to be referred to as the "Committee"), to grant incentive stock options to employees of the Company and its Subsidiaries (as defined in the Plan).

B. The Company desires to give the Optionee an inducement to acquire a proprietary interest in the Company and an added incentive to advance the interests of the Company by granting to the Optionee an option to purchase shares of common stock of the Company pursuant to the Plan.

Accordingly, the parties agree as follows:

1. Grant of Option.

The Company hereby grants to the Optionee the right, privilege, and option (the "Option") to purchase ( ) shares (the "Option Shares") of the Company's common stock, $0.0001 par value (the "Common Stock"), according to the terms and subject to the conditions hereinafter set forth and as set forth in the Plan. Subject to Section 9 of this Agreement, the Option is intended to be an "incentive stock option," as that term is used in Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").

2. Option Exercise Price.

The per share price to be paid by Optionee in the event of an exercise of the Option will be $, which represents 100% of the Fair Market Value of a share of Common Stock on the Date of Grant, as determined in accordance with the Plan.

3. Duration of Option and Time of Exercise.

3.1 Initial Period of Exercisability. The Option will become exercisable with respect to the Option Shares [immediately/in installments]. [The following table sets forth the initial dates of exercisability of each installment and the number of Option Shares as to which this Option will become exercisable on such dates:

Exercisability	**Available for Exercise**

[The foregoing rights to exercise this Option will be cumulative with respect to the Option Shares becoming exercisable on each such date.] In no event will this Option be exercisable after, and this Option will become void and expire as to all unexercised Option Shares at 5:00 p.m. Central time on (the "Time of Termination").

3.2 Termination of Employment.

(a) Termination Due to Death, Disability or Retirement. In the event the Optionee's employment with the Company and all Subsidiaries is terminated by reason of death, Disability or Retirement, this Option will remain exercisable, to the extent exercisable as of the date of such termination, for a period of one year after such termination (but in no event after the Time of Termination).

[1] Only to be used for Named Executive Officers party to an Executive Employment Agreement

(b) Termination for Reasons Other Than Death, Disability or Retirement. In the event that the Optionee's employment with the Company and all Subsidiaries is terminated for any reason other than death, Disability or Retirement, or the Optionee is in the employ of a Subsidiary and the Subsidiary ceases to be a Subsidiary of the Company (unless the Optionee continues in the employ of the Company or another Subsidiary), all rights of the Optionee under the Plan and this Agreement will immediately terminate without notice of any kind, and this Option will no longer be exercisable; provided, however, that if such termination is (a) by the Company or any Subsidiary for any reason other than "cause" (as defined in the Optionee's employment agreement with the Company) or (b) by the Optionee for "good reason" (as defined in such Optionee's employment agreement with the Company), then this Option will become immediately exercisable in full and remain exercisable through the Time of Termination.

(c) Breach of Employment, Consulting, Confidentiality or Non-Compete Agreements. Notwithstanding anything in this Agreement to the contrary and in addition to the rights of the Committee under Section 12.4 of the Plan, in the event that the Optionee materially breaches the terms of any employment, consulting, confidentiality or non-compete agreement entered into with the Company or any Subsidiary (including an employment, consulting, confidentiality or non-compete agreement made in connection with the grant of the Option), whether such breach occurs before or after termination of the Optionee's employment with the Company or any Subsidiary, the Committee in its sole discretion may require the Optionee to surrender shares of Common Stock received, and to disgorge any profits (however defined by the Committee), made or realized by the Optionee in connection with this Option or any shares issued upon the exercise or vesting of this Option.

3.3 Change in Control. If a Change in Control (as defined in the Plan) of the Company occurs, this Option will become immediately exercisable in full and will remain exercisable until the Time of Termination. In addition, if a Change in Control of the Company occurs, the Committee, in its sole discretion and without the consent of the Optionee, may determine that the Optionee will receive, with respect to some or all of the Option Shares, as of the effective date of any such Change in Control of the Company, cash in an amount equal to the excess of the Fair Market Value (as defined in the Plan) of such Option Shares immediately prior to the effective date of such Change in Control of the Company over the option exercise price per share of this Option (or, in the event that there is no excess, that this Option will be terminated.

