ANI PHARMACEUTICALS INC
Form 10-K
February 28, 2014

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

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2013

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

For the transition period from _____ to _____.

Commission file number 001-31812

ANI PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

(218) 634-3500
(Registrant's telephone number, including area code)

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES x NO ¨

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

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

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 28, 2013, was $36.8 million (based upon the last reported sale price of $6.00 per share on June 28, 2013, on The NASDAQ Global Market).

As of February 14, 2014, 9,639,941 shares of common stock and 10,868 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 2014 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, 2013

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Available Information

ANI Pharmaceuticals, Inc. and its consolidated subsidiary, ANIP Acquisition Company (together, the “Company” or "ANI") 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"). The Company makes available free of charge on its website (www.anipharmaceuticals.com) its 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 the Company's website in the “Investors Corporate Governance” section are the Company's 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, the Company's website is not a part of, and is not incorporated into, this report or any other SEC filing. Copies of ANI's SEC filings or corporate governance materials are available without charge upon written request to Investor Relations, c/o ANI Pharmaceuticals, Inc., 210 Main Street West, Baudette, Minnesota, 56623.

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

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

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Exchange Act. Such statements include, but are not limited to, statements about the potential benefits of the recent Merger, the Company’s plans, objectives, expectations and intentions with respect to future operations and products, the anticipated financial position, operating results and growth prospects of the Company 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. Forward-looking statements by their nature address matters that are, to different degrees, subject to change. You should not place undue reliance on those statements because they are subject to numerous uncertainties, risks and other factors relating to the Company’s operations and business environment and other factors, all of which are difficult to predict and many of which are beyond the Company’s control.

Uncertainties and risks may cause the Company’s actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that the Company may in the future face increased difficulty in importing raw materials and/or increased competition, for its Esterified Estrogen with Methyltestosterone Tablet product; competitive conditions for the Company's other products may intensify; the Company may be required to seek the approval of the U.S. Food and Drug Administration ("FDA") for its unapproved products or withdraw such products from the market; general business and economic conditions;

the Company's expectations regarding trends in markets for the Company's current and planned products; the Company's future cash flow and its ability to support its operations; the Company's ability to obtain additional financing as needed; the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance of such products; and the marketing success of the Company's licensees or sublicensees.

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More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" section in Part I, Item 1A. of this annual report on Form 10-K and in other cautionary statements and risks included in other reports the Company files with the SEC. All forward-looking statements in this annual report speak only as of the date made and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

PART I

Item 1. Business

ANI Pharmaceuticals, Inc. and its consolidated subsidiary, ANIP Acquisition Company (together, the “Company” or “ANI”) is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. The Company has two pharmaceutical manufacturing facilities located in Baudette, Minnesota, which are capable of producing oral solid dose products, as well as liquids and topicals, narcotics, and potent products that must be manufactured in a fully-contained environment. The Company's strategy is to continue to use these manufacturing assets to develop, produce, and distribute niche generic pharmaceutical products.

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

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

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

Mission and Strategy

The Company is an integrated specialty pharmaceutical company, with its own research and development team, manufacturing facilities, and sales and regulatory compliance personnel. The Company's two facilities have a combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet. The facilities are specialized with diverse capabilities, enabling the Company to manufacture liquid, powder, and oral solid-dose products, topicals, narcotics and other products required to be manufactured in a fully contained environment. The Company also performs contract manufacturing for other pharmaceutical companies.

In addition to laboratories that support all of the requirements of raw material, finished product, and stability testing, the Company has 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 the Company’s high-potency manufacturing facility offers additional capabilities for

product development.

The Company's strategy is to use its assets to develop, manufacture and market branded and generic specialty pharmaceutical products. By developing and acquiring carefully-considered prescription pharmaceuticals, management believes the Company will be able to continue to grow its business, expand and diversify its product portfolio, and create long-term value for its investors.

Product Development Considerations

The Company considers a variety of criteria in determining which products to develop or acquire, all of which influence the level of competition and profitability upon product launch. These criteria include:

- ***Formulation Complexity.*** The Company's development and manufacturing capabilities enable it 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 the Company intends to leverage in selecting products to develop or manufacture.

- ***Patent Status.*** The Company seeks 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, management reviews the current and expected market size for that product at launch, as well as forecasted price erosion upon conversion from branded to generic pricing. The Company endeavors to manufacture products with sufficient market size to enable the Company to enter the market with a strong likelihood of being able to price its product both competitively and at a profit.

- ***Profit Potential.*** Management researches the availability and cost of active pharmaceutical ingredients along with anticipated market share in determining which products to develop or acquire. In determining the potential profit of a product, management forecasts the Company’s anticipated market share, pricing, which includes expected price erosion caused by competition from other generic manufacturers, and the estimated cost to manufacture the products.

- ***Manufacturing.*** The Company generally seeks to develop and manufacture products at its own manufacturing plants in order to maximize the capacity and utilization of its facilities, to ensure quality control in its products, and to maximize profit potential.

- ***Competition.*** When determining whether to develop or acquire an individual product, management researches the existing and expected market share of generic competitors. The Company seeks to develop products for which it can obtain a large market share, and may decline to develop a product if management anticipates that many generic competitors will be entering that product’s market. The Company’s highly specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies would be able to compete.

The Company believes its strategies are effective in leveraging the Company's human and capital assets and will result in measurable growth of the Company's business. Since 2011, the Company has successfully:

- Increased prescription product sales through market share gains on established products.
- Acquired the New Drug Application (“NDA”) for and began marketing Reglan®.
- Developed two new contract manufacturing customer relationships.
- Established two external product development partnerships to bolster the internal pipeline.
-

Filed five Abbreviated New Drug Applications ("ANDAs") and developed a pipeline of seven additional ANDAs.

- Entered into a contract to purchase the ANDAs for 31 previously marketed generic drug products, including 20 solid-oral immediate release products, four extended release products and seven liquid products for $12.5 million. This asset acquisition will help the Company expand and diversify its product lines over the next few years, help increase revenue, and reduce the Company's percentage of revenue derived from sales of unapproved products.

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The Company's cash resources and forecasted cash flows from operations are sufficient to enable the Company to meet its operational needs for the foreseeable future.

As part of the Merger, the Company acquired a license with Teva for a royalty stream related to a percentage of sales of a male testosterone gel that was developed initially by BioSante, and then licensed to Teva for late stage clinical development. The intangible asset related to the Teva license was valued at $10.9 million in the purchase accounting for the Merger and is being amortized over its estimated life of 11 years. In addition, immediately prior to the Merger, the Company distributed to its then current stockholders contingent value rights ("CVRs") providing payment rights arising from a future sale, transfer, license or similar transaction(s) involving LibiGel ® (female testosterone gel).

Products and Markets

Products

The Company's established product portfolio consists of both branded and generic pharmaceuticals, including:

Generic Products	Branded Products
Esterified Estrogen with Methyltestosterone Tablets	Cortenema®
Fluvoxamine Maleate Tablets	Reglan® Tablets
Hydrocortisone Enema	
Metoclopramide Syrup	
Opium Tincture	

Esterified Estrogen with Methyltestosterone ("EEMT") is used to treat moderate to severe vasomotor symptoms of menopause, such as hot flashes and heart palpations that are not improved by estrogen medications alone. For the year ended December 31, 2013, EEMT comprised 33% of the Company's net sales, a substantial increase over the prior year wherein EEMT comprised only 9% of the Company's net sales. In the third quarter of 2013, a significant competitor stopped producing EEMT, which led to a material increase in the Company's market share for the product and enabled the Company to significantly increase the price it charges for the product.

Fluvoxamine Maleate is used to treat obsessions and compulsions in patients with obsessive-compulsive disorder. It is generally used when the obsessions and compulsions in a patient interfere with the patient's ability to function socially and occupationally.

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

Metoclopramide syrup and its branded equivalent Reglan®, in tablet form, are prescribed for periods of four to twelve weeks for heartburn symptoms with gastroesophageal reflux disease ("GERD") when certain other treatments do not work. The products relieve daytime heartburn and heartburn after meals and also help ulcers in the esophagus to heal. The products also relieve symptoms of slow stomach emptying in people with diabetes and help treat symptoms such as nausea, vomiting, heartburn, feeling full long after a meal, and loss of appetite.

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

Markets

In determining which products to pursue for development, the Company targets markets whose products are complex to manufacture and therefore have higher barriers to entry. These market factors provide opportunities for the Company's growth consistent with its competitive strengths at the same time that they decrease the number of potential competitors in the markets. These markets currently include hormone and steroidal drugs, oncolytics, and narcotics and complex formulations, including extended release and combination products.

Hormone and Steroidal Drugs

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

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

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

Oncolytics

The Company is positioned to develop and manufacture niche oncolytic (anti-cancer) drugs due to the capabilities of the Company's containment facility and its expertise in manufacturing segregation. In particular, the Company is targeting products subject to priority review by the FDA those with no blocking patents and no generic competition. In addition to one such product already under development, the Company has identified additional priority review opportunities in oncolytics.

Narcotics

The Company's main manufacturing facility in Baudette, Minnesota is licensed by the DEA for the manufacture and distribution of Schedule II narcotics, i.e., drugs considered to have a high abuse risk but that also have safe and accepted medical uses in the United States. In addition to its existing pipeline of four ANDAs, the Company has identified additional product development opportunities in this market.

Contract Manufacturing

The Company manufactures pharmaceutical products for several branded and generic companies, which outsource production to the Company 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 the Company's specialized equipment and expertise.

The Company considers contract manufacturing to be an important component of its ongoing business. Given its highly specialized manufacturing capabilities, the Company is focused on attracting niche contract manufacturing

opportunities that fill idle capacity and offer high margins.

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Manufacturing, Suppliers and Raw Materials

The Company requires a supply of quality raw materials, including active pharmaceutical ingredients ("API"), and components to manufacture and package its pharmaceutical products. In order to manufacture Opium Tincture, the Company must submit a request to the DEA each year for a quota to purchase the amount of API (opium) needed to manufacture the product for the following year. Without an approved quota from DEA, the Company would not be able to purchase this ingredient from its supplier.

The Company sources the raw materials for its products from both domestic and international suppliers that the Company selects on the basis of their quality, reliability of supply, and long-term financial stability. Generally, the Company qualifies 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 by the Company in one of its API suppliers must usually be approved through a Prior Approval Supplement by the FDA. Certain of the Company's API for its drug products, including those that are marketed without approved NDAs or ANDAs, such as EEMT, are sourced from international suppliers. From time to time the Company has experienced temporary disruptions in the supply of certain of such imported API due to FDA inspections.

Government Regulation

The pharmaceutical industry is highly regulated by the federal government and the Company is subject to extensive and complex regulation, including physical inspection of its facilities, under multiple federal statutes, which are subject to revision from time to time. While the Company has experience with these regulations, there can be no assurance that the Company will be able to fully comply with all applicable regulations.

Generic Pharmaceutical Products

Prescription pharmaceutical products in the United States are generally marketed as either branded or generic drugs. Branded products are generally patent protected, which provides a period of market exclusivity during which time they are sold by the developer of the product with little or no competition for the compound, although typically there are other products in the same therapeutic area.

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

New Drug Application ("NDA") An NDA is filed when approval is sought to market a newly developed branded product and, in certain instances, for a new dosage form, a new delivery system or a new indication for a previously approved drug. The Company markets its Cortenema®, generic Hydrocortisone Enema, Reglan® tablets and generic Fluvoxamine tablets under approved NDAs.

Abbreviated New Drug Application ("ANDA") An ANDA is filed when approval is sought to market a generic equivalent of a drug product previously approved under an NDA. The Company markets its Metoclopramide syrup under an approved ANDA. The Company has submitted five ANDAs and had an additional seven ANDAs in its pipeline as of December 31, 2013.

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 reference branded drug previously 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 referenced branded drug.

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 reference branded drug.

Accordingly, generic products generally provide a safe, effective and cost-efficient alternative to users of reference 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 introduced to the marketplace 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 for the reference drug may be entitled to a period of non-patent market exclusivity, during which the FDA cannot approve an application for a generic product. If the reference drug is a new chemical entity ("NCE"), the FDA may not accept an ANDA for a generic product for up to five years following approval of the NDA for the NCE. If it 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 an ANDA for the reference branded product before the expiration of three years. Certain other periods of exclusivity may be available if the referenced drug is indicated for treatment of a rare disease or is studied for pediatric indications.

One requirement for FDA approval of NDAs and ANDAs is that the Company's manufacturing procedures and operations 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, the Company must consistently keep pace and comply with these changes.

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

Controlled Substances

The DEA regulates certain drug products containing controlled substances, such as opium, which is a significant component of one of the Company's current products, 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, the Company must submit a request to the DEA for a quota to purchase the amount of active pharmaceutical ingredient (opium) needed to manufacture Opium Tincture. Without an approved quota from DEA, the Company would not be able to purchase this ingredient from its supplier. As a result, the Company is dependent upon the DEA to approve, on an annual basis, a quota of active pharmaceutical ingredient that is sufficiently large to support the continued manufacture of Opium Tincture.

Unapproved Products

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

Medicaid/Medicare

Medicaid and Medicare, both United States federal health care programs, are major purchasers of pharmaceutical products, including those produced by the Company.

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 up to 138 percent of the federal poverty level, largely funded by the federal government. Although the United States Supreme Court in 2011 made the Medicaid expansion optional, many states are expanding their Medicaid programs. This expansion of Medicaid coverage may increase usage of pharmaceuticals.

On the other hand, the ACA also made changes to Medicaid law that could negatively impact the Company. In particular, pharmaceutical manufacturers must enter into rebate agreements with state Medicaid agencies, which require rebates based on the 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 percent of the average manufacturer price for sales of Medicaid-reimbursed products marketed under ANDAs. (Prior to the ACA the percentage rebate had been 11 percent.) Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of 23.1 percent (up from 15.1 percent) of the average manufacturer price or the difference between the average manufacturers price and the "best price" (as defined in the Medicaid statute) during a specific period. The Company believes that federal and/or state governments may continue to enact measures aimed at reducing the cost of drugs to the Medicaid program.

Medicare is run entirely 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. (Medicare previously did not cover prescription drugs.) The MMA has increased usage of pharmaceuticals, which is a trend that the Company believes 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. On the other hand, the ACA also required pharmaceutical companies to provide discounts to Medicare Part D beneficiaries for the cost of branded prescription drugs. Under the Medicare Coverage

Gap Discount Program authorized by the ACA, any pharmaceutical product marketed under an NDA, regardless of whether the product is marketed as a "generic," is subject to the discount requirement. The Company's Hydrocortisone Enema and Fluvoxamine Maleate products, while marketed as "generics," are actually the subject of approved NDAs and, therefore, are subject to the discount requirement. The Company benefits from Medicare changes that have reduced obstacles to drug usage. However, resulting sales increases may be offset by existing and future legislative efforts to curb the cost of drugs to the Medicare program.

Several of the Company's products are covered by Medicaid and Medicare, and the reimbursement calculations for these rebates are complex and subject to change. For Medicaid, these calculations may vary from state to state. If the Company does not calculate its rebates correctly or in alignment with state Medicaid programs or as calculated by Medicare, the Company could be subject to federal or state false claims litigation.

