IGI LABORATORIES, INC
Form 10-K
March 31, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

# FORM 10-K

(Mark One)

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

**For the fiscal year ended December 31, 2013**

OR

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

**For the transition period from _____ to _____.**

**Commission file number 001-08568**

**IGI Laboratories, Inc.**

(Name of small business issuer in its charter)

| **Delaware** | **01-0355758** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **105 Lincoln Ave., Buena, NJ** | **08310** |
| (Address of principal executive offices) | (Zip Code) |

**Registrant s telephone number: (856) 697-1441**

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

| **Title of each class** | **Name of each exchange on which registered** |
|---|---|
| Common Stock $0.01 Par Value | NYSE MKT |

Securities registered pursuant to Section 12(g) of the Exchange 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 if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ¨ No x

Indicate by check 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 (§ 232.405 of this chapter) 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. ¨

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 the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

| 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 the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No x

The aggregate market value of the registrant's voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold on June 28, 2013 was approximately $32.5 million.

As of March 25, 2014, there were 47,019,121 shares of the registrant s common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant s Proxy Statement for the 2013 Annual Meeting of Stockholders to be held on or about May 27, 2014.

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**PART I**

**ITEM 1.**

**BUSINESS**

**Overview**

IGI Laboratories, Inc. is a developer, manufacturer, and marketer of topical formulations. Our goal is to become a leader in the generic topical pharmaceutical market. Under our IGI label, we sell generic topical pharmaceutical products that are bioequivalent to their brand name counterparts. We also provide development, formulation, and manufacturing services to the pharmaceutical, over-the-counter (OTC) and cosmetic markets.

Currently, we have two platforms for growth:

Manufacturing, developing, and marketing a portfolio of generic pharmaceutical products in our own label in topical dosage forms; and,

Increasing our current contract manufacturing and formulation services business.

In addition, we will continue to explore ways to accelerate our growth through the creation of unique opportunities from the acquisition of additional intellectual property, and the expansion of the use of our existing intellectual property, including our licensed Novasome® technology.

In December 2012, we completed the implementation of our commercial infrastructure and launched our first generic topical pharmaceutical products under the IGI label. To date, we have filed fourteen Abbreviated New Drug Applications, or ANDAs, with the United States Food and Drug Administration, or FDA for additional

pharmaceutical products. On March 12, 2014, we received our first approval from the FDA for an ANDA. We expect to continue to expand our presence in the generic topical pharmaceutical market through the filing of additional ANDAs with the FDA and the subsequent launch of products as these applications are approved. Our target is to file at least ten ANDAs in 2014 through our internal research and development program. We will also seek to license or acquire further products, intellectual property, or ANDAs to expand our portfolio. On February 1, 2013, we acquired assets and intellectual property, including an ANDA, for econazole nitrate cream 1%, which we launched in September 2013.

IGI also develops manufactures, fills, and packages topical semi-solid and liquid products for branded and generic pharmaceutical customers as well as the OTC and cosmetic markets. These products are used in a wide range of applications from cosmetics and cosmeceuticals to the prescription treatment of conditions like dermatitis, psoriasis, and eczema.

We perform all of our product development and manufacturing at our facility in Buena, New Jersey. Our head office, product development laboratories, and manufacturing facility are located at 105 Lincoln Avenue, Buena, New Jersey. Our telephone number is 856-697-1441 and our website is *http://www.igilabs.com*. We have not incorporated by reference in this Annual Report on Form 10-K the information on, or accessible through, our website.

**Recent Developments**

We filed five ANDAs in 2013 with the FDA, one in January 2013, one in April 2013, one in July 2013, one in September 2013 and one in October 2013.

In December 2013, we executed a license, development, supply and marketing agreement with a large multi-national pharmaceutical company. In accordance with the confidentiality agreement in place, the name of the company remains undisclosed. The agreement designates us as the developer and manufacturer of a generic topical pharmaceutical drug product, which will be licensed, marketed and distributed in the United States by our partner, or its subsidiaries. The named product in the agreement was developed at IGI. We filed the ANDA associated with the named generic pharmaceutical product. In accordance with the agreement, our partner is required to pay IGI when certain milestones are met related to the filing and approval of the associated ANDA. In addition, in accordance with the agreement, IGI will also receive a share of the profits following the approval and commercialization of the product.

On March 3, 2014, we submitted our first ANDA for 2014 to the FDA, which brought our total number of ANDA submissions to fourteen.

On March 12, 2014, we received our first approval from the FDA for an ANDA. Lidocaine hydrochloride USP 4% topical solution is indicated for the production of topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract. Based on November 2013 IMS Health data, the total addressable market for this product is approximately $1.8 million, in which IGI will currently compete with two other manufacturers. IGI originally submitted this ANDA to the FDA in May, 2012.

On March 31, 2014, IGI filed a Form 8-K disclosing that on March 25, 2014, Joyce Erony, a director and the chairperson of the IGI Laboratories, Inc. s Board of Directors, advised us that she will not stand for re-election as a director at the IGI annual meeting to be held on May 27, 2014. Also included in the 8-K, was the announcement that on March 28, 2014, Michael B. Hemric advised IGI that he will be resigning as a director of the IGI Board of Directors effective April 1, 2014. We have begun the interview process to appoint new directors to IGI s Board.

**Our Services and Products**

*IGI s Generic Pharmaceutical Business*

IGI has been in the contract manufacturing and development business for several years, offering contract manufacturing and formulation services to its pharmaceutical, OTC, and cosmetic customers. In 2010, we leveraged our existing formulation capabilities and began the transformation from solely a contract manufacturing and development company into a generic pharmaceutical company. The foundation of our generic pharmaceutical business began in September 2010, when we filed our first ANDA with the FDA. From September 2010 to date, we have filed fourteen ANDAs, all for further expansion of our generic topical pharmaceutical portfolio of prescription products. On March 12, 2014, we received our first approval from the FDA for an ANDA. We now have thirteen filings pending at the FDA.