4. Manner of Option Exercise.

4.1 Notice. This Option may be exercised by the Optionee in whole or in part from time to time, subject to the conditions contained in the Plan and in this Agreement, by delivery, in person, by facsimile or electronic transmission or through the mail, to the Company at its principal executive office in Baudette, Minnesota, of a written notice of exercise. Such notice must be in a form satisfactory to the Committee, must identify the Option, must specify the number of Option Shares with respect to which the Option is being exercised, and must be signed by the person or persons so exercising the Option.

Except as otherwise provided in Section 4.2 below, such notice must be accompanied by payment in full of the total purchase price of the Option Shares purchased. In the event that the Option is being exercised, as provided by the Plan and Section 3.2 above, by any person or persons other than the Optionee, the notice must be accompanied by appropriate proof of right of such person or persons to exercise the Option. As soon as practicable after the effective exercise of the Option, the Optionee will be recorded on the stock transfer books of the Company as the owner of the Option Shares purchased, and the Company will deliver to the Optionee certificated or uncertificated ("book entry") shares. In the event that the Option is being exercised, as provided by resolutions of the Committee and Section 4.2 below, by tender of a Broker Exercise Notice, the Company will deliver such shares directly to the Optionee's broker or dealer or their nominee.

4.2 Payment.

(a) At the time of exercise of this Option, the Optionee must pay the total purchase price of the Option Shares to be purchased entirely in cash (including check, bank draft or money order); provided, however, that the Committee, in its sole discretion and upon terms and conditions established by the Committee, may allow such payments to be made, in whole or in part, by (i) tender of a Broker Exercise Notice; (ii) by tender, or attestation as to ownership, of Previously Acquired Shares that are acceptable to the Committee; (iii) by a "net exercise" of the Option (as described below); or (iv) by a combination of such methods.

(b) In the event the Optionee is permitted to pay the total purchase price of this Option in whole or in part with Previously Acquired Shares, the value of such shares will be equal to their Fair Market Value on the date of exercise of this Option.

(c) In the case of a "net exercise" of an Option, the Company will not require a payment of the exercise price of the Option from the Optionee but will reduce the number of shares of Common Stock issued upon the exercise by the largest number of whole shares that has a Fair Market Value on the exercise date that does not exceed the aggregate exercise price for the shares exercised under this method.

(d) Shares of Common Stock will no longer be issuable under this Option (and this Option will therefore not thereafter be exercisable) following the exercise of such Option to the extent of (i) shares used to pay the exercise price of an Option under the "net exercise," (ii) shares actually delivered to the Optionee as a result of such exercise and (iii) any shares withheld for purposes of tax withholding.

5. Rights of Optionee; Transferability.

5.1 Employment. Nothing in this Agreement will interfere with or limit in any way the right of the Company or any Subsidiary to terminate the employment of the Optionee at any time, nor confer upon the Optionee any right to continue in the employ of the Company or any Subsidiary at any particular position or rate of pay or for any particular period of time.

5.2 Rights as a Stockholder. The Optionee will have no rights as a stockholder of the Company unless and until all conditions to the effective exercise of this Option (including, without limitation, the conditions set forth in Sections 4 and 6 of this Agreement) have been satisfied and the Optionee has become the holder of record of such shares. No adjustment will be made for dividends or distributions with respect to this Option as to which there is a record date preceding the date the Optionee becomes the holder of record of such shares, except as may otherwise be provided in the Plan or determined by the Committee in its sole discretion.

5.3 Restrictions on Transfer. Except pursuant to testamentary will or the laws of descent and distribution or as otherwise expressly permitted by the Plan, no right or interest of the Optionee in this Option prior to exercise may be assigned or transferred, or subjected to any lien, during the lifetime of the Optionee, either voluntarily or involuntarily, directly or indirectly, by operation of law or otherwise. The Optionee will, however, be entitled to designate a beneficiary to receive this Option upon such Optionee's death, and, in the event of the Optionee's death, exercise of this Option (to the extent permitted pursuant to Section 3.2(a) of this Agreement) may be made by the Optionee's legal representatives, heirs and legatees.

