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# 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, 2020**

☐ **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<br>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, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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 the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the 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, 2020 was $316.1 million (based upon the last reported sale price of $32.34 per share on June 30, 2020, on The Nasdaq Global Market).

As of March 4, 2021, 12,354,398 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 2021 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, 2020**

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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.

**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, the announcement and pendency of the acquisition of Novitium Pharma LLC ("Novitium"), statements about future operations, strategies and growth potential, the revenue potential (licensing, royalty and sales) of products we sell, development timelines, expected timeframe for submission of new drug applications or supplemental new drug applications to the U.S. Food and Drug Administration (the "FDA"), pipeline or potential markets for our products, expected pre-launch charges for Cortrophin, impact of accounting principles, litigation expenses, liquidity and capital resources, the impact of the novel coronavirus ("COVID-19") global pandemic on our business, 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. Such forward-looking statements are based on the reasonable beliefs of our management as well as assumptions made by and information currently available to our management. Readers should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in our periodic reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including those discussed in the "Risk Factors" section in Part I, Item 1A.of this Annual Report on Form 10-K, and the following factors:*

- *the ability of the parties to complete the announced acquisition of Novitium or any delay in the completion of the acquisition;*
- *risks that we may face with respect to importing raw materials;*
- *delays or failure in obtaining approvals by the FDA of the products we sell;*
- *changes in policy or actions that may be taken by the FDA and other regulatory agencies, including drug recalls;*
- *the ability of our manufacturing partners to meet our product demands and timelines;*

- *our dependence on single source suppliers of ingredients due to the time and cost to validate a second source of supply;*
- *acceptance of our products at levels that will allow us to achieve profitability;*
- *our ability to develop, license or acquire, and commercialize new products;*
- *the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products;*
- *our ability to protect our intellectual property rights;*
- *the impact of legislative or regulatory reform on the pricing for pharmaceutical products;*
- *the impact of any litigation to which we are, or may become a party;*
- *our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries;*
- *our ability to maintain the services of our key executives and other personnel; and*
- *general business and economic conditions and the effects and duration of outbreaks of public health emergencies, such as COVID-19.*

**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, oncology products (anti-cancer), 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.

Through product launches, acquisitions of Abbreviated New Drug Applications (“ANDAs”), New Drug Applications (“NDAs”), product rights, and entry into agreements to obtain the distribution rights for various products, we have a commercial portfolio of 65 products as of December 31, 2020. In addition, in January 2016, we acquired the Cortrophin gel and Cortrophin-Zinc NDAs. We continue to focus on the re-commercialization of these products while increasing our portfolio of generic and mature brand products.

On August 6, 2018, our subsidiary, ANI Pharmaceuticals Canada Inc. (“ANI Canada”), acquired all the issued and outstanding equity interests of WellSpring Pharma Services Inc. (“WellSpring”), a Canadian company that performs contract development and manufacturing of pharmaceutical products. 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.

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.

#### Strategy

Our objective is to build a sustainable and growing biopharmaceutical company serving patients in need and creating long-term value for our investors. Our growth strategy is driven by the following key pillars:

***Building a successful Cortrophin Gel franchise.***

We acquired the NDAs for Cortrophin gel and Cortrophin-Zinc in January 2016; executed long-term supply agreements with a supplier of our primary raw material for corticotrophin active pharmaceutical ingredient (“API”), a supplier of corticotrophin API with whom we have advanced the manufacture of commercial scale batches of API, and a Cortrophin gel fill/finish contract manufacturer. In April 2020, the FDA issued a Refusal to File (“RTF”) letter for our Supplemental New Drug Application (“sNDA”) for Cortrophin Gel. Currently, our efforts are focused on the preparation of a complete resubmission of sNDA. We have retained a prominent regulatory consulting firm to support our efforts and augment the capabilities of our restructured internal Cortrophin development team. Together, we have performed a comprehensive review of the original sNDA filing and prepared an internal gap assessment and execution plan to address these gaps. Throughout, we have remained engaged with the FDA and plan to re-submit our supplemental NDA in the second quarter of 2021.

We have invested in leadership and expertise in the areas of commercialization of rare disease therapies to develop a launch strategy and commercial plan for this product.

***Strengthening our generics business with enhanced research and development capability and increased focus on niche opportunities***

We have grown our generics business through a combination of market share gains on existing products and new product launches. We have also successfully acquired numerous ANDAs through asset acquisitions, including, most recently, the U.S. portfolio of 23 generic products, including 10 commercial products at the time of the acquisition, from Amerigen Pharmaceuticals, Ltd. We also focus on niche lower competition opportunities such as injectables and Paragraph IV filings. Additionally, we will seek opportunities to enhance our research and development capabilities through strategic partnerships and acquisitions of businesses.

***Maximizing the value from our established brands through innovative "go-to-market" ("GTM") strategies and continued programmatic acquisitions***

We have acquired the NDAs for and market Atacand, Atacand HCT, Arimidex, Casodex, Lithobid, Vancocin, Inderal LA, Inderal XL, and InnoPran XL. We are innovating in our GTM strategy through creative partnerships. In addition, we will continue to explore opportunities in acquiring new brands to grow our established brands portfolio.

***Expansion of contract development and manufacturing organization ("CDMO") business by leveraging our unique manufacturing capabilities***

We built a CDMO business through our sites in Baudette and grew it through the acquisition of WellSpring Pharma Services Inc. ("ANI Canada"). Our North America based manufacturing and unique capabilities in high-potency, hormonal, steroid, and oncolytic products can be leveraged to expand our CDMO business.

The pillars of our strategy will be enabled by an empowered, collaborative, and purposeful team with high performance-orientation. We will also retain our continued programmatic approach to inorganic growth initiatives.

***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. Below are the principal criteria we consider.

- ***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 continue 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.

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.

**Products and Markets**

***Products***

A complete list of our generic and branded pharmaceutical products and descriptions is posted on our website, www.anipharmaceuticals.com.

***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, oncology products, hormones and steroids, injectables, and complex formulations, including extended release and combination products.

*Controlled Substances*

Schedule II controlled substances are drugs considered to have a high abuse risk but that also have safe and accepted medical uses. In addition to our four Schedule II products currently on the market, our pipeline includes two ANDAs in this market. 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.

*Oncology Products*

Due to the capabilities of our containment facility and our expertise in manufacturing segregation, we are focused on developing and manufacturing niche oncology products (anti-cancer). 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 five oncology 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 a long-accepted medical treatment for alleviating the symptoms of menopause. 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 boomer" population, of which women represent a majority, is expected to support continued growth in the HT market.

*Injectables*

Our burgeoning injectable portfolio contains five injectable ANDA products encompassing several key therapeutic areas. Additionally, Cortrophin Gel would be our first branded injectable product if we obtained approval for this product. We work with world-class manufacturing partners to support these efforts.

*Complex Formulations*

In addition to our 18 complex formulation products currently on the market, our pipeline includes 10 extended-release products and seven 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.

In conjunction with our acquisition of WellSpring Pharma Services Inc., we acquired WellSpring's pharmaceutical manufacturing facility. 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 selectively choose suppliers 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. In addition, certain of our products are manufactured, packaged, or manufactured and packaged by third parties.

**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.

In April 2020, the FDA issued an RTF letter for our sNDA for Cortrophin Gel. Since this time, our efforts have been focused on the preparation of a complete resubmission of the sNDA. We immediately retained a prominent regulatory consulting firm to support our efforts and augment the capabilities of our internal Cortrophin development team. In addition, we restructured the composition of the internal team. We have performed a comprehensive review of the original sNDA filing and prepared an internal gap assessment and execution plan to address these gaps. The resultant remediation activities are currently in-progress.

***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.

*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.

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"). Certain of our products contain significant components that are classified as controlled substances. 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. See **"Risk Factors —** ***We are entirely dependent on periodic approval by the 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."***

***Unapproved Products***

Two of our products, EEMT and Opium Tincture, are marketed without approved NDAs or ANDAs. Previously, the U.S. Food and Drug Administrations ("FDA's") Unapproved Drug Initiative included publication of their policy with respect to the continued marketing of unapproved products in the September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA had stated that it would follow a risk-based approach with regard to enforcement against marketing of unapproved products. The guideline allowed the FDA to evaluate whether to initiate enforcement action on a case-by-case basis, while giving higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. In November 2020 (effective December 2020), the Department of Health and Human Services ("HHS") published a notice in the Federal Register to terminate the FDA's Unapproved Drug Initiative, which would include the withdrawal of this September 2011 Compliance Policy Guide. Neither the HHS nor the FDA has provided any additional guidance, notice or statement regarding how they intend to approach enforcement against

marketing of unapproved products. We continue to believe that, so long as we comply with applicable manufacturing standards, the FDA will continue to operate on a risk-based approach and will not take action against us. However, we can offer no assurance that the FDA will continue to follow this approach or that it will not take a contrary position with any individual product or group of products. During the years ended December 31, 2020, 2019, and 2018, revenues for EEMT were 7%, 9%, and 11% of total revenue, respectively, and revenues from Opium Tincture were 1% of total revenue. See **"Risk Factors –** ***Two of our products, which together comprised 8% of our total revenue in 2020, are marketed without approved NDAs or ANDAs and we can offer no assurances that the 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."***

***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 has negatively impacted our business. 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. The ACA created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Under the Medicare Coverage Gap Discount Program, 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, Terbutaline, and Vancomycin products, while marketed as "generics," are marketed under approved NDAs and, therefore, are subject to the discount requirement.

Since its enactment, there have been judicial, administrative, executive and Congressional legislative challenges to certain aspects of the ACA. For example, the ACA is currently subject to a broad legal challenge in California vs. Azar before the U.S. Supreme Court. Additionally, in November 2020, the U.S. Supreme Court heard argument in Texas v. Azar, which challenges the constitutionality of the ACA. Were the Supreme Court to invalidate the ACA, that could have far-reaching consequences of an uncertain nature for our industry. However, the Biden administration and Democratically-controlled Congress are expected to take significant action to mitigate any ruling against the Affordable

Care Act. Further, the administration and Congress are expected to take steps towards expanding health care coverage beyond the ACA, which could have ramifications for the pharmaceutical industry.

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.

There has also been recent heightened federal governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the last Presidential administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

**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, which 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, and 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 2020, we recorded $1.4 million of royalties related to the license of these patent rights. See 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 for further information.

**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, 2020, approximately 74% of our net revenues were attributable to three wholesalers: AmerisourceBergen Corporation 31%, McKesson Corporation 24%, and Cardinal Health, Inc. 19%. For the years ended December 31, 2019 and 2018, McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Corporation, together accounted for approximately 80% and 81% 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.

Over the past several years, the pharmaceutical industry has experienced significant consolidation, particularly in distribution channels and among 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, which results in pricing pressure on our business and can result in a shift in sales to our competitors.

In addition, consolidation among 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 market their products more effectively to potential customers.

Our sales can also 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.

**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.

**Human Capital**

As of January 2021, we have 369 employees, of which 250 are located in the United States and another 119 are located in Canada. We occasionally use a small number of part-time and consultant resources to meet our operational

needs and are generally not impacted by significant turnover year-to-year. We are committed to creating a diverse and inclusive work environment within all levels of the business.

Attracting and retaining talented employees is critical to the success of our business, especially at our manufacturing operations in Baudette, Minnesota, which is located in a sparsely populated area of Northern Minnesota, with a population of less than 5,000. As a result, it can be challenging to find sufficiently qualified personnel in all functional areas. To address this, we support remote working arrangements for a number of employees in several functions throughout the business, including at the executive level. Additionally, our compensation plans are designed to be competitive within the pharmaceuticals industry as well as competitive with local employers for jobs of a cross-industry nature. Our approach provides ANI with the resources to recognize and reward employee performance, productivity, and quality commitment. Our total compensation program includes competitive base salaries, comprehensive benefits, and employee equity programs.

Our U.S. and Canada facilities are committed to the safety and health of our employees, patient-customers and the general public. It is critical within our mission to ensure we keep our employees and customers safe while accomplishing our business goals. We accomplish these initiatives through the following:

*Health and Safety Management and Training*

ANI has established a health and safety program with a focus on continuous improvement and employee engagement. ANI personnel are encouraged to take corrective actions where appropriate and to communicate concerns to management with a “see something, say something” approach. We recognize and reward personnel for contributing to the safety system within our working environment. The overall program continually evolves to reflect regulatory changes and compliance standard industry best practices. As part of onboarding new employees, we provide health and safety training and periodic training programs to maintain and improve employee awareness of safety issues. The goal of the safety training programs is to ensure that our staff are well informed on the subject matters and have the appropriate tools to make sound health and safety decisions in our day-to-day operations.

*Environmental Stewardship*

ANI is committed to minimizing waste and emissions, promoting reuse and recycling and conserving resources, where feasible, to reduce our environmental footprint on our environment.

*COVID-19 Actions*

Our U.S. and Canada facilities quickly responded to the COVID-19 pandemic by establishing a COVID-19 action plan to protect the health and safety of our employees as they performed their duties, as all of our facilities have remained open during the pandemic. Measures include social distancing requirements, increased and expanded sanitation for both employees and our property, face covering requirements for employees and visitors, staggered work schedules to minimize contact, flexible and work-from-home schedules, and employee illness and exposure protocols. These measures also seek to comply with all county, state, province, and/or city mandates as they relate to COVID-19. Please refer to Part I, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this Annual Report on Form 10-K for further discussion.

**Item 1A. Risk Factors**

**Risk Factor Summary**

Investing in our common stock involves a high degree of risk. You should carefully consider all information in this Annual Report on Form 10-K prior to investing in our common stock. These risks are discussed more fully in the section titled "Risk Factors." These risks and uncertainties include, but are not limited to, the following:

- The conditions under the merger agreement relating to our announced acquisition of Novitium Pharma LLC ("Novitium") may not be satisfied at all or in the anticipated timeframe.
- The uncertain impact that novel coronavirus ("COVID-19") will have on our business and results of operations;
- The continuing trend toward consolidation of customer groups that could result in declines in the sales volume and prices of our products, and increased fees charged by customers;
- The FDA does not provide guidance on safety labeling for products that are marketed without approved NDAs or ANDAs, which could increase our potential liability with respect to failure-to-warn claims for these products;
- If the Drug Enforcement Administration ("DEA") does not approve supply of the API we need to manufacture our controlled substances, we may be unable to manufacture controlled substances, which would eliminate our revenue on these products.
- Pharmaceutical product quality standards are steadily increasing on all products, and if we cannot meet these standards, we may be required to discontinue marketing and/or recall products from the market;
- Federal and state false claims litigation brought against us by private individuals and the government could result in civil and criminal penalties, damages, fines and other related actions;
- The use of legal, regulatory, and legislative strategies by competitors could result in increased costs to develop and market our products, delay new product introductions and reduce profit potential;
- Third-party payer actions may prevent us from effectively marketing our products or cause us to decrease pricing;
- Continuing studies of our products could produce results that could have a negative impact on our business;
- Healthcare reform legislation could have a material adverse effect on our business, financial position, and operating results;
- Barriers in achieving anticipated revenue growth and profitability could have a material adverse effect on our business, financial position, and operating results;
- In January 2016, we acquired two New Drug Applications ("NDAs") for $75.0 million and a percentage of future net sales of products under the NDAs. We have incurred substantial expense and may be unable to obtain FDA approval, successfully market and commercialize the product;
- The limited number of suppliers for our API could result in lengthy delays in production if we need to change suppliers;
- Several of the products we have acquired cannot be manufactured in our facilities and we must secure and maintain qualified and compliant contract manufacturers. Noncompliance by these contract manufacturers or our inability to find qualified contract manufacturers could result in us being unable to commercialize these products; Several of our products are manufactured and/or packaged by third parties, which we cannot control and could result in us being unable to market and distribute products;

- Future acquisitions and investments could disrupt our business and harm our 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;
- Our accruals for the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions;
- We face vigorous competition from other pharmaceutical manufacturers that threatens the commercial acceptance and pricing of our products;
- Our approved products may not achieve commercialization at levels of market acceptance that allow us to achieve profitability;
- We expect to spend a significant amount of resources on research and development efforts, and such efforts may not result in marketable products;
- Production at any or all of our three manufacturing facilities could be interrupted, which could cause us to fail to deliver product on a timely basis;
- We rely on third parties to assist with our clinical studies. If these parties do not perform or are non-compliant, it could negatively impact the clinical trial and potential of regulatory approval; Further, we may be required to audit or redo previously completed trials or recall already-approved commercial products;
- Inability to protect our intellectual property in the U.S. and foreign countries could negatively affect sales of our branded products;
- We have very limited staffing and are dependent upon key employees, the loss of whom could adversely affect our operations;
- We rely significantly on information technology and any failure, inadequacy, interruption, or security lapse of that technology could harm our ability to operate the business effectively;
- We are involved in and 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;
- We are susceptible to product liability claims that may not be covered by insurance, which, if successful, could require us to pay substantial sums;
- Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce revenues in future fiscal periods;
- Making interest and principal payments under our Senior Secured Credit Facility will continue to require a significant amount of cash;
- Financial and restrictive covenants on our secured term loan (“Term Loan”), senior secured revolving credit facility (the “Revolver”), and delayed draw term loan (“DDTL”). If we are non-compliant, we will be in default, which could result in the acceleration of our outstanding indebtedness; and
- 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.

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 Business**

***Our proposed acquisition of Novitium Pharma LLC may not be completed or the closing of the acquisition may be delayed, and if completed, we may not realize any or all of the anticipated benefits of the acquisition or within the timeframe we anticipate.***

As previously announced, on March 8, 2021, ANI entered into an Agreement and Plan of Merger (the "Merger Agreement") with Nile Merger Sub LLC, a Delaware limited liability company and our wholly-owned subsidiary ("Merger Sub"), Novitium, and certain other parties under which Merger Sub will merge with and into Novitium, with Novitium surviving the merger as a wholly owned subsidiary of ANI. While we expect to complete the proposed transaction in the second half of 2021, the proposed merger is subject to a number of conditions that must be satisfied in order for the transaction to be consummated, including, among others, the approval by our stockholders of the issuance of shares of our common stock in connection with the merger, and the closing of the new equity and debt arrangements related to the acquisition.

We cannot guarantee that the acquisition will be consummated on the terms or timeline currently contemplated or at all. Any delay in completing the acquisition could diminish the anticipated benefits of the acquisition and result in additional transaction costs, and failure to complete the acquisition could adversely impact the market price of our stock as well as our business and operating results.

If completed, the success of the Novitium acquisition will depend, in part, on our ability to successfully combine and integrate Novitium into our businesses and realize the anticipated benefits from the transaction. If we are unable to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits may not be realized fully or at all, or may take longer to realize than expected.

If the acquisition is not completed for any reason, including as a result of our shareholders declining to approve the issuance of shares of our common stock in connection with the merger, our ongoing business may be adversely affected and, without realizing any of the benefits of having completed the merger, we would be subject to a number of risks, including the following:

- we may experience negative reactions from the financial markets, including negative impacts on our stock price;
- we may experience negative reactions from our customers, vendors and employees;
- we will have incurred substantial expenses and will be required to pay certain costs relating to the acquisition, whether or not the acquisition is completed; and
- we will have spent substantial commitment of time and resources by management on matters relating to the acquisition, which would otherwise have been devoted to day-to-day operations and other opportunities that may have been beneficial to us.

***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 future 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 research and development expenses with respect to approval of sNDA of Cortrophin Gel. We have

made significant progress, including validation of drug substance and drug product manufacturing processes and initiation of manufacturing of commercial batches to prepare for a future product launch. We continue to press forward with the resubmission process and have developed a detailed plan for the completion of all activities related to the remediation efforts. Our internal team has been consolidated to ensure the appropriate expertise and headcount have been dedicated to this effort. Our team is working closely with prominent consultants in the industry and have remained engaged with the FDA throughout to ensure this submission meets current FDA expectations. However, in the instance where we may be unable to commercialize the products this could have a material adverse effect on our future 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. We may experience lengthy delays if we need to change an API supplier, which could have a material impact on business and results of operations.***

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 10% of our inventory from one supplier during the year ended December 31, 2020. We purchased approximately 13% of our inventory from one supplier during the years ended December 31, 2019 and 2018. 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. 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. 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 and are manufactured and/or packaged by third parties, which we cannot control. 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.

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 have and may continue to grow our business 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;
- difficulties relating to integrating the acquired business;
- 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.

***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 face vigorous competition from other pharmaceutical manufacturers that may adversely impact 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 which require us to reimburse the customer for the difference between our contract price and the price the customer was forced to pay to procure the substitute product in the event we failed to deliver the requested quantity within a specified period of time. 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 are currently involved in and may from time to time become involved in legal proceedings, some of which may result in substantial losses, government enforcement actions, damage to our business and reputation, and place a strain on our internal resources.***

We are currently involved in and in the future may become involved in legal proceedings in the ordinary course of our business, , 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. For a description of legal proceedings which are currently pending, 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.

***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.

**Risks Related to our Industry**

***The COVID-19 pandemic has resulted in significant financial market volatility, and its impact on the global economy and our operations remains uncertain. A continuation or worsening of the pandemic could have a material adverse impact on our business, results of operations and financial condition and on the market price of our common stock.***

On March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States and Canada, imposed unprecedented restrictions on travel, and there were business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. Significant uncertainty remains as to the continued potential impact of the COVID-19 pandemic on our operations and on the global economy as a whole.

Demand for the products we sell was negatively impacted by COVID-19 during the year ended December 31, 2020, and most significantly during the three month period ended June 30, 2020, as fewer patients visited physicians for conditions treated by our products, fewer elective surgeries occurred and visits to pharmacies declined due to government-mandated "shelter-in-place" orders and closures of or restrictions placed on visits to medical offices and facilities. This situation could continue or worsen depending on the duration and severity of the COVID-19 pandemic, the level of success in implementing mitigation measures, such as vaccines, the length of time it takes for normal economic and operating conditions to resume, additional governmental actions that may be taken and/or extensions of time for restrictions that been imposed to date, and numerous other uncertainties.

While many of government-mandated "shelter-in-place" or similar orders have elapsed or become less restrictive, it is possible future similar orders could be reinstituted due to uncertainty regarding the virus that causes COVID-19, including the emergence of new strains, which could negatively impact in future product sales.