In December of 2011, we executed an agreement with one of our pharmaceutical partners, Medimetriks Pharmaceuticals, Inc. (Medimetriks), a branded specialty pharmaceutical company dedicated to the dermatology market. This agreement included IGI s appointment as Medimetriks authorized generic (AG) distributor for certain products. In order to prepare to launch our first IGI label products, in 2012, we began to build our commercial infrastructure. We finalized all of our state licensing requirements, implemented our procedures with our third-party

logistics partner, designed our sales order to cash administrative processes and added our first manager of national accounts to manage our sales. These processes led to the execution of our first contracts with large drug wholesalers, distributors and national retail chains. In October 2012, Medimetriks launched its first three products in its Synalar® (fluocinolone acetonide) line of prescription topical products, and on November 1, 2012, IGI gained authorization to launch generic distribution of certain of these products. In December 2012, we launched our first product, the AG for fluocinolone acetonide topical solution, and in January 2013, we successfully launched the AG for the fluocinolone acetonide ointment and cream.

With the commercial infrastructure and the distribution channels in place, and three products successfully launched, we executed a product acquisition to expand our portfolio. On February 1, 2013, we acquired assets and intellectual property, including an ANDA, for econazole nitrate cream 1% from Prasco, LLC. a privately-held pharmaceutical company located in Ohio. Econazole nitrate cream 1%, which is available in 15g, 30g, and 85g tubes, is an anti-fungal cream that has FDA approved indications for the treatment of tinea pedis, tinea cruris, and tinea corporis as well as the treatment of cutaneous candidiasis and tinea versicolor. The FDA gave approval of the manufacturing site transfer in September of 2013 and IGI began to manufacture the product at our Company s facility in Buena, New Jersey, and distribute the product in an IGI label.

Our strategy is focused on the growth of our generic pharmaceutical business. We have filed fourteen ANDAs to date, and we have a number of additional product candidates in various stages of development. The addressable market, based on November 2013 IMS Health Reports data for the products we have pending at the FDA, totals over $330 million in annual sales. We expect to continue to expand our presence in the generic topical pharmaceutical market through the filing of additional ANDAs with the FDA and the subsequent launch of products as these applications are approved. Our target is to file ten ANDAs in 2014 through our internal research and development program. We will also seek to license or acquire further products, intellectual property, or ANDAs to expand our portfolio.

ANDAs are submitted to the FDA for generic drug products that are bioequivalent versions of innovator brand drug products. ANDA approval by the FDA allows for the interchangeability in the United States of the generic product with the innovator drug, meaning that the generic version may be substituted for the brand product by either a physician or pharmacist when dispensing a prescription. Our commercialization of each of these products is subject to approval of our ANDA applications by the FDA. The FDA reports that its current average review time is about 32 months and that there is a backlog of more than 3,900 applications. The Generic Drug User Fee (GDUFA) program that was implemented in 2012 is anticipated to reduce review times and the backlog.

Topical drugs are defined as those intended for local external application, meaning used on the skin, scalp, eyes, and ears. We believe that the topical market segment is an attractive niche due to a number of factors, including the aging of the US population. In November 2013, IMS Health reports the US topical pharmaceutical market at $11 billion in annual sales, of which generics make up $3.9 billion, leaving significant room for growth by generic companies. The market for prescription generic topical products is dominated by a few large companies. We believe that there is room for IGI to compete in selected product areas.

Topical products have distinctive requirements for demonstrating bioequivalence in the context of an ANDA. The sponsor of an ANDA can reference the innovator s original new drug application for safety and efficacy data, thus avoiding, in many cases, the costly studies required to demonstrate these qualities. It is the responsibility of the ANDA sponsor to demonstrate bioequivalence to the innovator drug product. For topical drugs there are three means of addressing bioequivalence: by requesting a waiver from the FDA for certain older products and solutions, performing vasoconstriction studies for corticosteroids, and by performing comparative clinical trials against the innovator drug for products indicated for the treatment of acne, rosacea, fungal infections, bacterial infections and viral infections of the skin. Over time, we intend to develop and submit ANDAs, and eventually market topical drugs which could be subject to any of these bioequivalence requirements.

*Contract Manufacturing and Development Business*

Our contract manufacturing and development business includes two services: contract formulation and contract manufacturing. These services are offered to pharmaceutical, OTC, and cosmetic customers. For our pharmaceutical contract services customers we formulate, test and/or manufacture prescription pharmaceutical products and medical devices. The products include pure cosmetic formulations sold by retail stores directly to the public as well as prescription drug formulations promoted directly to physicians. All contract manufacturing products are produced in our customer s label.

Contract development involves developing topical formulations to satisfy a customer s product request. Our experienced formulators can develop a novel formulation or replicate an existing formula through reverse engineering. We offer full support to the products we develop through developing test methods, full analytical services, manufacturing scale-up criteria, validation, and regulatory assistance. Upon completion of our contract formulation projects for a fee, we are often successful in obtaining the contract manufacturing services contract to manufacture the products we helped the customer develop. We have filed several 510 (k) submissions with the FDA on behalf of our customers to approve the marketing and distribution of certain medical devices. In December of 2012, after completion of the required formulation and regulatory requirements, we filed two ANDAs on behalf of one of our pharmaceutical partners.

We believe our contract manufacturing and development business provides a consistent and reliable source for quality product manufacturing to our customers. We offer flexibility in batch sizing and package design, which gives our customer the opportunity to select the appropriate presentation for each product. Our high-speed packaging lines can accommodate a variety of tubes, bottles, pumps, and jars.