Research and Development

The Company develops new generic products through a combination of internal development and fee-for-service arrangements with other firms. Additionally, the Company licenses and co-develops products through collaborations with other companies as noted below. During the years ended December 31, 2013 and 2012, the Company's research and development expenses were $1.7 million and $1.2 million, respectively.

Sofgen Pharmaceuticals

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

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

RiconPharma LLC

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

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

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

Patents, Trademarks and Licenses

The Company owns the trademark names for each of its branded products, Cortenema® and Reglan®. Generally, the branded pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. The Company does not own or license any patents associated with these products. Further, patent protection and market exclusivity for these two branded products have long-since expired. Therefore, the Company considers the trademark names to be of material value and acts to protect these rights from infringement. However, the Company's business is not dependent upon any single trademark. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and may be renewed indefinitely. The Company believes that sales of its branded products have benefited and will continue to benefit from the value of the product name.

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

Customers

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

In recent years, the wholesale distributor network for pharmaceutical products has been subject to increasing consolidation, which has increased the concentration of the Company’s 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 the Company’s 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, 2013, approximately 55% of the Company’s gross sales were attributable to three key wholesalers: McKesson Corporation (27%), Cardinal Health, Inc. (18%), and AmerisourceBergen Corporation (10%). In addition, as noted below, the Company's customers also distribute the Company's products. The loss of any of these customers, including in their role as distributors, could have a material adverse effect on the Company’s business.

Consistent with industry practice, the Company maintains 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 the Company's accruals for chargebacks, returns, and other allowances.

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Sales, Marketing and Distribution

The Company sells and markets its products in the United States. The Company's products are distributed through the following channels:

- ***Wholesalers.*** The Company has contracts with four major wholesalers in the United States: Cardinal, McKesson, AmerisourceBergen, and Morris Dickson, as well as access to their respective retail source programs.

- ***Retail Market Chains.*** The Company conducts business with four major retail chains in the United States: Walgreens, CVS, RiteAid, and Wal-Mart.

- ***Distributors and Mail Order Pharmacies.*** The Company has contracts with several major distributors and mail order pharmacies in the United States, including Anda, ExpressScripts, and Omnicare.

- ***Hospital Market.*** The Company has contracts with group purchasing organizations in the United States, such as Premiere, MedAssets, Minnesota Multi-State, and the Federal Supply Schedule (“FSS”).

Competition

The Company's target markets have more limited competition due to complexities in formulation, active pharmaceutical ingredient sourcing, materials handling and manufacturing, and regulatory hurdles. Nevertheless, the Company competes with numerous other pharmaceutical companies, including large, global pharmaceutical companies capable of addressing these complexities and hurdles with respect to products that the Company currently produces and products that are in the Company’s pipeline. In addition, the Company’s products are subject to competition from other generic substitutes and non-prescription alternative therapies.

The Company’s branded pharmaceutical products currently face competition from generic substitutes and may continue to face competition from generic substitutes in the future. For a manufacturer to launch a generic substitute (including by the Company, with respect to the generic products that it develops and manufactures), the manufacturer must apply to the FDA for an ANDA showing that the generic substitute is therapeutically equivalent to the reference branded drug product. (See “Government Regulation.")

The primary means of competition among generic drug manufacturers are pricing and contract terms, service levels, and supplier reliability. In addition, generic drug manufacturers compete based on brand recognition and customer loyalty, as well as the manufacturer's ability to produce other formulations that may complement its other generic products. To compete effectively, the Company seeks to consistently produce high-quality, reliable, and effective products. It also establishes active working relationships with each of its customers, continually gathers important market information in order to respond successfully to requests for proposals, maintains sufficient inventories to assure high service levels, and works to reduce product costs by sourcing and qualifying alternative suppliers whenever possible and rebidding product components on a routine basis.

The Company's sales can be impacted by new studies that indicate that a competitor's product has greater efficacy for treating a disease or particular form of a disease than one of the Company's products. If competitors introduce new products and processes with therapeutic or cost advantages, the Company’s products can be subject to progressive price reductions and/or decreased volume of sales.

Principal competitors for the types of drugs in which the Company transacts business are as follows:

Hormones and Steroids. Competition for hormone and steroidal drugs is limited because of the small number of plants in the United States capable of safely manufacturing these high-potency compounds. Current generic participants in hormone and steroidal drugs include Creekwood Pharmaceuticals, Endo Pharmaceuticals, Glenmark Pharmaceuticals, Watson Pharmaceuticals, and Teva Pharmaceuticals USA.

Oncolytics. Competitors for oncolytic products include both top-tier generic pharmaceutical companies as well as niche players. Current market participants include Mylan, Par Pharmaceutical Companies, Sandoz, the generic pharmaceuticals division of Novartis AG, Watson Pharmaceuticals, and Teva Pharmaceuticals USA.

Narcotics. Although market share in narcotic products is concentrated among two principal companies, i.e., Purdue Pharma and Mallinckrodt, several other companies with material market share in specific product categories within narcotics include Lannett, Endo Pharmaceuticals, Roxane Laboratories, and Watson Pharmaceuticals.

Generic Industry Trends

In recent years, the generic drug industry has experienced significant consolidation, particularly in established distribution channels and amongst generic drug manufacturers and competitors.

The wholesale distributor network for pharmaceutical products has been subject to increasing consolidation, which has increased the concentration of the Company’s 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 the Company’s retail customers. As a result of this trend toward consolidation, a smaller number of companies each control a larger share of pharmaceutical distribution channels.

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

Product Liability

Product liability litigation represents an inherent risk to all firms in the pharmaceutical industry. The Company utilizes traditional third-party insurance policies with regard to its product liability claims. Such insurance coverage at any given time reflects market conditions, including cost and availability, existing at the time the policy is written, and the decision to obtain commercial insurance coverage or to self-insure varies accordingly.

In February 2009, the FDA mandated a "black box" warning for the drug metoclopramide, specifically highlighting the risks of patients developing tardive dyskinesia, a movement disorder, when taking metoclopramide for longer than 12 weeks. As a result, numerous state-level lawsuits were brought against pharmaceutical manufacturers, both branded and generic, that had ever manufactured and/or sold metoclopramide. Among the defendants is the Company, which manufactures the generic version and since 2011 has been manufacturing the branded version under the name Reglan®. The plaintiffs in these lawsuits claim to have incurred bodily injuries as a result of ingestion of metoclopramide or Reglan® prior to the FDA's black box warning requirement. The allegations involve a failure, based on various state-level consumer protection laws, to adequately warn patients and doctors about the risks of using metoclopramide for longer than 12 weeks as evidenced by the FDA's mandate to strengthen the labeled warning.

As the state-level litigation progressed, the generic pharmaceutical defendants appealed to the U.S. Supreme Court arguing that generic companies could not comply with state laws that required them to strengthen their labels because generic companies are prohibited by federal law from making any changes except those adopted by the brand or mandated by FDA for all manufacturers, e.g. federal pre-emption. The U.S. Supreme Court decided in favor of the generic companies in June 2011 in what is known now as the Mensing decision. While many cases have since been dismissed by state courts, several judges, including in Pennsylvania and California, have allowed the plaintiffs to resubmit their complaints.

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At the present time, the Company's management is unable to assess the likely outcome of the remaining cases. The Company's insurance company has assumed the defense of this matter. In addition, the Company's insurance company renewed the Company's product liability insurance on September 1, 2012 and 2013 with absolute exclusions for claims related to Reglan® and metoclopramide. The Company cannot provide assurances that the outcome of these matters will not have an adverse effect on its business, results of operations, financial condition and cash flow. Furthermore, like all pharmaceutical manufacturers, the Company in the future may be exposed to other product liability claims, which could harm its business, results of operations, financial condition and cash flow.

Backlog

The Company had a backlog of $2.1 million and $2.0 million at December 31, 2013 and 2012, respectively, relating to contract manufacturing purchase orders from customers.

Employees

As of December 31, 2013, the Company's workforce included 81 full-time employees, including 39 salaried employees, and a flexible direct labor pool of 23 experienced pharmaceutical manufacturing and packaging staff. Of the 81 full-time employees, 53 are in selling, general and administrative, 23 in production and five in research and development.

Seasonality of Business

The Company does not believe its business is subject to seasonality. However, the Company's business can be subject to and affected by the business practices of our business partners. To the extent that the availability of inventory or materials from or development practices of our partners is seasonal, the Company's sales may be subject to fluctuations quarter to quarter or year over year.

Item 1A. Risk Factors

The following are significant factors known to the Company that could materially harm its business, financial condition or operating results or could cause its actual results to differ materially from its 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 the Company. Additional risks and uncertainties not currently known to management, or that management currently deems to be immaterial, also may adversely affect the Company's business, financial condition and/or operating results. If any of these risks actually occur, the Company's business, financial condition 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.

The Company has a history of losses and negative cash flow and cannot offer any assurances that it will ever achieve profitability.

The Company has not been profitable until this year, has an accumulated deficit of $48.5 million as of December 31, 2013, and has not generated positive cash flows from operations. To bridge the gap between revenues and operating and capital needs, the Company has been dependent on a variety of financing sources, including the issuance of equity securities and convertible notes, and revolving lines of credit.

The Company cannot predict whether it will achieve, sustain or increase profitability on a quarterly or annual basis in the future. If revenues grow more slowly than anticipated, or if operating expenses exceed the Company's expectations or cannot be adjusted accordingly, then the Company's business, results of operations, financial condition and cash flows will be materially and adversely affected.

Due to a recent and significant decrease in competition for Esterified Estrogen with Methyltestosterone tablets ("EEMT"), which the Company cannot be certain will continue, the Company's revenue and operating income has increased dramatically since the third quarter of 2013. If the Company experienced increased competition for the product, it could lose market share, be forced to lower prices, or both, any of which could have a material adverse effect on its business, financial position and results of operations.

The Company's sales of EEMT, which are sold without an approved NDA or ANDA, accounted for approximately 33% of net revenues, but only approximately 24% of cost of sales during the year ended December 31, 2013. Currently, the Company faces no significant competition for its EEMT product because, in the third quarter of 2013, a significant competitor stopped producing EEMT. This has led to a material increase in the Company's market share for the product and enabled the Company to significantly increase the prices it charges for the product. As a result of the Company's price increases, the market size for the product has also increased significantly, which could in turn increase the likelihood of the prior competitor re-entering the market. If the prior competitor or any third party is able to successfully produce, market and distribute a product competitive with EEMT, the Company's sales of EEMT could decrease, potentially materially, with a corresponding reduction in revenues, which would have a material, adverse impact on the Company's business, financial condition, cash flows and stock price.

In addition, as described below, the Company sells EEMT without an approved NDA or ANDA and can provide no assurances that the FDA will not require the Company to seek approval for the product or withdraw it from the market. If the FDA required the Company obtain an approved NDA or ANDA in order to sell EEMT, the Company's business, financial condition, cash flows and stock price would be materially and adversely impacted. The costs of and time involved in obtaining an approved NDA or ANDA would be significant and the Company may determine not to pursue such approvals. Unless the Company were successful in increasing sales of other products to replace any revenue lost from the sale of its EEMT product, whether due to competition, FDA actions or otherwise, its business and stock price would be materially harmed, potentially for the long term. Because of the increase in revenue related to sales of this product, the percentage of the Company's net revenues related to EEMT increased to 33% from

9% for the years ended December 31, 2013 and 2012, respectively.

Certain of the Company's generic products are marketed without approved New Drug Applications ("NDAs") or Abbreviated New Drug Applications ("ANDAs") and the Company can offer no assurances that the U.S. Food and Drug Administration ("FDA") will not require the Company to either seek approval for these products or withdraw them from the market. In either case, the Company's business, financial position and results of operations could be materially adversely affected.

Two of the Company's products, EEMT and Opium Tincture, are marketed without approved NDAs or ANDAs. During the years ended December 31, 2013 and 2012, net revenues for EEMT were 33% and 9% of total revenue, respectively and net revenues from Opium Tincture were 16% and 20% of total revenue, respectively.

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

In October 2012, the Company received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of Opium Tincture, which is an unapproved product. That meeting was held on October 25, 2012 by conference telephone call and included FDA representatives from the Office of Compliance at the Center for Drug Evaluation and Research. Counsel to the Company sent a letter to the FDA on November 9, 2012 in support of the Company's position. Although the FDA confirmed receipt of this letter, the Company has received no further response from the FDA. If, as a result of such discussions or otherwise, the FDA were to make a determination that the Company could not continue to sell Opium Tincture as an unapproved product, the Company would be required to seek FDA approval for such product or withdraw such product from the market. If the Company determined to withdraw the product from the market, the Company's net revenues for generic pharmaceutical products would decline materially, and if the Company decided to seek FDA approval, it would face increased expenses and might need to suspend sales of the product until such approval is obtained, and there are no assurances that the Company would receive such approval.

In addition, the Company manufactures a group of products on behalf of a contract manufacturing customer and receives royalties on the customer's sales of products, which are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market, which could materially adversely affect the Company's contract manufacturing and royalty revenues. The Company's contract manufacturing revenues from this group of unapproved products for the years ended December 31, 2013 and 2012 were 6.5% and 6.8% of total revenues, respectively. The Company's royalties on the net sales of these unapproved products for the years ended December 31, 2013 and 2012 were 1.1% and 1.4% of total revenues, respectively.

The Company is entirely dependent on periodic approval by the Drug Enforcement Administration for the supply of the active pharmaceutical ingredient needed to make Opium Tincture and inability to obtain such approval would reduce or eliminate revenues from the sale of Opium Tincture. In addition, the Company is subject to strict regulation by the Drug Enforcement Administration and is subject to sanctions if it is unable to comply with related regulatory requirements.

The Drug Enforcement Administration ("DEA") regulates certain drug products containing controlled substances, such as opium, 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, the Company must submit a request to the DEA for a quota to purchase the amount of active pharmaceutical ingredient needed to manufacture Opium Tincture, one of its major products. Without an approved quota from DEA, the Company would not be able to purchase this ingredient from its supplier. As a result, the Company is entirely dependent upon the DEA to approve, on an annual basis, a quota of active pharmaceutical ingredient that is sufficiently large to support the Company's plans for the continued manufacture of Opium Tincture at commercial levels.

The Company depends on a limited number of suppliers for active pharmaceutical ingredients.

The Company's ability to manufacture and distribute drug products is dependent, in part, upon ingredients and components supplied by others, including entities based outside the United States. The Company purchased approximately 37% and 63% of total costs of goods sold from three suppliers during the years ended December 31, 2013 and 2012, respectively. Any disruption in the supply of these ingredients or components or any problems in their quality could materially affect the Company's ability to manufacture and distribute drug product and could result in legal liabilities that could materially affect the Company's ability to realize profits or otherwise harm the Company's business, financial, and operating results. As described above, virtually all contracts for the supply of pharmaceutical products by the Company to customers contain "failure to supply" clauses. The ability to source sufficient quantities of active pharmaceutical ingredients ("API") for manufacturing is therefore critical to the Company. The Company sources the raw materials for its products, including API from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers must usually be approved through a Prior Approval Supplement by the FDA. As the API typically comprises the majority of a product's manufactured cost, and qualifying an alternative is costly and time-consuming, API suppliers must be selected carefully based on quality, reliability of supply and long-term financial stability.