It is currently not possible to predict how long the pandemic will last, whether "shelter-in-place" orders will be reinstituted, the availability of vaccines to the general population or the time that it will take for economic activity to return to pre-pandemic levels. The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, our pharmaceutical supply chain, our business, results of operations and financial condition, and the market price of our common stock.

***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 34%, 24%, and 19% of net revenues, respectively, during the year ended December 31, 2020. As of December 31, 2020, accounts receivable from these three customers was approximately 81% of our 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 8% of our total revenue in 2020, are marketed without approved 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.

Previously, the FDA's Unapproved Drug Initiative included publication of their policy with respect to the continued marketing of unapproved products in the September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA had stated that it would follow a risk-based approach with regard to enforcement against marketing of unapproved products. The guideline allowed the FDA to evaluate whether to initiate enforcement action on a case-by-case basis, while giving higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of

effectiveness. In November 2020 (effective December 2020), the Department of Health and Human Services ("HHS") published a notice in the Federal Register to terminate the FDA's Unapproved Drug Initiative, which would include the withdrawal of this September 2011 Compliance Policy Guide. Neither the HHS nor the FDA has provided any additional guidance, notice or statement regarding how they intend to approach enforcement against marketing of unapproved products.

We continue to believe that, so long as we comply with applicable manufacturing standards, the FDA will continue to operate on a risk-based approach and will not take action against us. However, we can offer no assurance that the FDA will continue to follow this approach or that it will 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 estrogen-androgen products. The hearing relates to the FDA's intent to reclassify certain estrogen-androgen combination drugs as lacking substantial evidence of their effectiveness for the treatment of moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone.

If the FDA were to move away from the risk-based approach to enforcement against marketing of unapproved products, 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.

***Imported 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 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 procurement quota in order to purchase the amount of API needed to manufacture our Schedule II controlled substances. Without approved procurement 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. In 2018, the DEA decreased quotas approved for Schedule II opioid painkillers. The DEA continues to closely monitor quotas of certain opioids and as a result there may be a reduction from what was requested; however, firms may file an application for a quota adjustment at any time during the calendar year. If the DEA does not approve our requested procurement 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, periodic guidance from the FDA regarding testing for impurities, such as nitrosamine, in our products, 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. In addition, results of periodic testing we conduct on our products may indicate the presence of substances at levels above which are acceptable under FDA or other standards, which will require a recall of the product. For example, 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 a nitrosamine impurity called N-nitrosdimethylamine ("NDMA") above acceptable thresholds. NDMA is classified as a probable human carcinogen. Appco Pharma, LLC, with whom we had partnered to develop and market the product, initiated a voluntary recall, and we elected to exit the market for Ranitidine in 2019. In July 2020, we were served with a complaint brought by the Office of the Attorney General of the State of New Mexico against manufacturers and sellers of ranitidine products. The complaint asserts a public nuisance claim and a negligence claim against the generic ranitidine manufacturer defendants, including us. The public nuisance claim asserts that the widespread sale of ranitidine products in the state created a public nuisance that requires a state-wide medical monitoring program of New Mexico residents for the development of colorectal cancer, stomach cancer, gastrointestinal disorders and liver disease.

***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.

***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 healthcare 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”) substantially changed the way healthcare is financed by both governmental and private insurers. 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 constitutionality of the PPACA is currently under review by the U.S. Supreme Court, and it is unclear when a decision will be reached. We expect that the PPACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products.

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 adversely affect the demand for our products and prevent us from maintaining prices for our products that are sufficient for us to realize profits and may otherwise harm our business, financial position, and operating results.

In addition, to the extent that our products are marketed outside of the U.S., foreign government pricing controls and other regulations may prevent us from maintaining prices for such products that are sufficient for us to realize profits and may otherwise harm our business, financial position, and operating results. We expect that legislators, policymakers and healthcare insurance funds in Europe will continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we will be able to charge for our products or the level of reimbursement available for these products from governmental authorities or third party payors. Further, an increasing number of European and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Additionally, if we become the subject of any future government investigation or U.S. Congressional oversight with respect to drug pricing or other business practices, we could incur significant expense and could be distracted from operation of our business and execution of our strategy. Any such investigation or hearing could also result in reduced market acceptance and demand for our products, could harm our reputation and our ability to market our products in the future, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

**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.

***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 2020 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 $0.4 million in the year ended December 31, 2020, in relation to a marketing and distribution right asset, and there can be no assurances that our remaining intangible assets will not be impaired in the future. We recorded an impairment charge of $75 thousand in the year ended December 31, 2019, in relation to a separate product right asset.

***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, and as a result, we incur 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 Stock 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 Stock 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 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 Term Loan and Delayed Draw Term Loan under our Senior Secured Credit Facility, 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 Senior Secured Credit Facility 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 Senior Secured Credit Facility contains customary covenants that require maintenance of certain specified financial ratios and restricts our ability to 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 Senior Secured 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. When 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 22% of our outstanding capital stock entitled to vote as of December 31, 2020. 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.

***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.

***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.

**General Risk Factors**

***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 credit losses, 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.

***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 increased and decreased significantly 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.

***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, 2020, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 99,000 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.

**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 employees in Minnetonka, Minnesota and Baudette, Minnesota. The leases will expire in 2022 and 2025, 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 March 4, 2021, there were approximately 123 shareholders of record of our common stock, which does not include stockholders that beneficially own shares held in a "nominee" or in "street" name, and six holders of record of Class C stock.

**Dividends**

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business.

**Recent Sales of Unregistered Securities**

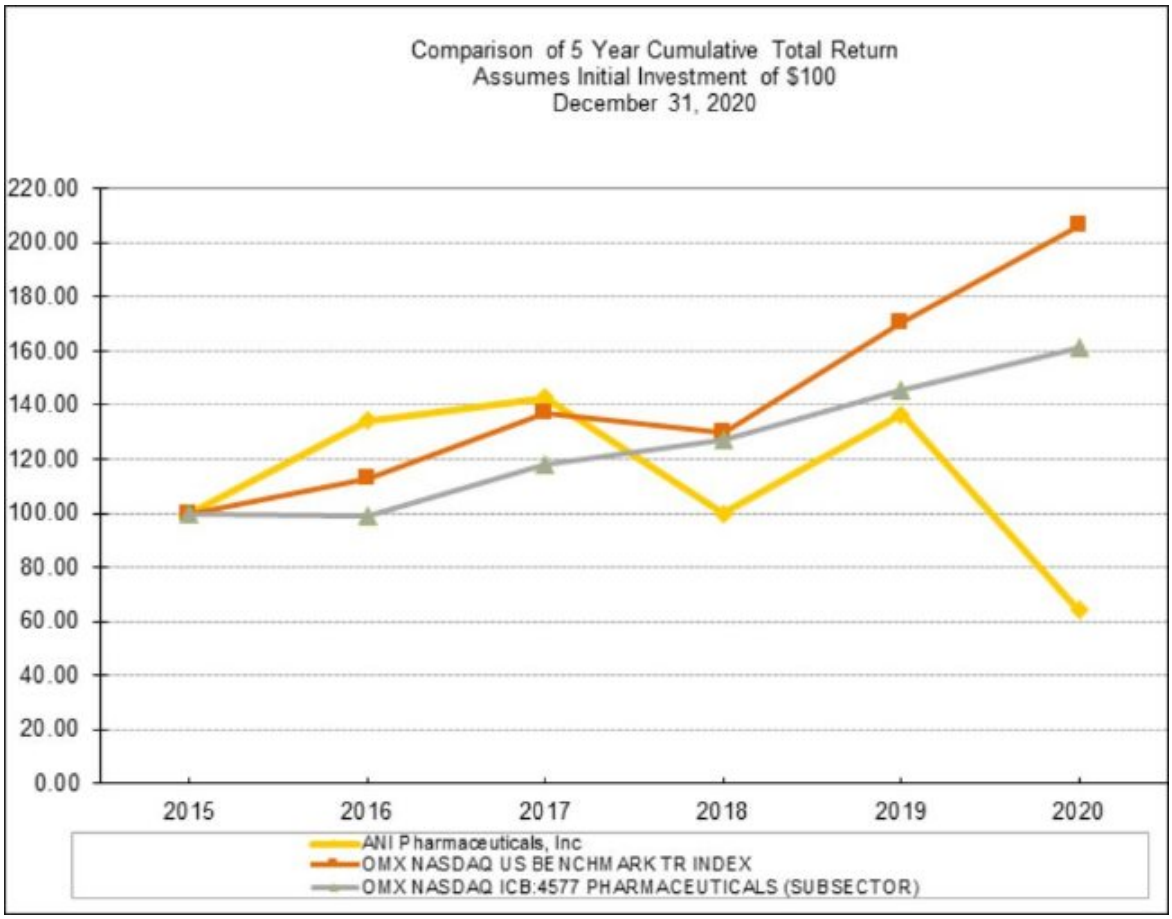
None.

**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, 2015, with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance.



**Item 6. Selected Financial Data**

The following table sets forth selected financial data as of and for the five years ended December 31, 2020. The information has been derived from our audited consolidated financial statements for each of the years ended December 31, 2020, 2019, 2018, 2017, and 2016. 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) | 2020 | 2019 | 2018(1) | 2017(2) | 2016 |
| **Statement of Operations Data:** | | | | | |
| Net revenues | $ 208,475 | $ 206,547 | $ 201,576 | $ 176,842 | $ 128,622 |
| Total operating expenses | 224,491 | 190,196 | 166,217 | 148,513 | 108,543 |
| Operating (loss)/income from continuing operations | (16,016) | 16,351 | 35,359 | 28,329 | 20,079 |
| Benefit/(provision) for income taxes | 3,414 | 2,937 | (4,557) | (17,425) | (4,744) |
| Net (loss)/income from continuing operations | $ (22,548) | $ 6,094 | $ 15,494 | $ (1,076) | $ 3,934 |
| Basic and diluted (loss)/income from continuing operations per share: | | | | | |
| Basic (loss)/income per share from continuing operations | $ (1.88) | $ 0.51 | $ 1.31 | $ (0.09) | $ 0.34 |
| Diluted (loss)/income per share from continuing operations | $ (1.88) | $ 0.50 | $ 1.30 | $ (0.09) | $ 0.34 |
| **Balance Sheet Data:** | | | | | |
| Total assets | $ 461,190 | $ 456,789 | $ 430,604 | $ 412,138 | $ 322,864 |
| Total Convertible Notes, net of deferred financing costs | — | — | 112,463 | 128,208 | 120,643 |
| Non-current debt, net of deferred financing costs and current component | 172,443 | 175,808 | 67,296 | 69,946 | — |
| Total stockholder's equity | $ 195,700 | $ 212,791 | $ 197,263 | $ 174,756 | $ 169,648 |

(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 2020 and 2019 items and year-to-year comparisons between 2020 and 2019. Discussions of 2018 items and year-to-year comparisons between 2019 and 2018 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, 2019, filed with the SEC on February 27, 2020.*

**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, oncology products (anti-cancer), 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. While generic products tend to have higher margins than branded products, margins decrease as the number of companies offering a generic form of a branded drug increases. To address this downward pressure on prices of generic products, we actively seek to acquire new drug products. By executing on this and other strategies, 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.

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. In addition, we acquired the ANDAs for three previously-commercialized generic products, the approved ANDAs for two generic products that had yet to be commercialized at the time of the acquisition, 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 (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.

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.

In 2020, we acquired the U.S. portfolio of 23 generic products, including 10 commercial products at the time of the acquisition, from Amerigen Pharmaceuticals, Ltd. During the 2020 year, we launched ten products.

**Recent Developments**

On March 8, 2021, ANI Pharmaceuticals, Inc. ("Parent") entered into an Agreement and Plan of Merger (the "Merger Agreement") by and among Parent, Nile Merger Sub LLC, a Delaware limited liability company and a wholly-owned subsidiary of Parent ("Merger Sub"), Novitium Pharma LLC, a Delaware limited liability company ("Novitium"), Esjay LLC, a Delaware limited liability company ("Esjay"), Chali Properties, LLC, a New Jersey limited liability company ("Chali"), Chad Gassert, Muthusamy Shanmugam, and Thorappadi Vijayaraj (collectively, the "Key Persons", and Muthusamy Shanmugam and Thorappadi Vijayaraj, together with Esjay and Chali, the "Principal Members") and Shareholder Representative Services LLC, a Colorado limited liability company, as the representative of the equity holders of Novitium.

Upon the terms and subject to the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Novitium, with Novitium surviving the merger as a wholly-owned subsidiary of Parent (the "Merger"). The closing of the Merger (the "Closing") will occur (a) within five business days after all of the conditions to the Closing set forth in the Merger Agreement are satisfied or waived or (b) at such other time, date and place as may be agreed by Parent and Novitium, subject to the completion of a minimum period.

The Merger consideration will consist of a combination of (i) an estimated cash amount of $89.5 million, subject to various adjustments and expected to be financed in part by a $25.0 million Private Investment in Public Equity ("PIPE Investment") (as defined below) and in part by new debt financing, (ii) an aggregate of 2,466,667 shares of Parent common stock, and (iii) up to $46.5 million in contingent future earn-out payments.

We will finance the transaction with a new $340.0 million Senior Secured Credit Facility (the "Facility"), consisting of a $300.0 million term loan and a $40.0 million revolving credit facility, the issuance of approximately $74.0 million in equity to the sellers, and a $25.0 million PIPE Investment by Ampersand Capital Partners. The new debt financing will be secured by substantially all the assets of ANI and its subsidiaries and used for the cash portion of the acquisition and to refinance ANI's existing senior credit facilities.

Concurrently with the execution of the Merger Agreement, on March 8, 2021, Parent entered into an Equity Commitment and Investment Agreement (the "Investment Agreement") with Ampersand 2020 Limited Partnership (the "PIPE Investor"), an affiliate of Ampersand Capital Partners, pursuant to which we agreed to issue and sell to the PIPE Investor, and the PIPE Investor agreed to purchase, 25,000 shares of our Series A Convertible Preferred Stock (the "PIPE Shares"), for a purchase price of $1,000 per share and an aggregate purchase price of $25.0 million, in a private placement (the "PIPE Investment").

The completion of the Merger transaction is subject to various closing conditions, including approval by ANI stockholders of the issuance of ANI common stock in connection with the Merger. For more information about the pending Merger transaction, please see the Form 8-K filed on March 9, 2021 by ANI Pharmaceuticals, Inc., which is incorporated by reference herein.

**Fiscal 2020 Developments**

***Asset Acquisitions***

In July 2020, we acquired an ANDA and certain related inventories from a private company for total consideration of $4.3 million. The transaction was funded using cash on hand.

In May 2020, we entered into an agreement with a private company to purchase an ANDA and API for one currently marketed generic drug product and certain API for $0.2 million. The transaction was funded using cash on hand.

In January 2020, we completed the acquisition of the U.S. portfolio of 23 generic products and API and finished goods related to certain of those products from Amerigen Pharmaceuticals, Ltd. ("Amerigen") for a purchase consideration of $56.8 million and up to $25.0 million in contingent payments over the next three years. The product portfolio at the time of the acquisition included 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. The transaction was funded using cash on hand and $15.0 million in borrowings under our $75.0 million Revolver.

***Product Launches***

During 2020, we launched the following products. Refer to our website at www.anipharmaceuticals.com for further information on the products, including indications/treatments.

| Product | Launch Date |
|---|---|
| Aminocaproic Acid Tablets USP 500mg | December 2020 |
| Mexiletine Hydrochloride Capsules USP, 150mg, 200mg, and 250mg | June 2020 |
| Omega-3-Acid Ethyl Esters Capsules, 1 gram | April 2020 |
| Polyethylene Glycol 3350, 17g/Packet (PEG-3350) | April 2020 |
| Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate and Amphetamine Sulfate Extended-Release Capsules 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg | April 2020 |
| Memantine Hydrochloride Extended-Release Capsules 7 mg, 14 mg, 21 mg, and 28 mg | March 2020 |
| Sulfamethoxazole and Trimethoprim Oral Suspension USP 200 mg/40 mg per 5 mL | February 2020 |
| Tolterodine Extended-Release Capsules, 2mg and 4 mg | February 2020 |
| Potassium Citrate Extended-Release Tablets USP 10m Eq and 15 mEq | January 2020 |
| Paliperidone Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg | January 2020 |

***Cortrophin Gel Re-commercialization Update***

In April 2020, the Food and Drug Administration (“FDA”) issued a Refusal to File (“RTF”) letter for our Supplemental New Drug Application (“sNDA”) for Cortrophin Gel. Since this time, our efforts have been focused on the preparation of a complete resubmission of the sNDA. We immediately retained a prominent regulatory consulting firm to support our efforts and augment the capabilities of our internal Cortrophin development team. In addition, we restructured the composition of the internal team. We have performed a comprehensive review of the original sNDA filing and prepared an internal gap assessment. The resultant remediation activities are currently in-progress and we currently anticipate re-submitting the sNDA in the second quarter of 2021.

In addition, 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.

***Management Transition***

On May 10, 2020, our former President and Chief Executive Officer, Arthur S. Przybyl, departed the Company. Our Board of Directors retained an executive search firm to lead the search for a new President and Chief Executive Officer. In August 2020, we announced that Nikhil Lalwani was named our President and Chief Executive Officer and his employment was effective September 8, 2020, at which time he also joined our Board of Directors.

***COVID-19 Impact***

We continue to closely monitor the impact of the novel coronavirus ("COVID-19") pandemic on our business and the geographic regions where we operate. During the three months ended June 30, 2020, per IQVIA/IMS data, total market generic and brand prescriptions in the United States declined when compared to each of the previous calendar quarters during the trailing 12 months. The decline was in part attributable to the COVID-19 pandemic, including but not limited to negative impacts from "shelter-in-place" and quarantine orders in certain states, restrictions on travel, the prohibition of elective medical procedures, and the related downstream impact of the global economic activity during this period. The decline in prescriptions due to the COVID-19 pandemic negatively impacted our generic and brand net revenues during the three months ended June 30, 2020. During the three month periods ending September 30, 2020 and December 31, 2020, IQVIA/IMS data indicates both brand and generic total market prescription volume increased when compared to the three month period ended June 30, 2020, in part due to the easing of COVID-19 related restrictions. However, total market prescription volume did not increase to pre-pandemic levels during this period. We have not experienced a significant impact to our manufacturing operations; however, we have seen minor disruptions to our supply chain from the COVID-19 pandemic during 2020. Our manufacturing facilities in Baudette, Minnesota and Oakville, Ontario have remained open throughout the pandemic and have operated in accordance with local, state and national safety guidelines. The pandemic has not impacted our access to capital and has not significantly impacted our use of funds, including but not limited to capital expenditures, spend on research and development activities and business development opportunities.

We are unable to predict the impact that the COVID-19 pandemic will have on our future financial condition, results of operations and cash flows due to numerous uncertainties. These uncertainties include the scope, severity and duration of the pandemic, the level of success of continued actions taken to contain the pandemic or mitigate its impact, including the availability of vaccines, and the direct and indirect economic effects of the pandemic and containment measures, among others. The outbreak of COVID-19 in many countries, including the United States and Canada, has had a significant adverse impact on global economic activity and has contributed to significant volatility and negative pressure in financial markets. As a result, the COVID-19 pandemic has negatively impacted almost every industry, either directly or indirectly. Further, the impacts of a potential worsening of global economic conditions and the continued disruptions to, and volatility in, the credit and financial markets, pharmaceutical supply chains, patient access to healthcare as well as other unanticipated consequences remain unknown.

**General**

| (in thousands) | Year Ended December 31, 2020 | 2019 |
|---|---|---|
| Net revenues | $ 208,475 | $ 206,547 |
| Operating expenses | | |
| Cost of sales (exclusive of depreciation and amortization) | 87,157 | 63,154 |
| Research and development | 16,001 | 19,806 |
| Selling, general, and administrative | 64,986 | 55,843 |
| Depreciation and amortization | 44,638 | 44,612 |
| Cortrophin pre-launch charges | 11,263 | 6,706 |
| Intangible asset impairment charge | 446 | 75 |
| Operating (loss)/income | (16,016) | 16,351 |
| Interest expense, net | (9,452) | (12,966) |
| Other expense, net | (494) | (228) |
| (Loss)/income before benefit for income taxes | (25,962) | 3,157 |
| Benefit for income taxes | 3,414 | 2,937 |
| Net (loss)/income | $ (22,548) | $ 6,094 |

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

| | Year Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Net revenues | 100.0 % | 100.0 % |
| Operating expenses | | |
| Cost of sales (exclusive of depreciation and amortization) | 41.8 % | 30.6 % |
| Research and development | 7.7 % | 9.6 % |
| Selling, general, and administrative | 31.2 % | 27.0 % |
| Depreciation and amortization | 21.4 % | 21.6 % |
| Cortrophin pre-launch charges | 5.4 % | 3.2 % |
| Intangible asset impairment charge | 0.2 % | — % |
| Operating (loss)/income | (7.7)% | 8.0 % |
| Interest expense, net | (4.5)% | (6.3)% |
| Other expense, net | (0.2)% | (0.1)% |
| (Loss)/income before benefit for income taxes | (12.4)% | 1.6 % |
| Benefit for income taxes | 1.6 % | 1.4 % |
| Net (loss)/income | (10.8)% | 3.0 % |

**Results of Operations for the Years Ended December 31, 2020 and 2019**

| (in thousands) | Year Ended December 31, 2020 | 2019 | Change | % Change |
|---|---|---|---|---|
| Generic pharmaceutical products | $ 147,257 | $ 128,729 | $ 18,528 | 14.4 % |
| Branded pharmaceutical products | 47,960 | 63,767 | (15,807) | (24.8)% |
| Contract manufacturing | 9,221 | 11,139 | (1,918) | (17.2)% |
| Royalty and other income | 4,037 | 2,912 | 1,125 | 38.6 % |
| Total net revenues | $ 208,475 | $ 206,547 | $ 1,928 | 0.9 % |

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, 2020 were $208.5 million compared to $206.5 million for the same period in 2019, an increase of $1.9 million, or 0.9%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $147.3 million during the year ended December 31, 2020, an increase of 14.4% compared to $128.7 million for the same period in 2019. The primary reasons for the increase are the January 2020 launches of Miglustat, Paliperidone, Penicillamine, Mixed Amphetamine Salts, Tolterodine, Bexarotene and other products acquired from Amerigen, the September 2019 launch of Vancomycin Oral Solution, the January 2020 launch of Potassium Citrate ER, and increased revenues of Candesartan. These increases were tempered by decreases in revenues of Ezetimibe Simvastatin, Erythromycin Ethylsuccinate ("EES"), Esterified Estrogen with Methyltestosterone ("EEMT"), Vancomycin Capsules, and Methazolamide. During the year ended December 31, 2020, and primarily during the second quarter ended June 30, 2020, the overall generic pharmaceutical product market and our generic revenue results were negatively impacted by the COVID-19 pandemic, including but not limited to effects from "shelter-in-place" orders and the prohibition of elective medical procedures. These actions resulted in a decline in generic prescriptions during the year ended December 31, 2020, primarily during the second quarter ended June 30, 2020, when compared to the year ended December 31, 2019.