We believe that our contract manufacturing and development business will continue to be an important component of our success. We believe our specialized services in topical dermatologic product forms and our high-quality formulation capabilities, set us apart from others in this competitive market space. An integral part of our strategy is to partner with leading pharmaceutical and skin care companies, and assist them in developing and manufacturing products for sale in the pharmaceutical, OTC and cosmetic markets. We will continue to seek out strategic partnerships, particularly with pharmaceutical partners.

*Novasome® Technology Platform*

We have an exclusive license for use of the patented Novasome® encapsulation technology in topical formulations, from Novavax, Inc., until December 11, 2015. The technology utilizes non-phospholipid structures for enhanced absorption via topical delivery of pharmaceuticals and cosmeceuticals. The Novasome® technology is inexpensive to manufacture, and its structures are stable, biodegradable, and highly hydrophobic and hydrophilic, making them suitable for a wide range of topical applications. Novasome® encapsulation has been demonstrated to provide the following benefits: improved product stability, reduced skin irritation, extended release of active ingredients, improved skin permeation, improved product aesthetics, and allowance of novel product forms.

Our Novasome® technology has been successfully used in a number of OTC products, including cosmetic and cosmeceutical products. We intend to continue to pursue collaboration opportunities with established skin care and pharmaceutical companies seeking to develop topical products with unique properties that allow us to utilize and capitalize on the Novasome® license. In addition, we will explore line extension opportunities through innovative packaging or alternate dosage forms of existing pharmaceutical molecules.

In February of 2013, we entered into a three-year agreement with Juventio, LLC, a New Jersey based company that distributes premium non-prescription health products, in partnership with healthcare professionals, to manufacture and supply finished dose forms of certain cosmetic and OTC products and formulations owned and developed by us. These products utilize the Novasome® technology. In the fourth quarter of 2013, we shipped the first products under this agreement.

Many of the Novasome® patents under this license have expired and more will expire before this license terminates on December 11, 2015. We have already filed our own patents based on this technology. An integral piece of this technology is manufacturing know-how which will not be lost as a result of the expiration of the license. As we continue to grow our generic pharmaceutical product portfolio, we believe that sales related to the Novasome® technology will constitute a smaller percentage of our sales in the future, but we believe we will be able to continue to utilize this technology subsequent to expiration of our license on December 11, 2015.

**Our Competitive Strategy**

Our goal is to become a leader in the generic topical pharmaceutical market. Under our IGI label, we sell generic topical pharmaceutical products that are bioequivalent to their brand name counterparts. In addition, we expect to

continue to grow our contract manufacturing and development business for topical cosmetic, cosmeceutical and pharmaceutical products, with a specific emphasis on expanding the percentage of our business from pharmaceutical customers. The key elements of our strategy include:

*Develop Generic Pharmaceuticals.* We intend to continue to develop topical generic products and utilize our expertise in pharmaceutical formulation and manufacture to expand our own generic topical prescription drug portfolio. Through the ANDA process, we target to develop at least ten topical products in 2014 and then to market these products to national chain drug stores and drug wholesalers through our own internal sales efforts.

*Continue to Expand Relationships with Customers*. We have developed strong customer relationships, which we believe provide us with both recurring revenue streams from those customers and opportunities to increase our product offerings to our customers. We intend to continue to capitalize on our strong customer relationships to increase our contract manufacturing and development revenues.

*Leverage Experience to Expand Contract Services*. Our senior management team has significant experience in product selection, formulation, methods development and regulatory affairs for topical pharmaceutical products. We intend to continue to leverage this significant experience to expand our contract services relationships with our current customers and to provide our contract development, manufacturing, filling and packaging services to new customers.

*Leverage our Flexible Manufacturing Capabilities*. We have an FDA-registered, cGMP-compliant facility that is equipped for manufacturing topical, semi-solid and liquid products. The design and configuration of our manufacturing facility provides flexibility in manufacturing batch sizes from 250 kg up to 4,000 kg. We intend to leverage this flexibility and capacity to increase our contract manufacturing and development business and further advance our generic IGI product manufacturing and development.

**Our Customers**

We have successfully broadened our customer base for our contract manufacturing and development business to increase our revenue growth. In 2013, we grew revenues from our contract development business, primarily as a result of our execution of three development services contracts with three of our pharmaceutical partners. We filed several 510 (k) submissions with the FDA on behalf of our partners, and in December 2012, we filed two ANDAs on behalf of one of these pharmaceutical partners, and under our agreement, if and when the ANDA is approved by the FDA we will be the named manufacturer of those topical pharmaceutical products.

Our customers in the contract manufacturing business generally consist of pharmaceutical companies as well as cosmetic, cosmeceutical and OTC product marketers who require product development/manufacturing support. In 2013, approximately sixty-one percent of our revenue was derived from pharmaceutical customers, as compared to forty-seven percent of total contract manufacturing revenue in 2012. We are focused on adding products and customers for our contract services business with a specific emphasis on pharmaceutical products and partners. We launched our first IGI labeled product in December 2012, and in 2013, we recorded $7.4 million of net sales from our generic prescription drug products.

**Research and Development**

Our R&D activities are integral to our business and are conducted at our facility in Buena, New Jersey. Our R&D department consists of eight full-time employees and their responsibilities include: formulation, reverse engineering, methods development, analytical and microbiologic testing and scale up. Our employees have specific expertise in developing topical products in a wide range of dosage forms, including simple solutions through complex creams. All ANDA development is conducted in-house except for bioequivalence testing, which is performed by what we believe to be a qualified contract research organization.

We have been steadily increasing our investment in R&D as we believe that R&D is the future of IGI. We incurred $2.7 and $2.8 million on R&D expenses in 2013 and 2012, respectively. We expect to at least double our R&D spending in 2014 to expand our ANDA submissions and pipeline.