Imported API is subject to inspection by the FDA and FDA can refuse to permit the importation of API for use in products that are marketed without approved NDAs or ANDAs. The Company is entirely dependent on imported API to make EEMT. If the FDA detained or refused to allow the importation of such API, the Company's revenues from the sales of EEMT would be reduced or eliminated and the Company's business, financial position and results of operations could be materially adversely affected.

The Company sources certain of the API for its drug products, including those that are marketed without approved NDAs or ANDAs, from international suppliers. From time to time, due to FDA inspections, the Company has experienced temporary disruptions in the supply of certain of such imported API, including EEMT. Any prolonged disruption in the supply of such imported API could materially affect the Company's ability to manufacture and distribute its drug products, such as EEMT, reduce or eliminate the Company's revenues from sales of EEMT, and have a material adverse effect on the Company's business, financial position and operating results.

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

The Company's future revenues and profitability are dependent upon its 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. The Company may not be

successful in commercializing products on a timely basis, if at all, which could adversely affect its business, financial position and results of operations.

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

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, the Company could be unable to grow or maintain market share with respect to generic pharmaceutical products, which could have a material adverse effect on the Company's ability to market that product profitably and on its business, financial position and results of operations.

Furthermore, if the Company is unable to address all regulatory requirements applicable to the development and commercialization of new products in a timely manner, its product introduction plans, business, financial position and results of operations 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 the company to change current practices and prevent unlawful activity in the future.

The Company faces vigorous competition from other pharmaceutical manufacturers that threatens the commercial acceptance and pricing of its products. If the Company is unable to successfully compete, such competition could have a material adverse effect on its business, financial position and results of operations and cash flows.

The generic pharmaceutical industry is highly competitive. The Company faces intense competition from U.S. and foreign manufacturers, many of whom are significantly larger than the Company. Its competitors may be able to develop products and processes competitive with or superior to the Company's 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.

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Any significant competitor of the Company, due to one or more of these and other factors, could have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

The Company's approved products may not achieve commercialization at levels of market acceptance that allow the Company to achieve profitability, which could have a material adverse effect on its business, financial position and results of operations.

The Company seeks to develop, license or acquire products that it can commercialize at levels of market acceptance that would allow the Company to recoup the costs of development and commercialization, grow market share, and achieve profitability. Even if the Company is able to obtain regulatory approvals for its pharmaceutical products, if the Company fails to accurately predict demand for such products, its business, financial position, and results of operations could be adversely impacted. Levels of market acceptance for products could be impacted by several factors, including but not limited to:

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

Some of these factors are not within the Company's control and, if any arises, the Company's profitability, business, financial position and results of operations could be materially adversely affected.

Although the Company's male testosterone gel is approved by the FDA, the Company is uncertain as to when Teva will begin to market and sell the male testosterone gel and thus when or if the Company would begin to receive royalties from such sales in light of Teva's settlement agreement with AbbVie Inc.

The Company's male testosterone gel was developed initially by the Company, and then licensed by the Company to Teva for late stage clinical development. Teva submitted an NDA, which was approved by the FDA in February 2012. Subsequent to Teva submitting the NDA, in April 2011, AbbVie Inc., a marketer of a testosterone gel for men, filed a complaint against Teva alleging patent infringement with respect to the male testosterone gel. The Teva/AbbVie patent infringement litigation was settled in December 2011. In light of the settlement agreement, the Company is uncertain as to when or if Teva will begin to market and sell its male testosterone gel and thus when or if the Company would begin to receive royalties from such sales. In addition, the intangible asset related to the Teva license was valued at $10.9 million in the purchase accounting for the Merger. If Teva does not begin to market or sell its male testosterone gel, the value of the intangible asset could be at risk of impairment, which could result in an impairment charge that could have a material negative impact on the Company's financial results.

Future acquisitions and investments could disrupt the Company's business and harm its financial condition and operating results.

The Company's growth will depend, in part, on its continued ability to develop, commercialize and expand its drug products, including in response to changing regulatory and competitive pressures. In some circumstances, the Company may determine to accelerate its growth through the acquisition of complementary businesses and

technologies rather than through internal development. The identification of suitable acquisition candidates or products can be difficult, time-consuming and costly, and the Company 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 the Company's 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, management information, human resources and other administrative systems;
- the need to implement or improve controls, procedures, and policies at a business that prior to the acquisition may have lacked effective controls, procedures and policies;
- liability for activities of the acquired company and/or products before the acquisition, including patent infringement claims, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company or product, including claims from product users, former stockholders or other third parties.

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

The Company began its own product development program in 2011 and expects to spend a significant amount of resources on research and development efforts that may not lead to successful product introductions. Failure to successfully introduce products into the market could have a material adverse effect on its business, financial position and results of operations.

The Company conducts research and development primarily to enable it to manufacture and market approved pharmaceuticals in accordance with applicable regulations. As the Company seeks to develop and develops new products, its research expenses will increase, potentially significantly. Research and development is expensive and time-consuming. The Company’s research and development expenditures may not result in the successful introduction of new pharmaceutical products approved by the FDA. Also, after the Company submits a marketing authorization application for a generic product, the FDA may change standards and/or request that the Company conduct additional studies and, as a result, the Company may incur total research and development costs to develop a particular product in excess of what it anticipated. Finally, the Company cannot be certain that any investment made in developing products will be recovered, even if it is successful in commercialization. To the extent that the Company spends significant resources on research and development efforts and is not able to introduce successful new products as a result of those efforts, its business, financial position and results of operations may be materially adversely affected.

The Company relies on third parties to assist it in its clinical studies. If these third parties do not perform as required contractually or expected, the Company’s clinical studies may be extended, delayed or terminated or may need to be repeated, and the Company may not be able to obtain regulatory approval for or commercialize the product being tested in such studies.

The Company relies on third parties, such as medical institutions, clinical investigators and contract laboratories, to assist it in its clinical studies. The Company is responsible for confirming that its studies are conducted in accordance with applicable regulations and that each of its clinical studies is conducted in accordance with its general investigational plan and protocol. The FDA requires the Company 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. The Company’s reliance on these third parties does not relieve it of these responsibilities. If the third parties assisting the Company with its 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 the Company’s protocols or otherwise fail to generate reliable clinical data, the Company may need to enter into new arrangements with alternative third parties and its clinical studies may be extended, delayed or terminated or may need to be repeated, and the Company may not be able to obtain regulatory approval for or commercialize the product being tested in such studies. In addition, if a third party fails to perform as agreed, the Company’s ability to collect damages may be limited contractually.

The Company does not own or license any material patents associated with its products, and its 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. The Company does not own or license any material patents associated with its products and therefore does not enjoy the same level of intellectual property protection with respect to such products as would a pharmaceutical manufacturer that markets a patented product. The Company has a 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. Also, others may gain access to the Company's trade secrets, and the Company may not be able to meaningfully protect its rights to its unpatented trade secrets. In addition, confidentiality agreements and other measures may not provide meaningful protection for the Company's 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 the Company's trade secrets, know-how and other technological innovation.

The use of legal, regulatory and legislative strategies by competitors, both branded and generic, including "authorized generics" and citizen's petitions, as well as the potential impact of proposed legislation, may increase the Company's costs associated with the introduction or marketing of the Company's generic products, could delay or prevent such introduction and/or could reduce significantly the Company's profit potential. These factors could have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

The Company's 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's petitions with the FDA or other regulatory bodies, including timing the filings so as to thwart generic competition by causing delays of the Company's 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 for which the Company seeks regulatory approval;

- 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 name 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 the Company cannot compete with such strategies, the Company's business, financial position, results of operations and cash flows could be materially negatively impacted.

Companies with greater resources than the Company could lobby Congress and other regulators for additional regulations that would benefit their situations but would negatively impact the Company.

The Company is at the early stages of growth and currently does not engage in lobbying activities. In the United States, some companies have lobbied Congress for amendments to the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") that would give them additional advantages over generic competitors. For example, although the term of a company's drug patent can be extended to reflect a portion of the time an NDA is under regulatory review, some companies have proposed extending the patent term by the full amount of time spent in clinical trials rather than by only one half of the time that is currently permitted.

If proposals like these were to become effective, the Company's entry into the market and its ability to generate revenues associated with new products may be delayed, reduced or eliminated, which could have a material adverse effect on its business, financial position, results of operations and cash flows.

The Company faces significant uncertainty with respect to the litigation brought against it and other manufacturers of metoclopramide and cannot provide assurances that the outcome of the matter will not have an adverse effect on its financial position, results of operations and/or cash flows from operations. In addition, the Company may be exposed to other product liability claims in the future.

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

At the present time, management is unable to assess the likely outcome of the cases in the remaining states. The Company's insurance company has assumed the defense of this matter. In addition, the Company's insurance company renewed the Company's product liability insurance on September 1, 2012 and 2013 with absolute exclusions for claims related to Reglan® and metoclopramide. Management cannot provide assurances that the outcome of these matters

will not have an adverse effect on its business, results of operations, financial condition and cash flow. Furthermore, like all pharmaceutical manufacturers, the Company in the future may be exposed to other product liability claims, which could harm its business, results of operations, financial condition and cash flow.

The Company's management does not have significant experience in addressing the extensive regulations that the Company must comply with as a public company and is required to devote substantial time to comply with public company regulations.

As a public company, the Company is required to comply with significant legal, accounting and other requirements that ANIP Acquisition Company did not face as a private company and as such, has incurred significant regulatory compliance-related expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act as well as rules implemented by the SEC and The NASDAQ Global Market, impose various requirements on public companies, including those related to corporate governance practices. The Company's management and other personnel devote a substantial amount of time to these requirements. Certain members of the Company's management do not have significant experience in addressing these requirements. Moreover, these rules and regulations have increased the company's 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 the Company maintain effective internal control for financial reporting and disclosure controls and procedures. In particular, the Company must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal control 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. The Company's compliance with these requirements has required that it incur substantial accounting and related expenses and expend significant management efforts. Moreover, if the Company is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, is unable to assert that its internal controls over financial reporting are effective, or identifies deficiencies in its internal control over financial reporting that are deemed to be material weaknesses, investors could lose confidence in the accuracy and completeness of the Company's financial reports, the market price of the Company's common stock could decline and the Company could be subject to sanctions or investigations by The NASDAQ Global Market, the SEC or other regulatory authorities.

The Company has very limited staffing and is dependent upon key employees, the loss of some of which could adversely affect its operations. Competition for talent is intense; if the Company cannot attract and retain personnel, the growth and success of the business could be adversely affected.

The Company's success is dependent upon the efforts of a relatively small management team and staff. The Company has no redundancy of personnel in key development areas, including clinical, regulatory, strategic planning and finance. The Company has employment arrangements in place with its executive and other officers, but none of these executive and other officers is bound legally to remain employed with the Company for any specific term. The Company does not have key person life insurance policies covering its executive and other officers or any of its other employees. If key individuals leave the Company, its business could be affected adversely if suitable replacement personnel are not recruited quickly. The population in northern Minnesota, where the Company's manufacturing resources are located, is small, and as a result, there are a limited number qualified personnel available in all functional areas, which could make it difficult to retain and attract the qualified personnel necessary for the development and growth of the Company's business.

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

Consolidation among wholesale distributors, chain drug stores, and group purchasing organizations has resulted in a smaller number of companies, each controlling a larger share of pharmaceutical distribution channels. For example, the Company's net revenues are concentrated among three customers representing 27%, 18% and 10% of net

revenues, respectively, during the year ended December 31, 2013. As of December 31, 2013, accounts receivable from these three customers was approximately 68% of the Company's net accounts receivable. Drug wholesalers and retain pharmacy chains, which represent an essential part of the distribution chain of generic pharmaceutical products, have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in declines in sales volume for the Company 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 the Company's business and enabling those groups to charge increased fees to the Company. 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 the Company's products. The result of these developments may have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

The Company's operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

The Company's principal operations are conducted in northern Minnesota. Natural disasters or other catastrophic events could disrupt the Company's operations or those of its strategic partners, contractors and vendors. Even though the Company believes it carries commercially reasonable business interruption and liability insurance, and its contractors may carry liability insurance that protect the Company in certain events, the Company might suffer losses as a result of business interruptions that exceed the coverage available under its and its contractors' insurance policies or for which it or its contractors do not have coverage. Any natural disaster or catastrophic event could have a significant negative impact on the Company's operations and financial results, and could delay its efforts to identify and execute any strategic opportunities.

The Company has two manufacturing facilities producing a substantial portion of its products. Production at any one of these facilities could be interrupted, which could cause the Company to fail to deliver sufficient product to customers on a timely basis and have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

The Company's manufacturing capacity is based in two facilities. While these facilities are sufficient for the Company's current needs, the facilities are highly specialized and any damage to or need for replacement of all or any significant function of the Company's facilities could be very costly and time-consuming and could impair or prohibit production and shipping. A significant disruption at any one of the facilities, even on a short-term basis, whether due to a labor strike, adverse quality or compliance observation, vandalism, storm or other environmental damage, or other events could impair the Company's ability to produce and ship products to the market on a timely basis and, among other consequences, could subject the Company to claims from customers. Any of these events could have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

Virtually all contracts for the supply of pharmaceutical products by the Company to its customers contain "failure to supply" clauses. Under these clauses, if the Company is 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 the Company must reimburse its customer for the difference between the Company's contract price and the price the customer was forced to pay to procure the substitute product. This difference can be substantial because of the much higher spot price at which the customer must cover its requirements, and can be far in excess of the revenue that the Company would otherwise have received on the sale of its own product. The ability to produce and ship a sufficient quantity of product is therefore critical to the Company. Failure to deliver products could have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

The Company's ability to utilize its net operating loss and tax credit carryforwards in the future is subject to substantial limitations.

Under Section 382 of the Internal Revenue Code of 1986, as amended ("the Code"), if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percent change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Further, if the historic business of BioSante Pharmaceuticals, Inc. ("BioSante") is not treated as being continued by the Company for the two-year period beginning on the date of the Merger (referred to as the "continuity of business requirement"), the pre-transaction net operating loss carryforward deductions become substantially reduced or unavailable for use by the surviving corporation in the transaction. In 2009, an "ownership change" occurred with respect to BioSante, and the Merger resulted in another "ownership change" of the Company. Although the Company does not currently believe that ANIP Acquisition Company experienced an ownership change as a result of the Merger, due to the complexity of certain aspects of the applicable regulations, there is no assurance that the IRS will not successfully challenge this determination. Accordingly, the Company's ability to utilize BioSante's (and, if successfully challenged by the IRS, ANIP Acquisition

Company's) net operating loss and tax credit carryforwards may be substantially limited. These limitations, in turn, could result in increased future tax payments for the Company, which could have a material adverse effect on the business, financial condition or results of operations of the Company.