6. Withholding Taxes.

The Company is entitled to (a) withhold and deduct from future wages of the Optionee (or from other amounts that may be due and owing to the Optionee from the Company or a Subsidiary), or make other arrangements for the collection of, all amounts the Company reasonably determines are necessary to satisfy any and all federal, foreign, state and local withholding and employment-related tax requirements attributable to the Option, including, without limitation, the grant, exercise or vesting of, this Option or a disqualifying disposition of any Option Shares; (b) withhold cash paid or payable or shares of Common Stock from the shares issued or otherwise issuable to the Optionee in connection with this Option; or (c) require the Optionee promptly to remit the amount of such withholding to the Company before taking any action, including issuing any shares of Common Stock, with respect to this Option. Shares of Common Stock issued or otherwise issuable to the Optionee in connection with this Option that gives rise to the tax withholding obligation that are withheld for purposes of satisfying the Optionee's withholding or employment-related tax obligation will be valued at their Fair Market Value on the Tax Date.

7. Adjustments.

In the event of any reorganization, merger, consolidation, recapitalization, liquidation, reclassification, stock dividend, stock split, combination of shares, rights offering, divestiture or extraordinary dividend (including a spin-off), or any other similar change in the corporate structure or shares of the Company, the Committee (or, if the Company is not the surviving corporation in any such transaction, the board of directors of the surviving corporation), in order to prevent dilution or enlargement of the rights of the Optionee, will make appropriate adjustment (which determination will be conclusive) as to the number and kind of securities or other property (including cash) subject to, and the exercise price of, this Option.

8. Stock Subject to Plan.

The Option and the Option Shares granted and issued pursuant to this Agreement have been granted and issued under, and are subject to the terms of, the Plan. The terms of the Plan are incorporated by reference in this Agreement in their entirety, and the Optionee, by execution of this Agreement, acknowledges having received a copy of the Plan. The provisions of this Agreement will be interpreted as to be consistent with the Plan, and any ambiguities in this Agreement will be interpreted by reference to the Plan. In the event that any provision of this Agreement is inconsistent with the terms of the Plan, the terms of the Plan will prevail.

9. Incentive Stock Option Limitations.

9.1 Limitation on Amount. To the extent that the aggregate Fair Market Value (determined as of the date of grant) of the shares of Common Stock with respect to which incentive stock options (within the meaning of Section 422 of the Code) are exercisable for the first time by the Optionee during any calendar year (under the Plan and any other incentive stock option plans of the Company or any subsidiary or parent corporation of the Company (within the meaning of the Code)) exceeds $100,000 (or such other amount as may be prescribed by the Code from time to time), such excess incentive stock options will be treated as non-statutory stock options in the manner set forth in the Plan.

9.2 Limitation on Exercisability; Disposition of Option Shares. Any incentive stock option that remains unexercised more than one year following termination of employment by reason of death or disability or more than three months following termination for any reason other than death or disability will thereafter be deemed to be a non-statutory stock option. In addition, in the event that a disposition (as defined in Section 424(c) of the Code) of shares of Common Stock acquired pursuant to the exercise of an incentive stock option occurs prior to the expiration of two years after its date of grant or the expiration of one year after its date of exercise (a “disqualifying disposition”), such incentive stock option will, to the extent of such disqualifying disposition, be treated in a manner similar to a non-statutory stock option.

9.3 No Representation or Warranty. Section 422 of the Code and the rules and regulations thereunder are complex, and neither the Plan nor this Agreement purports to summarize or otherwise set forth all of the conditions that need to be satisfied in order for this Option to qualify as an incentive stock option. In addition, this Option may contain terms and conditions that allow for exercise of this Option beyond the periods permitted by Section 422 of the Code, including, without limitation, the periods described in Section 9.2 of this Agreement. Accordingly, the Company makes no representation or warranty regarding whether the exercise of this Option will qualify as the exercise of an incentive stock option, and the Company recommends that the Optionee consult with the Optionee’s own advisors before making any determination regarding the exercise of this Option or the sale of the Option Shares.