**Sales and Marketing**

We make, sell, distribute and market our IGI label generic topical prescription drug products to national chain drug stores and drug wholesalers and distributors. This commercialization infrastructure includes satisfying our state licensing requirements, procedures with our third-party logistics partner, an appropriate sales order to cash administrative processes and a manager of national accounts to manage our sales.

Our additional sales and marketing activities are currently focused on increasing our contract development and manufacturing activities, led by our senior vice president of contract services. We offer our contract manufacturing services directly to our customer base of pharmaceutical, OTC and cosmetic customers.

We will also look to out-license in-house developed products arising from Novasome® technology and products that are granted market exclusivity. This technology consists of the technology we license from Novavax, Inc. as well as our own patented technologies.

**Competition**

In our generic topical prescription drug business, we face competition in the topical generic drug market from other generic drug manufacturers and brand-name pharmaceutical companies through authorized generics. Although there are a significant number of competitors in the generic drug market, there are fewer competitors in the topical generic drug market. The four dominant companies in the topical generic drug market consist of Taro Pharmaceutical Industries, Ltd., Sandoz, the generic pharmaceutical division of Novartis, Actavis, Inc. and Perrigo Company. Collectively, these four competitors control approximately sixty percent (60%) of the generic topical market by value based on IMS data in November 2013. We believe the concentrated nature of the topical generic drug market creates an opportunity for us. We believe we will be able to compete based on a variety of factors, including our focus on niche opportunities within the market segment and our dedication to quality in every area of our business.

The contract manufacturing services market is highly competitive and includes larger organizations with substantially greater resources than us. Many of our competitors are companies that commercialize and/or manufacture their required products at their own facilities. These competitors include major pharmaceutical companies, generic drug manufacturers and consumer health product companies who generally have substantially greater manufacturing, R&D, marketing and financial resources than us and, in some cases, have more geographically diversified international operations. We compete specifically with a number of different privately held contract manufacturing companies, including DPT Laboratories, Ltd. and Ei. Although this market is competitive, the competition is limited due to the need for specific expertise in topical formulations and cGMP facilities. We believe that we have the expertise required and that we will continue to create opportunities in this market by providing high quality, customer-oriented service, complemented by our contract development expertise in topical formulations.

**Government Regulation and Regulatory Proceedings**

The R&D, manufacturing and marketing of our products are subject to extensive regulation by the FDA and by other federal, state and local entities, which regulate, among other things, R&D activities, testing, manufacturing, labeling, storage, record keeping, advertising and promotion of pharmaceutical and OTC products.

FDA approval is required before any dosage form of any drug product, including a generic equivalent of a previously approved drug product, can be marketed. All applications for FDA approval must contain information relating to product formulation, stability, manufacturing processes, packaging, labeling and quality control. Compliance with FDA s cGMP regulations is required at all times during the manufacture and processing of drugs. Such compliance requires considerable time and resources in the areas of production and quality control.

We are subject to the periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA and other authorities, which conduct periodic inspections to ensure that our facilities remain in compliance with cGMP regulations. In addition, in connection with its review of our applications for new products, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes comply with cGMP and other FDA regulations. Our last FDA inspections took place in February 2012 and December 2013.

The FDA may deny an ANDA if applicable regulatory criteria are not satisfied. The FDA may withdraw product approvals if compliance with regulatory standards is not maintained.

FDA policy and its stringent requirements have increased the time and expense involved in obtaining ANDA approvals and in complying with the FDA's cGMP standards. The ANDA approval process takes approximately 32 months but may at times take even longer. The FDA has implemented review processes early in an application review that may result in the FDA refusing to receive an application.

We are also subject to regulation under other federal, state and local regulations regarding work place safety, environmental protection and hazardous substance controls, among others.

Reimbursement legislation, such as Medicaid, Medicare, and other programs, governs reimbursement levels. All pharmaceutical manufacturers rebate to individual states a percentage of their revenues arising from Medicaid-reimbursed drug sales. Federal law requires that a pharmaceutical manufacturer, as a condition of having federal funds being made available to the states for the manufacturer s drugs under Medicaid and Medicare Part B, must enter into a rebate agreement to pay rebates to state Medicaid programs for the manufacturer s covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. The Centers for Medicare and Medicaid Services ("CMS") is responsible for administering the Medicaid rebate agreements between the federal government and pharmaceutical manufacturers. Rebates are due on the utilization of Medicaid managed care organizations, as well as under fee-for-service arrangements.

Drug manufacturers Medicaid rebate agreements, which are between each manufacturer and the Secretary of Health and Human Services, provide that the drug manufacturer will remit rebates to each state Medicaid agency on a quarterly basis. Those rebates are based on pricing data reported by manufacturers to CMS, including Average Manufacturer Price ("AMP"), which is reported on a monthly and quarterly basis, and, in the case of innovator products, Best Price, which is reported on a quarterly basis.

Health reform legislation changed the definition of AMP effective the fourth quarter of calendar 2010. Pursuant to the same legislation, effective for rebate periods beginning with the first quarter of calendar 2010, the rebate formulas used to determine the minimum rebate amounts due are as follows: for noninnovator products, in general generic drugs marketed under ANDAs, the rebate amount is 13% of the AMP for the quarter; for innovator products, in general brand-name products marketed under NDAs, the rebate amount is the greater of 23.1% of the AMP for the quarter or the difference between such AMP and the Best Price for that same quarter. This rate is 17.1% for innovator drugs approved exclusively for pediatric indications, as well as for certain clotting factors. Manufacturers also pay an additional rebate on innovator drugs where price increases since launch has outpaced inflation.