Under Section 384 of the Code, available net operating loss carryovers of BioSante or ANIP Acquisition Company may not be available to offset certain gains arising after the Merger from assets held by the other corporation at the effective time of the Merger. This limitation will apply to the extent that the gain is attributable to an unrealized built-in-gain in the assets of BioSante or ANIP Acquisition Company existing at June 19, 2013, the date of the Merger. To the extent that any such gains are recognized in the five year period after the Merger upon the disposition of any such assets, the net operating loss carryovers of the other corporation will not be available to offset such gains (but the net operating loss carryovers of the corporation that owned such assets will not be limited by Section 384 although they may be subject to other limitations under Section 382 as described above).

Management uses a variety of estimates, judgments, and assumptions in preparing the Company's 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 the Company's business, financial position and results of operations.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management 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 the Company's business, financial position and results of operations.

In the consolidated financial statements included in the periodic reports filed with the SEC, estimates, judgments, and assumptions are used for, but not limited to, revenue recognition, allowance for doubtful accounts, accruals for chargebacks, returns and other allowances, allowance for inventory obsolescence, stock-based compensation, valuation of intangible assets, allowances for contingencies and litigation, deferred tax valuation allowance, and the depreciable lives of fixed 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 the Company's business, financial position, and results of operations.

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

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

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

The Company is 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 as a result of a successful Qui Tam action. If the Company's past or present operations are found to be in violation of any of such laws or other applicable governmental regulations, it may be subject to civil and criminal penalties, damages, fines, exclusion from federal health care programs, and/or the curtailment or restructuring of its operations. Any penalties, damages, fines, curtailment, or restructuring of operations could adversely affect the Company. Actions brought against the Company for violations of these laws, even if successfully defended, could have a material adverse effect on its business, financial position and results of operations.

The Company's reporting and payment obligations under the Medicaid rebate program and other governmental purchasing and rebate programs are complex and may involve subjective decisions.

The regulations regarding reporting and payment obligations with respect to Medicaid reimbursement and rebates and other governmental programs are complex. The Company's calculations and methodologies are subject to review and challenge by governmental agencies, and it is possible that such reviews could result in changes. In addition, because the Company's 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. Any determination by governmental agencies that the Company has failed to comply with its reporting and payment obligations could subject it to penalties and sanctions, which could have a material adverse effect on its business, financial position and results of operations.

Healthcare reform legislation could have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

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 United States, and it is likely that federal and state legislatures and health agencies will continue to focus on health care reform in the future. The Patient Protection and Affordable Care Act ("PPACA") and the Health Care and Education and Reconciliation Act of 2010, which amends the PPACA (collectively, "the ACA"), were signed into law in March 2010. While the ACA may increase the number of patients who have insurance coverage for the Company's products and may otherwise increase drug coverage, they also include provisions such as, among others, the assessment of a pharmaceutical manufacturer fee, the requirement that manufacturers provide discounts to Medicare beneficiaries through the Medicare Coverage Gap Discount program, and an increase in the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs.

The cost-containment measures that government programs and healthcare insurers are instituting both as a result of general cost pressure in the industry and healthcare reforms contained in the ACA may prevent the Company from maintaining prices for its products that are sufficient for the Company to realize profits and may otherwise significantly harm its business, financial condition and operating results. In addition, to the extent that the Company's

approved products are marketed outside of the United States, foreign government pricing controls and other regulations may prevent the Company from maintaining prices for such products that are sufficient for the Company to realize profits and may otherwise significantly harm its business, financial condition and operating results.

The Company is unable to predict the future course of federal or state healthcare legislation. The ACA and further changes in the law or regulatory framework that reduce the Company's revenues or increase its costs could have a material adverse effect on its business, financial condition, results of operations and cash flows.

The Company is subject to federal, state and local laws and regulations, and complying with these may cause the Company to incur significant additional costs.

The pharmaceutical industry is subject to regulation by various federal authorities, including principally the FDA and, to a lesser extent, the DEA, and state governmental authorities. Federal and certain state statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of the Company's 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, injunction, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, civil penalties, debarment and criminal prosecution.

The Company's research, product development and manufacturing activities have involved the controlled use of hazardous materials, and the Company may incur significant costs as a result of the need to comply with numerous laws and regulations. The Company is 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 the Company's products, materials used to develop and manufacture such products, and resulting waste products. For example, certain of the Company's products, including EEMT, must be manufactured in a fully contained environment due to their potency and/or toxicity, and compliance with related OSHA requirements is costly.

The Company 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, the Company could be held liable for any damages that result, and any resulting liability could exceed its resources. The Company may also be required to incur significant costs to comply with environmental laws and regulations in the future. The Company is 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 its business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm the Company's business, results of operations, financial condition, cash flow and future prospects.

If third-party payers deny coverage, substitute another company's generic product for the Company's product, or offer inadequate levels of reimbursement, the Company may not be able to market its products effectively or it may be required to offer its products at prices lower than anticipated.

Third-party payers increasingly are 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 the Company's product, or offer inadequate levels of reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA, or foreign equivalent, or other government regulators, 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 offer inadequate levels of reimbursement, the Company may not be able to market its products effectively or it may be required to offer its products at prices lower than anticipated.

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The Company relies significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm management's ability to operate the business effectively.

The Company relies significantly on its information technology and manufacturing infrastructure to effectively manage and maintain inventory and financial reports, to manufacture and ship products to customers and to invoice them in a timely manner. Any failure, accidents, inadequacy, or interruption of that infrastructure or security lapse of that technology, including cybersecurity incidents, could harm management's ability to operate the business effectively. Management's ability to manage and maintain inventory and financial reports, to manufacture and ship products to customers and invoice them timely depends significantly on the Company's general ledger, its 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 the Company's general ledger, its contracted electronic data interface system, and other 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 management's 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 the Company's business, financial condition and results of operations.

After completion of the June 19, 2013 merger of BioSante Pharmaceuticals, Inc. ("BioSante") and ANIP Acquisition Company (the "Merger"), the Company possesses not only all of the assets but also all of the liabilities of both BioSante and ANIP Acquisition Company. Discovery of previously undisclosed or unknown liabilities could have an adverse effect on the Company's business, operating results and financial condition.

Acquisitions involve risks, including inaccurate assessment of undisclosed, contingent or other liabilities or problems. After completion of the Merger, the Company possesses not only all of the assets, but also all of the liabilities of both BioSante and ANIP Acquisition Company. Although BioSante conducted a due diligence investigation of ANIP Acquisition Company and its known and potential liabilities and obligations, and ANIP Acquisition Company conducted a due diligence investigation of BioSante and its known and potential liabilities and obligations, it is possible that undisclosed, contingent or other liabilities or problems may arise after completion of the merger, which could have an adverse effect on the combined company's business, operating results and financial condition.

A substantial number of shares of the Company's common stock is held by former stockholders of ANIP Acquisition Company and management, including by persons and entities that are not subject to legal restrictions on the resale of Company common stock. As part of the Merger, these shares were subject to a lock-up period, which expired six months after the Merger. If a substantial number of these shares are sold, in particular over a short period of time, it could adversely affect the market price of the Company's common stock.

Sales by significant stockholders of a substantial number of shares of the Company's common stock in the public market, or the perception that these sales could occur, could adversely affect the market price of such shares and could materially impair the Company's ability to raise capital through equity offerings in the future. The Company is unable to predict what effect, if any, substantial market sales of securities held by significant stockholders, directors or officers of the Company, or the availability of these securities for future sale could have on the market price of the Company's common stock.

The Company's principal stockholders, directors and executive officers own a significant percentage of the Company's stock and will be able to exercise significant influence over the Company's affairs.

The Company’s current principal stockholders, directors and executive officers beneficially own approximately 52.0% of the Company’s outstanding capital stock entitled to vote as of December 31, 2013. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by the Company’s 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 the Company, could deprive stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company, and might ultimately affect the market price of the Company’s common stock.

Raising additional funds by issuing additional equity securities may cause dilution to existing stockholders. Raising additional funds by issuing new debt financing may restrict the Company's operations.

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

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

The trading price of the Company's common stock has been volatile, and an investment in the Company's common stock could decline in value.

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

- general stock market and general economic conditions in the United States and abroad, even if not directly related to the Company or its business;
- any inability to manufacture EEMT, whether due to FDA determinations or otherwise;
- disruptions in the supply of API and other ingredients used in the Company's current and planned products;
- actual or anticipated governmental agency actions, including in particular decisions or actions by the FDA or FDA advisory committee panels with respect to the Company's current products, products in development, or its competitors' products;
- changes in anticipated or actual timing of the Company's product development programs;
- competition in the Company's industry;
- the Company entering into new strategic partnering arrangements or termination of existing strategic partnering arrangements;
- public concern as to the safety or efficacy of the Company's products;
- the Company's need and ability to obtain additional financing;

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- changes in laws or regulations applicable to the Company’s products or business;
- period-to-period fluctuations in the Company’s financial results;
- changes in key management;
- sales of shares of the Company's common stock by the Company or its stockholders;
- failure of securities analysts to initiate and maintain coverage of the Company and, with respect to any analyst coverage, the Company's failure to meet analyst estimates or the expectations of investors;
- announcements by the Company or its competitors of new products or services;
- the public’s reaction to the Company's press releases, other public announcements and filings with the SEC;
- rumors and market speculation involving the Company or other companies in the Company’s business;
- actual or anticipated changes in the Company's operating results or fluctuations in its operating results;
- actual or anticipated developments in the Company's business, its competitors’ businesses or the competitive landscape generally;
- litigation involving the Company, its industry or both, or investigations by regulators into the Company's operations or those of its competitors;
- announced or completed acquisitions of businesses or products by the Company or its competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to the Company's business;
- changes in accounting standards, policies, guidelines, interpretations or principles; and
- slow or negative growth of the Company's products or markets.

In addition, the occurrence of any of the risks described in this report or in subsequent reports the Company files with or submits to the SEC from time to time could have a material and adverse impact on the market price of the Company’s 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. The Company currently is subject to such litigation. Securities litigation, whether with or without merit, could result in substantial costs and divert management’s attention and resources, which could harm the Company’s business and financial condition, as well as the market price of the Company’s common stock.

If shareholder approval is received to increase the number of shares available for issuance under the Company's Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan"), it could increase dilution for shareholders and the Company could incur significant expense in accounting for stock-based compensation granted under the 2008 Plan.

On July 12, 2013, the Company's Board of Directors approved grants of stock options to employees, including certain executive officers, under the 2008 Plan, subject to shareholder approval of an increase in the total shares available for issuance under the 2008 Plan, which the Company intends to seek at its next annual meeting in 2014. As of December 31, 2013, the Company had grants of 325 thousand common stock options outstanding pending shareholder approval. These grants were approved by the board on July 12, 2013, but expense related to these stock options will begin to be recognized only upon shareholder approval. While stock compensation expense is not material for the year ended December 31, 2013, if shareholders approve the increase in the total shares available for issuance under the 2008 Plan and the previously-approved stock options are issued, the stock compensation expense would be significantly greater and changes to the estimates involved in the calculation of stock compensation expense could have a material effect on the Company's consolidated financial statements. Based on stock price information at December 31, 2013, if the increase in total shares available for issuance under the 2008 Plan had been approved on December 31, 2013 and these options had been issued as of December 31, 2013, there would have been approximately $5.0 million of expense related to these options, to be expensed over the remainder of the four year service period. However, because the stock compensation expense will be calculated based on the stock price as of the date of approval by the shareholders, the actual expense could be materially higher or lower, depending on the Company's stock price as of that date. Furthermore, if additional grants are made under the 2008 Plan, the Company could incur significant expense related to stock-based compensation in future periods, and shareholders could find their holdings diluted by the increase in shares.

Continuing studies of the Company's products could result in a negative result, which could require discontinuance of product marketing, or other risk management programs.

Continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products, including those produced by the Company. In some cases, studies have resulted, and in the future may result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry. These situations, should they occur with respect to any products of the Company, could have a material adverse effect on the Company's profitability, business, financial position and results of operations.

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

The market for hormone therapy products has been affected negatively by the Women's Health Initiative ("WHI") study and other studies that have found that the overall health risks from the use of certain hormone therapy products may exceed the benefits from the use of those products among postmenopausal women. In July 2002, the National Institutes of Health ("NIH") released data from its WHI study on the risks and benefits associated with long-term use of oral hormone therapy by women. The NIH announced that it was discontinuing the arm of the study investigating the use of oral estrogen/progestin combination hormone therapy products after an average follow-up period of 5.2 years because the product used in the study was shown to cause an increase in the risk of invasive breast cancer. The study also found an increased risk of stroke, heart attacks and blood clots and concluded that overall health risks exceeded benefits from use of combined estrogen plus progestin among postmenopausal women. Also, in July 2002, results of an observational study sponsored by the National Cancer Institute on the effects of estrogen therapy were announced. The main finding of the study was that postmenopausal women who used estrogen therapy for 10 or more years had a higher risk of developing ovarian cancer than women who never used hormone therapy. In October 2002, a significant

hormone therapy study being conducted in the United Kingdom also was halted. In March 2004, the NIH announced that the estrogen-alone study was discontinued after nearly seven years because the NIH concluded that estrogen alone does not affect (either increase or decrease) heart disease, the major question being evaluated in the study. The findings indicated a slightly increased risk of stroke as well as a decreased risk of hip fracture and breast cancer. Preliminary data from the memory portion of the WHI study suggested that estrogen alone may possibly be associated with a slight increase in the risk of dementia or mild cognitive impairment.

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

Provisions in the Company's charter documents and Delaware law could discourage or prevent a takeover, even if an acquisition would be beneficial to the Company's stockholders.

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

- authorizing the issuance of "blank check" preferred shares that could be issued by the Company's 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 the Company's stockholders to bring business to be considered by its stockholders at a meeting or replace its board of directors; and
- as a Delaware corporation, the Company is 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 the Company's outstanding common stock from engaging in certain business combinations without approval of the holders of at least two-thirds of its outstanding common stock not held by such 15% or greater stockholder.

Any provision of the Company's 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 the Company's stockholders to receive a premium for their shares of the Company's common stock, and could also affect the price that some investors are willing to pay for its common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

The Company's corporate offices are located at 210 Main Street West, Baudette, Minnesota 56623. The Company-owned facility includes oral solid dose and liquid manufacturing and packaging, warehouse facilities, analytical, stability and microbiological laboratory space, and employee, office and mechanical space. The Company also owns 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.

The Company has leased office space for its financial headquarters in Wilmington, Delaware. The lease will expire in September 2018. The Company also leases office space in Laguna Beach, California for an executive office. This lease will expire in February 2016.

Management considers its leased and owned properties suitable and adequate for its current and foreseeable needs.

Item 3. Legal Proceedings

A discussion of legal matters as of December 31, 2013 follows:

Shareholder Class Action and Derivative Lawsuits

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes naming the Company and its former President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of the Company's disclosures relating to the efficacy of LibiGel® and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of the Company's securities resulting in violations of Section 10(b) of the Exchange Act, Rule 10b-5 and Section 20(a) of the Exchange Act.

Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The plaintiff sought to represent a class of persons who purchased the Company's securities between February 12, 2010 and December 15, 2011, and sought unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys' fees on behalf of such purchasers. On November 6, 2012, the plaintiff filed a consolidated amended complaint. On December 28, 2012, the Company and Mr. Simes filed motions to dismiss the consolidated amended complaint. On September 11, 2013, the Illinois district court judge granted defendants' motions to dismiss, without prejudice, and gave plaintiffs 28 days to file an amended complaint. The plaintiffs did not file an amended complaint and the matter has been concluded.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of the Company, filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption Weinstein v. BioSante Pharmaceuticals, Inc. et al., naming the Company's directors as defendants and the Company as a nominal defendant. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits generally related to the same events that are the subject of the class action litigation described above. The complaints allege breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaints seek unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in the Company's corporate governance and internal control procedures.

On September 24, 2012, the United States District Court consolidated the two shareholder derivative cases before it and on November 20, 2012, the plaintiffs filed their consolidated amended complaint. On January 11, 2013, the defendants filed a motion to dismiss the amended complaint. On September 11, 2013, the Illinois district court judge granted defendants' motions to dismiss, without prejudice, and gave plaintiffs 28 days to file an amended complaint. The plaintiffs did not file an amended complaint and the district court matter has been concluded.

On November 27, 2012, the plaintiff in the shareholder derivative action pending in Illinois state court filed an amended complaint. On January 18, 2013, the defendants filed a motion to dismiss the amended complaint. On July 1, 2013, the Illinois state court judge granted defendants' motions to dismiss, without prejudice, and gave plaintiffs until July 31, 2013 to file an amended complaint. On September 9, 2013, the Illinois state court judge granted defendants' motion to dismiss, with prejudice. On October 9, 2013, the plaintiffs filed a notice of appeal to Illinois state appellate court. The Company believes the state court complaint is without merit and will continue to defend the action vigorously.

Management is unable to predict the outcome of the remaining lawsuit and the possible loss or range of loss, if any, associated with its resolution or any potential effect the lawsuit may have on the Company's operations. Depending on

the outcome or resolution of the remaining lawsuit, it could have a material effect on the Company's operations, including its financial condition, results of operations, or cash flows. No amounts have been accrued related to this legal action as of December 31, 2013.

Louisiana Medicaid Lawsuit

On September 11, 2013, the Attorney General of the State of Louisiana filed a lawsuit in Louisiana state court against the Company and numerous other pharmaceutical companies, under various state laws, alleging that each defendant caused the state's Medicaid agency to provide reimbursement for drug products that allegedly were not approved by the FDA and therefore allegedly not reimbursable under the federal Medicaid program. The lawsuit relates to three cough and cold prescription products manufactured and sold by the Company's former Gulfport, Mississippi operation, which was sold in September 2010. Through its lawsuit, the state seeks unspecified damages, statutory fines, penalties, attorney's fees and costs. On October 15, 2013, the defendants removed the lawsuit to the U.S. District Court. On November 14, 2013, the state filed a motion to remand the lawsuit to the Louisiana state court. While the Company cannot predict the outcome of the lawsuit at this time, it could be subject to material damages, penalties and fines. The Company intends to vigorously defend against all claims in the lawsuit.

Other Commitments and Contingencies

All manufacturers of the drug Reglan ® and its generic equivalent metoclopramide, including the Company, are facing 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. The Company has been named and served in 85 separate complaints, including three in Pennsylvania, nine in New Jersey, and 73 in California, covering 2,934 plaintiffs in total. In August 2012, the Company was dismissed with prejudice from all New Jersey cases. Management considers the Company's exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide manufactured by the Company prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) the Company's market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once the Company received a request for change of labeling from the FDA, it submitted its proposed changes within 30 days, and such changes were subsequently approved by the FDA. At the present time, management is unable to assess the likely outcome of the remaining cases. The Company's insurance company has assumed the defense of this matter. In addition, the Company's insurance company renewed the Company's product liability insurance on September 1, 2012 and 2013 with absolute exclusions for claims related to Reglan® and metoclopramide. Management is unable to predict the outcome of these matters and the possible loss or range of loss, if any, associated with their resolution or any potential effect the legal action may have on the Company's operations. Furthermore, management cannot provide assurances that the outcome of these matters will not have an adverse effect on its business, results of operations, financial condition, and cash flow. Like all pharmaceutical manufacturers, the Company in the future may be exposed to other product liability claims, which could harm its business, results of operations, financial condition and cash flow.

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

The Company's common stock trades on the NASDAQ Global Market under the symbol "ANIP." The following table shows the high and low sales price for ANIP common stock as reported by the NASDAQ Global Market for each quarter in the years ended December 31, 2013 and 2012, as adjusted for the one-for-six reverse stock splits that occurred on June 4, 2012 and July 17, 2013:

	Common Stock Price			
	2013		2012	
	High	Low	High	Low
First Quarter	$ 9.48	$ 6.60	$ 44.28	$ 15.84
Second Quarter	$ 8.64	$ 4.80	$ 27.36	$ 12.00
Third Quarter	$ 9.94	$ 5.46	$ 15.72	$ 7.26
Fourth Quarter	$ 23.00	$ 9.75	$ 11.82	$ 6.48

Stockholder Information

As of February 14, 2014, there were approximately 200 shareholders of record of the Company's common stock, as well as approximately 22 thousand beneficial shareholders, and six holders of record of Class C stock.

Dividends

The Company has not paid cash dividends in the years ended December 31, 2013 and 2012. The Company does not anticipate paying cash dividends in the near term.

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

None.

Issuer Purchases of Equity Securities

None.

Performance Graph

Not required due to Smaller Reporting Company status.

Item 6. Selected Consolidated Financial Data

Not required due to Smaller Reporting Company status.

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 the Company's 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 in Item 1. ("Business").

Overview

ANI Pharmaceuticals, Inc. (the "Company") is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. The Company has two pharmaceutical manufacturing facilities located in Baudette, Minnesota that are capable of producing oral solid dose products, as well as liquids and topicals, narcotics, and potent products that must be manufactured in a fully-contained environment. The Company's strategy is to continue to use these manufacturing assets to develop, produce, and distribute niche generic pharmaceutical products.

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

Recent Developments

The Company's strategy is to use its assets to develop and acquire, manufacture, and market branded and generic specialty prescription pharmaceuticals. By developing and acquiring carefully-considered prescription pharmaceutical products, management believes the Company will be able to continue to grow its business, expand and diversify its product portfolio, and create long-term value for its investors.

In August 2013, the Company entered into an agreement with Sofgen to develop an oral soft gel prescription product indicated for cardiovascular health. The product will be subject to an abbreviated new drug application ("ANDA") filing once developed. Sofgen will be responsible for the development, manufacturing and regulatory submission of the product, including preparation of the ANDA, and the Company will be responsible for the marketing and distribution of the product in the U.S.

In December 2013, the Company entered into an agreement to acquire the ANDAs for 31 previously marketed generic drug products from Teva Pharmaceuticals for $12.5 million in cash and a percentage of future gross profits from product sales. An initial payment of $8.5 million was paid on January 2, 2014, and the balance will be paid upon receipt of hard copy materials, which receipt shall not exceed ninety (90) days from the date of agreement. The acquisition, which the Company accounted for as an asset acquisition, included 20 solid-oral immediate release products, four extended release products, and seven liquid products. All of the products have been previously approved by U.S. Food and Drug Administration ("FDA") as ANDAs.

General

The following table sets forth, for the periods indicated, the percentage that items in the Company's consolidated statements of operations bear to net revenues.

	Years Ended December 31,			
	2013		2012	
Net revenues	100.0	%	100.0	%
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	33.2	%	45.0	%
Research and development	5.7	%	5.7	%
Selling, general and administrative	54.5	%	46.7	%
Depreciation and amortization	3.6	%	2.8	%
Operating income (loss) from continuing operations	3.0	%	(0.2)	%
Interest expense	1.6	%	6.5	%
Other expense	1.0	%	1.2	%
Net income (loss) from continuing operations	0.4	%	(7.7)	%
Gain on discontinued operation	0.6	%	0.3	%
Net income (loss)	1.0	%	(7.4)	%

The following table summarizes the Company's results of operations for the years ended December 31, 2013 and 2012.

	Years Ended December 31,			
(in thousands)	2013		2012	
Net revenues	$	30,082	$	20,371
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)		9,974		9,167
Research and development		1,712		1,158
Selling, general and administrative		16,388		9,521
Depreciation and amortization		1,110		567
Operating income (loss) from continuing operations		898		(42)
Interest expense		467		1,327
Other expense		305		241
Net Income/(Loss) from Continuing Operations Before (Provision) Benefit for Income Taxes		126		(1,610)
(Provision) benefit for income taxes		(20)		36
Net income (loss) from continuing operations		106		(1,574)
Gain on discontinued operation		195		68
Net income (loss)	$	301	$	(1,506)

Results of Operations for the Years Ended December 31, 2013 and 2012

Net Revenues

(in thousands)	Years Ended December 31,			
	2013	2012	Change	% Change
Generic pharmaceutical products	$ 19,281	$ 10,157	$ 9,124	89.8 %
Branded pharmaceutical products	3,370	1,829	1,541	84.3 %
Contract manufacturing	6,018	7,557	(1,539)	(20.4) %
Contract services and other income	1,413	828	585	70.7 %
Total net revenues	$ 30,082	$ 20,371	$ 9,711	47.7 %

The Company has historically derived substantially all of its 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 contract manufactured products. Revenue for the year ended December 31, 2013 was $30.1 million compared to $20.4 million for 2012.

Revenue for the year ended December 31, 2013 increased $9.7 million, or 47.7%, compared to 2012, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $19.3 million in the year ended December 31, 2013, an increase of 89.8% compared to $10.2 million for 2012. A primary reason for the $9.1 million increase was an $8.1 million increase in revenue related to Esterified Estrogen with Methyltestosterone tablets (“EEMT”), which was the result of increases in both market share and prices per bottle, due to a significant decrease in competition, beginning in the third quarter of 2013, which the Company cannot be certain will continue. For the year ended December 31, 2013, EEMT comprised 33% of the Company’s net sales, a substantial increase over the prior year wherein EEMT comprised only 9% of the Company’s net sales. In the third quarter of 2013, a significant competitor stopped producing EEMT, which led to a material increase in the Company’s market share for the product and enabled the Company to significantly increase the price it charges for the product. Market share gains on Opium Tincture and Fluvoxamine Maleate tablets also contributed to increased generic product revenues.

  As discussed further under Item 1. Business Government Regulations Unapproved Products, the Company markets EEMT and Opium Tincture without FDA-approved NDAs or ANDAs. The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While the Company believes that, so long as it complies with applicable manufacturing and labeling standards, the FDA will not take action against it under the current enforcement policy, it can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. The Company's combined net revenues for these products for the years ended December 31, 2013 and 2012 were $14.6 million and $6.0 million, respectively.

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- Net revenues for branded pharmaceutical products were $3.4 million in the year ended December 31, 2013, an increase of 84.3% compared to $1.8 million for the same period in 2012. The primary reason for the increase was higher unit sales of Reglan® tablets. Higher unit sales of Cortenema® contributed to the increase to a lesser extent.

- Contract manufacturing revenues were $6.0 million for the year ended December 31 2013, a decrease of 20.4% from $7.6 million for 2012, due to decreased orders from contract manufacturing customers during the 2013 period. One group of products that the Company manufactures on behalf of a contract customer is marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. The Company's contract manufacturing revenue for the group of unapproved products for the years ended December 31, 2013 and 2012 was $2.0 million and $1.4 million, respectively.

- Contract services and other income were $1.4 million for the year ended December 31, 2013, an increase of 70.7% from approximately $0.8 million for 2012, due to a $0.5 million non-recurring payment from Teva in relation to the Teva license agreement acquired in the Merger. The Company receives royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. The Company’s royalties on the net sales of these unapproved products for the years ended December 31, 2013 and 2012 were $330 thousand and $284 thousand, respectively.

Cost of Sales (Exclusive of Depreciation and Amortization)

(in thousands)	Years Ended December 31,			
	2013	2012	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 9,974	$ 9,167	$ 807	8.8 %

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

For the year ended December 31, 2013, cost of sales increased to $10.0 million from $9.2 million for 2012, an increase of $0.8 million or 8.8%, primarily as a result of an increase in sales of generic and branded pharmaceutical products.

Cost of sales as a percentage of net revenues decreased to 33.2% during the year ended December 31, 2013 from 45.0% for 2012, primarily as a result of a price increase for EEMT. Sales of EEMT provided approximately 33% of total net revenues, but only approximately 24% of cost of sales in 2013. In addition, the Company experienced decreases in the costs of raw materials for Fluvoxamine Maleate tablets and EEMT, which were the result of establishing long-term supply agreements with vendors.

The Company sources the raw materials for its products, including active pharmaceutical ingredients (“API”), from both domestic and international suppliers. As discussed in Item 1. Business Manufacturing, Suppliers and Raw Materials, only a single source of API is generally qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers usually must be approved by the FDA, which can take 18 months or longer. As a result, the Company is dependent upon its current vendors to supply reliably the API

required for ongoing product manufacturing. In addition, certain of the Company's API for its drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time the Company has experienced temporary disruptions in the supply of certain of such imported API due to FDA inspections.

During the year ended December 31, 2013, the Company purchased approximately 37% of total costs of sales from three suppliers. As of December 31, 2013, amounts payable to these suppliers was immaterial.

The Company has supply agreements with two vendors that include purchase minimums. Pursuant to these agreements, the Company will be required to purchase a total of $2.2 million of API from these two vendors in the year ended December 31, 2014.

Other Operating Expenses

(in thousands)	Years Ended December 31,			
	2013	2012	Change	% Change
Research and development	$ 1,712	$ 1,158	$ 554	47.8 %
Selling, general and administrative	16,388	9,521	6,867	72.1 %
Depreciation and amortization	1,110	567	543	95.8 %
Total other operating expenses	$ 19,210	$ 11,246	$ 7,964	70.8 %

Other operating expenses consist of research and development costs, selling, general and administrative expenses, and depreciation and amortization. For year ended December 31, 2013, other operating expenses increased to $19.2 million from $11.2 million for the same period in 2012, an increase of $8.0 million, or 70.8%, primarily as a result of the following factors:

- Research and development expenses increased from $1.2 million in 2012 to $1.7 million in 2013, due to increased expenses incurred with respect to the RiconPharma and Sofgen collaborative arrangements. The Company anticipates that research and development costs will continue to increase based on the Company’s strategy to expand its product portfolio.

- Selling, general and administrative expenses increased from $9.5 million in 2012 to $16.4 million in 2013, primarily as a result of $6.2 million of expenses incurred relating to the Merger, including $4.5 million of non-cash transaction bonuses paid to the Company’s executives upon completion of the Merger. In addition, one-time bonuses paid to certain officers after completion of the merger and increases in personnel contributed to the increase in expense.

- Depreciation and amortization increased from $0.6 million in 2012 to $1.1 million in 2013, an increase of 95.8%, due to amortization of the Teva license acquired in the Merger. The Teva license is being amortized over its estimated useful life of 11 years.

The Company expects other operating expenses to continue to increase in the future to support anticipated additional revenue growth, as well as from anticipated additional research and product development costs.