10. Miscellaneous.

10.1 Binding Effect. This Agreement will be binding upon the heirs, executors, administrators and successors of the parties to this Agreement.

10.2 Governing Law. This Agreement and all rights and obligations under this Agreement will be construed in accordance with the Plan and governed by the laws of the State of Delaware, without regard to conflicts of laws provisions. Any legal proceeding related to this Agreement will be brought in an appropriate Delaware court and the parties to this Agreement consent to the exclusive jurisdiction of the court for this purpose.

10.3 Entire Agreement. This Agreement and the Plan set forth the entire agreement and understanding of the parties to this Agreement with respect to the grant and exercise of this Option and the administration of the Plan and supersede all prior agreements, arrangements, plans and understandings relating to the grant and exercise of this Option and the administration of the Plan.

10.4 Amendment and Waiver. Other than as provided in the Plan, this Agreement may be amended, waived, modified or canceled only by a written instrument executed by the parties to this Agreement or, in the case of a waiver, by the party waiving compliance.

10.5 Construction. Wherever possible, each provision of this Agreement will be interpreted so that it is valid under the applicable law. If any provision of this Agreement is to any extent invalid under the applicable law, that provision will still be effective to the extent it remains valid. The remainder of this Agreement also will continue to be valid, and the entire Agreement will continue to be valid in other jurisdictions.

10.6 Counterparts. For convenience of the parties hereto, this Agreement may be executed in any number of counterparts, each such counterpart to be deemed an original instrument, and all such counterparts together to constitute the same agreement.

[Remainder of page intentionally left blank]

The parties to this Agreement have executed this Agreement effective the day and year first above written.

ANI PHARMACEUTICALS, INC.

By _____

Its _____

By execution of this Agreement, the Optionee acknowledges having received a copy of the Plan.

OPTIONEE

_____
(Signature)

_____
(Name and Address)

_____

_____

Exhibit 10.27

FORM OF NON-STATUTORY STOCK OPTION AGREEMENT[1]

THIS NON-STATUTORY STOCK OPTION AGREEMENT is entered into and effective as of this _____ day of _____, 20__ (the "**Date of Grant**"), by and between ANI Pharmaceuticals, Inc., formerly known as BioSante Pharmaceuticals, Inc. (the "**Company**") and _____ (the "**Optionee**").

A. The Company has adopted the BioSante Pharmaceuticals, Inc. Third Amended and Restated 2008 Stock Incentive Plan (the "**Plan**") authorizing the Board of Directors (the "**Board**") of the Company, or a committee as provided for in the Plan (the Board or such a committee to be referred to as the "**Committee**"), to grant non-statutory stock options to employees (including, without limitation, officers and directors who are also employees) of the Company or any Subsidiary, and any non-employee directors, consultants, advisors and independent contractors of the Company or any Subsidiary (as defined in the Plan).

B. The Company desires to give the Optionee an inducement to acquire a proprietary interest in the Company and an added incentive to advance the interests of the Company by granting to the Optionee an option to purchase shares of common stock of the Company pursuant to the Plan.

Accordingly, the parties agree as follows:

1. Grant of Option.

The Company hereby grants to the Optionee the right, privilege, and option (the "**Option**") to purchase _____ (_____) shares (the "**Option Shares**") of the Company's common stock, $0.0001 par value (the "**Common Stock**"), according to the terms and subject to the conditions hereinafter set forth and as set forth in the Plan. The Option is not intended to be an "incentive stock option," as that term is used in Section 422 of the Internal Revenue Code of 1986, as amended (the "**Code**").

2. Option Exercise Price.

The per share price to be paid by Optionee in the event of an exercise of the Option will be $_____, which represents 100% of the Fair Market Value of a share of Common Stock on the Date of Grant, as determined in accordance with the Plan.