In the United States, our sales are dependent upon the availability of coverage and reimbursement for our products from third-party payors, including federal and state programs such as Medicare and Medicaid, and private organizations such as commercial health insurance and managed care companies. Such third-party payors increasingly challenge the price of medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. Over the past several years, the rising costs of providing health care services has triggered legislation to make certain changes to the way in which pharmaceuticals are covered and reimbursed, particularly by government programs. For instance, recent federal legislation and regulations have created a voluntary prescription drug benefit, Medicare Part D, revised the formula used to reimburse health care providers and physicians under Part B and imposed significant revisions to the Medicaid Drug Rebate Program. These changes have resulted in, and may continue to result in, coverage and reimbursement restrictions and increased rebate obligations by manufacturers. In addition, there continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. Examples of how limits on drug coverage and reimbursement in the United States may cause reduced payments for drugs in the future include:

changing Medicare reimbursement methodologies;

revising drug rebate calculations under the Medicaid program;

reforming drug importation laws;

fluctuating decisions on which drugs to include in formularies; and

requiring pre-approval of coverage for new or innovative drug therapies.

We cannot predict the likelihood or pace of such additional changes or whether there will not be significant legislative or regulatory reform impacting our products, nor can we predict with precision what effect such governmental measures would have if they were ultimately enacted into law. However, in general, we believe that legislative and regulatory reform activity likely will continue.

**Environmental Matters**

Our operations are subject to a variety of environmental, health and safety laws and regulations, including those of the United States Environmental Protection Agency and equivalent state and local regulatory agencies. These laws and regulations govern, among other things, air emissions, wastewater discharges, the use, handling and disposal of hazardous substances and wastes, soil and groundwater contamination and employee health and safety. Our manufacturing facility uses, in varying degrees, hazardous substances in its processes. Contamination at our facility can result and has resulted in liability to us, for which we have recorded appropriate reserves as needed. For example, two of the Company s facilities have undergone remediation of environmental contamination. See Note 14 to the Company s Consolidated Financial Statements.

**Intellectual Property**

To compete effectively, we need to develop and maintain a proprietary position with regard to our own technology, product candidates and business. Our goal is to safeguard our trade secrets and know-how, attain, maintain and enforce patent protection for our product candidates, formulations, processes, methods and other proprietary technologies, and operate without infringing on the proprietary rights of others. We seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology. We seek to achieve this protection through a combination of contractual arrangements and patents.

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We depend upon the skills, knowledge, experience and know-how of our management and R&D personnel, as well as that of our consultants, advisors and collaborators. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on confidentiality agreements to protect our interests. We require our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the disclosure of confidential information to any other parties. We also require our employees and consultants to disclose and assign to use their ideas, developments, discoveries and inventions. We understand that these agreements may not provide us with adequate protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use or disclosure.

We also seek to obtain patent protection when necessary and we understand that this may not provide us with complete protection against competitors who may attempt to circumvent our patents.

**Facility and Operations**

Our executive administrative offices are located in Buena, New Jersey, in a 23,000 square foot facility built on 7.3 acres of land in 1995, which we own. This facility is used for production, product development, marketing and warehousing for our pharmaceutical, cosmeceutical and cosmetic products. Our manufacturing capabilities encompass a full suite of competencies including regulatory, quality assurance and in-house validation.

The facility is equipped to manufacture semi-solids, ointments, gels and liquids in solution form. The facility is also configured to provide flexibility in manufacturing. Pilot batches typically range from 30 kg to 250 kg, while commercial batches may range from 250 kg to 4,000 kg.

We operate our facility in accordance with GMP, utilizing the same high standards as our pharmaceutical customers. Our facility is registered with the FDA. We believe that our facility and equipment are in good condition, are well maintained and are able to operate at present levels. Our manufacturing operations are focused on regulatory compliance, continuous improvement, process standardization and excellence in quality and execution across the organization.

**Employees**

On December 31, 2013, we had a total of 52 full-time employees. In addition, as the need arises, we occasionally utilize short-term, part-time employees who are paid on an hourly basis. In addition, we utilize temporary employees provided by a third party on a regular basis, primarily in our production department. We do not have a collective bargaining agreement with our employees and we believe that our employee relations are good.

**ITEM 1A.**

**RISK FACTORS**

Our current business and future results may be affected by a number of risks and uncertainties, including those described below. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not currently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.

***Risks Related to our Business***

***We have a history of losses and cannot assure you that we will become profitable. As a result, we may have to cease operations and liquidate our business.***

Our expenses have exceeded our revenue in each of the last eight years, and no net income has been available to common stockholders during each of these years. As of December 31, 2013, our stockholders equity was $7.2 million and we had an accumulated deficit of $44.8 million. Our future profitability depends on revenue exceeding expenses, but we cannot assure you that this will occur. If we do not become profitable or continue to raise external financing, we could be forced to curtail operations and sell or liquidate our business, and you could lose some or all of your investment.

***We face intense competition in the consumer products business.***

Our business competes with large, well-financed cosmetic, pharmaceutical and consumer products companies with development and marketing groups that are experienced in the industry and possess far greater resources than those available to us. There is no assurance that we can compete successfully against our competitors or that we can develop and market products that will be favorably received in the marketplace. In addition, certain of our customers that use our Novasome® lipid vesicles in their products may decide to reduce their purchases from us or shift their business to other technologies.

***Rapidly changing technologies and developments by our competitors may make our technologies and products obsolete.***

We expect to sublicense our technologies to third parties, which would manufacture and market products incorporating these technologies. However, if our competitors develop new and improved technologies that are superior to our technologies, our technologies could be less acceptable in the marketplace and our business could be harmed.

***The pharmaceutical industry in which we operate is intensely competitive. We are particularly subject to the risks of competition. For example, the competition we encounter may have a negative impact upon the prices we may charge for our products, the market share of our products and our revenue and profitability.***

The pharmaceutical industry in which we operate is intensely competitive. The competition which we encounter has an effect on our product prices, market share, revenue and profitability. Depending upon how we respond to this competition, its effect may be materially adverse to us. We compete with:

the original manufacturers of the brand-name equivalents of our generic products; and

other generic drug manufacturers.