- Net revenues for branded pharmaceutical products were $48.0 million during the year ended December 31, 2020, a decrease of 24.8% compared to $63.8 million for the same period in 2019. The primary reasons for the decrease were lower unit sales of Inderal LA, Inderal XL and InnoPran XL, as well as a decrease in sales of

Arimidex and Atacand. During the year ended December 31, 2020, and primarily during the second quarter ended June 30, 2020, the overall brand pharmaceutical product market and our brand revenue results were negatively impacted by the COVID-19 pandemic, including but not limited to effects from "shelter-in-place" orders and the prohibition of elective medical procedures. These actions resulted in a decline in brand prescriptions during the year ended December 31, 2020, primarily during the second quarter ended June 30, 2020, when compared to the year ended December 31, 2019.

- Contract manufacturing revenues were $9.2 million during the year ended December 31, 2020, a decrease of 17.2% compared to $11.1 million for the same period in 2019, due to a decreased volume of orders from contract manufacturing customers in the period.

- Royalty and other were $4.0 million during the year ended December 31, 2020, an increase of $1.1 million from $2.9 million for the same period in 2019, primarily due to an increase in product development revenues earned by ANI Canada and an increase in royalty revenues.

***Cost of Sales (Excluding Depreciation and Amortization)***

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| (in thousands) | 2020 | 2019 | Change | % Change |
| Cost of sales (excl. depreciation and amortization) | $ 87,157 | $ 63,154 | $ 24,003 | 38.0 % |

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, 2020, cost of sales increased to $87.2 million from $63.2 million for the same period in 2019, an increase of $24.0 million or 38.0%, primarily as a result of increased volumes during 2020, including a shift in product mix toward generic products, a $4.3 million increase in cost of sales representing the excess of fair value over cost for inventory acquired in the Amerigen acquisition and subsequently sold during the period, a $4.6 million increase related to increased sales of products subject to profit-sharing arrangements, and 2020 inventory reserve charges of $5.6 million related to excess inventory on hand, expired product and discontinued projects. The increases were partially offset by the non-recurrence of the January 2019 royalty buy out from the Asset Purchase Agreement Amendment with Teva Pharmaceuticals USA, Inc. and the non-recurrence of the fourth quarter 2019 $4.6 million inventory reserve charge primarily related to the exit from the market of Methylphenidate Extended Release. Cost of sales, exclusive of the $4.3 million net impact related to excess of fair value over the cost of inventory sold during the period, as a percentage of net revenues increased to 39.7% during the year ended December 31, 2020, from 30.6% during same period in 2019, primarily as a result of the same factors previously discussed.

During the year ended December 31, 2020, we purchased 10% of our inventory from one supplier. In the year ended December 31, 2019, we purchased 13% of our inventory from one supplier.

***Other Operating Expenses***

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| (in thousands) | 2020 | 2019 | Change | % Change |
| Research and development | $ 16,001 | $ 19,806 | $ (3,805) | (19.2)% |
| Selling, general, and administrative | 64,986 | 55,843 | 9,143 | 16.4 % |
| Depreciation and amortization | 44,638 | 44,612 | 26 | 0.1 % |
| Cortrophin pre-launch charges | 11,263 | 6,706 | 4,557 | 68.0 % |
| Intangible asset impairment charge | 446 | 75 | 371 | 494.7 % |
| Total other operating expenses | $ 137,334 | $ 127,042 | $ 10,292 | 8.1 % |

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, 2020, other operating expenses increased to $137.3 million from $127.0 million for the same period in 2019, an increase of $10.3 million, or 8.1%, primarily as a result of the following factors:

- Research and development expenses decreased from $19.8 million to $16.0 million, a decrease of 19.2%, primarily due to a decrease in expense related to the Cortrophin re-commercialization project, the non-recurrence of the $2.3 million of expense related to in-process research and development acquired from Coeptis during the year ended December 31, 2019 and the non-recurrence of 2019 expenses related to Bretylium Tosylate and Methylphenidate Extended Release projects. These decreases were tempered by the $3.8 million in-process research and development expense from the Amerigen acquisition in January 2020.

- Selling, general, and administrative expenses increased from $55.8 million to $65.0 million, an increase of 16.4%, primarily due to $6.5 million of termination benefit expenses related to the departure of our former President and CEO, comprised of $3.4 million of stock-based compensation expense and $3.1 million of expense for salary continuation, bonus, and fringe benefits, increased quality assurance and outside testing expenses, and increased headcount. We also incurred $0.8 million in recruitment and related legal charges associated with our CEO search. The increases were tempered by a decrease in legal fees.

- Depreciation and amortization expense was $44.6 million for the years ended December 31, 2020 and 2019. In 2020, the non-recurrence of amortization expense related to the January 2019 royalty buy out decreased amortization expense, and this decrease was offset by the amortization of the ANDAs and marketing and distribution rights acquired in January 2020 from Amerigen and the ANDA acquired in July 2020.

- As described 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 $11.3 million in the year ended December 31, 2020. We recognized Cortrophin pre-launch charges of $6.7 million in the year ended December 31, 2019. We currently expect to incur total expense related to this activity of approximately $15.0-$20.0 million for 2021.

- We recognized an impairment charge of $0.4 million in relation to a marketing and distribution right intangible asset during the year ended December 31, 2020. We recognized an impairment charge of $75 thousand in relation to our Ranitidine product right intangible asset during the year ended December 31, 2019.

***Other Expense, net***

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| (in thousands) | 2020 | 2019 | Change | % Change |
| Interest expense, net | $ (9,452) | $ (12,966) | $ 3,514 | (27.1)% |
| Other expense, net | (494) | (228) | (266) | 116.7 % |
| Total other expense, net | $ (9,946) | $ (13,194) | $ 3,248 | (24.6)% |

For the year ended December 31, 2020, we recognized other expense, net of $9.9 million versus other expense, net of $13.2 million for the same period in 2019, a decrease of $3.2 million. Interest expense, net for 2020 consists primarily of interest expense on our Term Loan, DDTL, and Revolver. Interest expense, net for 2019 consists primarily of interest expense on our convertible debt, including amortization of related debt discount, and interest expense on borrowings under our Term Loan and DDTL. For the year ended December 31, 2020 and 2019, there was $0.1 million of interest capitalized into construction in progress. The decrease in expense in 2020 is due primarily to the non-recurrence of amortization of the debt discount related to the convertible debt, which matured and was repaid in November 2019. The decrease was tempered by increased borrowing rates on the Term Loan and DDTL and new borrowings under the Revolver.

***Benefit for Income Taxes***

| (in thousands) | Year Ended December 31, 2020 | 2019 | Change | % Change |
|---|---|---|---|---|
| Benefit for income taxes | $ 3,414 | $ 2,937 | $ 477 | 16.2 % |

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, 2020, we recognized an income tax benefit of $3.4 million, an effective benefit rate of 13.1% of consolidated pre-tax losses reported in the period. Our effective tax rate for 2020 was impacted by changes in state tax rates due to our changing presence in certain states, certain non-deductible expenses, and the impact of current period stock-based compensation, among other items.

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.

**Liquidity and Capital Resources**

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

| (in thousands) | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Cash and cash equivalents | $ 7,864 | $ 62,332 |
| Accounts receivable, net | 95,793 | 72,129 |
| Inventories, net | 60,803 | 48,163 |
| Prepaid income taxes | — | 1,076 |
| Prepaid expenses and other current assets | 5,861 | 3,995 |
| Total current assets | $ 170,321 | $ 187,695 |
| | | |
| Current debt, net of deferred financing costs | $ 13,243 | $ 9,941 |
| Accounts payable | 11,261 | 14,606 |
| Accrued expenses and other | 2,456 | 2,362 |
| Accrued royalties | 6,407 | 5,084 |
| Accrued compensation and related expenses | 6,231 | 3,736 |
| Current income taxes payable, net | 3,906 | — |
| Accrued government rebates | 7,826 | 8,901 |
| Returned goods reserve | 27,155 | 16,595 |
| Deferred revenue | 80 | 451 |
| Total current liabilities | $ 78,565 | $ 61,676 |

On December 31, 2020, we had $7.9 million in unrestricted cash and cash equivalents. On December 31, 2019, we had $62.3 million in unrestricted cash and cash equivalents. We generated $15.3 million of cash from operations in the year ended December 31, 2020. In January 2020, we acquired the U.S. portfolio of 23 generic products and certain commercial and development inventory and materials from Amerigen Pharmaceuticals, Ltd., for which we have used $57.4 million in cash and could make future payments of up to $25.0 million in contingent profit share payments over

the next three years. The contingent payments are earned if annual gross profit exceeds a minimum threshold and are earned on a subset of the acquired products. No payment was due to Amerigen for the fiscal year ended December 31, 2020. At the time of the acquisition, the acquired portfolio included 10 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. The transaction was funded from cash on hand and $15.0 million of borrowings from our Revolver, of which $7.5 million was repaid in the second quarter 2020. In July 2020, we acquired an ANDA and certain inventories from a private company for total consideration of $4.3 million. The transaction was funded using cash on hand. During 2020, we incurred expenses of $11.3 million related to purchases of Cortrophin pre-launch inventory and expect to continue to incur related costs in 2021.

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.

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 2.2 as of December 31, 2020. We believe that our financial resources, consisting of current working capital, anticipated future operating cash flows, and $67.5 million of available borrowings under our Revolver as of December 31, 2020, 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 we are not profitable or do not 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 31%, 24%, and 19% of net revenues during the year ended December 31, 2020. As of December 31, 2020 accounts receivable from these three customers totaled approximately 81% of accounts receivable, net. As a result, negotiated payment terms with these customers have a material impact on our liquidity and working capital.

None of our products accounted for 10% or more of our net revenues in 2020 or 2019.

***Sources and Uses of Cash***

*Debt Financing*

Our amended and restated Senior Secured Credit Facility for up to $265.2 million consists of a $72.2 million Term Loan, a $118.0 million DDTL, and a $75.0 million Revolver. The Company had previously fully drawn on the Term Loan and DDTL, and in March 2020, drew $15.0 million under the Revolver, of which $7.5 million was repaid during the year ended December 31, 2020. As of December 31, 2020, we had a $186.9 million outstanding balance on the Credit Facility. As of December 31, 2020, we had $67.5 million available for borrowing under 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 Revolver, 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 on 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, as of December 31, 2020, is 3.25 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.

*Customer Payments*

In addition to the financings in prior years, payments from customers are a significant source of cash in 2020, 2019, and 2018 and were our primary source of cash in 2020 and 2019.

*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 2020, we acquired the U.S. portfolio of 23 generic products and certain commercial and development inventory and materials from Amerigen Pharmaceuticals, Ltd., for which we have used $57.4 million in cash and could make future payments of up to $25.0 million in contingent profit share payments over the next three years. The contingent payments are earned if annual gross profit exceeds a minimum threshold and are earned on a subset of the acquired products. No payment was due to Amerigen for the fiscal year ended December 31, 2020. At the time of the acquisition, the acquired portfolio included 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. The transaction was funded using cash on hand and $15.0 million of borrowings from our Revolver, of which $7.5 million was repaid in the second quarter of 2020. In the third quarter of 2020, we acquired an ANDA and certain inventories from a private company for total consideration of $4.4 million. The transaction was funded using cash on hand. In 2020, we had $6.1 million of capital expenditures.

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.

***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:

| | Year Ended December 31, | |
|---|---|---|
| (in thousands) | 2020 | 2019 |
| Operating Activities | $ 15,267 | $ 45,631 |
| Investing Activities | $ (68,322) | $ (27,549) |
| Financing Activities | $ (1,439) | $ 1,250 |

*Net Cash Provided by Operating Activities*

Net cash provided by operating activities was $15.3 million for the year ended December 31, 2020, compared to $45.6 million provided by operating activities during the same period in 2019, a decrease of $30.3 million. The decrease was due to changes in working capital and the net loss during the year ended December 31, 2020, including payments made for Cortrophin pre-launch materials and increases to trade accounts receivable.

*Net Cash Used in Investing Activities*

Net cash used in investing activities for the year ended December 31, 2020 was $68.3 million, principally due to the January 2020 acquisition of 23 generic products and inventory and materials from Amerigen Pharmaceuticals, Ltd. for $57.4 million, cash payments for the July 2020 acquisition of an ANDA and certain inventories of $4.0 million, and $6.1 million of capital expenditures during the period.

*Net Cash (Used In) / Provided by Financing Activities*

Net cash used in financing activities was $1.4 million for the year ended December 31, 2020, principally due to net borrowings of $7.5 million on the Revolver and $0.6 million of proceeds from stock option exercises, offset by $8.0 million of maturity payments on the Term Loan and DDTL and $1.5 million of treasury stock purchased related to restricted stock vests.

**Contractual Obligations**

The following table summarizes our long-term contractual obligations and commitments as of December 31, 2020.

| | 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] | $ 186,946 | $ 13,691 | $ 173,255 | $ — | $ — |
| Interest on long-term debt obligations [2] | 21,595 | 7,767 | 13,828 | — | — |
| Operating lease obligations | 319 | 138 | 150 | 31 | — |
| Purchase obligations [3] | 7,089 | 5,471 | 1,616 | 2 | — |
| Total | $ 215,949 | $ 27,067 | $ 188,849 | $ 33 | $ — |

(1) Represents our $65.9 million Term Loan due December 27, 2023, our $113.6 million Delayed Draw Term Loan due December 2023, and our $7.5 million Revolver 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, Delayed Draw Term Loan and Revolver and commitment fee due on our Revolver. Interest for the Term Loan and Delayed Draw Term Loan is calculated based on our payment schedule as prescribed in the Senior Secured Credit Facility (the "Credit Facility") and using an estimated interest rate of 4.235%, which is the estimated interest rate on the Term Loan and Delayed Draw Term Loan as fixed by our interest rate swap. Interest on the Revolver is based on the recent 1-month LIBOR rate plus applicable spread per the Credit Facility, which is based on our leverage ratio. The commitment fee is estimated using the applicable rate per the Credit Facility, which is based on our leverage ratio.
(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 consolidated 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 credit losses, 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 or fulfill 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' payment terms are generally fewer than 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 generally transferred to the customer upon delivery of the product to the customer, as our pharmaceutical products are generally 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 fewer than 100 days. We recognized $195.2 million and $192.5 million of revenue related to sales of generic and branded pharmaceutical products in 2020 and 2019, 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 $40.8 million for the year ended December 31, 2020.

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.

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 $1.4 million for the year ended December 31, 2020.

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 $3.0 million for the year ended December 31, 2020.

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 $3.8 million for the year ended December 31, 2020.

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 $1.4 million for the year ended December 31, 2020.

*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 fewer than two months. We estimate returns based on historical experience. Historically, we have not had material returns for contract manufactured products. We

recognized $9.2 million and $11.1 million of revenue related to sales of contract manufactured products in 2020 and 2019, 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. 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.

Pursuant to a 2012 Tripartite Agreement (the "Tripartite Agreement") between the Company, The Regents of the University of California ("The Regents"), and Cabaret Biotech Ltd., an Israeli corporation ("Cabaret") (as assignee of Dr. Zelig Eshhar's rights under the Tripartite Agreement), and subsequent amendments thereto and assignments thereof, we are entitled to receive a percentage of the milestone and sales royalty payments paid to Cabaret by Kite Pharma, Inc. ("Kite"), a subsidiary of Gilead Sciences, Inc., under a license agreement. Under such license agreement, Kite licensed from Dr. Eshhar and Cabaret the patent rights covered by the Tripartite Agreement and agreed to make certain payments to Cabaret based on, among other things, Kite's sales of Yescarta®. Under the Tripartite Agreement, portions of these payments are to be distributed to The Regents and to us.

We record royalty income related to Yescarta® on an accrual basis utilizing our best estimate of royalties earned based upon information available in the public domain, our understanding of the various agreements governing the royalty, and other information received from time to time from the relevant parties. Generally, cash is received directly from Cabaret once a year. The agreements governing this royalty are subject to multiple litigations in multiple jurisdictions, including litigation between Cabaret and Kite, and separately, the Company and Cabaret. We recently became aware that the litigation between Cabaret and Kite was dismissed and are working with our counsel to determine the potential impact the resolution of that matter may have on our rights under the agreements. In addition, the Israeli Tax Authority has taken the position that any payments from Cabaret to us are subject to mandatory withholding tax. The Company and its tax counsel have disputed this position and are actively seeking to resolve the issue. The ultimate outcome of these matters, either individually or in the aggregate, may impact the amount of cash due to us, and may result in the termination of future payments or further claims that royalties received by us in the past be repaid.

*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 $1.9 million and $1.1 million of revenue related to product development services in 2020 and 2019, 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 $188.5 million as of December 31, 2020. 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 seven to 10 years, generally 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. We elected to exit the market for Ranitidine and determined that the carrying value of the asset has been impaired. During the fourth quarter 2019, we recognized a full impairment of the remaining $75 thousand carrying value of the asset.

In April 2019, we entered into an agreement with Pharmaceutics International, Inc. ("PII") and BAS ANDA LLC ("BAS"), under which a previously-commercialized product would 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 was capitalized as an intangible asset. During the fourth quarter 2020, we recognized a full impairment of the remaining $0.4 million carrying value of the asset.

No events or circumstances arose in 2020 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 our 2013 merger with BioSante Pharmaceuticals, Inc. 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, 2020 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 are 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.

On September 8, 2020, we granted stock options to our Chief Executive Officer, through an inducement grant outside of our 2008 Plan to induce him to accept employment with us (the "Inducement Grant"). The grant was made pursuant to inducement grants outside of our shareholder approved equity plan as permitted under the Nasdaq Stock Market listing rules.

The following table summarizes stock-based compensation expense incurred under the 2008 Plan, Inducement Grant, and 2016 Employee Stock Purchase Plan and included in our consolidated statements of operations:

| | Years Ended December 31, | | |
|---|---|---|---|
| (in thousands) | 2020 | 2019 | 2018 |
| Cost of sales | $ 137 | $ 119 | $ 98 |
| Research and development | 597 | 785 | 787 |
| Selling, general, and administrative | 12,202 | 8,313 | 5,897 |
| | $ 12,936 | $ 9,217 | $ 6,782 |

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.

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 for Income Taxes would be affected by $1.3 million for the year ended December 31, 2020.

***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 an 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 for 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 was permitted, including adoption in an interim period. We will adopt this guidance as of January 1, 2021. We expect that the adoption of this guidance will not have a material impact on our consolidated financial statements.

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

*Recently Adopted Accounting Pronouncements*

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 was effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2020. The adoption of this guidance did not 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 was effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2020. The adoption of this guidance did not 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 now reflects 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. We adopted this guidance as of January 1, 2020 using the modified retrospective method for all financial assets measured at amortized cost. Results for reporting periods beginning after January 1, 2020 are presented under the new guidance while prior period amounts continue to be reported in accordance with previously applicable GAAP. We recognized an $8 thousand decrease to retained earnings as of January 1, 2020 for the cumulative effect of adopting the new guidance.

**Off-Balance Sheet Arrangements**

As of December 31, 2020, 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.

In December 2018, we refinanced our previous $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 five-year Credit Facility is comprised of a $72.2 million term loan (the “Term Loan”), a $118.0 million delayed draw term loan (the “DDTL”) and a $75.0 million revolving credit facility (the “Revolver”), all of which mature in December 2023. The Credit Facility has a subjective acceleration clause in case of a material adverse event. In March 2020, we drew $15.0 million under the Revolver, of which $7.5 million was repaid during the nine months ended September 30, 2020. As of December 31, 2020, $67.5 million remained available for borrowing under the Revolver. Amounts drawn on the Term Loan, DDTL, and Revolver 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 on 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, 2020, we had a $186.9 million outstanding balance on the Credit Facility.

In April 2020, we entered into an interest rate swap to manage our exposure to the variable interest rate on our Term Loan and DDTL borrowings. The interest rate swap hedges the variable cash flows associated with interest payments on borrowings under the Term Loan and DDTL, effectively providing a fixed rate of interest throughout the life of these borrowings. 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, 2020 by approximately $3,000.

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, 2020.

**Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2020, 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, 2020, 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 March 11, 2021 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.

***Critical Audit Matters***

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Evaluation of certain assumptions impacting the chargeback accrual*

As described in Note 1 to the consolidated financial statements, the Company records certain variable consideration including discounts, which are estimated at the time of sale generally using the expected value method. Amounts accrued for chargebacks as of December 31, 2020 are approximately $89 million and are evaluated on a quarterly basis. Management's estimate of chargebacks is based on the inventory levels in the distribution channel as provided by

wholesalers, as well as the actual average selling price for each product which is impacted by changes in customer mix, changes in negotiated terms with customers, changes in the volume of off-contract purchases, and changes in the wholesaler acquisition cost, in order to estimate the expected provision.