Other Expenses

(in thousands)	Years Ended December 31,				
	2013	2012	Change	% Change	
Interest expense	$ 467	$ 1,327	$ (860)	(64.8)	%
Other expense	305	241	64	26.4	%
Total other expenses	$ 772	$ 1,568	$ (796)	(50.8)	%

For the year ended December 31, 2013, other expenses decreased to $0.8 million from $1.6 million in 2012, a decrease of $0.8 million, or 50.8%, primarily as a result of the following factors:

- Interest expense decreased from $1.3 million to $0.5 million. In June 2012, all of ANIP's subordinated debt was converted to Series D convertible preferred stock. In addition, the Company paid down its revolving line of credit in the second quarter of 2013, in connection with the Merger. The resulting reductions from both the subordinated debt conversion and repayment of the revolving line of credit were partially offset by an early termination fee and accelerated amortization of deferred loan costs incurred upon repayment of the line of credit.

- Other expense increased from $0.2 million to $0.3 million as a result of payments totaling $0.4 million to certain of the Company's investors for monitoring and advisory fees, partially offset by other income from the third quarter resulting from the settling of several aged liabilities.

Gain on Discontinued Operation

(in thousands)	Years Ended December 31,				
	2013	2012	Change	% Change	
Gain on discontinued operation, net of tax	$ 195	$ 68	$ 127	187.6	%

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

For the year ended December 31, 2013, gain on discontinued operation, net of $38 thousand of tax, was the result of finalizing a portion of the discontinued operation's remaining liabilities. For the year ended December 31, 2012, gain on discontinued operation, net of $36 thousand of tax, consisted of various vendor settlements.

Liquidity and Capital Resources

The following table highlights selected liquidity and working capital information from the Company's consolidated balance sheets.

(in thousands)	December 31, 2013	2012
Cash and cash equivalents	$ 11,105	$ 11
Accounts receivable, net	12,513	5,432
Inventories	3,518	2,810
Prepaid expenses	580	313
Total current assets	$ 27,716	$ 8,566
Accounts payable	$ 1,429	$ 1,994
Accrued expenses	1,326	927
Returned goods reserve	736	411
Deferred revenue	47	315
Borrowing under line of credit	-	4,065
Total current liabilities	$ 3,538	$ 7,712

At December 31, 2013, the Company had approximately $11.1 million in cash and cash equivalents. On January 2, 2014 the Company paid $8.5 million to Teva Pharmaceuticals as the first installment in a transaction in which the Company acquired ANDAs for 31 products for $12.5 million. The remaining $4 million will be paid from funds stemming from operating cash flows. At December 31, 2012, the Company had $11 thousand in cash and cash equivalents and unused availability of $0.9 million under its then-existing line of credit.

The Company believes that the combination of its current cash and cash equivalents and other financial resources, consisting of current working capital and anticipated future operating revenue, will be sufficient to enable it to meet its working capital requirements for at least the next 12 months. If the Company's assumptions underlying estimated revenue and expenses prove to be wrong, or if its cash requirements change materially as a result of shifts in its business or strategy, the Company may require additional financing. The Company does not currently have any bank credit lines. If in the future the Company does not turn profitable or generate cash from operations as anticipated and additional capital is needed to support operations, management may be unable to obtain such financing, or obtain it on favorable terms, in which case the Company may be required to curtail development of new products, limit expansion of operations or accept financing terms that are not as attractive as desired.

The Company has never generated positive cash flows from operations. To bridge the gap between revenues and operating and capital needs, the Company has, in the past, relied on a variety of financing sources, including the issuance of equity and equity-linked securities and revolving lines of credit. The Company’s consolidated financial statements have been prepared on a basis that assumes that it will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. These statements do not include any adjustments that might result if the carrying amount of recorded assets and liabilities are not realized.

The Company's primary cash requirements are to fund operations, including research and development programs and collaborations, to support general and administrative activities, and to fund acquisitions of products or businesses. The Company's future capital requirements will depend on many factors, including, but not limited to:

- proportions of net revenues comprised of contract manufacturing and sales of the Company’s generic and branded products;

- pricing and payment terms with customers;

- costs of raw materials and payment terms with suppliers;
- capital expenditures and equipment purchases to support product launches; and
- business and product acquisitions.

Consolidation among wholesale distributors, chain drug stores and group purchasing organizations has resulted in a smaller number of companies each controlling a larger share of pharmaceutical distribution channels. The Company's net revenues were concentrated among three customers representing 27%, 18%, and 10% of net revenues, respectively, during the year ended December 31, 2013. As of December 31, 2013, accounts receivable from these three customers totaled approximately 68% of the Company's net accounts receivable. As a result, negotiated payment terms with these customers have a material impact on the Company's liquidity and working capital.

Two of the Company's generic pharmaceutical products, EEMT and Opium Tincture, account for approximately 33% and 16% of the Company's net revenues in 2013, respectively, versus 9% and 20% of net revenues in 2012, respectively. As a result, market pricing for these products, combined with the costs of raw materials and payment terms with suppliers, have a material impact on the Company's liquidity and working capital. The increase in revenue related to EEMT has had a significant impact on the Company’s financial results and if revenues from EEMT were to decrease substantially or entirely, it would have a material, negative impact on the Company’s cash flows and liquidity.

Sources and Uses of Cash

Debt Financing

At December 31, 2013, all of the Company’s previous lines of credit had either expired or were repaid and terminated, with no amounts outstanding. In June 2012, the Company entered into a new revolving loan agreement with a commercial bank in the amount of $5.0 million. As of December 31, 2012, approximately $4.1 million was outstanding under the loan agreement, at an effective interest rate of 6.0%. The Company was not in compliance with certain covenants under the loan agreement as of December 31, 2012. The Company obtained a waiver from its lender, the loan covenants were revised, and the revolver loan limit was increased to $6 million. The Company remained in compliance with the revised covenants until the loan was repaid in June 2013.

At December 31, 2013, the Company had approximately $11.1 million in cash and cash equivalents. At December 31, 2012, the Company had approximately $11 thousand in cash and cash equivalents and unused availability under its line of credit of approximately $0.9 million.

Equity Financing

In December 2013, a warrant-holder exercised warrants to purchase approximately 90 thousand shares at $9 per share. The Company received $0.8 million as a result of this exercise.

Uses of Cash

On January 2, 2014 the Company paid $8.5 million to Teva Pharmaceuticals as the first installment in a transaction in which the Company acquired ANDAs for 31 products for $12.5 million.

Discussion of Cash Flows

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

(in thousands)	Years ended December 31,	
	2013	2012
Operating Activities	$ (5,484)	$ (137)
Investing Activities	$ 20,267	$ (292)
Financing Activities	$ (3,689)	$ 440

Net Cash Used In/Provided By Operations

Net cash used in operating activities was $5.5 million for the year ended December 31, 2013 compared to $0.1 million during the same period in 2012, an increase in the use of cash of $5.3 million between the periods. This increase was due to changes in current assets and current liabilities, partially offset by the change from a net loss in 2012 to net income in 2013. There was a $6.0 million increase in cash provided in 2013 due to the Company's net income/(loss) from continuing operations, after adjusting for non-cash expenses. $1.8 million of this increase was due to the change from a net loss in 2012 to net income in 2013. In addition, increases in non-cash expenses, primarily due to $4.4 million of non-cash expenses related to the Merger and a $0.5 million increase in depreciation and amortization expense were partially offset by a $0.9 million decrease in non-cash interest relating to equity-linked securities and loan cost amortization.

Increases in current assets and decreases in current liabilities (in each case a use of cash) for the year ended December 31, 2013 totaled $11.4 million compared to $0.1 million for the same period in 2012, an increase of approximately $11.3 million between the periods. Accounts receivable and prepaid expenses increased by $6.8 million and $0.1 million more in the years ended December 31, 2013 and 2012, respectively, than in the prior year periods. The increase in accounts receivable was due to increased sales in the third and fourth quarters of 2013. Accrued compensation and accounts payable decreased by $2.9 million and $1.4 million more in the years ended December 31, 2013 and 2012, respectively, than in the prior year periods. Finally, accrued expenses increased by $0.2 million less than it increased in the prior year.

Net Cash Provided by/Used in Investing Activities

Net cash provided by investing activities for the year ended December 31, 2013 was $20.3 million, principally due to $18.2 million of cash acquired in the Merger and the release of $2.2 million of restricted cash held for severance payments, partially offset by capital expenditures during the period. Net cash used in investing activities was $0.3 million for the year ended December 31, 2012 and related primarily to capital expenditures.

Net Cash Used in/Provided by Financing Activities

Net cash used in financing activities was $3.7 million for the year ended December 31, 2013, resulting primarily from the $4.1 million repayment in June 2013 of the Company’s revolving line of credit in connection with the Merger and $0.4 million of treasury stock repurchases, partially offset by $0.8 million of proceeds received for a warrant exercised in December 2013. Net cash provided by financing activities was $0.4 million for the year ended December 31, 2012, which included $1.0 million in increased borrowings under ANI's revolving line of credit, net of payment of debt issuance costs of $0.3 million and $0.3 million in note payable repayments.

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Critical Accounting Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on the Company's 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 the Company's consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, returns and other allowances, allowance for inventory obsolescence, valuation of derivative liabilities, accruals for contingent liabilities, fair value of long-lived assets, deferred taxes and valuation allowance, and the depreciable lives of fixed assets.

On an ongoing basis, the Company evaluates these estimates and assumptions, including those described below. The Company bases its estimates on historical experience and on various other assumptions that it believes 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 the Company's business operations, financial condition and results of operations.

Revenue Recognition

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

Occasionally, the Company engages in contract services, which include product development services, laboratory services, and royalties on net sales of certain contract manufactured products. For these services, revenue is recognized according to the terms of the agreement with the customer, which sometimes include substantive, measurable risk-based milestones, and when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured, and the Company has no further performance obligations under the agreement. The Company recognized $1.4 million and $0.8 million of revenue related to contract services in 2013 and 2012, respectively.

The Company's 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. These estimates are based on historical experience.

The Company has not made any material changes to its revenue recognition policies during the years ended December 31, 2013 and 2012. Management believes it is unlikely that there will be a material change in the future estimates or

assumptions used to measure estimates for discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments. However, if actual results were not consistent with management's estimates, the Company could be exposed to losses or gains that could be material, as any changes to these estimates could cause an increase or decrease in revenue recognized during the year. For example, if there were a 10% change to these adjustments throughout the year, Net Revenues and Net Income/(Loss) from Continuing Operations before (Provision)/Benefit for Income Taxes for the year ended December 31, 2013 would be affected by $3.3 million.

Accruals for Chargebacks, Returns and Other Allowances

The Company's generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates and prompt payment discounts. The Company accrues for these items at the time of sale based on the estimates and methodologies described below. In the aggregate, these accruals, reflected as a decrease to gross sales, exceed 60% of generic and branded gross product sales, reduce gross revenues to net revenues in the consolidated statements of operations, and are presented as current liabilities or reductions in accounts receivable in the consolidated balance sheets. The Company continually monitors and re-evaluates the accruals as additional information becomes available, which includes, among other things, updates to trade inventory levels and customer product mix. The Company makes adjustments to the accruals at the end of each reporting period, to reflect any such updates to the relevant facts and circumstances. Accruals are relieved upon receipt of payment from or issuance of credit to the customer.

Chargebacks

As discussed in Note 1 of Item 8. Consolidated Financial Statements, the Company estimates the amount of chargebacks based its 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, product sales mix, volume of off-contract purchases, and wholesale acquisition cost (“WAC”).

The Company has not made any material changes to its policy for estimating chargeback accruals during the years ended December 31, 2013 and 2012. Management believes it is unlikely that there will be a material change in the future estimates or assumptions used to measure chargeback estimates. However, if actual results were not consistent with management’s estimates, the Company 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, the Company’s net earnings would be affected by $2.8 million for the year ended December 31, 2013.

Returns

As discussed in Note 1 of Item 8. Consolidated Financial Statements, the Company's estimate for returns is based upon its 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.

The Company has not made any material changes to its policy for estimating returns during the years ended December 31, 2013 and 2012. Management believes it is unlikely that there will be a material change in the future estimates or assumptions used to measure estimates of goods returned. However, if actual results were not consistent with management’s estimates, the Company 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, the Company’s net earnings would be affected by $0.2 million for the year ended December 31, 2013.

Administrative Fees and Other Rebates

As discussed in Note 1 of Item 8. Consolidated Financial Statements, the Company accrues 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.

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The Company has not made any material changes to its policy for estimating administrative fee accruals during the years ended December 31, 2013 and 2012. Management believes it is unlikely that there will be a material change in the future estimates or assumptions used to measure estimates of administrative fees. However, if actual results were not consistent with management's estimates, the Company 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, the Company's net earnings would be affected by $0.2 million for the year ended December 31, 2013.

Prompt Payment Discounts

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

The Company has not made any material changes to its policy for estimating prompt payment discounts accruals during the years ended December 31, 2013 and 2012. Management believes that it is unlikely that there will be a material change in the future estimates or assumptions used to measure estimates of prompt payment discounts. If customers do not take 100% of available discounts as estimated by the Company, the Company could need to re-adjust its methodology for calculating the prompt payment discount reserve. If there were a 10% decrease in the prompt payment discounts estimates throughout the year, the Company's net earnings would increase by $0.1 million for the year ended December 31, 2013.

Intangible Assets

Intangible assets consist of rights to produce pharmaceutical products and a license. These intangible assets were recorded at fair value and are stated net of accumulated amortization.

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

In addition, the Company tests 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 it is determined 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.

Goodwill

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

In addition, goodwill is reviewed annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. Judgment is used in determining when these events and circumstances arise. The Company performs its review of goodwill on its one reporting unit. If it is determined 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, 2013 was $1.8 million. Management believes 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 management's estimates or assumptions, the Company may be exposed to an impairment charge that could be material.

Stock-Based Compensation

The Company has a stock-based compensation plan that includes stock options and restricted stock, which are awarded in exchange for employee and non-employee director services. The Company recognizes the estimated fair value of stock-based awards and classifies the expense where the underlying salaries are classified, For the year ended December 31, 2013, all stock-based awards were classified as sales, general and administrative expense in the accompanying statements of operations. Stock-based compensation cost for stock options is determined at the grant date using an option pricing model and stock-based compensation cost for restricted stock is based on the closing market price of the stock at the grant date. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the employee's requisite service period.

Valuation of stock awards requires management 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 the Company’s stock price, dividend yields, future employee turnover rates, and future employee stock option exercise behaviors. Changes in these assumptions can affect the fair value estimate.

Estimation of awards that will ultimately vest requires judgment for the amounts that will be forfeited due to failure to fulfill service conditions. To the extent actual results or updated estimates differ from current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised. Changes in estimates could affect compensation expense within individual periods.