Most of the products that we are developing are either generic drugs or products without patent protection. These drugs and products do not benefit from patent protection and are therefore more subject to the risk of competition than patented products. In addition, because many of our competitors have substantially greater financial, production and research and development resources, substantially larger sales and marketing organizations, and substantially greater name recognition than we have, we are particularly subject to the risks inherent in competing with them. For example, many of our competitors may be able to develop products and processes competitive with, or superior to, our own. Furthermore, we may not be able to successfully develop or introduce new products that are less costly than those of our competitors or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors.

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***As our competitors introduce their own generic equivalents of our generic pharmaceutical products, our revenues and gross margin from such products generally decline, often rapidly.***

Revenues and gross margin derived from generic pharmaceutical products often follow a pattern based on regulatory and competitive factors that we believe are unique to the generic pharmaceutical industry. As the patent(s) for a brand name product and the statutory marketing exclusivity period (if any) expires, the first generic manufacturer to receive regulatory approval for a generic equivalent of the product often is able to capture a substantial share of the market. However, as other generic manufacturers receive regulatory approvals for competing products, that market share, and the price of that product, will typically decline depending on several factors, including the number of competitors, the price of the brand product and the pricing strategy of the new competitors. We cannot provide assurance that we will be able to continue to develop such products or that the number of competitors with such products will not increase to such an extent that we may stop marketing a product for which we previously obtained approval, which may have a material adverse impact on our revenues and gross margin.

***We may need to raise additional capital that will be required to operate and grow our business, and we may not be able to raise capital on terms acceptable to us or at all.***

Operating our business and maintaining our growth efforts will require additional cash outlays and capital expenditures. If cash on hand and cash generated from operations are not sufficient to meet our cash requirements, we will need to seek additional capital, potentially through debt or equity financings, to fund our growth. We cannot assure you that we will be able to raise needed cash on terms acceptable to the Company, our significant stockholders, or at all. Financings may be on terms that are dilutive or potentially dilutive to our stockholders, and the prices at which new investors would be willing to purchase our securities may be lower than the current price per share of our common stock. The holders of new securities may also have rights, preferences or privileges which are senior to those of existing holders of common stock. If new sources of financing are required, but are insufficient or unavailable, we will be required to modify our growth and operating plans based on available funding, if any, which would harm our ability to grow our business or even stay in business.

***We rely on a limited number of customers for a large portion of our revenues.***

We depend on a limited number of customers for a large portion of our revenue. For the years ended December 31, 2013 and 2012, three of our customers accounted for 39% and two of our customers accounted for 54% of our revenue, respectively.

***Sales of our products may continue to be adversely affected by the continuing consolidation of our distribution network and the concentration of our customer base. The result of such developments could have a material adverse effect on our business, financial position and results of operations, and could cause the market value of our ordinary shares to decline.***

Our principal customers are wholesale drug distributors and major retail drug store chains. These customers comprise a significant part of the distribution network for pharmaceutical products in the U.S. This distribution network is continuing to undergo significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. We expect that consolidation of drug wholesalers and retailers will increase pricing and other competitive pressures on drug manufacturers. In addition, the Company generally does not enter into long-term supply agreements with its customers that would require them to purchase our products. The result of these developments may have a material adverse impact on our business, financial position and results of operations, and could cause the market value of our ordinary shares to decline.

***Lack of availability, issues with quality or significant increases in the cost of raw materials used in manufacturing our products could adversely impact our profit margins and operating results.***

Affordable high quality raw materials and packaging components are essential to our business due to the nature of the products we manufacture. Raw materials and packaging components are generally available from multiple suppliers. Supplies of certain raw materials, and finished goods purchased by us are limited, or are available from one or only a few suppliers. In these situations, increased prices, rationing and shortages can occur. In response to these problems we try to identify alternative materials or suppliers for such raw materials, and finished goods. FDA requirements for products approved through the ANDA or NDA process could substantially lengthen the approval of an alternate material source. Certain material shortages and approval of alternate sources could adversely affect our financial results. The rapid increase in cost of many raw materials from inflationary forces, such as increased energy costs, and our ability or inability to pass on these increases to our customers, could have a material impact on our financial results.

We maintain several single-source supplier relationships, either because alternative sources are not available or the relationship is advantageous due to regulatory, performance, quality, support, or price considerations. Unavailability or delivery delays of single-source components or products could adversely affect our ability to ship the related product in a timely manner. The effect of unavailability or delivery delays would be more severe if associated with our higher volume or more profitable products. Even where alternative sources of supply are available, qualifying the alternate suppliers and establishing reliable supplies could cost more or could result in delays and a loss of revenues. As a result, the loss of a single-source supplier could have a material adverse effect on our results of operations.

In addition, raw materials purchased from third parties, including those from foreign countries, may contain counterfeit ingredients or other adulterants. We maintain a strict program of verification and product testing throughout the ingredient sourcing and manufacturing process to identify potential counterfeit ingredients, adulterants and toxic substances. Nevertheless, discovery of previously unknown problems with the raw materials or product manufacturing processes or new data suggesting an unacceptable safety risk associated therewith, could result in a voluntary or mandatory withdrawal of the contaminated product from the marketplace, either temporarily or permanently. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers or the quality of their products may result in production delays or higher raw material costs. Also, any future recall or removal would result in additional costs to us, and may give rise to product liability or other litigation, either of which could have a material adverse effect on our operating results.

Our products, and the raw materials used to make those products, generally have limited shelf lives. Our inventory levels are based, in part, on expectations regarding future sales. We may experience build-ups in inventory if sales slow. Any significant shortfall in sales may result in higher inventory levels of raw materials and finished products,

thereby increasing the risk of inventory spoilage and corresponding inventory write-downs and write-offs, which may materially and adversely affect our results of operations. Additionally, labeling changes required for regulatory compliance could render packaging inventories obsolete. Cargo thefts and/or diversions and economically or maliciously motivated product tampering in store shelves may be experienced from time to time, causing unexpected shortages.