The principal consideration for our determination that performing procedures relating to the chargeback reserve is a critical audit matter is that there was significant judgment required by management with respect to measurement uncertainty, as the calculation of the chargeback reserve includes assumptions such as average selling price, purchasing trends of distributors and historical product sales used to predict future sales. This in turn led to a high degree of auditor judgment, subjectivity and effort in applying the procedures related to those assumptions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the chargeback reserve, including management's controls over the assumptions used to estimate the corresponding accruals. We recalculated the chargeback accrual for a selection of products, based on a combination of Company internal data, historical actual information, and executed third-party contracts. We performed a sensitivity analysis of the Company's accrual by recalculating the accrual using our independent assumptions. We evaluated the Company's ability to accurately estimate the accrual for chargebacks by comparing historically recorded accruals to the actual amount that was ultimately claimed by the wholesalers. We analyzed year over year trends in the reserve in comparison with revenue trends to further evaluate reasonableness of the estimate and consistency with expectations.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 11, 2021

**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, 2020, 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, 2020, 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, 2020 and 2019, 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, 2020, and the related notes and our report dated March 11, 2021 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
Philadelphia, Pennsylvania
March 11, 2021

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

| | *December 31, 2020* | *December 31, 2019* |
|---|---|---|
| Assets | | |
| Current Assets | | |
| Cash and cash equivalents | $ 7,864 | $ 62,332 |
| Accounts receivable, net of $100,328 and $59,946 of adjustments for chargebacks and other allowances at December 31, 2020 and 2019, respectively | 95,793 | 72,129 |
| Inventories, net | 60,803 | 48,163 |
| Prepaid income taxes | — | 1,076 |
| Prepaid expenses and other current assets | 5,861 | 3,995 |
| Total Current Assets | 170,321 | 187,695 |
| Property and equipment, net | 41,269 | 40,551 |
| Restricted cash | 5,003 | 5,029 |
| Deferred tax assets, net of deferred tax liabilities and valuation allowance | 51,704 | 38,326 |
| Intangible assets, net | 188,511 | 180,388 |
| Goodwill | 3,580 | 3,580 |
| Other non-current assets | 802 | 1,220 |
| Total Assets | $ 461,190 | $ 456,789 |
| Liabilities and Stockholders' Equity | | |
| Current Liabilities | | |
| Current debt, net of deferred financing costs | $ 13,243 | $ 9,941 |
| Accounts payable | 11,261 | 14,606 |
| Accrued expenses and other | 2,456 | 2,362 |
| Accrued royalties | 6,407 | 5,084 |
| Accrued compensation and related expenses | 6,231 | 3,736 |
| Current income taxes payable, net | 3,906 | — |
| Accrued government rebates | 7,826 | 8,901 |
| Returned goods reserve | 27,155 | 16,595 |
| Deferred revenue | 80 | 451 |
| Total Current Liabilities | 78,565 | 61,676 |
| Non-current Liabilities | | |
| Non-current debt, net of deferred financing costs and current component | 172,443 | 175,808 |
| Derivatives and other non-current liabilities | 14,482 | 6,514 |
| Total Liabilities | $ 265,490 | $ 243,998 |
| Commitments and Contingencies (Note 12) | | |
| Stockholders' Equity | | |
| Common Stock, $0.0001 par value, 33,333,334 shares authorized; 12,429,916 shares issued and 12,354,398 outstanding at December 31, 2020; 12,104,875 shares issued and 12,089,565 shares outstanding at December 31, 2019 | 1 | 1 |
| Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively | — | — |
| Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively | — | — |
| Treasury stock, 75,518 shares of common stock, at cost, at December 31, 2020 and 15,310 shares of common stock, at cost, at December 31, 2019 | (2,246) | (723) |
| Additional paid-in capital | 214,354 | 200,800 |
| (Accumulated deficit)/retained earnings | (4,972) | 17,584 |
| Accumulated other comprehensive loss, net of tax | (11,437) | (4,871) |
| Total Stockholders' Equity | 195,700 | 212,791 |
| Total Liabilities and Stockholders' Equity | $ 461,190 | $ 456,789 |

*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,* | | |
|---|---|---|---|
| | ***2020*** | ***2019*** | ***2018*** |
| Net Revenues | $ 208,475 | $ 206,547 | $ 201,576 |
| Operating Expenses | | | |
| Cost of sales (excluding depreciation and amortization) | 87,157 | 63,154 | 73,024 |
| Research and development | 16,001 | 19,806 | 15,388 |
| Selling, general, and administrative | 64,986 | 55,843 | 44,063 |
| Depreciation and amortization | 44,638 | 44,612 | 33,742 |
| Cortrophin pre-launch charges | 11,263 | 6,706 | — |
| Intangible asset impairment charge | 446 | 75 | — |
| Total Operating Expenses | 224,491 | 190,196 | 166,217 |
| Operating (Loss)/Income | (16,016) | 16,351 | 35,359 |
| Other Expense, net | | | |
| Interest expense, net | (9,452) | (12,966) | (14,758) |
| Other expense, net | (494) | (228) | (550) |
| (Loss)/Income Before Benefit/(Provision) for Income Taxes | (25,962) | 3,157 | 20,051 |
| Benefit/(provision) for income taxes | 3,414 | 2,937 | (4,557) |
| Net (Loss)/Income | $ (22,548) | $ 6,094 | $ 15,494 |
| **Basic and Diluted (Loss)/Earnings Per Share:** | | | |
| Basic (Loss)/Earnings Per Share | $ (1.88) | $ 0.51 | $ 1.31 |
| Diluted (Loss)/Earnings Per Share | $ (1.88) | $ 0.50 | $ 1.30 |
| Basic Weighted-Average Shares Outstanding | 11,964 | 11,841 | 11,677 |
| Diluted Weighted-Average Shares Outstanding | 11,964 | 12,040 | 11,772 |

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

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | ***2020*** | ***2019*** | ***2018*** |
| Net (loss)/income | $ (22,548) | $ 6,094 | $ 15,494 |
| Other comprehensive (loss)/income, net of tax: | | | |
| (Losses)/gains on interest rate swap | (6,566) | (4,492) | (379) |
| Total other comprehensive (loss)/income, net of tax | (6,566) | (4,492) | (379) |
| Total comprehensive (loss)/income, net of tax | $ (29,114) | $ 1,602 | $ 15,115 |

*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, 2020, 2019, and 2018**
(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, 2017 | $ 1 | 11,656 | $ — | $ 179,020 | 5 | $ (259) | $ — | $ (4,006) | $174,756 |
| Stock-based Compensation Expense | — | — | — | 6,782 | — | — | — | — | 6,782 |
| Treasury Stock Purchases for Restricted Stock Vests | — | — | — | — | 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 | — | — | — | — | — | — | — |
| (Losses)/Gains on Interest Rate Swap | — | — | — | — | — | — | (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, Net of Tax | — | — | — | — | — | — | — | 2 | 2 |
| Stock-based Compensation Expense | — | — | — | 9,217 | — | — | — | — | 9,217 |
| Treasury Stock Purchases for Restricted Stock Vests | — | — | — | — | 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 | — | — | — |
| (Losses)/Gains on Interest Rate Swap | — | — | — | — | — | — | (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 |
| Cumulative Effect of Change in Accounting Principle, Net of Tax | — | — | — | — | — | — | — | (8) | (8) |
| Stock-based Compensation Expense | — | — | — | 12,936 | — | — | — | — | 12,936 |
| Treasury Stock Purchases for Restricted Stock Vests | — | — | — | — | 61 | (1,523) | — | — | (1,523) |
| Issuance of Common Shares upon Stock Option and ESPP Exercise | — | 21 | — | 618 | — | — | — | — | 618 |
| Issuance of Restricted Stock Awards | — | 304 | — | — | — | — | — | — | — |
| (Losses)/Gains on Interest Rate Swap | — | — | — | — | — | — | (6,566) | — | (6,566) |
| Net Loss | — | — | — | — | — | — | — | (22,548) | (22,548) |
| Balance, December 31, 2020 | $ 1 | 12,430 | $ — | $ 214,354 | 76 | $ (2,246) | $ (11,437) | $ (4,972) | $195,700 |

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

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Cash Flows From Operating Activities | | | |
| Net (loss)/income | $ (22,548) | $ 6,094 | $ 15,494 |
| Adjustments to reconcile net income/(loss) to net cash and cash equivalents provided by operating activities: | | | |
| Stock-based compensation | 12,936 | 9,217 | 6,782 |
| Deferred taxes | (13,205) | (9,134) | (5,180) |
| Depreciation and amortization | 44,638 | 44,612 | 33,742 |
| Acquired in-process research and development ("IPR&D") | 3,753 | 2,324 | 1,335 |
| Non-cash interest | 1,876 | 7,024 | 8,465 |
| Loss on repurchase of Convertible notes | — | — | 468 |
| Asset impairment charge | 445 | 75 | — |
| Changes in operating assets and liabilities, net of acquisitions: | | | |
| Accounts receivable, net | (23,664) | (7,287) | (4,743) |
| Inventories, net | (2,759) | (7,660) | (379) |
| Prepaid expenses and other current assets | (1,866) | 403 | (1,142) |
| Accounts payable | (2,294) | 5,039 | 3,466 |
| Accrued royalties | 1,323 | (3,372) | (3,708) |
| Current income taxes, net | 4,982 | (6,098) | 6,184 |
| Accrued government rebates | (1,075) | (73) | 1,044 |
| Returned goods reserve | 10,369 | 4,043 | 4,278 |
| Accrued expenses, accrued compensation, and other | 2,356 | 424 | 968 |
| Net Cash and Cash Equivalents Provided by Operating Activities | 15,267 | 45,631 | 67,074 |
| 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 | (62,187) | (20,914) | (5,169) |
| Acquisition of property and equipment, net | (6,135) | (6,635) | (5,743) |
| Net Cash and Cash Equivalents Used in Investing Activities | (68,322) | (27,549) | (27,379) |
| Cash Flows From Financing Activities | | | |
| Payment of debt issuance and convertible debt repurchase costs | — | — | (1,572) |
| Payments on Term Loan and Delayed Draw Term Loan agreements | (8,034) | (2,707) | (2,813) |
| Borrowings under Revolver agreement | 15,000 | — | — |
| Payments on Revolver agreement | (7,500) | — | — |
| Borrowings under Delayed Draw Term Loan agreement | — | 118,000 | — |
| Proceeds from stock option exercises and ESPP purchases | 618 | 5,738 | 2,978 |
| Repayment of Convertible Notes | — | (118,750) | (26,125) |
| Unwinding of portion of call option overlay, net | — | — | 375 |
| Treasury stock purchases for restricted stock vests | (1,523) | (1,031) | (659) |
| Net Cash and Cash Equivalents (Used in)/Provided by Financing Activities | (1,439) | 1,250 | (27,816) |
| Net Change in Cash and Cash Equivalents | (54,494) | 19,332 | 11,879 |
| Cash and cash equivalents, beginning of period | 67,361 | 48,029 | 36,150 |
| Cash and cash equivalents, end of period | $ 12,867 | $ 67,361 | $ 48,029 |
| Reconciliation of cash, cash equivalents, and restricted cash, beginning 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, beginning of period | 67,361 | 48,029 | 36,150 |
| Reconciliation of cash, cash equivalents, and restricted cash, end of period | | | |
| Cash and cash equivalents | 7,864 | 62,332 | 43,008 |
| Restricted cash | 5,003 | 5,029 | 5,021 |
| Cash, cash equivalents, and restricted cash, end of period | 12,867 | 67,361 | 48,029 |
| **Supplemental disclosure for cash flow information:** | | | |
| Cash paid for interest, net of amounts capitalized | $ 6,931 | $ 6,092 | $ 6,285 |
| Cash paid for income taxes | $ 4,984 | $ 10,033 | $ 6,397 |
| **Supplemental non-cash investing and financing activities:** | | | |
| Acquisition of product rights, IPR&D, and other related assets included in returned goods reserve and derivatives and other non-current liabilities | $ 391 | $ 500 | $ — |
| Property and equipment purchased and included in accounts payable | $ 172 | $ 723 | $ 521 |

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

**ANI Pharmaceuticals, Inc. and Subsidiaries**
**Notes to the Consolidated Financial Statements**
**For the years ended December 31, 2020, 2019, and 2018**

## 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 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 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. 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.

### 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, 2020, 2019, and 2018. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar.

### 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 credit losses, 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 or benefit, 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.

We are subject to risks and uncertainties as a result of the novel coronavirus ("COVID-19") pandemic. We are unable to predict the impact that the COVID-19 pandemic will have on our future business, financial condition, and

results of operations due to numerous uncertainties. These uncertainties include the occurrence of recurring outbreaks and their severity and the duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact and the direct and indirect economic effects of the pandemic and containment measures, among others. While we experienced a negative impact to our net revenues during the year ended December 31, 2020 in part due to the COVID-19 pandemic, we remain unable to predict the future impact on our estimates and assumptions. There was not a material impact to these estimates or assumptions in our consolidated financial statements as of and for the year ended December 31, 2020. Actual results could differ from those estimates, which may change our estimates in future periods. We continue to closely monitor the impact of the COVID-19 pandemic on our business.

**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 derivatives and other non-current liabilities in our consolidated balance sheets. As of December 31, 2020, we did not have any finance leases.

**Comprehensive Income/(Loss)**

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

**Credit Concentration**

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

During the years ended December 31, 2020 and 2019 we had three customers that accounted for 10% or more of net revenues. As of December 31, 2020, accounts receivable from these customers totaled 81% of accounts receivable, net.

The three customers represent the total percentage of net revenues as follows:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| **Customer 1** | 31 % | 32 % | 33 % |
| **Customer 2** | 24 % | 25 % | 23 % |
| **Customer 3** | 19 % | 23 % | 21 % |

**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, 2020, we purchased approximately 10% of our inventory from one supplier. As of December 31, 2020, amounts payable to this supplier was $0.9 million. During the year ended December 31, 2019, we purchased approximately 13% of our inventory from one supplier. During the year ended December 31, 2018, we purchased approximately 13% of our inventory from one supplier.

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**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.

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)** | **2020** | **2019** | **2018** |
| Sales of generic pharmaceutical products | $ 147,257 | $ 128,729 | $ 117,451 |
| Sales of branded pharmaceutical products | 47,960 | 63,767 | 60,554 |
| Sales of contract manufactured products | 9,221 | 11,139 | 9,119 |
| Royalties from licensing agreements | 1,396 | 807 | 12,504 |
| Product development services | 1,858 | 1,125 | 1,019 |
| Other[1] | 783 | 980 | 929 |
| Total net revenues | $ 208,475 | $ 206,547 | $ 201,576 |

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

| **Timing of Revenue Recognition** | **Years Ended December 31,** | | |
|---|---|---|---|
| **(in thousands)** | **2020** | **2019** | **2018** |
| Performance obligations transferred at a point in time | $ 206,617 | $ 205,422 | $ 200,557 |
| Performance obligations transferred over time | 1,858 | 1,125 | 1,019 |
| Total | $ 208,475 | $ 206,547 | $ 201,576 |

During the year ended December 31, 2020, we did not incur, and therefore did not defer, any material incremental costs to obtain contracts or costs to fulfill contracts. We recognized a decrease of $9.9 million of net revenue from performance obligations satisfied in prior periods during the year ended December 31, 2020, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. We provide technical transfer services to customers, for which services are transferred over time. As a result, we had $0.1 million of contract assets related to revenue recognized based on percentage of completion but not yet billed at December 31, 2019. At December 31, 2020, we did not have any contract assets related to revenue recognized based on percentage of completion but not yet billed. We also had $0.1 million and $0.5 million of deferred revenue at December 31, 2020 and 2019, respectively. For the year ended December 31, 2020, we recognized $0.3 million of revenue that was included in deferred revenue as of December 31, 2019. 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.

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***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 generally transferred to the customer upon delivery of the product to the customer, as our pharmaceutical products are generally 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 fewer 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.

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*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

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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.

*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, 2020, 2019, and 2018:

| | 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, 2018 (1) | $ 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 (1) | $ 49,882 | $ 8,901 | $ 16,595 | $ 8,281 | $ 2,549 |
| Accruals/Adjustments | 408,265 | 14,240 | 30,333 | 37,588 | 14,347 |
| Credits Taken Against Reserve | (369,401) | (15,315) | (19,773) | (36,963) | (13,057) |
| Balance at December 31, 2020 (1) | $ 88,746 | $ 7,826 | $ 27,155 | $ 8,906 | $ 3,839 |

(1) Chargebacks are included as a reduction to accounts receivable, net of chargebacks and other allowances in the consolidated balance sheets. Administrative Fees and Other Rebates and Prompt Payment Discounts are included as a reduction to accounts receivable, net of chargebacks and other allowances or accrued expenses and other in the consolidated balance sheets. Returns are included in returned goods reserve in the consolidated balance sheets. Government Rebates are included in accrued government rebates in the consolidated balance sheets.

***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 fewer 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, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was $6.8 million, which consists of firm orders for contract manufactured products. We will recognize revenue for these performance obligations as they are satisfied, which is anticipated within twelve 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.

Pursuant to a 2012 Tripartite Agreement (the "Tripartite Agreement") between the Company, The Regents of the University of California ("The Regents"), and Cabaret Biotech Ltd., an Israeli corporation ("Cabaret") (as assignee of Dr. Zelig Eshhar's rights under the Tripartite Agreement), and subsequent amendments thereto and assignments thereof, we are entitled to receive a percentage of the milestone and sales royalty payments paid to Cabaret by Kite Pharma, Inc. ("Kite"), a subsidiary of Gilead Sciences, Inc., under a license agreement. Under such license agreement, Kite licensed from Dr. Eshhar and Cabaret the patent rights covered by the Tripartite Agreement and agreed to make certain payments to Cabaret based on, among other things, Kite's sales of Yescarta®. Under the Tripartite Agreement, portions of these payments are to be distributed to The Regents and to us.

We record royalty income related to Yescarta® on an accrual basis utilizing our best estimate of royalties earned based upon information available in the public domain, our understanding of the various agreements governing the royalty, and other information received from time to time from the relevant parties. Generally, cash is received directly from Cabaret once a year. The agreements governing this royalty are subject to multiple litigations in multiple jurisdictions, including litigation between Cabaret and Kite, and separately, the Company and Cabaret. We recently became aware that the litigation between Cabaret and Kite was dismissed and are working with our counsel to determine the potential impact the resolution of that matter may have on our rights under the agreements. In addition, the Israeli Tax Authority has taken the position that any payments from Cabaret to us are subject to mandatory withholding tax. The Company and its tax counsel have disputed this position and are actively seeking to resolve the issue. The ultimate outcome of these matters, either individually or in the aggregate, may impact the amount of cash due to us, and may result in the termination of future payments or further claims that royalties received by us in the past be repaid.

***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, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligations for all product development services contracts was $0.6 million. We expect to satisfy these performance obligations within the next 18 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, 2020.

**Accounts Receivable**

We extend credit to customers on an unsecured basis. We measure expected credit losses on our financial assets at amortized cost, including trade and unbilled receivables, on a collective basis, based on their similar risk characteristics. Expected credits losses are based on historical credit loss experience, review of the current aging or

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status of accounts receivable and current and forward-looking views from an economic and industry perspective. 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 credit losses was immaterial as of December 31, 2020. Our allowance for doubtful accounts as of December 31, 2019, as accounted for and reported under previously applicable U.S. GAAP, was also immaterial.

**Inventories**

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

**Property and Equipment**

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

| | | | | |
|---|---|---|---|---|
| Buildings and improvements | 20 | - | 40 | years |
| Machinery, furniture, and equipment | 1 | | 10 | years |

Construction in progress consists of multiple projects, primarily related to new equipment to expand our manufacturing capability as our product lines 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, 2020, 2019, and 2018. 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, 2020 and 2019.

**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 seven to 10 years, generally 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, 2020, we recognized an impairment charge of $0.4 million relating to a marketing and distribution right asset (Note 7). 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.

**Goodwill**

Goodwill relates to the 2013 merger with BioSante Pharmaceuticals, Inc. 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

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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, 2020, 2019, and 2018.

**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.

**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 $16.0 million, $19.8 million, and $15.4 million for the years ended December 31, 2020, 2019, and 2018, 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. From time to time, we may make awards through an inducement grant outside of our plan to induce prospective employees to accept employment with us. These grants are made pursuant to inducement grants outside of our shareholder approved equity plan as permitted under the Nasdaq Stock Market listing rules. 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

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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 $12.8 million, $9.1 million, and $6.7 million of non-cash, stock-based compensation cost for the years ended December 31, 2020, 2019, and 2018, respectively, and $180 thousand, $147 thousand, and $102 thousand of the 2020, 2019, and 2018 expense related to the ESPP, respectively. In 2020, we recognized $3.4 million of stock compensation expense related to the modification of awards of our former President and Chief Executive Officer, pursuant to his termination without good cause (Note 9).

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

**Income Taxes**

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The 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 also provided a valuation allowance against ANI Canada's net deferred tax assets of $1.9 million and against certain of our state NOL carryforwards that were not expected to be used during the carryforward periods. As a result of a newly adopted transfer pricing policy in 2019, our assessment of the amount of ANI Canada's deferred tax assets that were more likely than not to be realized changed. During 2019, we released ANI Canada's valuation allowance and, as a result, our valuation allowance at December 31, 2020 of $0.3 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.

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 material amounts accrued as of December 31, 2020, 2019, and 2018. 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 2020, we entered in an interest rate swap agreement (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 (the "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

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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, and unvested restricted stock awards, 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 excludes the impact of those shares from the denominator.

For purposes of determining diluted earnings (loss) per share in 2019, we elected a policy to settle the principal portion of our 3% Convertible Senior Notes (the "Notes"), which matured and were settled in December 2019, 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 per share using the treasury method. The warrants issued in conjunction with the issuance of the Notes were considered to be dilutive if 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.

Earnings per share for the years ended December 31, 2020, 2019, and 2018 are calculated for basic and diluted earnings (loss) per share as follows:

| (in thousands, except per share amounts) | Basic | | | Diluted | | |
|---|---|---|---|---|---|---|
| | Years Ended December 31, | | | Years Ended December 31, | | |
| | 2020 | 2019 | 2018 | 2020 | 2019 | 2018 |
| Net (loss)/income | $ (22,548) | $ 6,094 | $ 15,494 | $ (22,548) | $ 6,094 | $ 15,494 |
| Net income allocated to restricted stock | — | (97) | (154) | — | (97) | (154) |
| Net (loss)/income allocated to common shares | $ (22,548) | $ 5,997 | $ 15,340 | $ (22,548) | $ 5,997 | $ 15,340 |
| Basic Weighted-Average Shares Outstanding | 11,964 | 11,841 | 11,677 | 11,964 | 11,841 | 11,677 |
| Dilutive effect of stock options and ESPP | | | | — | 103 | 95 |
| Dilutive effect of Notes | | | | — | 96 | — |
| Diluted Weighted-Average Shares Outstanding | | | | 11,964 | 12,040 | 11,772 |
| (Loss)/Earnings per share | $ (1.88) | $ 0.51 | $ 1.31 | $ (1.88) | $ 0.50 | $ 1.30 |

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 1.3 million, 3.0 million, and 4.4 million for the years ended December 31, 2020, 2019, and 2018, respectively. Due to the net loss in the year ended December 31, 2020, 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-

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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 (for 2019 only) and out-of-the-money warrants exercisable for common stock.