3. Duration of Option and Time of Exercise.

3.1 Initial Period of Exercisability. The Option will become exercisable with respect to the Option Shares [immediately/in _____ installments]. [The following table sets forth the initial dates of exercisability of each installment and the number of Option Shares as to which this Option will become exercisable on such dates:

Exercisability	Available for Exercise
_____	_____
_____	_____
_____	_____
_____	_____

[The foregoing rights to exercise this Option will be cumulative with respect to the Option Shares becoming exercisable on each such date.] In no event will this Option be exercisable after, and this Option will become void and expire as to all unexercised Option Shares at 5:00 p.m. Lincolnshire, Illinois time on _____ (the "**Time of Termination**").

[1] Only to be used for Named Executive Officers party to an Executive Employment Agreement

3.2 Termination of Employment or Other Service.

(a) Termination Due to Death, Disability or Retirement. In the event the Optionee's employment or other service with the Company and all Subsidiaries is terminated by reason of death, Disability or Retirement, this Option will remain exercisable, to the extent exercisable as of the date of such termination, for a period of one year after such termination (but in no event after the Time of Termination).

(b) Termination for Reasons Other Than Death, Disability or Retirement. In the event that the Optionee's employment or other service with the Company and all Subsidiaries is terminated for any reason other than death, Disability or Retirement, or the Optionee is in the employ of or performs services to a Subsidiary and the Subsidiary ceases to be a Subsidiary of the Company (unless the Optionee continues in the employ of or performs services to the Company or another Subsidiary), all rights of the Optionee under the Plan and this Agreement will immediately terminate without notice of any kind, and this Option will no longer be exercisable; provided, however, that if such termination is (a) by the Company or any Subsidiary for any reason other than "cause" (as defined in the Optionee's employment agreement with the Company) or (b) by the Optionee for "good reason" (as defined in such Optionee's employment agreement with the Company), then this Option will become immediately exercisable in full and remain exercisable through the Time of Termination.

(c) Breach of Employment, Consulting, Confidentiality or Non-Compete Agreements. Notwithstanding anything in this Agreement to the contrary and in addition to the rights of the Committee under Section 12.4 of the Plan, in the event that the Optionee materially breaches the terms of any employment, consulting, confidentiality or non-compete agreement entered into with the Company or any Subsidiary (including an employment, consulting, confidentiality or non-compete agreement made in connection with the grant of the Option), whether such breach occurs before or after termination of the Optionee's employment or other service with the Company or any Subsidiary, the Committee in its sole discretion may require the Optionee to surrender shares of Common Stock received, and to disgorge any profits (however defined by the Committee), made or realized by the Optionee in connection with this Option or any shares issued upon the exercise or vesting of this Option.

3.3 Change in Control. If a Change in Control (as defined in the Plan) of the Company occurs, this Option will become immediately exercisable in full and will remain exercisable until the Time of Termination. In addition, if a Change in Control of the Company occurs, the Committee, in its sole discretion and without the consent of the Optionee, may determine that the Optionee will receive, with respect to some or all of the Option Shares, as of the effective date of any such Change in Control of the Company, cash in an amount equal to the excess of the Fair Market Value (as defined in the Plan) of such Option Shares immediately prior to the effective date of such Change in Control of the Company over the option exercise price per share of this Option (or, in the event that there is no excess, that this Option will be terminated).

4. Manner of Option Exercise.

4.1 Notice. This Option may be exercised by the Optionee in whole or in part from time to time, subject to the conditions contained in the Plan and in this Agreement, by delivery, in person, by facsimile or electronic transmission or through the mail, to the Company at its principal executive office in Lincolnshire, Illinois, of a written notice of exercise. Such notice must be in a form satisfactory to the Committee, must identify the Option, must specify the number of Option Shares with respect to which the Option is being exercised, and must be signed by the person or persons so exercising the Option. Such notice must be accompanied by payment in full of the total purchase price of the Option Shares purchased. In the event that the Option is being exercised, as provided by the Plan and Section 3.2 above, by any person or persons other than the Optionee, the notice must be accompanied by appropriate proof of right of such person or persons to exercise the Option. As soon as practicable after the effective exercise of the Option, the Optionee will be recorded on the stock transfer books of the Company as the owner of the Option Shares purchased, and the Company will deliver to the Optionee certificated or uncertificated ("book entry") shares. In the event that the Option is being exercised, as provided by resolutions of the Committee and Section 4.2 below, by tender of a Broker Exercise Notice, the Company will deliver such shares directly to the Optionee's broker or dealer or their nominee.