On July 12, 2013, the Company’s Board of Directors approved grants of stock options to employees, including certain executive officers, under the 2008 Plan, subject to shareholder approval of an increase in the total shares available for issuance under the 2008 Plan, which the Company intends to seek at its next annual meeting in 2014. As of December 31, 2013, the Company had grants of 325 thousand common stock options outstanding pending shareholder approval. These grants were approved by the board on July 12, 2013, but expense related to these stock options will begin to be recognized only upon shareholder approval. While stock compensation expense is not material for the year ended December 31, 2013, if shareholders approve the increase in the total shares available for issuance under the 2008 Plan and the previously-approved stock options are issued, the stock compensation expense would be significantly greater and changes to the estimates involved in the calculation of stock compensation expense could have a material effect on the Company’s consolidated financial statements. Based on stock price information at December 31, 2013, if the increase in total shares available for issuance under the 2008 Plan had been approved on December 31, 2013 and these options had been issued as of December 31, 2013, there would have been approximately $5.0 million of expense related to these options, to be expensed over the remainder of the four year service period. However, because the stock compensation expense will be calculated based on the stock price as of the date of approval by the shareholders, the actual expense could be materially higher or lower, depending on the Company’s stock price as of that date. Estimates and assumptions are based upon information currently available. However, if actual results are not consistent with current estimates or assumptions, the Company could be exposed to changes in stock-based compensation expense that could be material.

Income Taxes

The Company uses 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.

Management uses 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, as well as guidance on derecognition, classification, interest and penalties and financial statement reporting disclosures. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The Company has not identified any uncertain income tax positions that could have a material impact to the consolidated financial statements. The Company is subject to taxation in various United States jurisdictions and remains 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 the Company prevails in matters for which a liability has been established, or is required to pay amounts in excess of its established liability, the Company’s effective income tax rate in a given financial statement period could be materially affected. An unfavorable tax settlement generally would require use of the Company’s cash and may result in an increase in the Company’s effective income tax rate in the period of resolution. A favorable tax settlement may reduce the Company’s effective income tax rate and would be recognized in the period of resolution.

The Company considers potential tax effects resulting from discontinued operations and records intra-period tax allocations, when those effects are deemed material. The Company's effective income tax rate is also affected by changes in tax law, the level of earnings and the results of tax audits.

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

Recently Issued Accounting Standards

In February 2013, the Financial Accounting Standards Board ("FASB") issued guidance related to additional reporting and disclosure of amounts reclassified out of accumulated other comprehensive income ("OCI"). Under this new guidance, companies are required to disclose the amount of income or loss reclassified out of OCI to each respective line item on the income statement where net income is presented. The guidance allows companies to elect whether to disclose the reclassification either in the notes to the financial statements, or on the face of the income statement. The adoption of this standard in 2013 did not have a material impact on the Company's consolidated results of operations, cash flows or financial position.

In July 2012, the FASB issued accounting guidance to simplify the evaluation for impairment of indefinite-lived intangible assets. Under the updated guidance, an entity has the option of first performing a qualitative assessment to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired before proceeding to the quantitative impairment test under which it would calculate the asset's fair value. When performing the qualitative assessment, the entity must evaluate events and circumstances that may affect the significant inputs used to determine the fair value of the indefinite-lived intangible asset. The adoption of this standard in 2013 did not have a material impact on the Company's consolidated results of operations, cash flows or financial position.

Off-Balance Sheet Arrangements

As of each of December 31, 2013 and 2012, the Company did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

Tabular Disclosure of Contractual Obligations

Not required due to Smaller Reporting Company status.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not required due to Smaller Reporting Company status.

Item 8. CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
ANI Pharmaceuticals, Inc. and Subsidiary

We have audited the accompanying consolidated balance sheets of ANI Pharmaceuticals, Inc. and Subsidiary (the "Company") as of December 31, 2013 and 2012, and the related consolidated statements of operations, changes in stockholders' equity/(deficit), and cash flows for each of the years in the two-year period ended December 31, 2013. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of ANI Pharmaceuticals, Inc. and Subsidiary as of December 31, 2013 and 2012, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

New York, New York
February 28, 2014

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

	December 31, 2013	December 31, 2012
Assets		
Current Assets		
Cash and cash equivalents	$ 11,105	$ 11
Accounts receivable, net of $5,104 and $6,124 of adjustments for chargebacks and other allowances at December 31, 2013 and 2012, respectively	12,513	5,432
Inventories, net	3,518	2,810
Prepaid expenses	580	313
Total Current Assets	27,716	8,566
Property and Equipment, net	4,537	4,880
Deferred loan costs, net	-	217
Intangible assets, net	10,409	85
Goodwill	1,838	-
Total Assets	$ 44,500	$ 13,748
Liabilities and Stockholders' Equity/(Deficit)		
Current Liabilities		
Accounts payable	$ 1,429	$ 1,994
Accrued expenses	1,326	927
Returned goods reserve	736	411
Deferred revenue	47	315
Borrowings under line of credit	-	4,065
Total Current Liabilities	3,538	7,712
Commitments and Contingencies (Note 14)		
Redeemable Convertible Preferred Stock (Note 9)	-	48,751
Stockholders' Equity/(Deficit)		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 9,629,174 shares issued and 9,619,941 shares outstanding at December 31, 2013; 4,070,373 shares issued and outstanding at December 31, 2012	1	-
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,868 shares issued and outstanding at December 31, 2013 and 2012, respectively	-	-
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and	-	-

outstanding at December 31, 2013 and 2012, respectively		
Treasury stock, 9,233 shares of common stock, at cost, at December 31, 2013	(68)	-
Additional paid-in capital	89,501	1,083
Accumulated deficit	(48,472)	(43,798)
Total Stockholders' Equity/(Deficit)	40,962	(42,715)
Total Liabilities and Stockholders' Equity/(Deficit)	$ 44,500	$ 13,748

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

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

	Years ended December 31, 2013	2012	
Net Revenues	$ 30,082	$ 20,371	
Operating Expenses			
Cost of sales (excluding depreciation and amortization)	9,974	9,167	
Research and development	1,712	1,158	
Selling, general and administrative	16,388	9,521	
Depreciation and amortization	1,110	567	
Total Operating Expenses	29,184	20,413	
Operating Income/(Loss) from Continuing Operations	898	(42)	
Other Expense			
Interest expense	(467)	(1,327)	
Other expense	(305)	(241)	
Net Income/(Loss) from Continuing Operations Before Benefit for Income Taxes	126	(1,610)	
(Provision)/Benefit for income taxes	(20)	36	
Net Income/(Loss) from Continuing Operations	106	(1,574)	
Discontinued Operation			
Gain on discontinued operation, net of provision (benefit) for income taxes	195	68	
Net Income/(Loss)	$ 301	$ (1,506)	
Computation of Income/(Loss) from Continuing Operations Attributable to Common Stockholders:			
Net Income/(Loss) from Continuing Operations	$ 106	$ (1,574)	
Preferred stock dividends	(4,975)	(6,922)	
(Loss) from Continuing Operations Attributable to Common Stockholders	$ (4,869)	$ (8,496)	
Basic and Diluted Income/(Loss) Per Share:			
Continuing operations	$ (0.96)	N/A	(1)
Discontinued operation	0.04	N/A	(1)
Basic and Diluted Income/(Loss) Per Share	$ (0.92)	N/A	(1)
Basic and Diluted Weighted-Average Shares Outstanding	5,071	N/A	(1)

(1) Earnings per common share is not calculable because common shareholders from ANIP Acquisition Company did not receive consideration from the June 19, 2013 Merger with BioSante. See Note 1 for further details.

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARY
Consolidated Statements of Changes in Stockholders' Equity/(Deficit)
For the years ended December 31, 2013 and 2012
(in thousands)

	Common Stock Par Value	Common Stock Shares	Class C Special Stock	Additional Paid-in Capital	Treasury Stock Shares	Treasury Stock	Accumulated Deficit	Total
Balance, December 31, 2011	$ -	3,045	$ -	$ 1,086	-	$ -	$ (35,370)	$ (34,284)
Issuance of Common Stock upon Cashless Warrant Exercise	2	22	-	(2)	-	-	-	-
Issuance of Peferred Stock upon Cashless Warrant Exercise	-	-	-	(3)	-	-	-	(3)
Preferred Stock Dividends	-	-	-	-	-	-	(6,922)	(6,922)
Effect of Reverse Merger	(2)	1,003	-	2	-	-		-
Net loss	-		-	-	-	-	(1,506)	(1,506)
Balance, December 31, 2012	$ -	4,070	$ -	$ 1,083	-	$ -	$ (43,798)	$ (42,715)
Preferred Stock Dividends	-		-	-		-	(4,975)	(4,975)
Non-cash Compensation Relating to Business Combination	-	-	-	4,418	-	-	-	4,418
Cancellation of Convertible Preferred Stock	-	-	-	53,726	-	-	-	53,726
Shares Issued in Merger	1	5,469	-	29,794	-	-	-	29,795
Stock-based Compensation Expense	-	-	-	36	-	-	-	36
Purchase of Common Stock for Treasury	-	-	-	-	59	(433)	-	(433)
Issuance of Common Stock upon Warrant Exercise	-	90	-	809		-	-	809
Treasury Stock Shares Issued as Restricted Stock	-	-	-	(365)	(50)	365	-	-
Net Income	-	-	-	-		-	301	301
Balance, December 31, 2013	$ 1	9,629	$ -	$ 89,501	9	$ (68)	$ (48,472)	$ 40,962

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARY
Consolidated Statements of Cash Flows

(in thousands)

For the years ended December 31,	2013	2012
Cash Flows From Operating Activities		
Net income/(loss)	$ 301	$ (1,506)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Stock-based compensation	36	-
Depreciation and amortization	1,110	567
Non-cash interest relating to equity-linked securities and loan cost amortization	217	1,071
Non-cash compensation relating to business combination	4,418	-
Changes in operating assets and liabilities, net of those acquired in business combination:		
Accounts receivable	(7,081)	(327)
Inventories	(708)	(702)
Prepaid expenses	(188)	(88)
Accounts payable	(565)	785
Accrued compensation	(2,854)	-
Accrued expenses, returned goods reserve and deferred revenue	25	205
Net Cash and Cash Equivalents Used in Continuing Operations	(5,289)	5
Net Cash Used in Discontinued Operation	(195)	(142)
Net Cash and Cash Equivalents Used in Operating Activities	(5,484)	(137)
Cash Flows From Investing Activities		
Cash acquired in business combination	18,198	-
Release of restricted cash	2,260	
Acquisition of property and equipment	(191)	(292)
Net Cash and Cash Equivalents Provided by/(Used in) Investing Activities	20,267	(292)
Cash Flows From Financing Activities		
(Repayments)/borrowings under line of credit, net	(4,065)	1,001
Payment of debt issuance costs	-	(261)
Proceeds from warrant exercise	809	-
Treasury stock purchases	(433)	-
Net Cash and Cash Equivalents (Used in)/Provided by Continuing Operations	(3,689)	740
Net Cash Used in Discontinued Operation	-	(300)
Net Cash and Cash Equivalents (Used in)/Provided by Financing Activities	(3,689)	440

Change in Cash and Cash Equivalents		11,094		11
Cash and cash equivalents, beginning of period		11		-
Cash and cash equivalents, end of period	$	11,105	$	11
Supplemental disclosure for cash flow information:				
Cash paid for interest	$	250	$	255
Supplemental non-cash investing and financing activities:				
Issuance of common stock in connection with business combination	$	40,034	$	-
Cancellation of Series D, Series C, Series B, and Series A preferred stock	$	53,726	$	-
Acquired non-cash net assets	$	11,597	$	-
Preferred stock dividends accrued	$	4,975	$	6,922
Issuance of common and preferred stock upon cashless warrant exercise	$	-	$	5
Issuance of preferred stock upon convertible debt conversion	$	-	$	17,610

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

ANI Pharmaceuticals, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the years ended December 31, 2013 and 2012

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business

ANI Pharmaceuticals, Inc. and its consolidated subsidiary, ANIP Acquisition Company (together, the "Company") is a specialty pharmaceutical company, developing and marketing generic and branded prescription products. The Company was organized as a Delaware corporation in April 2001. At its two facilities located in Baudette, Minnesota, which have a combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet, the Company manufactures oral solid dose products, as well as liquids and topicals, including those that must be manufactured in a fully contained environment due to their potency. The Company also performs contract manufacturing for other pharmaceutical companies.

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

The Company's operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, dependence on significant customers, lack of operating history and uncertainty of future profitability and possible fluctuations in financial results. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future profitable operations, the ability to generate sufficient cash from operations, and potential other funding sources, including cash on hand, to meet the Company's obligations as they become due. Management believes the going-concern basis is appropriate for the accompanying consolidated financial statements based on its current operating plan through December 31, 2014.

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 wholly-owned subsidiary, ANIP. All significant intercompany accounts and transactions are eliminated in consolidation.

Use of Estimates

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 the accompanying consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, returns and other allowances, allowance for inventory obsolescence, valuation of derivative liabilities, accruals for contingent liabilities, fair value of long-lived assets, deferred taxes and valuation allowance, and the depreciable lives of fixed assets. Actual results could differ from those estimates.

ANI Pharmaceuticals, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the years ended December 31, 2013 and 2012

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

Credit Concentration

The Company's customers are primarily wholesale distributors, chain drug stores, group purchasing organizations, and other pharmaceutical companies.

During the year ended December 31, 2013, three customers represented approximately 27%, 18%, and 10% of net revenues, respectively. As of December 31, 2013, accounts receivable from these customers totaled 68% of net accounts receivable. During the year ended December 31, 2012, three customers represented approximately 25%, 21%, and 11% of net revenues, respectively.

Vendor Concentration

The Company sources the raw materials for its 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, the Company is dependent upon its current vendors to supply reliably the API required for ongoing product manufacturing. During the year ended December 31, 2013, the Company purchased approximately 37% of total costs of goods sold from three suppliers. As of December 31, 2013, amounts payable to these suppliers was immaterial. During the year ended December 31, 2012, the Company purchased approximately 63% of total costs of goods sold from three suppliers.

Revenue Recognition

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

Occasionally, the Company engages in contract services, which include product development services, laboratory services, and royalties on net sales of certain contract manufactured products. For these services, revenue is recognized according to the terms of the agreement with the customer, which sometimes include substantive, measurable risk-based milestones, and when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured, and the Company has no further performance obligations under the agreement. The Company recognized $1.4 million and $0.8 million of revenue related to contract services in 2013 and 2012, respectively.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. All interest bearing and non-interest bearing accounts are guaranteed by the FDIC up to $250 thousand. The Company may maintain cash balances in excess of FDIC coverage. Management considers this to be a normal business risk.

ANI Pharmaceuticals, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the years ended December 31, 2013 and 2012

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

In conjunction with the Merger, the Company acquired restricted cash, none of which remained at December 31, 2013.

Accounts Receivable

The Company extends credit to customers on an unsecured basis. The Company utilizes the allowance method to provide for doubtful accounts based on management's evaluation of the collectability of accounts receivable, whereby the Company provides an allowance for doubtful accounts equal to the estimated uncollectible amounts. Management’s estimate is based on historical collection experience and a review of the current status of trade accounts receivable. The Company determines trade receivables to be delinquent when greater than 30 days past due. Receivables are written off when it is determined that amounts are uncollectible. The Company determined that no allowance for doubtful accounts was necessary as of December 31, 2013 and 2012.