**Hedge Accounting**

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 (loss)/income, net of tax in our consolidated balance sheets and will be reclassified to earnings when the hedged item affects earnings.

**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** | **2020** | **2019** | **2018** |
| United States | $ 202,881 | $ 199,663 | $ 196,886 |
| Canada | 5,594 | 6,884 | 4,690 |
| Total Revenue | $ 208,475 | $ 206,547 | $ 201,576 |

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

| (in thousands) | December 31, 2020 | December 31, 2019 |
|---|---|---|
| United States | $ 26,960 | $ 26,708 |
| Canada | 14,309 | 13,843 |
| Total property and equipment, net | $ 41,269 | $ 40,551 |

**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 an 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 for 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 was permitted, including adoption in an interim period. We will adopt this guidance as of January 1, 2021. We expect that the adoption of this guidance will not have a material impact on our consolidated financial statements.

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

*Recently Adopted Accounting Pronouncements*

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 was effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2020. The adoption of this guidance did not 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 was effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2020. The adoption of this guidance did not have a material impact on our consolidated financial statements.

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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 now reflects 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. We adopted this guidance as of January 1, 2020 using the modified retrospective method for all financial assets measured at amortized cost. Results for reporting periods beginning after January 1, 2020 are presented under the new guidance while prior period amounts continue to be reported in accordance with previously applicable GAAP. We recognized an $8 thousand decrease to retained earnings as of January 1, 2020 for the cumulative effect of adopting the new guidance.

## 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. We incurred approximately $1.1 million in transaction costs related to the acquisition, all of which were expensed in 2018. 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.

### 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*

Our five-year Senior Secured Credit Facility (the "Credit Facility") is comprised of a $72.2 million Term Loan, a $118.0 million DDTL, and a $75.0 million revolving credit facility (the "Revolver"), all of which mature in December 2023. The Credit Facility has a subjective acceleration clause in case of a material adverse event. The Term Loan includes a repayment schedule, pursuant to which $6.3 million of the loan will be paid in quarterly installments during the 12 months ended December 31, 2021. As of December 31, 2020, $6.3 million of the loan is recorded as current borrowings in the consolidated balance sheets. The DDTL includes a repayment schedule,

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pursuant to which $7.4 million will be paid in quarterly installments during the 12 months ended December 31, 2021. As of December 31, 2020, $7.4 million of the loan is recorded as current borrowings in the consolidated balance sheets. In March 2020, we drew $15.0 million under the Revolver, of which $7.5 million has been repaid as of December 31, 2020. As of December 31, 2020, $67.5 million remained available for borrowing under the Revolver. Amounts drawn on the Term Loan, DDTL, and Revolver 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 on 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, 2020, our interest rate on outstanding borrowings is LIBOR plus 2.25% and our commitment fee rate is 0.4%.

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 was, as of December 31, 2020, no greater than 3.25 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. As of December 31, 2020, we are compliant with our financial covenants.

The carrying value of the current and non-current components of the Term Loan and DDTL as of December 31, 2020 and 2019 are:

| | Current | |
|---|---|---|
| **(in thousands)** | **December 31, 2020** | **December 31, 2019** |
| Current borrowing on debt | $ 13,691 | $ 10,412 |
| Deferred financing costs | (448) | (471) |
| Current debt, net of deferred financing costs | $ 13,243 | $ 9,941 |

| | Non-Current | |
|---|---|---|
| **(in thousands)** | **December 31, 2020** | **December 31, 2019** |
| Non-current borrowing on debt | $ 165,755 | $ 177,069 |
| Deferred financing costs | (812) | (1,261) |
| Non-current debt, net of deferred financing costs and current component | $ 164,943 | $ 175,808 |

As of December 31, 2020, we had a $65.9 million balance on the Term Loan, $113.6 million balance on the DDTL, and $7.5 million balance on the Revolver. Of the $0.8 million of deferred debt issuance costs allocated to the Revolver, $0.5 million is included in other non-current assets in the accompanying consolidated balance sheets and $0.3 million is included in prepaid expenses and other current assets in the accompanying consolidated balance sheets. Of the $0.3 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 $0.2 million is classified as a direct reduction to the non-current portion of the DDTL in the accompanying consolidated balance sheets. Of the $0.9 million of deferred debt issuance costs allocated to the Term Loan, $0.3 million is classified as a direct deduction to the current portion of the Term Loan in the accompanying consolidated balance sheets and $0.6 million is classified as a direct deduction to the non-current portion of the Term Loan in the accompanying consolidated balance sheets.

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

| (in thousands) | Term Loan | DDTL | Revolver |
|---|---|---|---|
| 2021 | $ 6,316 | $ 7,375 | $ — |
| 2022 | 5,414 | 8,850 | — |
| 2023 | 54,141 | 97,350 | 7,500 |
| Total | $ 65,871 | $ 113,575 | $ 7,500 |

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

| | Years Ended December 31, | | |
|---|---|---|---|
| (in thousands) | 2020 | 2019 | 2018 |
| Contractual coupon | $ 8,847 | $ 6,635 | $ 7,170 |
| Amortization of debt discount | — | 5,647 | 7,002 |
| Amortization of finance fees | 720 | 1,377 | 1,463 |
| Capitalized interest | (88) | (191) | (724) |
| | $ 9,479 | $ 13,468 | $ 14,911 |

**4. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY**

In December 2018, we refinanced our previous Credit Agreement and, at the same time, entered into an interest rate swap, 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 Term Loan. In February 2019, we entered into an interest rate swap, 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 DDTL. The hedges had been designated as effective cash flow hedges and qualified for hedge accounting. The interest rate swaps related to the Term Loan and DDTL had a weighted average fixed rate of 2.60% and 2.47%, respectively, with a maturity in December 2023. In April 2020, we terminated the remaining $184.2 million notional value of these interest rate swaps. We discontinued hedge accounting for these instruments and are recognizing the net loss in accumulated other comprehensive loss of $13.2 million to interest expense over the remaining terms through December 2023.

At the same time in April 2020, we entered into an interest rate swap with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying total borrowings under our Term Loan and DDTL. The interest rate swap matures in December 2026. As of December 31, 2020, the notional amount of the interest rate swap was $179.4 million and decreases in line with maturities of our Term Loan and DDTL until December 2023, after which it remains static until maturity in 2026. The interest rate swap provides an effective fixed interest rate of 1.99% throughout the term of our Term Loan and DDTL and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As of December 31, 2020, the fair value of the interest rate swap liability recorded in derivatives and other non-current liabilities in the accompanying consolidated balance sheets was $14.1 million. As of December 31, 2020, $11.4 million was recorded in accumulated other comprehensive loss, net of tax in the accompanying consolidated balance sheets.

During the year ended December 31, 2020, the change in fair value of the interest rate swaps was $9.2 million. During the year ended December 31, 2020, losses on the interest rate swap of $6.6 million were recorded in accumulated other comprehensive loss, net of tax in our consolidated statements of comprehensive (loss)/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 and DDTL based on the LIBOR rate. In the year ended December 31, 2020, $3.9 million of interest expense was recognized in relation to the interest rate swaps.

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## 5. INVENTORIES

Inventories consist of the following as of December 31:

| (in thousands) | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Raw materials | $ 41,591 | $ 34,881 |
| Packaging materials | 3,194 | 2,902 |
| Work-in-progress | 886 | 361 |
| Finished goods | 20,363 | 16,750 |
| | 66,034 | 54,894 |
| Reserve for excess/obsolete inventories | (5,231) | (6,731) |
| Inventories, net | $ 60,803 | $ 48,163 |

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) | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Land | $ 4,667 | $ 4,566 |
| Buildings | 11,633 | 10,275 |
| Machinery, furniture, and equipment | 39,111 | 34,984 |
| Construction in progress | 3,385 | 3,496 |
| | 58,796 | 53,321 |
| Less: accumulated depreciation | (17,527) | (12,770) |
| Property and equipment, net | $ 41,269 | $ 40,551 |

Depreciation expense for the years ended December 31, 2020, 2019, and 2018 totaled $4.8 million, $4.4 million, and $2.1 million, respectively. During the years ended December 31, 2020, 2019, and 2018 there was $0.1 million, $0.2 million, and $0.7 million of interest capitalized into construction in progress, respectively.

## 7. INTANGIBLE ASSETS

### Goodwill

As a result of our 2013 merger with BioSante Pharmaceuticals, Inc., 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.

For the goodwill impairment analyses performed at October 31, 2020 and 2019, 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, 2020 and 2019, and therefore no quantitative testing for impairment was required.

In addition to the qualitative impairment analysis performed at October 31, 2020, 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, 2020 to December 31, 2020. No impairment loss was recognized during the years ended December 31, 2020, 2019, and 2018, and the balance of goodwill was $3.6 million as of December 31, 2020 and 2019.

**Definite-lived Intangible Assets**

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

| | December 31, 2020 | | December 31, 2019 | | Weighted Average |
|---|---|---|---|---|---|
| (in thousands) | Gross Carrying Amount | Accumulated Amortization | Gross Carrying Amount | Accumulated Amortization | Amortization Period |
| Acquired ANDA intangible assets | $ 106,415 | $ (42,367) | $ 64,704 | $ (30,169) | 8.8 years |
| NDAs and product rights | 230,974 | (112,483) | 230,974 | (87,352) | 10.0 years |
| Marketing and distribution rights | 17,157 | (11,386) | 10,923 | (8,982) | 5.7 years |
| Non-compete agreement | 624 | (423) | 624 | (334) | 7.0 years |
| | $ 355,170 | $ (166,659) | $ 307,225 | $ (126,837) | 9.4 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 certain NDA, we use an accelerated amortization method to better match the anticipated economic benefits expected to be provided. Amortization expense was $39.9 million, $40.2 million, and $31.7 million for the years ended December 31, 2020, 2019, and 2018, respectively. Refer to Note 8 for more details on acquired definite-lived intangible assets.

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 $0.4 million in the year ended December 31, 2020, in relation to a marketing and distribution right asset. We recognized an impairment of $75 thousand in the year ended December 31, 2019, in relation to a product right asset. No impairment losses related to intangible assets were recognized in the year ended December 31, 2018. No events or circumstances arose in 2020, 2019, or 2018 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) | |
|---|---|
| 2021 | $ 38,605 |
| 2022 | 35,199 |
| 2023 | 34,451 |
| 2024 | 31,474 |
| 2025 | 28,127 |
| 2026 and thereafter | 20,655 |
| Total | $ 188,511 |

**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, DDTL, and Revolver 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 carrying values of these borrowings approximated their fair values at December 31, 2020 and 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 Pharmaceuticals, Inc. 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, 2020 and 2019. We also determined that the changes in such fair value were immaterial for the years ended December 31, 2020, 2019, and 2018.

In April 2020, we terminated two interest rate swaps used to manage interest rate exposure on underlying interest payments for our Term Loan and DDTL and entered into one new interest rate swap agreement to manage our total exposure under these borrowings (Note 4). 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 $14.1 million liability at December 31, 2020.

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of December 31, 2020 and December 31, 2019, by level within the fair value hierarchy:

| (in thousands) Description | Fair Value at December 31, 2020 | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| Liabilities | | | | |
| Interest rate swaps | $ 14,109 | $ — | $ 14,109 | $ — |
| CVRs | $ — | $ — | $ — | $ — |

| Description | Fair Value at December 31, 2019 | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| Liabilities | | | | |
| Interest rate swaps | $ 6,215 | $ — | $ 6,215 | $ — |
| 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, ROU assets, 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, 2020, we recognized a $0.4 million impairment charge related to marketing and distribution right asset (Note 7). There were no other fair value impairments recognized in the year ended December 31, 2020. 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.

***Acquired Non-Financial Assets***

In July 2020, we acquired an ANDA and certain related inventories from a private company for total consideration of $4.3 million. We also incurred and paid $0.1 million in transaction costs directly related to the acquisition. We accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. We recognized $3.0 million as an acquired ANDA intangible asset and $1.4 million in inventory at fair value. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. The ANDA will be amortized in full over its useful life of seven years 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, 2020 and therefore no impairment loss was recognized for the year ended December 31, 2020.

In May 2020, we entered into an agreement with a private company to purchase an ANDA and API for one currently marketed generic drug product and certain API for $0.2 million using cash on hand. We accounted for this transaction as an asset acquisition. The API inventory was recognized at fair value. The ANDA will be amortized in full over its useful life of seven years 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, 2020 and therefore no impairment loss was recognized for the year ended December 31, 2020.

In January 2020, we completed the acquisition of the U.S. portfolio of 23 generic products and API and finished goods related to certain of those products from Amerigen Pharmaceuticals, Ltd. ("Amerigen") for a purchase consideration of $56.8 million and up to $25.0 million in contingent payments over the subsequent four years from the acquisition. The product portfolio at the time of the acquisition included 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. Payments were made using cash on hand and through borrowings of $15.0 million under our Revolver. We also incurred and paid $0.7 million in transaction costs directly related to the acquisition. We accounted for the transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. We recognized $38.5 million as acquired ANDA intangible assets and $6.7 million as acquired marketing and distribution rights related to the licensed products, which are being amortized over their useful lives of seven years. We also recognized $3.8 million of the purchase price as research and development expense because certain of the generic products have significant remaining work required in order to be commercialized and the products do not have an alternative future use. The payment was allocated to the two asset categories and in-process research and development based on relative fair value, which was determined using Level 3 unobservable inputs. To determine the fair value of the acquired intangible assets and in-process research and development, we used the present value of the estimated cash flows related to the products, using a discount rate of 8%. We also recognized $8.4 million in inventory at fair value, including $1.7 million of API and $6.7 million of finished goods. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. Contingent liabilities will be accrued when they are both estimable and probable. The intangible assets 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, 2020 and therefore no impairment loss was recognized for the year ended December 31, 2020.

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.

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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 paid 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 was being amortized over its 10-year useful life. During the fourth quarter of 2020, we recognized a full impairment of the remaining $0.4 million carrying value of the asset, as it was determined that the asset would not generate future cash flows.

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 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 are being 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, 2020 and therefore no impairment loss was recognized for the years ended 2019 and 2020.

In January 2019, we entered into an amendment to asset purchase agreements (the "Asset Purchase Agreement Amendment") with Teva Pharmaceuticals USA, Inc. ("Teva") related to three purchases of baskets of ANDAs. This transaction was unrelated to the March 2019 transaction with Teva discussed herein. 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 is being 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, 2020 and therefore no impairment loss was recognized for the years ended 2019 and 2020.

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 had not yet been commercialized at the time of the acquisition, the development package for one generic drug product, a license, supply, and distribution agreement for a generic drug product with an ANDA that was pending approval, and certain manufacturing equipment required to manufacture one of the products, for $2.3 million in cash. 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 elected to purchase the finished goods from Amneal for this period, we could have been 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. The payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. The launch of one of the acquired products had the potential to trigger a milestone payment of $25.0 million to Teva, depending on the number of competitors selling the product at the time of launch. We launched this product in 2019 and the payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. Additionally, depending on the number of competitors selling the product one year after the launch date, we could have been required to pay a second milestone of $15.0 million to Teva. The one-year anniversary of the launch occurred during the year ended December 31, 2020 and the payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. We made the $2.3 million cash payment using cash on hand and 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 are being 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 is being amortized in full over its five 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, 2020 and therefore no impairment loss was recognized for the year ended December 31, 2020. 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.

## 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, 2020.

There were 12.4 million and 12.3 million shares of common stock issued and outstanding as of December 31, 2020, respectively, and 12.1 million shares of common stock issued and outstanding as of December 31, 2019.

There were 11 thousand shares of class C special stock issued and outstanding as of December 31, 2020 and 2019. 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, 2020 and 2019.

## 10. STOCK-BASED COMPENSATION

### Employee Stock Purchase Plan

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. 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 13 thousand, six thousand, and five thousand shares in the years ended December 31, 2020, 2019, and 2018, respectively.

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

| (in thousands) | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Cost of sales | $ 21 | $ 18 | $ 11 |
| Research and development | 36 | 29 | 16 |
| Selling, general, and administrative | 123 | 100 | 75 |
| | $ 180 | $ 147 | $ 102 |

**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, 2020, 1.1 million shares of our common stock remained available for issuance under the 2008 Plan.

On September 8, 2020, we granted 179,643 stock options to our President and Chief Executive Officer, through an inducement grant outside of our 2008 Plan to induce him to accept employment with us (the "Inducement Grant"). The options were granted at an exercise price equal to the fair market value of a share of our common stock on the respective grant date and will be exercisable in four equal annual installments beginning on the first anniversary of the respective grant date. The grant was made pursuant to inducement grants outside of our shareholder approved equity plan as permitted under the Nasdaq Stock Market listing rules.

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 Inducement Grant and included in our consolidated statements of operations:

| (in thousands) | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Cost of sales | $ 115 | $ 101 | $ 87 |
| Research and development | 561 | 756 | 771 |
| Selling, general, and administrative | 12,080 | 8,213 | 5,822 |
| | $ 12,756 | $ 9,070 | $ 6,680 |

We recognized income tax benefits of $1.6 million, $1.4 million, and $1.2 million for stock-based compensation-related tax deductions in our 2020, 2019, and 2018 consolidated statements of operations, respectively.

**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.

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For 2020, 2019, and 2018, the fair value of each option grant was estimated using the Black-Scholes option-pricing model, using the following assumptions:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Expected option life (years) | 5.50 - 6.25 | 5.50 - 6.25 | 5.48 - 6.25 |
| Risk-free interest rate | 0.31% - 1.63% | 1.91% - 2.58% | 2.64% - 2.93% |
| Expected stock price volatility | 49.2% - 51.2% | 63.1% - 66.7% | 55.1% - 60.6% |
| Dividend yield | — | — | — |

We use the simplified method to estimate the expected option 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 our historical stock price. 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.

A summary of stock option activity under the 2008 Plan and Inducement Grant during the years ended December 31, 2020, 2019, and 2018 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, 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 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 |
| Granted | 231 | 30.29 | $ 14.39 | | |
| Exercised | (8) | 36.81 | | | 216 |
| Forfeited | (44) | 54.54 | | | |
| Expired | — | — | | | |
| Outstanding at December 31, 2020 | 936 | $ 48.44 | | 7.1 | $ 372 |
| Exercisable at December 31, 2020 | 571 | $ 53.06 | | 5.9 | $ 347 |

As of December 31, 2020, there was $6.0 million of total unrecognized compensation cost related to non-vested stock options granted under the 2008 Plan and Inducement Grant. The cost is expected to be recognized over a weighted-average period of 2.6 years. During the year ended December 31, 2020, we received $0.3 million in cash from the exercise of stock options and recorded a $43 thousand tax provision related to these exercises. 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.

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**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, 2020, 2019, and 2018 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, 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 |
| Granted | 305 | 44.42 | |
| Vested | (127) | 58.88 | |
| Forfeited | (18) | 51.53 | |
| Unvested at December 31, 2020 | 352 | $ 48.14 | 2.7 |

As of December 31, 2020, there was $12.6 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 2.7 years.

On January 17, 2020, we entered into employment agreements with our Named Executive Officers ("NEOs") at that time. As part of the employment agreements, the NEOs' Non-Statutory Stock Option, Incentive Option and Restricted Stock Grant agreements ("NEO Stock Agreements") were modified to provide for accelerated vesting of unvested non-statutory stock options and restricted stock awards in the event of a termination for any reason other than "cause" as defined in the employment agreements or by the NEOs for "good reason" as defined in the employment agreements. Additionally, any vested incentive or non-statutory stock options and unvested non-statutory stock options subject to acceleration and held unexercised by the NEOs at the time of such termination at the time will retain their contractual term, which is generally 10 years from grant date. At this time, we did not recognize any incremental stock-based compensation expense associated with these modifications, as no assumptions regarding the assumed probability of these awards' future vests were changed on this modification date.

In May 2020, our former President and Chief Executive Officer departed the Company. The departure constituted a Termination Without Good Cause as defined in his employment agreement, and he received separation payments and benefits under his employment agreement in respect of a termination without good cause, including those related to his non-statutory stock options and restricted stock awards as discussed above. This action was accounted for as a modification of the underlying awards and the full expense related to the modified awards was recognized in the second quarter 2020. As part of the benefits, 48,448 previously unvested restricted stock awards and 63,305 previously unvested non-statutory stock options vested upon the termination. Additionally, these 63,305 previously unvested non-statutory stock options that vested upon termination and 101,376 previously

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vested and unexercised non-statutory stock options retained their original contractual term. Upon the Termination Without Good Cause, we recognized $3.4 million of stock-based compensation expense associated with this termination and modification of awards.

## 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 part of purchase accounting, 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 would not be realized. During 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 2019, we released the remaining net valuation allowance related to ANI Canada's deferred tax assets.