4.2 Payment.

(a) At the time of exercise of this Option, the Optionee must pay the total purchase price of the Option Shares to be purchased entirely in cash (including check, bank draft or money order); provided, however, that the Committee, in its sole discretion and upon terms and conditions established by the Committee, may allow such payments to be made, in whole or in part, by (i) tender of a Broker Exercise Notice; (ii) by tender, or attestation as to ownership, of Previously Acquired Shares that are acceptable to the Committee; (iii) by a "net exercise" of the Option (as described below); or (iv) by a combination of such methods.

(b) In the event the Optionee is permitted to pay the total purchase price of this Option in whole or in part with Previously Acquired Shares, the value of such shares will be equal to their Fair Market Value on the date of exercise of this Option.

(c) In the case of a "net exercise" of an Option, the Company will not require a payment of the exercise price of the Option from the Optionee but will reduce the number of shares of Common Stock issued upon the exercise by the largest number of whole shares that has a Fair Market Value on the exercise date that does not exceed the aggregate exercise price for the shares exercised under this method.

(d) Shares of Common Stock will no longer be outstanding under this Option (and will therefore not thereafter be exercisable) following the exercise of such Option to the extent of (i) shares used to pay the exercise price of an Option under the "net exercise," (ii) shares actually delivered to the Optionee as a result of such exercise and (iii) any shares withheld for purposes of tax withholding.

5. Rights of Optionee; Transferability.

5.1 Employment or Service. Nothing in this Agreement will interfere with or limit in any way the right of the Company or any Subsidiary to terminate the employment or service of the Optionee at any time, nor confer upon the Optionee any right to continue in the employ of or provide services to the Company or any Subsidiary at any particular position or rate of pay or for any particular period of time.

5.2 Rights as a Stockholder. The Optionee will have no rights as a stockholder of the Company unless and until all conditions to the effective exercise of this Option (including, without limitation, the conditions set forth in Sections 4 and 6 of this Agreement) have been satisfied and the Optionee has become the holder of record of such shares. No adjustment will be made for dividends or distributions with respect to this Option as to which there is a record date preceding the date the Optionee becomes the holder of record of such shares, except as may otherwise be provided in the Plan or determined by the Committee in its sole discretion.

5.3 Restrictions on Transfer. Except pursuant to testamentary will or the laws of descent and distribution or as otherwise expressly permitted by the Plan, no right or interest of the Optionee in this Option prior to exercise may be assigned or transferred, or subjected to any lien, during the lifetime of the Optionee, either voluntarily or involuntarily, directly or indirectly, by operation of law or otherwise. The Optionee will, however, be entitled to designate a beneficiary to receive this Option upon such Optionee's death, and, in the event of the Optionee's death, exercise of this Option (to the extent permitted pursuant to Section 3.2(a) of this Agreement) may be made by the Optionee's legal representatives, heirs and legatees.

6. Withholding Taxes.

The Company is entitled to (a) withhold and deduct from future wages of the Optionee (or from other amounts that may be due and owing to the Optionee from the Company or a Subsidiary), or make other arrangements for the collection of, all amounts the Company reasonably determines are necessary to satisfy any and all federal, foreign, state and local withholding and employment-related tax requirements attributable to the Option, including, without limitation, the grant, exercise or vesting of, this Option or a disqualifying disposition of any Option Shares; (b) withhold cash paid or payable or shares of Common Stock from the shares issued or otherwise issuable to the Optionee in connection with this Option; or (c) require the Optionee promptly to remit the amount of such withholding to the Company before taking any action, including issuing any shares of Common Stock, with respect to this Option. Shares of Common Stock issued or otherwise issuable to the Optionee in connection with this Option that gives rise to the tax withholding obligation that are withheld for purposes of satisfying the Optionee's withholding or employment-related tax obligation will be valued at their Fair Market Value on the Tax Date.