***Due to our dependence on a limited number of products, our business will be materially adversely affected if these products do not perform as well as expected.***

We expect to generate a significant portion of our total revenues and gross margin from the sale of a limited number of products. Any material adverse developments, including increased competition and supply shortages, with respect to the sale or use of our products and prospective products, or our failure to successfully introduce such products, could have a material adverse effect on our revenues and gross margin.

***We are subject to stringent regulatory requirements. Failure to adhere to such requirements could harm our business and results of operations.***

In the United States, pharmaceuticals are subject to rigorous FDA regulations. Any non-compliance with the regulatory guidelines may necessitate corrective action that may result in additional expenses and use of more of our resources.

We and our suppliers of raw materials are also subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state or local regulations. Failure to adhere to such regulations, by either us or our suppliers, could harm our business and results of operations. In addition, our analytical department uses certain hazardous materials and chemicals in limited and controlled quantities. We have implemented safety procedures for handling and disposing of such materials, however, such procedures may not comply with the standards prescribed by federal, state and local regulations. Even if we follow such safety procedures for handling and disposing of hazardous materials and chemicals and such procedures comply with applicable law, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages and any such liability could exceed our resources.

Our operations and properties are also subject to a wide variety of increasingly complex and stringent federal, state and local environmental laws and regulations, including those governing the remediation of contaminated soil and groundwater. Such environmental laws may apply to conditions at properties and facilities presently or formerly owned or operated by us, as well as to conditions at properties at which wastes or other contamination attributable to us have been sent or otherwise come to be located. Two of our facilities are currently undergoing remediation of environmental contamination. The total estimated costs for the clean-up and remediation is $739,000, of which approximately $6,000 remains accrued as of December 31, 2013. Based on information provided to us from our environmental consultants and what is known to date, we believe the reserves are sufficient for the remaining remediation of the environmental contamination. There is a possibility, however, that the remediation costs may exceed our estimates. In addition, we can give no assurance that the future cost of compliance with existing environmental laws will not give rise to additional significant expenditures or liabilities that would be material to us. Future events, such as new information, changes in existing environmental laws or their interpretation, and more vigorous enforcement policies of federal, state or local regulatory agencies, may have a material adverse effect on our business, financial condition and results of operations.

***We are subject to extensive government regulation that increases our costs and could prevent us from marketing or selling our products.***

The manufacturing, processing, formulation, packaging, labeling, testing, storing, distributing, marketing, advertising and sale of our products is subject to extensive regulation by one or more U.S. agencies, including the FDA, the Federal Trade Commission and the Consumer Products Safety Commission, as well as by several state and local agencies in localities where the Company s products are stored, distributed or sold. In addition, we manufacture and market certain of our products in accordance with standards set by organizations, such as the United States Pharmacopeial Conventions, or the USP.

The FDA regulates the testing, manufacture, labeling, marketing and sale of pharmaceutical products. Approval by the FDA is generally required before any new drug or the generic equivalent to any previously approved drug may be marketed or sold in the United States. In order to receive approval from the FDA for our product candidates that are generic versions of brand-name drugs, we intend to use the Abbreviated New Drug Application, or ANDA, process and thus demonstrate to the FDA that each generic product candidate is bioequivalent to a drug previously approved by the FDA through the new drug approval process, known as an innovator, or brand-name reference drug. Bioequivalency may be demonstrated by comparing the generic product to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. However, if the FDA determines that an ANDA for a generic drug product is not adequate to support approval, it could deny our application or request additional information, including preclinical and clinical trials, which could delay approval of the product and impair our ability to compete with other versions of the generic drug product.

If our product candidates receive FDA approval through the ANDA process, the labeling claims and marketing statements that we can make for our generic drugs are generally limited by statutes and regulations and by the claims made in the brand-name product s label. In addition, following regulatory approval, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive and ongoing regulatory requirements. As a manufacturer of pharmaceutical products distributed in the United States, we must also comply with cGMPs, which include requirements related to production processes, quality control and assurance and recordkeeping. Our manufacturing facilities and procedures and those of our suppliers are subject to periodic inspection by the FDA and foreign regulatory agencies. Any material deviations from cGMPs or other applicable standards identified during such inspections may result in enforcement actions, including delaying or preventing new product approvals, a delay or suspension in manufacturing operations, consent decrees or civil or criminal penalties. Further, discovery of previously unknown problems with a product or manufacturer may result in restrictions or sanctions, including withdrawal of the product from the market.

***We operate in a highly regulated industry. An inability to meet current or future regulatory requirements in connection with existing or future ANDAs could have a material adverse effect on our business, financial position and operating results.***

The design, development and marketing of pharmaceutical compounds, on which our success depends, are intensely regulated by governmental regulatory agencies, in particular the FDA. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, injunction actions and criminal prosecution based on products or manufacturing practices that violate statutory requirements. In addition, administrative remedies can involve voluntary withdrawal of products, as well as the refusal of the FDA to approve ANDAs. The FDA also has the authority to withdraw approval of drugs in accordance with statutory due process procedures. Before a pharmaceutical product may be marketed, it must be approved by the FDA by an ANDA, of which no assurance can be provided. If the FDA does not approve our existing or future ANDAs, it would result in substantial additional costs, delay or suspension of the commercialization of our products. If we are unable to timely commercialize our existing or future products, it could have a material adverse effect on our business, financial position and operating results.