As of December 31, 2020 and 2019, our consolidated valuation allowance was $0.3 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, 2020, 2019, and 2018:

| (in thousands) | 2020 | 2019 | 2018 |
|---|---|---|---|
| Current income tax provision: | | | |
| Federal | $ 9,232 | $ 4,985 | $ 7,985 |
| State | 559 | 1,212 | 1,751 |
| Total | 9,791 | 6,197 | 9,736 |
| Deferred income tax (benefit)/provision: | | | |
| Federal | (14,125) | (6,274) | (4,630) |
| State | 744 | (2,027) | (556) |
| Foreign | 345 | 1,000 | (214) |
| Total | (13,036) | (7,301) | (5,400) |
| Change in valuation allowance | (169) | (1,833) | 221 |
| Total (benefit)/provision for income taxes | $ (3,414) | $ (2,937) | $ 4,557 |

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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, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| US Federal statutory rate | 21.0 % | 21.0 % | 21.0 % |
| State taxes, net of Federal benefit | 1.9 % | 3.2 % | 2.4 % |
| Foreign taxes | (0.1)% | 0.4 % | 26.5 % |
| Change in valuation allowance | 0.7 % | (58.1)% | (26.5)% |
| Stock-based compensation | (2.5)% | (6.7)% | (1.8)% |
| Non-deductible costs | (3.5)% | 9.1 % | — % |
| Change in state apportionment factors, state and foreign rates | (7.3)% | (28.1)% | — % |
| Research and experimentation and charitable credits | 0.9 % | (33.5)% | — % |
| Transfer pricing and other | 2.0 % | (0.2)% | 1.1 % |
| Effective income tax rate | 13.1 % | (93.0)% | 22.7 % |

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) | 2020 | 2019 |
| Deferred tax assets: | | |
| Accruals and advances | $ 7,174 | $ 8,586 |
| Stock-based compensation | 4,277 | 3,750 |
| Accruals for chargebacks and returns | 13,831 | 7,603 |
| Inventory | 6,101 | 4,720 |
| Intangible asset | 21,911 | 14,923 |
| Net operating loss carryforwards | 4,090 | 4,767 |
| Other | 2,171 | 1,459 |
| Total deferred tax assets | $ 59,555 | $ 45,808 |
| Deferred tax liabilities: | | |
| Depreciation | $ (5,913) | $ (6,029) |
| Intangible assets | (11) | (13) |
| Other | (1,664) | (1,008) |
| Total deferred tax liabilities | $ (7,588) | $ (7,050) |
| Valuation allowance | (263) | (432) |
| Deferred tax assets, net of deferred tax liabilities and valuation allowance | $ 51,704 | $ 38,326 |

As of December 31, 2020, we had U.S. federal net operating loss carryforwards of approximately $10.5 million, all of which arose as a result of the 2013 merger with BioSante Pharmaceuticals, Inc. 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, 2020 we have total net operating losses in Canada of $6.5 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 income tax positions as of December 31, 2020 and 2019.

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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. 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, 2020 are classified as operating leases. As of December 31, 2020, we have twelve material operating leases for facilities and office equipment with remaining terms expiring from 2021 through 2025 and a weighted average remaining lease term of 1.6 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 3.99% and 8.95%.

Rent expense for the years ended December 31, 2020 and 2019 consisted of the following:

| | Year Ended December 31, | |
|---|---|---|
| (in thousands) | 2020 | 2019 |
| Operating lease costs | $ 223 | $ 190 |
| Variable lease costs | 66 | 60 |
| Total lease costs | $ 289 | $ 250 |

A maturity analysis of our operating leases follows:

| (in thousands) | |
|---|---|
| Future payments: | |
| 2021 | $ 138 |
| 2022 | 97 |
| 2023 | 52 |
| 2024 | 26 |
| 2025 and thereafter | 6 |
| Total | $ 319 |
| | |
| Discount | (18) |
| Lease liability | 301 |
| Current lease liability | (129) |
| Non-current lease liability | $ 172 |

### 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 $2.8 million of API from these four vendors during the year ended December 31, 2021.

### Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies, such as the Drug Enforcement Administration (“DEA”), the Food and Drug Administration (“FDA”), the Centers for Medicare and Medicaid Services (“CMS”), and Health Canada. The FDA, in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our products. The DEA and Health Canada maintain oversight over our products that are considered controlled substances.

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**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, 2020, 2019, and 2018, net revenues for these products totaled $16.9 million, $20.7 million, and $24.9 million, respectively.

Previously, the FDA's Unapproved Drug Initiative included publication of their policy with respect to the continued marketing of unapproved products in the September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA had stated that it would follow a risk-based approach with regard to enforcement against marketing of unapproved products. The guideline allowed the FDA to evaluate whether to initiate enforcement action on a case-by-case basis, while giving higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. In November 2020 (effective December 2020), the Department of Health and Human Services ("HHS") published a notice in the Federal Register to terminate the FDA's Unapproved Drug Initiative, which would include the withdrawal of this September 2011 Compliance Policy Guide. Neither the HHS nor the FDA has provided any additional guidance, notice or statement regarding how they intend to approach enforcement against marketing of unapproved products.

We continue to believe that, so long as we comply with applicable manufacturing standards, the FDA will continue to operate on a risk-based approach and will not take action against us. However, we can offer no assurance that the FDA will continue to follow this approach or that it will not take a contrary position with any individual product or group of products. If the FDA were to move away from the risk-based approach to enforcement against marketing of unapproved products, 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, 2020, 2019, and 2018 were $2.8 million, $3.1 million, and $2.0 million, respectively.

**Legal proceedings**

We are involved, and from time to time may become involved, in various disputes, governmental and/or regulatory inquiries, investigations, government reimbursement related actions and litigation. These matters are complex and subject to significant uncertainties. As such, we cannot accurately predict the outcome, or the effects of the legal proceedings described below. While we believe that we have valid claims and/or defenses in the litigation and other matters described below, litigation is inherently unpredictable, and the outcome of the proceedings could result in losses, including substantial damages, fines, civil or criminal penalties and injunctive or administrative remedies. We intend to vigorously prosecute and/or defend these matters, as appropriate, 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, and therefore remain undisclosed. 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.

Furthermore, like all pharmaceutical manufacturers, we are periodically exposed to product liability claims. The prevalence of these claims 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. Recent trends in the product liability and director and officer insurance markets is to exclude matters related to certain classes of drugs, such as opioids. Our policies have been subject to such exclusions which place further potential risk of financial loss on us.

Legal fees for litigation-related matters are expensed as incurred and included in the consolidated statements of operations under the selling, general, and administrative expense line item.

***Commercial Litigation***

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, under the premise that we sold an unapproved Erythromycin Ethylsuccinate ("EES") product during the period between September 27, 2016 and November 2, 2018. The complaint seeks a trial by jury and monetary damages (inclusive of actual and consequential damages, treble damages, disgorgement of ANI profit, and legal fees) of an unspecified amount. Discovery in this action closed on March 31, 2019. Trial is currently expected to be in August 2021. In light of the significant disagreement over the facts and legal theories in this case which will be determined at trial, we are unable to predict or reasonably estimate the potential loss or effect on our operations at this time. We have not established any reserves related to this action and it is not covered by insurance. We believe the action is without merit and continue to defend this lawsuit vigorously. Any adverse outcome in this case could have a material adverse impact on our financial condition, results of operations or cash flows.

On December 3, 2020, class action complaints were filed against the Company on behalf of putative classes of direct and indirect purchasers of the drug Bystolic. On December 23, 2020, six individual purchasers of Bystolic: CVS, Rite Aid, Walgreen, Kroger, Albertsons, and H-E-B, filed substantively identical complaints against the Company. The plaintiffs in these actions allege that Forest Laboratories, the manufacturer of Bystolic, entered into anticompetitive agreements when settling patent litigation related to Bystolic with seven potential manufacturers of a generic version of Bystolic: Hetero, Torrent, Alkem/Indchemie, Glenmark, Amerigen, Watson, and various of their corporate parents, successors, subsidiaries, and affiliates. ANI itself has not been a party to patent litigation with Forest concerning Bystolic and did not settle patent litigation with Forest. The plaintiffs named the Company as a defendant based on the Company's January 8, 2020 Asset Purchase Agreement with Amerigen. The complaints allege that the 2013 patent litigation settlement agreement between Forest and Amerigen violates federal and state antitrust laws and state consumer protection laws by delaying the market entry of generic versions of Bystolic. Plaintiffs allege they paid higher prices as a result of delayed generic competition. Plaintiffs seek treble damages, injunctive relief, and attorneys' fees. The complaints do not specify the amount of damages sought from the Company or other defendants and the Company at this early stage of the litigation cannot reasonably estimate the potential damages that the plaintiffs will seek. The cases have been consolidated in the United States District Court for the Southern District of New York. The Company has filed a motion to dismiss the complaints that is pending before the Court and disputes any liability.

***Industry Related Litigation***

In July 2020, we were served with a complaint brought by the Office of the Attorney General of the State of New Mexico against manufacturers and sellers of ranitidine products. The complaint asserts a public nuisance claim and a negligence claim against the generic ranitidine manufacturer defendants, including the Company. The public nuisance claim asserts that the widespread sale of ranitidine products in the state created a public nuisance that requires a state-wide medical monitoring program of New Mexico residents for the development of colorectal cancer, stomach cancer, gastrointestinal disorders and liver disease. As damages, New Mexico asks that the

defendants fund this medical monitoring program. The negligence claims assert that the defendants were negligent in selling the product, essentially alleging that it was unreasonable to have the product on the market. With respect to that claim, New Mexico asserts that it paid for ranitidine products through state-funded insurance and health-care programs. The case was removed to federal court and transferred to the In re Zantac multidistrict litigation ("MDL") on December 15, 2020. New Mexico has moved for remand to state court. The MDL court granted the remand motion on February 25, 2021. In December 2020, the City of Baltimore served ANI with a complaint against manufacturers and sellers of ranitidine products. The City of Baltimore complaint tracks the allegations of the New Mexico complaint. The Baltimore action was removed to federal court and transferred to the In re Zantac MDL on February 1, 2021. We dispute any liability in these matters and intend to vigorously defend ourselves in the litigation.

***Product Liability Related Litigation***

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. Our insurance company assumed the defense of the legacy claims and paid all losses in settlement of the California legacy claims. In 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.

In June 2020, we were served with a personal injury complaint in the case of Koepsel v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-80882-RLR, filed in the Southern District of Florida, in which the plaintiff alleges that he developed kidney cancer in 2018 as a result of taking over the counter medication containing ranitidine. The Koepsel action was filed within an existing multidistrict litigation concerning ranitidine-containing drugs pending in the Southern District of Florida before Judge Robin L. Rosenberg, In re Zantac MDL, 20 MDL 2924. A Master Personal Injury Complaint ("MPIC") in that MDL that was filed on June 22, 2020 also named the Company as a defendant. The Company was dismissed from the Koepsel case on August 21, 2020 and was dismissed from the MPIC on September 8, 2020. On December 31, 2020, after ANI was dismissed, the district court dismissed the MPIC claims against generic manufacturer defendants partially with prejudice and partially with leave to replead. The failure to warn and design defect claims were dismissed with prejudice on preemption grounds. An Amended Master Personal Injury Complaint was filed on February 8, 2021, which does not name ANI. The Company has been named in other individual personal injury complaints filed in MDL 20 MD 2924 in which plaintiffs allege that they developed cancer after taking prescription and over the counter medication containing ranitidine. To date, the Company has been served with complaints in five of those additional cases: Cooper v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81130-RLR (served September 30, 2020), Lineberry v. Amneal Pharmaceuticals, LLC, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81079-RLR (served August 20, 2020), Lovette v. Amneal Pharmaceuticals, LLC, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81040-RLR (served August 26, 2020), Hightower v. Pfizer, et al, MDL No. 20-MD-2924, Case No. 9-20-cv-82214-RLR (served December 16, 2020) and Bird v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9-20-cv-80837-RLR (served December 30, 2020). We have informed counsel for the plaintiffs that we did not sell an over the counter ranitidine product and sold a generic prescription ranitidine product for a limited two-month period of time, from July 2019 to September 2019. Our product was voluntarily recalled in January 2020. Each of the plaintiffs in the five pending cases alleges a cancer diagnosis prior to the time that ANI sold ranitidine, and we have informally sought dismissal from these cases on that basis. ANI was voluntarily dismissed from the Cooper, Lineberry and Lovette actions on November 20, 2020. ANI's informal dismissal requests are pending for the Hightower and Bird actions. We dispute any liability in these MDL matters and intend to vigorously defend ourselves in the litigation.

***Other Industry Related Matters***

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. We have been cooperating and intend 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 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 quarter 2019, all purchases of material, including pig pituitary glands and API, related to the re-commercialization efforts were 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 years ended December 31, 2020 and 2019, we incurred related charges for the purchase of materials of $11.3 million and $6.7 million, respectively. Due to the inherent uncertainty of the timing of FDA approval for this product, we cannot reasonably predict whether these materials will ultimately be eligible for use in commercial finished goods inventory. 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. CEO DEPARTURE**

In May 2020, our former President and Chief Executive Officer departed the Company. The departure constituted a Termination Without Good Cause as defined in his employment agreement, and he receives separation payments and benefits under his employment agreement in respect of a termination without good cause, including cash payments for salary continuation, bonus and fringe benefits for two years, and benefits related to his non-statutory stock options and restricted stock awards. During the year ended December 31, 2020, we recognized $6.5 million of expense associated with his termination, comprised of $3.1 million for salary continuation, bonus, and fringe benefits and $3.4 million of stock-based compensation expense (Note 10).

**15. RELATED PARTY TRANSACTIONS**

In August 2020, we appointed Jeanne Thoma as a director of the Company. Ms. Thoma is the former Chief Executive Officer of SPI Pharmaceuticals, Inc. ("SPI"), who retired in October 2020. SPI supplies ingredients to the Company. We made payments totaling approximately $352,000 and $208,000 in the years ended 2020 and 2019, respectively, to SPI, related to the purchase of ingredients.

**16. SUBSEQUENT EVENT**

On March 8, 2021, ANI Pharmaceuticals, Inc. ("Parent") entered into an Agreement and Plan of Merger (the "Merger Agreement") by and among Parent, Nile Merger Sub LLC, a Delaware limited liability company and a wholly-owned subsidiary of Parent ("Merger Sub"), Novitium Pharma LLC, a Delaware limited liability company ("Novitium"), Esjay LLC, a Delaware limited liability company ("Esjay"), Chali Properties, LLC, a New Jersey limited liability company ("Chali"), Chad Gassert, Muthusamy Shanmugam, and Thorappadi Vijayaraj (collectively, the "Key Persons", and Muthusamy Shanmugam and Thorappadi Vijayaraj, together with Esjay and Chali, the "Principal Members") and Shareholder Representative Services LLC, a Colorado limited liability company, as the representative of the equity holders of Novitium.

**ANI Pharmaceuticals, Inc. and Subsidiaries**
**Notes to the Consolidated Financial Statements**
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Upon the terms and subject to the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Novitium, with Novitium surviving the merger as a wholly-owned subsidiary of Parent (the "Merger"). The closing of the Merger (the "Closing") will occur (a) within five business days after all of the conditions to the Closing set forth in the Merger Agreement are satisfied or waived or (b) at such other time, date and place as may be agreed by Parent and Novitium, subject to the completion of a minimum period.

The Merger consideration will consist of a combination of (i) an estimated cash amount of $89.5 million, subject to various adjustments and expected to be financed in part by a $25.0 million Private Investment in Public Equity ("PIPE Investment") (as defined below) and in part by new debt financing, (ii) an aggregate of 2,466,667 shares of Parent common stock, and (iii) up to $46.5 million in contingent future earn-out payments.

We will finance the transaction with a new $340.0 million Senior Secured Credit Facility (the "Facility"), consisting of a $300.0 million term loan and a $40.0 million revolving credit facility, the issuance of approximately $74.0 million in equity to the sellers, and a $25.0 million PIPE Investment by Ampersand Capital Partners. The new debt financing will be secured by substantially all the assets of ANI and its subsidiaries and used for the cash portion of the acquisition and to refinance ANI's existing senior credit facilities.

Concurrently with the execution of the Merger Agreement, on March 8, 2021, Parent entered into an Equity Commitment and Investment Agreement (the "Investment Agreement") with Ampersand 2020 Limited Partnership (the "PIPE Investor"), an affiliate of Ampersand Capital Partners, pursuant to which we agreed to issue and sell to the PIPE Investor, and the PIPE Investor agreed to purchase, 25,000 shares of our Series A Convertible Preferred Stock (the "PIPE Shares"), for a purchase price of $1,000 per share and an aggregate purchase price of $25.0 million, in a private placement (the "PIPE Investment").

The completion of the Merger transaction is subject to various closing conditions, including approval by ANI stockholders of the issuance of ANI common stock in connection with the Merger. For more information about the pending Merger transaction, please see the Form 8-K filed on March 9, 2021 by ANI Pharmaceuticals, Inc., which is incorporated by reference herein.

## 17. 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.

| | 2020 Quarters (unaudited) | | | |
|---|---|---|---|---|
| **(in thousands, except per share data)** | **First** | **Second** | **Third** | **Fourth** |
| Net revenues | $ 49,774 | $ 48,470 | $ 52,979 | $ 57,252 |
| Total operating expenses | 57,616 | 59,777 | 50,177 | 56,921 |
| Operating (loss)/income | (7,842) | (11,307) | 2,802 | 331 |
| Benefit/(provision) for income taxes | 2,853 | 1,443 | 371 | (1,253) |
| Net (loss)/income | $ (7,011) | $ (12,336) | $ 434 | $ (3,635) |
| **Basic and diluted (loss)/earnings per share:** | | | | |
| Basic (loss)/earnings per share | $ (0.59) | $ (1.03) | $ 0.04 | $ (0.30) |
| Diluted (loss)/earnings per share | $ (0.59) | $ (1.03) | $ 0.04 | $ (0.30) |

**ANI Pharmaceuticals, Inc. and Subsidiaries**
**Notes to the Consolidated Financial Statements**
**For the years ended December 31, 2020, 2019, and 2018**

| | 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/(loss) | 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.

**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, 2020. 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, 2020. 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, 2020, 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, 2020 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, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

None.

**PART III**

**Item 10. Directors, Executive Officers, and Corporate Governance**

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 "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 2021 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 2021 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 "Delinquent Section 16(a) Reports" in our definitive proxy statement for our 2021 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 2021 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 2021 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" and information relating to our equity compensation plans will be

set forth under "Equity Compensation Plan Information" in our definitive proxy statement for our 2021 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 2021 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 2021 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 and 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, 2020 and 2019, 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, 2020, 2019, and 2018, the footnotes thereto, and the reports of EisnerAmper LLP, independent registered public accounting firm, are filed herewith.

**(b) Financial Statement Schedules:**

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

**(c) Exhibits**

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

**ANI PHARMACEUTICALS, INC.**

**EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K**
**FOR THE YEAR ENDED DECEMBER 31, 2020**

| 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 | Description of Securities | Filed herwith |
| 10.1 | 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) |
| 10.2* | 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) |
| 10.3* | 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) |
| 10.4* | 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) |

| Exhibit No. | Exhibit | Method of Filing |
|---|---|---|
| 10.5 | 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) |
| 10.6 | 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) |
| 10.7* | 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 |
| 10.8 | 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) |
| 10.9 | 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) |
| 10.10* | 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) |
| 10.11 | 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) |
| 10.12 | 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) |
| 10.13 | 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) |
| 10.14 | 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) |

| Exhibit No. | Exhibit | Method of Filing |
|---|---|---|
| 10.15 | Amended and Restated Credit Agreement between Citizens Bank, N.A. and ANI Pharmaceuticals, Inc. (2) | 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) |
| 10.16 | 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) |
| 10.17 | Asset Purchase Agreement between Amerigen Pharmaceuticals LTD. and ANI Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 10.24 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (File No. 001-31812) |
| 10.18 | ANI Pharmaceuticals, Inc. Sixth Amended and Restated 2008 Incentive Plan | Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2020 (File No. 001-31812) |
| 10.19* | Form of Restricted Stock Grant Agreement | Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement for the 2020 Virtual Annual Meeting filed on April 23, 2020 (File No. 001-31812) |
| 10.20* | Form of Option Agreement | Filed herewith |
| 10.21* | Employment Agreement between Nikhil Lalwani and ANI Pharmaceuticals, Inc., dated July 24, 2020 | Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K filed August 3, 2020 (File No. 001-31812) |
| 10.22* | Inducement Stock Option Award Agreement, effective as of September 8, 2020, between ANI Pharmaceuticals, Inc. and Nikhil Lalwani | Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2020 (File No. 001-31812) |
| 21 | List of subsidiaries | Filed herewith |
| 23.1 | Consent of EisnerAmper LLP | Filed herewith |
| 31.1 | Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14 | Filed herewith |
| 31.2 | Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14 | Filed herewith |
| 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 financial information from this annual report on Form 10-K for the fiscal year ended December 31, 2020, formatted in Inline XBRL: (i) the audited consolidated Balance Sheets, (ii) the audited | Filed herewith |

| | | |
|---|---|---|
| | 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. | |
| 104 | The cover page from the Company Annual Report on Form 10-K for the year ended December 31, 2020 formatted in inline XBRL (included in Exhibit 101) | Filed herewith |

(1) All exhibits to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. ANI will furnish the omitted exhibits to the SEC upon request by the SEC.
(2) Confidential treatment has been granted with respect to redacted portions of this document.
* Management contract or compensatory plan or arrangement required to be filed as an exhibit to this Annual Report on Form 10-K pursuant to Item 15(a).

**Item 16. Form 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/ Nikhil Lalwani
Nikhil Lalwani
President and Chief Executive Officer
(principal executive officer)

Date: March 11, 2021

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

Date: March 11, 2021

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/ Nikhil Lalwani<br>Nikhil Lalwani | Director, President, and Chief Executive Officer | March 11, 2021 |
| /s/ Patrick D. Walsh<br>Patrick D. Walsh | Director and Chairman of the Board of Directors | March 11, 2021 |
| /s/ Thomas J. Haughey<br>Thomas J. Haughey | Director | March 11, 2021 |
| /s/ David B. Nash, M.D., M.B.A.<br>David B. Nash, M.D., M.B.A. | Director | March 11, 2021 |
| /s/ Robert E. Brown, Jr.<br>Robert E. Brown, Jr. | Director | March 11, 2021 |
| /s/ Jeanne Thoma<br>Jeanne Thoma | Director | March 11, 2021 |
| /s/ Antonio Pera<br>Antonio Pera | Director | March 11, 2021 |

**Exhibit 4.1**

**DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934**

The following is a summary of information concerning the common stock of ANI Pharmaceuticals, Inc. (the "Company"). The summary below does not purport to be complete statements of the relevant provisions of the Company's Restated Certificate of Incorporation and Amended and Restated Bylaws and are entirely qualified by these documents.

**Authorized Capital Shares**

Our authorized capital stock consists of 35,781,282 shares, of which 33,333,334 shares, par value $0.0001 per share, are designated as common stock, 1,666,667 shares, par value $0.001 per share, are designated as preferred stock and 781,281 shares, par value $0.0001 per share, are designated as class C special stock. No shares preferred stock are currently outstanding.

**Voting Rights**

The holders of our common stock are entitled to one vote per share on all matters to be voted on by our stockholders and do not have any right to cumulate votes in the election of directors. Holders of common stock possess exclusive voting rights, except to the extent the board of directors specifies voting power for any preferred stock that, in the future, may be issued.

