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;