Accruals for Chargebacks, Returns and Other Allowances

The Company's generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates and prompt payment discounts. The Company accrues for these items at the time of sale based on the estimates and methodologies described below. In the aggregate, these accruals exceed 60% of generic and branded gross product sales and reduce gross revenues to net revenues in the accompanying consolidated statements of operations, and are presented as current liabilities or reductions in accounts receivable in the accompanying consolidated balance sheets. The Company continually monitors and re-evaluates the accruals as additional information becomes available, which includes, among other things, updates to trade inventory levels and customer product mix. The Company makes adjustments to the accruals at the end of each reporting period, to reflect any such updates to the relevant facts and circumstances. Accruals are relieved upon receipt of payment from or upon issuance of credit to the customer.

Chargebacks

Chargebacks, primarily from wholesalers, result from arrangements the Company has with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, the Company may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, the Company provides 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 product sales mix

A change in the volume of off-contract purchases
Changes in WAC

As necessary, the Company adjusts ASPs based on anticipated changes in the factors above.

ANI Pharmaceuticals, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the years ended December 31, 2013 and 2012

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

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

To evaluate the adequacy of its chargeback accruals, the Company obtains 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. The Company continually monitors chargeback activity and adjusts ASPs when it believes that actual selling prices will differ from current ASPs.

Returns

The Company maintains 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. The Company's product returns are settled through the issuance of a credit to the customer. The Company's estimate for returns is based upon its 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. The Company continually monitors its estimates for returns and makes adjustments when it believes 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. The Company accrues for fees and rebates, by product by wholesaler, at the time of sale based on contracted rates and ASPs.

To evaluate the adequacy of its administrative fee accruals, the Company obtains 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. The Company continually monitors administrative fee activity and adjusts its accruals when it believes 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

The Company often grants sales discounts for prompt payment. The reserve for sales discounts is based on invoices outstanding. The Company assumes 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.

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ANI Pharmaceuticals, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the years ended December 31, 2013 and 2012

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

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the years ended December 31, 2013 and 2012:

(in thousands)	Accruals for Chargebacks, Returns and Other Allowances			
	Chargebacks	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2011	$ 3,681	$ 252	$ 238	$ 166
Accruals/Adjustments	22,912	698	1,369	775
Credits Taken Against Reserve	(20,931)	(539)	(1,376)	(699)
Balance at December 31, 2012	5,662	411	231	242
Accruals/Adjustments	28,009	1,595	2,355	1,129
Credits Taken Against Reserve	(29,595)	(1,270)	(1,851)	(1,039)
Balance at December 31, 2013	$ 4,076	$ 736	$ 735	$ 332

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. The Company periodically reviews and adjusts standard costs, which generally approximates 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	3 - 10 years

Construction in progress includes the cost of construction and other direct costs attributable to the construction, along with capitalized interest, if any. Depreciation is not recorded on construction in progress until such time as the assets are placed in service.

Management reviews 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. Assets held for disposal are reportable at the lower of the carrying amount or fair value, less costs to sell. Management determined that no assets were impaired and no assets were held for disposal as of December 31, 2013 and 2012.

Intangible Assets

Intangible assets were acquired as part of the Merger and asset acquisition transactions and consist of rights to produce pharmaceutical products and a license. These intangible assets originally were recorded at fair value and are stated net of accumulated amortization.

ANI Pharmaceuticals, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the years ended December 31, 2013 and 2012

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

The rights and licenses are amortized over their remaining estimated useful lives, ranging from 2 to 11 years, based on the straight-line method. Management reviews definite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable, in a manner similar to that for property and equipment.

Goodwill

Goodwill relates to the Merger and represents the excess of the total purchase consideration over the fair value of acquired assets and assumed liabilities, using the purchase method of accounting. Goodwill is not amortized, but is subject to periodic review for impairment. Goodwill is reviewed annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. The Company performs its review of goodwill on its one reporting unit.

Before employing detailed impairment testing methodologies, management first evaluates the likelihood of impairment by considering qualitative factors relevant to its reporting unit. When performing the qualitative assessment, management evaluates 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 the Company, industry and market considerations for the generic pharmaceutical industry that could affect the Company, cost factors that could affect the Company’s performance, the Company’s financial performance (including share price), and consideration of any Company-specific events that could negatively affect the Company, its business, or its fair value. If management determines that it is more likely than not that goodwill is impaired, management will then apply detailed testing methodologies. Otherwise, management will conclude that no impairment has occurred.

Detailed impairment testing involves comparing the fair value of the Company's 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 the Company. If the fair value exceeds carrying value, then it is concluded that no goodwill impairment has occurred. If the carrying value of the reporting unit exceeds its fair value, a second step is required to measure possible goodwill impairment loss. The second step includes hypothetically valuing the tangible and intangible assets and liabilities of the Company's one reporting unit as if it had been acquired in a business combination. Then, the implied fair value of the Company's one reporting unit's goodwill is compared to the carrying value of that goodwill. If the carrying value of the Company's one reporting unit's goodwill exceeds the implied fair value of the goodwill, the Company recognizes an impairment loss in an amount equal to the excess, not to exceed the carrying value.

Collaborative Arrangements

Third party costs incurred and revenues generated by arrangements involving the Company and one or more parties, both of whom are actively involved and exposed to risks and rewards of the activities, are classified in the consolidated statements of operations on a gross basis only if the Company is determined to be the principal participant in the arrangement. Otherwise, third party revenues and costs generated by collaborative arrangements are presented on a net basis. Payments between participants are recorded and classified based on the nature of the payments.

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 $1.7 million and $1.2 million for the years ended December 31, 2013 and 2012, respectively.

ANI Pharmaceuticals, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the years ended December 31, 2013 and 2012

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

Stock-Based Compensation

The Company has a stock-based compensation plan that includes stock options and restricted stock, which are awarded in exchange for employee and non-employee director services. The Company recognizes the estimated fair value of stock-based awards and classifies the expense where the underlying salaries are classified. For the year ended December 31, 2013, all stock-based awards were classified as sales, general and administrative expense in the accompanying consolidated statements of operations. Stock-based compensation cost for stock options is determined at the grant date using an option pricing model and stock-based compensation cost for restricted stock is based on the closing market price of the stock at the grant date. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the employee's requisite service period.

Valuation of stock awards requires management 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 the Company’s stock price, dividend yields, future employee turnover rates, and future employee stock option exercise behaviors. Changes in these assumptions can affect the fair value estimate.

Income Taxes

The Company uses 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.

Management uses 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, as well as guidance on derecognition, classification, interest and penalties and financial statement reporting disclosures. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The Company has not identified any uncertain income tax positions that could have a material impact to the consolidated financial statements. The Company is subject to taxation in various jurisdictions in the United States and remains subject to examination by taxing jurisdictions for the years 1998 and all subsequent periods due to the availability of net operating loss carryforwards.

The Company recognizes interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense. The Company did not have any amounts accrued relating to interest and penalties as of December 31, 2013 and 2012.

The Company considers potential tax effects resulting from discontinued operations and records 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 (loss) 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, diluted earnings per share is computed 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, unvested restricted stock awards, and stock purchase warrants, using the treasury stock method.

ANI Pharmaceuticals, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the years ended December 31, 2013 and 2012

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

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. The number of anti-dilutive shares, consisting of Class C Special stock, common stock options, unvested restricted stock awards, and warrants exercisable for common stock (and prior to the Merger, equity-linked securities, convertible preferred stock, and stock purchase warrants exercisable for preferred stock), which have been excluded from the computation of diluted earnings (loss) per share, were 2.7 million for both of the years ended December 31, 2013 and 2012. The Company's unvested restricted shares contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; the calculation of basic and diluted income (loss) per share excludes net income (but not net loss) attributable to the unvested restricted shares from the numerator and excludes the impact of those shares from the denominator.

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

As of December 31, 2013, the Company had 120 thousand common stock options, 50 thousand unvested restricted stock awards, and 686 thousand warrants exercisable for common stock outstanding.

Stock Splits and Other Reclassifications

In July 2013, the Company's Board of Directors and stockholders approved a resolution to effect a one-for-six reverse stock split of the Company's common stock and Class C Special stock with no corresponding change to the par values. The number of authorized shares of common stock, Class C Special stock and blank check preferred stock was reduced proportionally. Common stock and Class C Special stock for all periods presented have been adjusted retrospectively to reflect the one-for-six reverse stock split.

Redeemable Convertible Preferred Stock

Prior to the Merger, the carrying value of ANIP's redeemable convertible preferred stock was increased by the accretion of any related discounts and accrued but unpaid dividends so that the carrying amount would equal the redemption amount at the dates the stock became redeemable. ANIP's Series A, B, C and D preferred stock was redeemable at the option of the holders, subject to certain additional requirements. All of ANIP's Series D preferred stock was canceled and exchanged for shares of BioSante common stock and all of ANIP's Series A, B and C preferred stock were canceled in conjunction with the Merger (Note 2).

Fair Value of Financial Instruments

The Company's consolidated balance sheets include various financial instruments (primarily cash and cash equivalents, prepaid expenses, accounts receivable, accounts payable, accrued expenses, borrowings under line of credit, and other current liabilities) 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 6 for additional information regarding fair value.

Segment Information

The Company currently operates in a single business segment.

ANI Pharmaceuticals, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the years ended December 31, 2013 and 2012

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

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board ("FASB") issued guidance related to additional reporting and disclosure of amounts reclassified out of accumulated other comprehensive income ("OCI"). Under this new guidance, companies will be required to disclose the amount of income or loss reclassified out of OCI to each respective line item on the income statement where net income is presented. The guidance allows companies to elect whether to disclose the reclassification in the notes to the financial statements, or on the face of the income statement. The adoption of this standard in 2013 did not have a material impact on the Company's consolidated results of operations, cash flows or financial position. The Company does not have a Statement of Comprehensive Income because the Company has no Other Comprehensive Income.

In July 2012, the FASB issued accounting guidance to simplify the evaluation for impairment of indefinite-lived intangible assets. Under the updated guidance, an entity has the option of first performing a qualitative assessment to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired before proceeding to the quantitative impairment test under which it would calculate the asset's fair value. When performing the qualitative assessment, the entity must evaluate events and circumstances that may affect the significant inputs used to determine the fair value of the indefinite-lived intangible asset. The adoption of this standard in 2013 did not have a material impact on the Company's consolidated results of operations, cash flows or financial position.

The Company has evaluated all issued and unadopted Accounting Standards Updates and believes the adoption of these standards will not have a material impact on its consolidated results of operations, financial position, or cash flows.

2. BUSINESS COMBINATION

On June 19, 2013, BioSante acquired ANIP in an all-stock, tax-free reorganization. The Company is operating under the leadership of the ANIP management team and the board of directors is comprised of two former directors from BioSante and five former ANIP directors.

BioSante issued to ANIP stockholders shares of BioSante common stock such that the ANIP stockholders owned 57% of the combined company's shares outstanding, and the former BioSante stockholders owned 43%. In addition, immediately prior to the Merger, BioSante distributed to its then current stockholders contingent value rights ("CVR") providing payment rights arising from a future sale, transfer, license or similar transaction(s) involving BioSante's LibiGel ® (female testosterone gel).

The Merger was accounted for as a reverse acquisition pursuant to which ANIP was considered the acquiring entity for accounting purposes. As such, ANIP's historical results of operations replace BioSante's historical results of operations for all periods prior to the Merger. BioSante, the accounting acquiree, was a publicly-traded pharmaceutical company focused on developing high value, medically-needed products. ANIP entered into the Merger to secure additional capital and gain access to capital market opportunities as a public company.

The results of operations of both companies are included in the Company's consolidated financial statements for all periods after completion of the Merger.

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ANI Pharmaceuticals, Inc. and Subsidiary
Notes to the Consolidated Financial Statements
For the years ended December 31, 2013 and 2012

2. BUSINESS COMBINATION (Continued)

Transaction Costs

In conjunction with the Merger, the Company incurred approximately $7.1 million in transaction costs, which were expensed in the periods in which they were incurred. Costs incurred through December 31, 2013, include:

Category	(in thousands)
Legal fees	$ 1,227
Accounting fees	122
Consulting fees	119
Monitoring and advisory fees	390
Transaction bonuses	4,801
Other	429
Total transaction costs	$ 7,088

Of the total expenses, $0.9 million was incurred and expensed in the year ended December 31, 2012 as selling, general and administrative expense in the accompanying consolidated statements of operations. The remaining $6.2 million was incurred and expensed in the year ended December 31, 2013, $5.5 million as selling, general and administrative expense $0.3 million as interest expense, and $0.4 million as other expense, in the accompanying consolidated statements of operations.

Purchase Consideration and Net Assets Acquired

The fair value of BioSante's common stock used in determining the purchase price was $1.22 per share, the closing price on June 19, 2013, which resulted in a total purchase consideration of $29.8 million. The fair value of all additional consideration, including the vested BioSante stock options and CVRs, was immaterial. The following presents the preliminary allocation of the purchase consideration to the assets acquired and liabilities assumed on June 19, 2013:

	(in thousands)
Total purchase consideration	$ 29,795
Assets acquired	
Cash and cash equivalents	18,198
Restricted cash	2,260
Teva license intangible asset	10,900
Other tangible assets	79
Deferred tax assets, net	-
Goodwill	1,838
Total assets	33,275
Liabilities assumed	
Accrued severance	2,965
Other liabilities	515
Total liabilities	3,480
Total net assets acquired	$ 29,795

Any changes in the estimated fair values of the net assets recorded for this business combination upon the finalization of more detailed analyses of the facts and circumstances that existed at the date of the transaction will change the allocation of the purchase price. Any subsequent changes to the purchase allocation during the measurement period that are material will be adjusted retrospectively.

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2. BUSINESS COMBINATION (Continued)

The Teva license is related to a generic male testosterone gel product and is being amortized on a straight-line basis over its estimated useful life of 11 years. Goodwill, which is not tax deductible since the transaction was structured as a tax-free exchange, is considered an indefinite-lived asset and relates primarily to intangible assets that do not qualify for separate recognition. As a result of purchase accounting related to the Merger, the Company established deferred tax assets of $9.6 million, deferred tax liabilities of $3.9 million, and a valuation allowance of $5.7 million, netting to deferred tax assets of $0.

Former BioSante operations generated $0.5 million of revenue in a non-recurring payment related to the Teva license, and no expense from the acquisition date through December 31, 2013.

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 Merger had been completed as of January 1, 2012. Pro forma information reflects adjustments relating to (i) elimination of the interest on ANIP's senior and equity-linked securities, (ii) elimination of monitoring and advisory fees payable to two ANIP investors, (iii) elimination of transaction costs, and (iv) amortization of intangibles acquired. The pro forma amounts do not purport to be indicative of the results that would have actually been obtained if the Merger had occurred as of January 1, 2012 or that may be obtained in the future.

	Year ended December 31,	
(in thousands)	2013	2012
Net revenues	$ 30,228	$ 22,671
Net income/(loss)	$ 89	$ (27,718)

3. INVENTORIES

Inventories consist of the following as of December 31:

(in thousands)	2013	2012
Raw materials	$ 1,480	$ 975
Packaging materials	766	585
Work-in-progress	162	374
Finished goods	1,152	891
	3,560	2,825
Reserve for excess/obsolete inventories	(42)	(15)
Inventories, net	$ 3,518	$ 2,810

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4. PROPERTY, PLANT, AND EQUIPMENT

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

(in thousands)	2013	2012
Land	$ 87	$ 87