**Dividends**

Subject to any preferential rights of any preferred stock created by the board of directors, holders of common stock are entitled to receive such dividends as may be declared by the board of directors from time to time out of funds legally available therefor.

**Liquidation Rights**

In the event of our liquidation, dissolution or winding up, only holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and distribution of liquidation preferences of any then outstanding shares of preferred stock. Holders of common stock have no preemptive rights and no conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock.

**Stock Exchange Listing**

Our common stock is listed on The Nasdaq Global Market. The trading symbol for our common stock is "ANIP."

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

**Impact of Preferred Stock**

Our board of directors has the authority, without further action by our stockholders, to issue shares of preferred stock from time to time in one or more series and to fix the number of shares constituting each series of preferred stock and the designations, powers, preferences, rights, qualifications, limitations and restrictions of the shares of such series, including such provisions as may be desired concerning voting, redemption, dividends, dissolution or

the distribution of assets, conversion or exchange, and such other subjects or matters as may be fixed by resolution of the board of directors, any or all of which may be greater than or senior to the rights of the common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and reduce the likelihood that such holders will receive dividend payments or payments upon liquidation. Such issuance could have the effect of decreasing the market price of the common stock. The issuance of preferred stock or even the ability to issue preferred stock could also have the effect of discouraging a takeover or other transaction which holders of some, or a majority, of such shares might believe to be in their best interests or in which holders of some, or a majority, of such shares might receive a premium for their shares over the then-market price of such shares.

Prior to the issuance of shares of a series of preferred stock, our board of directors will adopt resolutions and file a certificate of designation with the Securities and Exchange Commission. The certificate of designation will fix for each series the designation and number of shares and the rights, preferences, privileges and restrictions of the shares including, but not limited to, the following:

- the maximum number of shares in the series and the distinctive designation;
- voting rights, if any, of the preferred stock;
- the dividend rate(s), period(s) and/or payment date(s) or method(s) of calculation applicable to the preferred stock;
- whether dividends are cumulative or non-cumulative, and if cumulative, the date from which dividends on the preferred stock will accumulate;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon the liquidation, dissolution or winding up of our affairs;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into common stock, another series of preferred stock, or any other class of securities being registered hereby, including the conversion price (or manner of calculation) and conversion period;
- the provision for redemption, if applicable, of the preferred stock;
- the provisions for a sinking fund, if any, for the preferred stock;
- liquidation preferences;
- any limitations on the issuance of any class or series of preferred stock ranking senior to or on a parity with the class or series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs; and
- any other specific terms, preferences, rights, limitations or restrictions of the preferred stock.

Except as otherwise required by law, or as otherwise fixed by resolution or resolutions of our board of directors with respect to one or more series of preferred stock, the entire voting power and all voting rights will be vested exclusively in the common stock.

**Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws**

Our certificate of incorporation and our bylaws contain certain provisions that could have the effect of delaying, deterring or preventing another party from acquiring control of us. These provisions and certain provisions of Delaware law, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability

to negotiate more favorable terms with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us.

***Undesignated preferred stock***

As discussed above, our board of directors has the ability to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

***Limits on ability of stockholders to call a special meeting***

Our bylaws provide that special meetings of the stockholders may be called only by the chairman of the board, the president and chief executive officer, the chief financial officer or the board of directors. Stockholders may not call a special meeting, which may delay the ability of our stockholders to force consideration of a proposal or for holders controlling a majority of our capital stock to take any action, including the removal of directors.

***No cumulative voting***

Our certificate of incorporation and bylaws do not provide for cumulative voting in the election of directors. Cumulative voting allows a stockholder to vote a portion or all of its shares for one or more candidates for seats on the board of directors. Without cumulative voting, a minority stockholder may not be able to gain as many seats on our board of directors as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board's decision regarding a takeover.

***Delaware anti-takeover statute***

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, calculated as provided under Section 203; or

- at or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

These provisions of Delaware law and of our certificate of incorporation and bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover

attempts. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

**Exhibit 10.20**

**ANI PHARMACEUTICALS, INC.**

**SIXTH AMENDED AND RESTATED**
**2008 STOCK INCENTIVE PLAN**

**NOTICE OF STOCK OPTION GRANT**

Participant: _____

You have been granted an Option to purchase Common Stock ("***Shares***") of ANI Pharmaceuticals, Inc., a Delaware corporation (the "***Company***"), subject to the terms and conditions of this Notice of Stock Option Grant (the "***Notice of Grant***"), the ANI Pharmaceuticals, Inc. Sixth Amended and Restated Stock Incentive Plan (the "***Plan***") and the attached Stock Option Agreement (which includes the Country-Specific Addendum, the "***Award Agreement***"), as set forth below. Unless otherwise defined herein, the terms used in this Notice of Grant shall have the meanings defined in the Plan.

| | |
|---|---|
| Date of Grant: | _____ |
| Exercise Price per Share: | USD $ _____ |
| Total Number of Shares: | _____ |
| Total Exercise Price: | USD $ _____ |
| Type of Option: | _____ Incentive Stock Option* |
| | _____ Non-Statutory Stock Option |
| | * If this Option was granted by the Company as an Incentive Stock Option, this Option shall be treated as an Incentive Stock Option to the maximum extent permitted by Applicable Laws (as defined in the Award Agreement). |
| Term/Expiration Date: | _____ years / _____ |
| Vesting Commencement Date: | _____ |
| Vesting Schedule: | [TBD][1] |
| Termination Period: | This Option will be exercisable for [three (3)][2] months after Participant ceases to be a Service Provider (as defined in the Award Agreement), unless such termination is due to Participant's death, Disability, Retirement or for Cause. If Participant's relationship as a Service Provider is terminated as a result of Participant's death, Disability or Retirement, this Option will be exercisable for twelve |

[1] NTD: To be conformed for the different types of grants (executive, non -executive, director), but for filing purposes, this will be blank.
[2] NTD: This is the default for a normal termination, but may be adjusted for other awards. Any specific terms for the executive grants can be set forth in this notice of grant.

| | |
|---|---|
| | (12) months after Participant ceases to be a Service Provider. If Participant's relationship as a Service Provider is terminated for Cause, this Option (including any vested and exercisable portion thereof) shall immediately terminate in its entirety upon the Participant's being first notified of such termination for Cause and Participant will be prohibited from exercising this Option from and after the date of such termination. Notwithstanding the foregoing, in no event may this Option be exercised after the Term/Expiration Date as provided above and this Option may be subject to earlier termination as provided in Section 14.3 of the Plan. |
| Transferability: | Participant may not transfer this Option except as set forth in Section 8 of the Award Agreement (subject to compliance with Applicable Laws). |
| Special Provision(s): | [TBD]. |

By accepting this Option (whether electronically or otherwise), Participant acknowledges and agrees to the following:

1. This Option is governed by the terms and conditions of this Award Agreement and the Plan. In the event of a conflict between the terms of the Plan and this Award Agreement, the terms of the Plan will prevail.

2. Participant has received a copy of the Plan, the Award Agreement, the Plan prospectus, the Company's Insider Trading Policy and the Company's Clawback Policy (if any) and represents that Participant has read these documents and is familiar with their terms. Participant further agrees to accept as binding, conclusive, and final all decisions and interpretations of the Committee (or its delegees) regarding any questions relating to this Option and the Plan.

3. The vesting and exercisability of the Option is subject to Participant's continuous status as a Service Provider, which is for an unspecified duration and may be terminated at any time, with or without Cause, and nothing in the Award Agreement or the Plan changes the nature of that relationship. Any unvested and unexercisable Options will be automatically forfeited upon the cessation of the Participant's status as a Service Provider without further notice or any payment in connection with such forfeiture.

4. The Company is not providing any tax, legal, or financial advice, nor is the Company making any recommendations regarding participation in the Plan. Participant should consult with his or her own

personal tax, legal, and financial advisors regarding participation in the Plan before taking any action related to the Plan.

5. Participant consents to electronic delivery, acceptance of terms and conditions and participation as set forth in the Award Agreement.

| PARTICIPANT: | ANI PHARMACEUTICALS, INC. |
| --- | --- |
| Signature | Stephen Carey<br>Chief Financial Officer |
| Print Name | |

**ANI PHARMACEUTICALS, INC.**

**SIXTH AMENDED AND RESTATED**
**2008 STOCK INCENTIVE PLAN**

**STOCK OPTION AGREEMENT**

1. Grant of Option. The Company hereby grants to the individual (the "***Participant***") named in the Notice of Stock Option Grant (the "***Notice of Grant***") an option (the "***Option***") under the ANI Pharmaceuticals, Inc. Sixth Amended and Restated Stock Incentive Plan (the "***Plan***") to purchase the number of Shares set forth in the Notice of Grant, at the exercise price per Share set forth in the Notice of Grant (the "***Exercise Price***"), subject to all of the terms and conditions set forth in the Notice of Grant, this Stock Option Agreement (the "***Award Agreement***") and the Plan, which is incorporated herein by reference. Subject to Section 20 below, if there is a conflict between the terms and conditions of the Plan and the terms and conditions of this Award Agreement, the terms and conditions of the Plan will prevail. For purposes of the Notice of Grant and this Award Agreement, "***Applicable Laws***" means all applicable laws, rules, regulations and requirements, including, but not limited to, all applicable U.S. federal or state laws, rules and regulations, the rules and regulations of any stock exchange or quotation system on which the Company's Common Stock is listed or quoted, and the applicable laws, rules and regulations of any other country or jurisdiction where Awards are, or will be, granted under the Plan or Participants reside or provide services to the Company or any Subsidiary, as such laws, rules, and regulations shall be in effect from time to time.

If designated in the Notice of Grant as an Incentive Stock Option ("***ISO***"), this Option is intended to qualify as an ISO to the maximum extent permitted under Section 422 of the U.S. Internal Revenue Code of 1986, as amended (the "***Code***"). However, if for any reason this Option (or portion thereof) will not qualify as an ISO, then, to the extent of such non-qualification, such Option (or portion thereof) shall be regarded as a Non-Statutory Stock Option ("***NSO***") granted under the Plan. In no event will the Committee, the Company or any Subsidiary or any of their respective employees or directors have any liability to Participant (or any other person) due to the failure of the Option to qualify for any reason as an ISO.

2. Vesting Schedule. Except as provided in Section 3, the Option awarded by this Award Agreement will vest and become exercisable in accordance with the Vesting Schedule set forth in the Notice of Grant. Options scheduled to vest and become exercisable on a certain date or upon the occurrence of a certain condition will not vest or become exercisable in accordance with any of the provisions of this Award Agreement, unless Participant will have been continuously providing services to the Company or any Subsidiary as an employee, director, officer, consultant, advisor or independent contractor (a "***Service Provider***") from the date of grant until the date such vesting and exercisability occurs.

(a) Termination as Service Provider. Participant will cease to be a Service Provider for purposes of this Option on the day that Participant no longer actively provides services to the Company or any Subsidiary as an employee, director, officer, consultant, advisor or independent contractor (except, in certain circumstances, to the extent Participant is on a Company-approved leave of absence and subject to any Company policy or Applicable Laws regarding such leaves). Participant will not be considered to be a Service Provider during any notice period or "garden leave" that may be required contractually or under any Applicable Laws. Notwithstanding the foregoing, the Committee (or any delegate) shall have the sole and absolute discretion to determine when Participant is no longer providing active services for purposes of this Award Agreement and participation in the Plan. The date Participant ceases to be a Service Provider is referred to herein as the "***Termination Date***." Following the Termination Date, Participant may exercise the Option only as set forth in the Notice of Grant and this Section 2(a). Unless otherwise provided by the Committee, if on the Termination Date the Option is not vested and exercisable as to all its Shares, the Shares that are not then vested and exercisable will revert to the Plan. If Participant does not exercise the Option within the termination period

set forth in the Notice of Grant or below, the Option will terminate and the Shares subject to the Option will revert to the Plan. In no event may the Option be exercised after the Expiration Date set forth in the Notice of Grant.

(i) General Termination. In the event Participant ceases to be a Service Provider for any reason other than as a result of Participant's Disability, death, Retirement or termination for Cause, Participant may, to the extent the Option is then vested and exercisable, exercise this Option during the termination period set forth in the Notice of Grant, or in the absence of a specified time, within three (3) months following the Termination Date.

(ii) Termination upon Disability or Retirement of Participant**.** In the event Participant ceases to be a Service Provider as a result of Participant's Disability or Retirement, Participant may, to the extent the Option is then vested and exercisable, exercise this Option within twelve (12) months following the Termination Date.

(iii) Death of Participant. In the event Participant ceases to be a Service Provider as a result of Participant's death, or in the event of Participant's death within three (3) months following Participant's Termination Date, to the extent this Option is vested and exercisable on the Termination Date, this Option may be exercised within twelve (12) months following the Termination Date, or if later, twelve (12) months following the date of death, by any beneficiaries designated in accordance with Section 15.3(b) of the Plan or, if there are no such beneficiaries, by Participant's estate or by a person who acquired the right to exercise the Option by bequest or inheritance.

(iv) Termination for Cause. In the event Participant's relationship as a Service Provider is terminated for Cause, this Option (including any vested and exercisable portion thereof) shall immediately terminate in its entirety upon the first notification to Participant of such termination for Cause. If Participant's relationship as a Service Provider is suspended pending an investigation of whether Participant will be terminated for Cause, all Participant's rights under this Option, including the right to exercise this Option, shall be suspended during the investigation for a period of up to days.

(b) Actions Constituting Cause. In the event that Participant is determined by the Committee, in its sole discretion, to have committed any action that would constitute Cause, irrespective of whether such action or the Committee's determination occurs before or after Participant's Termination Date, all rights of the Participant under the Plan, in any Incentive Award granted under the Plan, including this Option (and including any vested and exercisable portion thereof), and under any agreement evidencing any Incentive Award then held by Participant shall terminate and be forfeited without notice of any kind. The Company may defer the exercise of this Option for a period of up to [45] days in order for the Committee to make a determination as to the existence of Cause.

(c) 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.

(d) Breach of Agreements or Policies. Notwithstanding anything in this Award Agreement to the contrary and in addition to the rights of the Committee under Section 12.4 of the Plan and Section 2(b) above, in the event that Participant materially breaches the terms of any employment, consulting, advisory, confidentiality or non-compete agreement entered into with the Company or any Subsidiary (including an

employment, consulting, advisory, confidentiality or non-compete agreement made in connection with the grant of the Option), whether such breach occurs before or after the Termination Date, the Committee in its sole discretion may require the Participant to surrender this Option and/or the Shares issued upon the exercise of this Option, and to disgorge any profits (however defined by the Committee), made or realized by Participant in connection with this Option or any Shares issued upon the exercise of this Option. In addition, this Option will be subject to the terms and conditions of any clawback policy as may be established and/or amended from time to time by the Company.

(e) Change in Time Commitment. In the event Participant's regular level of time commitment in the performance of his or her services for the Company or any Subsidiaries is reduced (for example, and without limitation, if the Participant is an employee of the Company and the employee has a change in status from full-time to part-time or takes an extended leave of absence) after the date of grant of an Option, the Committee in its sole discretion, may (i) make a corresponding reduction in the number of Shares of the Option that is scheduled to vest and become exercisable after the date of such change in time commitment, and (ii) in lieu of or in combination with such a reduction, extend the Vesting Schedule applicable to the Option (in accordance with Section 409A of the Code, as applicable). In the event of any such reduction, the Participant will have no right with respect to any portion of the Option that is so amended.

3. Exercise of Option.

(a) Right to Exercise. This Option may be exercised only within the term set forth in the Notice of Grant and may be exercised during such term only in accordance with the Plan and the terms of this Award Agreement.

(b) Method of Exercise. This Option is exercisable by delivery of an exercise notice, in the form attached as Exhibit A (the "***Exercise Notice***"), or in a manner and pursuant to such procedures as the Committee may determine, which will state the election to exercise the Option, the number of Shares in respect of which the Option is being exercised (the "***Exercised Shares***"), and such other representations and agreements as may be required by the Company pursuant to the provisions of the Plan. The Exercise Notice will be completed by Participant and delivered to the Company. In the event that the Option is being exercised as provided by the Plan and Section 2(a) above by any person or persons other than the Participant, the Exercise Notice must be accompanied by appropriate proof of right of such person or persons to exercise the Option. The Exercise Notice will be accompanied by payment of the aggregate Exercise Price as to all Exercised Shares together with any Tax-Related Items (as defined below) required to be withheld, paid or provided pursuant to any Applicable Laws. This Option will be deemed to be exercised upon receipt by the Company of such fully executed Exercise Notice accompanied by such aggregate Exercise Price, any such Tax-Related Items and any other requirements or restrictions that may be imposed by the Company to comply with Applicable Laws or facilitate administration of the Plan. Notwithstanding the above, Participant understands that the Applicable Laws of the country in which Participant is residing or working at the time of grant, vesting and exercisability, and/or exercise of this Option (including any rules or regulations governing securities, foreign exchange, tax, labor or other matters) may restrict or prevent the exercise of this Option, and neither the Company nor any Subsidiary assumes any liability in relation to this Option in such case.

4. Method of Payment. Unless otherwise elected by Participant, payment of the aggregate Exercise Price will be made via a "net exercise" of the Option in which the Company will not require a payment of the Exercise Price, but will reduce the number of Shares issued upon the exercise by the largest number of whole Shares that have a Fair Market Value on the exercise date that is equal to or less than the aggregate Exercise Price. Upon election by Participant, payment of the aggregate Exercise Price can also be made by any of the following, or a combination thereof:

(a) cash (in U.S. dollars; including check, bank draft or money order); or

(b) tender of a Broker Exercise Notice.

Participant understands and agrees that, unless otherwise permitted by the Company, any cross-border remittance made to exercise this Option or transfer proceeds received upon the sale of Shares must be made through a locally authorized financial institution or registered foreign exchange agency and may require the Participant to provide such entity with certain information regarding the transaction.

5. Tax Obligations. Regardless of any action the Company or Participant's employer or former employer, if applicable (the "***Employer***") takes with respect to any or all applicable national, local, or other tax or social contribution, withholding, required deductions, or other payments, if any, that arise upon the grant, vesting, or exercise of this Option, the holding or subsequent sale of Shares, and the receipt of dividends, if any, or otherwise in connection with this Option or the Shares ("***Tax-Related Items***"), Participant acknowledges and agrees that the ultimate liability for all Tax-Related Items legally due by Participant is and remains Participant's responsibility and may exceed any amount actually withheld by the Company or the Employer. Participant further acknowledges and agrees that Participant is solely responsible for filing all relevant documentation that may be required in relation to this Option or any Tax-Related Items (other than filings or documentation that are the specific obligation of the Company or a Subsidiary or Employer pursuant to Applicable Laws) such as but not limited to personal income tax returns or reporting statements in relation to the grant, vesting or exercise of this Option, the holding of Shares or any bank or brokerage account, the subsequent sale of Shares, and the receipt of any dividends. Participant further acknowledges that the Company and the Employer (a) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Option, including the grant, vesting and exercisability, or exercise of the Option, the subsequent sale of Shares acquired under the Plan and the receipt of dividends, if any; and (b) do not commit to and are under no obligation to structure the terms of the Option or any aspect of the Option to reduce or eliminate Participant's liability for Tax-Related Items, or achieve any particular tax result. Participant also understands that Applicable Laws may require varying Share or Option valuation methods for purposes of calculating Tax-Related Items, and the Company assumes no responsibility or liability in relation to any such valuation or for any calculation or reporting of income or Tax-Related Items that may be required of Participant under Applicable Laws. Further, if Participant has become subject to tax in more than one jurisdiction between the date of grant and the date of any relevant taxable event, Participant acknowledges that the Company and/or the Employer may be required to withhold or account for Tax- Related Items in more than one jurisdiction.

6. Tax-Related Items.

(a) Satisfaction of Tax-Related Items. As a condition to the grant, vesting and exercisability, and exercise of this Option and in accordance with Section 13 of the Plan, Participant hereby agrees to make adequate provision for the satisfaction of (and will indemnify the Company and any Subsidiary or Employer for) any Tax-Related Items. No payment will be made to Participant (or his or her estate or beneficiary) related to an Option, and no Shares will be issued pursuant to an Option, unless and until satisfactory arrangements (as determined by the Company) have been made by Participant with respect to the payment of any Tax-Related Items obligations of the Company and/or any Subsidiary or Employer with respect to the grant, vesting or exercise of the Option. Unless otherwise elected by Participant, payment of the aggregate Tax-Related Items will be made via a "net exercise" of the Option in which the Company will not require a payment of the Exercise Price, but will reduce the number of Shares issued upon the exercise by the largest number of whole Shares that have a Fair Market Value on the exercise date that is equal to or less than amount necessary to satisfy the obligations with regard to all Tax-Related Items. Upon election by Participant, payment of the Tax-Related Items can also be made by any of the following, or a combination thereof:

(i) cash (in U.S. dollars; including check, bank draft or money order); or

(ii) tender of a Broker Exercise Notice.

If the obligation for Tax-Related Items is satisfied by withholding Shares, the Participant is deemed to have been issued the full number of Shares purchased for tax purposes, notwithstanding that a number of Shares is held back solely for the purpose of paying the Tax-Related Items due as a result of the Participant's participation in the Plan. Participant shall pay to the Company or a Subsidiary or Employer any amount of Tax-Related Items that the Company, Subsidiary or Employer may be required to withhold, pay or otherwise provide for as a result of Participant's participation in the Plan that cannot be satisfied by one or more of the means previously described in this paragraph 6. Participant acknowledges and agrees that the Company may refuse to honor the exercise and refuse to issue or deliver the Shares or the proceeds of the sale of Shares if Participant fails to comply with his or her obligations in connection with the Tax-Related Items.

(b) Notice of Disqualifying Disposition of ISO Shares. If the Option granted to Participant herein is an ISO, and if Participant sells or otherwise disposes of any of the Shares acquired pursuant to the ISO on or before the later of (i) the date two (2) years after the date of grant, or (ii) the date one (1) year after the date of exercise, Participant will immediately notify the Company in writing of such disposition.