7. Adjustments.

In the event of any reorganization, merger, consolidation, recapitalization, liquidation, reclassification, stock dividend, stock split, combination of shares, rights offering, divestiture or extraordinary dividend (including a spin-off), or any other similar change in the corporate structure or shares of the Company, the Committee (or, if the Company is not the surviving corporation in any such transaction, the board of directors of the surviving corporation), in order to prevent dilution or enlargement of the rights of the Optionee, will make appropriate adjustment (which determination will be conclusive) as to the number and kind of securities or other property (including cash) subject to, and the exercise price of, this Option.

8. Stock Subject to Plan.

The Option and the Option Shares granted and issued pursuant to this Agreement have been granted and issued under, and are subject to the terms of, the Plan. The terms of the Plan are incorporated by reference in this Agreement in their entirety, and the Optionee, by execution of this Agreement, acknowledges having received a copy of the Plan. The provisions of this Agreement will be interpreted as to be consistent with the Plan, and any ambiguities in this Agreement will be interpreted by reference to the Plan. In the event that any provision of this Agreement is inconsistent with the terms of the Plan, the terms of the Plan will prevail.

9. Miscellaneous.

9.1 Binding Effect. This Agreement will be binding upon the heirs, executors, administrators and successors of the parties to this Agreement.

9.2 Governing Law. This Agreement and all rights and obligations under this Agreement will be construed in accordance with the Plan and governed by the laws of the State of Illinois, without regard to conflicts of laws provisions. Any legal proceeding related to this Agreement will be brought in an appropriate Illinois court, and the parties to this Agreement consent to the exclusive jurisdiction of the court for this purpose.

9.3 Entire Agreement. This Agreement and the Plan set forth the entire agreement and understanding of the parties to this Agreement with respect to the grant and exercise of this Option and the administration of the Plan and supersede all prior agreements, arrangements, plans and understandings relating to the grant and exercise of this Option and the administration of the Plan.

9.4 Amendment and Waiver. Other than as provided in the Plan, this Agreement may be amended, waived, modified or canceled only by a written instrument executed by the parties to this Agreement or, in the case of a waiver, by the party waiving compliance.

9.5 Construction. Wherever possible, each provision of this Agreement will be interpreted so that it is valid under the applicable law. If any provision of this Agreement is to any extent invalid under the applicable law, that provision will still be effective to the extent it remains valid. The remainder of this Agreement also will continue to be valid, and the entire Agreement will continue to be valid in other jurisdictions.

9.6 Counterparts. For convenience of the parties hereto, this Agreement may be executed in any number of counterparts, each such counterpart to be deemed an original instrument, and all such counterparts together to constitute the same agreement.

[*Remainder of page intentionally left blank*]

The parties to this Agreement have executed this Agreement effective the day and year first above written.

ANI PHARMACEUTICALS, INC.

By _____

Its _____

By execution of this Agreement,

_____

OPTIONEE

the Optionee acknowledges having received a copy of the Plan.

_____

(Signature)

_____

(Name and Address)

Exhibit 21

ANI PHARMACUTICALS, INC.

The following is a list of subsidiaries of ANI Pharmaceuticals, Inc., omitting subsidiaries which, considered in the aggregate as a single subsidiary, would not constitute a significant subsidiary, as of December 31, 2019:

Name	**Jurisdiction of Incorporation or Organization**
ANIP Acquisition Company	Delaware
ANI Pharmaceuticals Canada Inc.	Canada

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of ANI Pharmaceuticals, Inc. on Form S-3 (No. 333-218671) and on Form S-8 (Nos. 333-196518, 333-214416, and 333-218120) of our reports dated February 27, 2020, on our audits of the consolidated financial statements as of December 31, 2019 and 2018 and for each of the years in the three-year period ended December 31, 2019, and the effectiveness of ANI Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2019, which reports are included in this Annual Report on Form 10-K to be filed on or about February 27, 2020.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, New Jersey
February 27, 2020

Exhibit 31.1

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

I, Arthur S. Przybyl, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 27, 2020

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

Exhibit 31.2

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

I, Stephen P. Carey, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: February 27, 2020

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of ANI Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2019 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

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

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

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

Dated: February 27, 2020

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

Dated: February 27, 2020

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

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