(c) Code Section 409A (Applicable Only to Participants Subject to U.S. Taxes). Under Code Section 409A, an option that is granted with an Exercise Price per Share that is determined by the Internal Revenue Service (the "***IRS***") to be less than the Fair Market Value of a Share on the date of grant (a "***Discount Option***") may be considered "deferred compensation." A Discount Option may result in (i) income recognition by Participant prior to the exercise of the option, (ii) an additional twenty percent (20%) federal income tax, and (iii) potential penalty and interest charges. The Discount Option may also result in additional state income, penalty and interest charges to the Participant. Participant acknowledges that the Company cannot and has not guaranteed that the IRS will agree that the Exercise Price per Share of this Option equals or exceeds the Fair Market Value of a Share on the date of grant in a later examination. Participant agrees that if the IRS determines that the Option was granted with an Exercise Price per Share that was less than the Fair Market Value of a Share on the date of grant, Participant will be solely responsible for Participant's costs related to such a determination.

7. Incentive Stock Option Provisions.

(d) $100,000 USD Limitation. Each Option is designated in the Notice of Grant as either an Incentive Stock Option or a Non-Statutory Stock Option. However, notwithstanding such designation, to the extent that the aggregate Fair Market Value of the Shares with respect to which Incentive Stock Options are exercisable for the first time by the Participant during any calendar year (under all plans of the Company and any Subsidiary) exceeds one hundred thousand United States Dollars (USD $100,000), such Options will be treated as Non-Statutory Stock Options. For purposes of this Section 7(a), Incentive Stock Options will be taken into account in the order in which they were granted.

(e) Term of Option. The term of the Option is stated in the Notice of Grant. In the case of an Incentive Stock Option, the term will be ten (10) years from the date of grant or such shorter term as may be provided in the Notice of Grant. Moreover, in the case of an Incentive Stock Option granted to a Participant who, at the time the Incentive Stock Option is granted, owns stock representing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Subsidiary, the term of the Incentive Stock Option will be five (5) years from the date of grant or such shorter term as may be provided in the Notice of Grant.

(f) Option Exercise Price. In the case of an Incentive Stock Option:

(iii) granted to an employee who, at the time the Incentive Stock Option is granted, owns stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company or any Subsidiary, the Exercise Price per Share will be no less than one hundred ten percent (110%) of the Fair Market Value per Share on the date of grant; and

(iv) granted to any employee other than an employee described in subparagraph (i) immediately above, the Exercise Price per Share will be no less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(g) Leaves of Absence. If an employee of the Company or any Subsidiary is holding an Incentive Stock Option and is on a Company-approved leave of absence that exceeds three (3) months, then, for purposes of Incentive Stock Option status only, such employee's service as an employee shall be deemed terminated on the first (1st) day following such three (3) month period, and the Incentive Stock Option shall thereafter automatically treated for tax purposes as a Non-Statutory Stock Option in accordance with Applicable Laws, unless reemployment upon the expiration of such leave is guaranteed by contract or statute, or unless provided otherwise pursuant to a written Company policy.

8. Non-Transferability of Option. This Option may not be transferred in any manner otherwise than by will or by the laws of descent or distribution and may be exercised during the lifetime of Participant only by Participant. Participant will, however, be entitled to designate a beneficiary to receive this Option upon such Participant's death, and, in the event of the Participant's death, the exercise of this Option (to the extent permitted pursuant to Section 3(b) above) may be made by Participant's legal representatives, heirs and legatees.

9. Rights as Stockholder. Neither Participant nor any person claiming under or through Participant will have any of the rights or privileges of a stockholder of the Company in respect of any Shares unless and until such Shares will have been issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). After such issuance, Participant will have all the rights of a stockholder of the Company with respect to voting such Shares and receipt of dividends and distributions on such Shares, but prior to such issuance, Participant will not have any rights to dividends and/or distributions on such Shares.

10. No Guarantee of Continued Service or Grants. PARTICIPANT ACKNOWLEDGES AND AGREES THAT THE VESTING AND EXERCISABILITY OF SHARES PURSUANT TO THE VESTING SCHEDULE IN THE NOTICE OF GRANT SHALL OCCUR ONLY BY CONTINUING AS A SERVICE PROVIDER AT THE WILL OF THE EMPLOYER OR CONTRACTING ENTITY (AS APPLICABLE) AND NOT THROUGH THE ACT OF BEING HIRED, BEING GRANTED THE OPTION OR ACQUIRING SHARES HEREUNDER. PARTICIPANT FURTHER ACKNOWLEDGES AND AGREES THAT THIS AWARD AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREUNDER AND THE VESTING SCHEDULE SET FORTH IN THE NOTICE OF GRANT DO NOT CONSTITUTE AN EXPRESS OR IMPLIED PROMISE OF CONTINUED ENGAGEMENT AS A SERVICE PROVIDER FOR THE VESTING PERIOD, FOR ANY PERIOD, OR AT ALL, AND WILL NOT INTERFERE IN ANY WAY WITH PARTICIPANT'S RIGHT OR THE RIGHT OF THE EMPLOYER OR THE COMPANY OR SUBSIDIARY TO TERMINATE PARTICIPANT'S RELATIONSHIP AS A SERVICE PROVIDER AT ANY TIME, WITH OR WITHOUT CAUSE (SUBJECT TO LOCAL APPLICABLE LAWS).

11. Nature of Grant. In accepting the Option, Participant acknowledges, understands and agrees that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time;

(b) the grant of the Option is voluntary and occasional and does not create any contractual or other right to receive future grants of Options, or benefits in lieu of Options even if Options have been granted repeatedly in the past;

(c) all decisions with respect to future awards of Options, if any, will be at the sole discretion of the Company;

(d) Participant's participation in the Plan is voluntary;

(e) the Option and the Shares subject to the Option are extraordinary items that do not constitute regular compensation for services rendered to the Company or the Employer, and that are outside the scope of Participant's employment contract, if any;

(f) the Option and the Shares subject to the Option are not intended to replace any pension rights or compensation;

(g) the Option and the Shares subject to the Option are not part of normal or expected compensation or salary for any purposes, including, but not limited to, calculating any severance, resignation, termination, redundancy, dismissal, or end of service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments and in no event should be considered as compensation for, or relating in any way to, past services for the Company or the Employer, subject to Applicable Laws;

(h) the future value of the underlying Shares is unknown and cannot be predicted with certainty; further, if Participant exercises the Option and obtains Shares, the value of the Shares acquired upon exercise may increase or decrease in value, even below the Exercise Price;

(i) Participant also understands that neither the Company nor any Subsidiary is responsible for any foreign exchange fluctuation between local currency and the United States Dollar or the selection by the Company or any Subsidiary in its sole discretion of an applicable foreign currency exchange rate that may affect the value of the Option (or the calculation of income or Tax-Related Items thereunder);

(j) in consideration of the grant of the Option, no claim or entitlement to compensation or damages shall arise from forfeiture of the Option resulting from termination of service or employment by the Company or the Employer (for any reason whatsoever and whether or not in breach of Applicable Laws, including, without limitation, applicable local labor laws), and Participant irrevocably releases the Company and the Employer from any such claim that may arise; if, notwithstanding the foregoing, any such claim is found by a court of competent jurisdiction to have arisen, Participant shall be deemed irrevocably to have waived his or her entitlement to pursue such claim; and

(k) the Option and the benefits under the Plan, if any, will not automatically transfer to another company in the case of a merger, take-over or transfer of liability.

12. Additional Conditions to Issuance of Stock. If at any time the Company will determine, in its discretion, that the listing, registration, qualification or compliance of the Shares upon or with any securities exchange or under any Applicable Laws, the tax code and related regulations or the consent or approval of any governmental regulatory authority is necessary or desirable as a condition to the grant or vesting of the Option or purchase by, or issuance of Shares to, Participant (or his or her estate) hereunder, such purchase or issuance will not occur unless and until such listing, registration, qualification, compliance, consent or approval will have been completed, effected or obtained free of any conditions not acceptable to the Company. The Company will make all reasonable efforts to meet the requirements of any Applicable Laws. Assuming such compliance, for purposes of the Tax-Related Items, the Exercised Shares will be considered transferred to Participant on the date the Option is exercised with respect to such Exercised Shares. The Company shall not be obligated to issue any Shares pursuant to this Option at any time if the issuance of Shares, or the exercise of an Option by Participant, violates or is not in compliance with any Applicable Laws.

13. Imposition of Other Requirements. The Company reserves the right to impose other requirements on Participant's participation in the Plan, on the Option and on any Shares acquired under the Plan, to the extent the Company determines it is necessary or advisable in order to comply with any Applicable Laws or facilitate the administration of the Plan, and to require Participant to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing. Furthermore, Participant understands that the Applicable Laws of the country in which he or she is resident at the time of grant, vesting, and/or exercise of this Option or the holding or disposition of Shares (including any rules or regulations governing securities, foreign exchange, tax, labor or other matters) may restrict or prevent exercise of this Option or may subject Participant to additional procedural or regulatory requirements he or she is solely responsible for and will have to independently fulfill in relation to this Option or the Shares. Notwithstanding any provision herein, this Option and any Shares shall be subject to any special terms and conditions or disclosures as set forth in any addendum (the "***Country-Specific Addendum***," which forms part this Award Agreement) or in any Sub-Plan to the Plan for Participant's country. Participant also understands and agrees that if he works, resides, moves to, or otherwise is or becomes subject to Applicable Laws or company policies of another jurisdiction at any time, certain sub-plans, country-specific notices, disclaimers and/or terms and conditions may apply to him as from the date of grant, unless otherwise determined by the Company in its sole discretion.

14. Committee Authority. The Committee will have the power to interpret the Plan and this Award Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret or revoke any such rules (including, but not limited to, the determination regarding whether any Shares subject to the Option have vested and become exercisable). All actions taken, and all interpretations and determinations made, by the Committee in good faith will be final and binding upon Participant, the Company and all other interested persons. No member of the Committee will be personally liable for any action, determination or interpretation made in good faith with respect to the Plan or this Award Agreement.

15. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding Participant's participation in the Plan, or Participant's acquisition or sale of the underlying Shares. Participant is hereby advised to consult with his or her own personal tax, legal and financial advisors regarding Participant's participation in the Plan before taking any action related to the Plan.

***16. Data Privacy. Participant hereby explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of Participant's Personal Data (as described below) by and among, as applicable, the Company, any Subsidiary, or third parties as may be selected by the Company for the exclusive purpose of implementing, administering and managing Participant's participation in the Plan. Participant understands that refusal or withdrawal of consent will affect Participant's ability to participate in the Plan; without providing consent, Participant will not be able to participate in the Plan or realize benefits (if any) from the Option.***

***Participant understands that the Company and any Subsidiary, or designated third parties may hold personal information about Participant, including, but not limited to, Participant's name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any shares of stock or directorships held in the Company or any Subsidiary, details of all Options or any other entitlement to Shares awarded, canceled, exercised, vested, unvested or outstanding in Participant's favor ("Personal Data"). Participant understands that Personal Data may be transferred to any Subsidiary, or third parties assisting in the implementation, administration and management of the Plan, that these recipients may be located in the United States, Participant's country (if different than the United States), or elsewhere, and that the recipient's country may have different data privacy laws and protections than Participant's country. In particular, the Company may transfer Personal Data to the***

***broker or stock plan administrator assisting with the Plan, to its legal counsel and tax/accounting advisor, and to the Subsidiary or entity that is Participant's employer and its payroll provider.***

***Participant should also refer to any data privacy policy implemented by the Company (which will be available to Participant separately and may be updated from time to time) for more information regarding the collection, use, storage, and transfer of Participant's Personal Data.***

17. Address for Notices. Any notice to be given to the Company under the terms of this Award Agreement will be addressed to the Company, in care of its Secretary at ANI Pharmaceuticals, Inc., 210 Main Street West, Baudette, MN 56623, or at such other address as the Company may hereafter designate in writing.

18. Binding Agreement. Subject to the limitation on the transferability of this Option contained herein, this Award Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

19. Plan Governs. This Award Agreement is subject to all terms and provisions of the Plan. If there is a conflict between one or more provisions of this Award Agreement and one or more provisions of the Plan, the provisions of the Plan will govern. Capitalized terms used and not defined in this Award Agreement will have the meaning set forth in the Plan.

20. Corporate Records Control. In the event that the corporate records (e.g., Board or Committee consents, resolutions or minutes) documenting the corporate action constituting the grant of this Option contain terms (e.g., exercise price, vesting schedule or number of Shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the papering of the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

21. Electronic Delivery and Acceptance. By accepting this Option, Participant agrees to participate in the Plan through an on-line or electronic system established and maintained by the Company or a third party designated by the Company, and consents (a) to the electronic delivery of the Award Agreement, the Plan, account statements, Plan prospectuses, and all other documents, communications and information related to the Option, Shares and Participant's current or future participation in the Plan, and (b) to the use of electronic signatures and acceptances (including click-through acceptances) of terms and conditions. Electronic delivery may include the delivery of a link to the Company intranet or the internet site of a third party involved in administering the Plan, the delivery of the document via e-mail, or such other delivery determined at the Company's discretion. Participant may receive from the Company a paper copy of any documents delivered electronically at no cost if Participant contacts the Company by telephone, through a postal service, or email to Sherri Bitter, VP of Human Resources.

22. Translation. If Participant has received this Award Agreement, including appendices, or any other document related to the Plan or the Option translated into a language other than English, and the meaning of the translated version is different than the English version, the English version will control.

23. Captions. Captions provided herein are for convenience only and are not to serve as a basis for interpretation or construction of this Award Agreement.

24. Agreement Severable. If any provision in this Award Agreement will be held invalid or unenforceable, such provision will be severable from, and such invalidity or unenforceability will not be construed to have any effect on, the remaining provisions of this Award Agreement.

25. Modifications to the Agreement. This Award Agreement constitutes the entire understanding of the parties on the subjects covered. Participant expressly warrants that he or she is not accepting this Award

Agreement in reliance on any promises, representations, or inducements other than those contained herein. Modifications to this Award Agreement or the Plan can be made only in an express written contract executed by a duly authorized officer of the Company. Notwithstanding anything to the contrary in the Plan or this Award Agreement, the Company reserves the right to revise this Award Agreement as it deems necessary or advisable, in its sole discretion and without the consent of Participant, to comply with Code Section 409A or to otherwise avoid imposition of any additional tax or income recognition under Code Section 409A in connection to this Option.

26. Amendment, Suspension or Termination of the Plan. By accepting this Incentive Award, Participant expressly warrants that he or she has received an Option under the Plan, and has received, read and understood a description of the Plan. Participant understands that the Plan is discretionary in nature and may be amended, suspended or terminated by the Company at any time.

27. Governing Law and Venue. This Award Agreement will be governed by the laws of the State of Delaware, without giving effect to the conflict of law principles thereof. For purposes of litigating any dispute that arises under this Award Agreement, the parties hereby submit to and consent to the jurisdiction of the State of Delaware and agree that such litigation will be conducted in the courts of Delaware, or the federal courts for the United States for the District of Delaware and no other courts.

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**Country-Specific Addendum**

This Addendum includes additional country-specific notices, disclaimers, and/or terms and conditions that apply to Participants who are working or residing in the countries listed below, if any, and that may be material to their participation in the Plan. Such notices, disclaimers, and/or terms and conditions may also apply, as from the date of grant, if Participant moves to or otherwise is or becomes subject to the Applicable Laws or company policies of any country listed below. However, because foreign exchange regulations and other local laws are subject to frequent change, Participant is advised to seek advice from his or her own personal legal and tax advisor prior to accepting or exercising an Option or holding or selling Shares acquired under the Plan. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding Participant's acceptance of the Option or participation in the Plan. Unless otherwise noted below, capitalized terms shall have the same meaning assigned to them under the Plan, the Notice of Grant and the Award Agreement. This Addendum forms part of the Award Agreement and should be read in conjunction with the Award Agreement and the Plan.

**Securities Law Notice:** Unless otherwise noted, neither the Company nor the Shares are registered with any local stock exchange or under the control of any local securities regulator outside the United States. The Award Agreement (of which this Addendum is a part), the Notice of Grant, the Plan and any other communications or materials that Participant may receive regarding participation in the Plan do not constitute advertising or an offering of securities outside the United States, and the issuance of securities described in any Plan-related documents is not intended for public offering or circulation in Participant's jurisdiction.

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| **Canada** | **Plan Matters**<br><br>In the case of an Eligible Recipient who is a resident of Canada for purposes of the *Income Tax Act* (Canada), the following provisions shall apply:<br><br>1. All Options shall be treated as Non-Statutory Stock Options.<br><br>2. Shares issuable upon the exercise or settlement of an Option shall be newly and previously unissued shares of the applicable capital stock.<br><br>3. The reference to "the Code" in the definition of "Tax Date" in the Plan shall be replaced with "the *Income Tax Act* (Canada)".<br><br>4. If the number of Shares issuable upon the exercise of all or a part of an Option would, but for Section 4.3 of the Plan, result in the issuance of fractional Shares, the number of Shares so issuable shall be rounded down to the nearest whole number.<br><br>5. Notwithstanding Sections 4 and 6 of the Award Agreement, payment of the aggregate Exercise Price and/or aggregate Tax-Related Items will be made via a "net exercise" of the Options only with the consent and agreement of the Participant. In the event the Participant agrees to such a "net exercise", the Corporation agrees that an election pursuant to subsection 110(1.1) of the *Income Tax Act* (Canada) will be made in respect of the Options.<br><br>6. Section 14.3(a)(ii) of the Plan shall be replaced with "(ii) in the case of Options, exchange any or all outstanding Options for similar rights having a value not exceeding an amount equal to the amount the Participant would have received (net of the exercise price) with respect to |

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|---|---|
| | such vested Options had such Options been exercised immediately prior to the consummation of the Corporate Transaction."<br><br>**Securities Law Notice**<br><br>The security represented by this Option was issued pursuant to an exemption from the prospectus requirements of applicable securities legislation in Canada. Participant acknowledges that as long as the Company is not a reporting issuer in any jurisdiction in Canada, the Option and the underlying Shares will be subject to an indefinite hold period in Canada and subject to restrictions on their transfer in Canada. Subject to the terms and conditions of the Agreement and applicable securities laws, Participant is permitted to sell Shares provided the sale of such Shares takes place outside of Canada.<br><br>**Foreign Share Ownership Reporting**<br><br>If Participant is a Canadian resident, Participant's ownership of certain foreign property (including shares of foreign corporations) in excess of CAD $100,000 may be subject to ongoing annual reporting obligations. Participant should refer to CRA Form T1135 (Foreign Income Verification Statement) and consult Participant's tax advisor for further details. It is Participant's responsibility to comply with all applicable tax reporting requirements.<br><br>**Quebec: Consent to Receive Information in English**<br><br>The following applies if Participant is a resident of Quebec: The parties acknowledge that it is their express wish that this Award Agreement, as well as all documents, notices and legal proceedings entered into, given or instituted pursuant hereto or relating directly or indirectly hereto, be drawn up in English. *Les parties reconnaissent avoir exigé la redaction en anglais de cette convention, ainsi que de tous documents exécutés, avis donnés et procedures judiciaries intentées, directement ou indirectement, relativement à la présente convention.* |

**EXHIBIT A**

**ANI PHARMACEUTICALS, INC.**

**SIXTH AMENDED AND RESTATED**
**2008 STOCK INCENTIVE PLAN**

**EXERCISE NOTICE**

Baudette, MN 56623
Attention: _____

1. Exercise of Option. Effective as of today, _____, _____, the undersigned ("***Purchaser***") hereby elects to purchase, _____, shares (the "***Shares***") of the Common Stock of ANI Pharmaceuticals, Inc. (the "***Company***") under and pursuant to the Company's Sixth Amended and Restated 2008 Stock Incentive Plan (the "***Plan***"), the Notice of Stock Option Grant and the Stock Option Agreement dated _____, _____ (the **"*Award Agreement*"**). The purchase price for the Shares will be USD $ _____, as required by the Award Agreement.

2. Delivery of Payment. Purchaser herewith delivers to the Company, or otherwise makes adequate arrangements satisfactory to the Company, the full purchase price of the Shares and any Tax-Related Items (as defined in the Agreement) to be paid in connection with the exercise of the Option.

3. Representations of Purchaser. Purchaser acknowledges that Purchaser has received, read and understood the Plan and the Award Agreement and agrees to abide by and be bound by their terms and conditions.

4. Rights as Stockholder. Until the issuance (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company) of the Shares, no right to vote or receive dividends or any other rights as a stockholder will exist with respect to the Shares subject to the Option, notwithstanding the exercise of the Option. The Shares so acquired will be issued to Purchaser as soon as practicable after exercise of the Option. No adjustment will be made for a dividend or other right for which the record date is prior to the date of issuance, except as provided in Section 4.3 of the Plan.

5. Tax Consultation. Purchaser understands that Purchaser may suffer adverse tax consequences as a result of Purchaser's purchase or disposition of the Shares. Purchaser represents that Purchaser has consulted with any tax consultants Purchaser deems advisable in connection with the purchase or disposition of the Shares and that Purchaser is not relying on the Company for any tax advice.

6. Entire Agreement; Governing Law. The Plan and Award Agreement are incorporated herein by reference. This Exercise Notice, the Plan and the Award Agreement constitute the entire agreement of the parties with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and Purchaser with respect to the subject matter hereof, and may not be modified

adversely to the Purchaser's interest except by means of a writing signed by the Company and Purchaser. This agreement is governed by the internal substantive laws, but not the choice of law rules, of the State of Delaware.

| Submitted by: | Accepted by: |
| --- | --- |
| PURCHASER: | ANI PHARMACEUTICALS, INC. |
| Signature | Stephen Carey<br>Chief Financial Officer |
| Print Name | |
| | Date Received |

**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, 2020:

| **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. 333-239771) and on Form S-8 (Nos. 333-196518, 333-214416, 333-218120, and 333-250892) of our reports dated March 11, 2021, on our audits of the consolidated financial statements as of December 31, 2020 and 2019 and for each of the years in the three-year period ended December 31, 2020, and the effectiveness of ANI Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2020, which reports are included in this Annual Report on Form 10-K to be filed on or about March 11, 2021.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 11, 2021

**Exhibit 31.1**

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

I, Nikhil Lalwani, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 11, 2021

/s/ Nikhil Lalwani
Nikhil Lalwani
President and Chief Executive Officer

**Exhibit 31.2**

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

I, Stephen P. Carey, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 11, 2021

/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, 2020 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

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

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

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

Dated: March 11, 2021

/s/ Nikhil Lalwani
Nikhil Lalwani
President and
Chief Executive Officer
(principal executive officer)

Dated: March 11, 2021

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