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

We are subject to state and federal laws that govern the submission of claims for reimbursement. The Federal False Claims Act ( FFCA ), also known as Qui Tam, imposes civil liability and criminal fines on individuals or entities that knowingly submit, or cause to be submitted, false or fraudulent claims for payment to the government. Violations of the FFCA and other similar laws may result in criminal fines, imprisonment, and civil penalties for each false claim submitted and exclusion from federally funded health care programs, including Medicare and Medicaid. The FFCA also allows private individuals to bring a suit on behalf of the government against an individual or entity for violations of the FFCA. These suits, also known as Qui Tam actions, may be brought by, with only a few exceptions, any private citizen who has material information of a false claim that has not yet been previously disclosed. These suits have increased significantly in recent years because the FFCA allows an individual to share in any amounts paid to the federal government in fines or settlement as a result of a successful Qui Tam action. If our past or present operations are found to be in violation of any of such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal health care programs, and/or the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, or restructuring of our operations could adversely affect our ability to operate our business and our financial results, action against us for violation of these laws, even if we successfully defend against them, it could cause us to incur significant legal expenses and divert our management s attention from the operation of our business.

***Product recalls could harm our business.***

Product recalls or product field alerts may be issued at our discretion or at the discretion of the FDA, other governmental agencies or other companies having regulatory authority for pharmaceutical product sales. From time to time, we may recall products for various reasons, including failure of our products to maintain their stability through their expiration dates. Any recall or product field alert has the potential of damaging the reputation of the product or our reputation. Any significant recalls could materially affect our sales. In these cases, our business, financial condition, results of operations and cash flows could be materially adversely affected.

***We are susceptible to product liability claims that may not be covered by insurance and could require us to pay substantial sums.***

We face the risk of loss resulting from, and adverse publicity associated with, product liability lawsuits, whether or not such claims are valid. We may not be able to avoid such claims. In addition, our product liability insurance may not be adequate to cover such claims and we may not be able to obtain adequate insurance coverage in the future at acceptable costs. A successful product liability claim that exceeds our policy limits could require us to pay substantial sums. In addition, product liability coverage for pharmaceutical companies is becoming more expensive and increasingly difficult to obtain and, as a result, we may not be able to obtain the type and amount of coverage we desire or to maintain our current coverage.

***The manufacture and storage of pharmaceutical and cosmetics products are subject to inherent risk.***

Because chemical ingredients are used in the manufacture of our products and due to the nature of the manufacturing process itself, there is a risk of incurring liability for damages caused by or during the storage or manufacture of both the chemical ingredients and the finished products. Although we have never incurred any material liability for damages of that nature, we may be subject to liability in the future. In addition, while we believe our insurance coverage is adequate, it is possible that a successful claim would exceed our coverage, requiring us to pay a substantial sum.

***The failure to obtain, maintain or protect patents, trade secrets, know-how and other intellectual property could impact our ability to compete effectively.***

To compete effectively, we need to develop and maintain a proprietary position with regard to our own technology, products and business. We rely on a combination of patents, trade secrets, proprietary know-how and other intellectual property to protect our proprietary technology and rights. We own nine patents and through a license agreement we have obtained the use of patents relating to the Novasome® technology for specified uses. We also maintain a number of trade secrets, know-how and other intellectual property.

The risks and uncertainties that we face with respect to patents and other proprietary rights include the following:

the pending patent applications we have filed or may file, or to which we have exclusive rights, may not result in issued patents, or may take longer than we expect to result in issued patents;

changes in U.S. patent laws may adversely affect our ability to obtain or maintain our patent protection;

we may be subject to interference proceedings;

the claims of any patents that are issued may not provide meaningful protection;

we may not be able to develop additional proprietary technologies that are patentable;

the patents licensed or issued to us or our collaborators may not provide a competitive advantage;

other companies may challenge patents licensed or issued to us or our collaborators;

other companies may independently develop similar or alternative technologies, or duplicate our technology;

other companies may design around technologies we have licensed or developed; and

enforcement of patents is complex, uncertain and expensive.

If we are unable to effectively enforce our proprietary rights, or if we are found to infringe the rights of others, we may be in breach of our license agreements with our partners.

Our success also depends upon trade secrets, proprietary know-how and the skills, knowledge and experience of our personnel. As a result, we require our employees, consultants, advisors, and collaborators to enter into confidentiality agreements that prohibit the disclosure of confidential information to any other parties. We also require our employees and consultants to disclose and assign to us their ideas, developments, discoveries, and inventions. These agreements may not, however, provide adequate protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use or disclosure. If any material trade secret or proprietary know-how were to be disclosed to or independently developed by a competitor, our competitive position may be materially harmed.

***Our product offerings and our customers products may infringe on the intellectual property rights of third parties.***

From time to time, third parties have asserted intellectual property infringement claims against us and our customers and there can be no assurance that third parties will not assert infringement claims against either us or our customers in the future. While we believe that our product offerings do not infringe in any material respect upon proprietary rights of other parties and/or that meritorious defenses would exist with respect to any assertions to the contrary, there can be no assurance that we would not be found to infringe on the proprietary rights of others.

Patent applications in the U.S. and some foreign countries are generally not publicly disclosed until the patent is issued or published, and we may not be aware of currently filed patent applications that relate to our offerings or processes. If patents later issue on these applications, we may be found liable for subsequent infringement. There has been substantial litigation in the pharmaceutical and biotechnology industries with respect to the manufacture, use and sale of products and processes that are the subject of conflicting patent rights.

Any claims that our product offerings or processes infringe these rights, regardless of their merit or resolution, could be costly and may divert the efforts and attention of our management and technical personnel. We may not prevail in such proceedings given the complex technical issues and inherent uncertainties in intellectual property litigation. If such proceedings result in an adverse outcome, we could, among other things, be required to:

pay damages in the form of lost profits and/or a reasonable royalty for any infringement;

pay substantial damages (potentially treble damages in the U.S. if any such infringement is found to be willful);

pay attorney fees of a prevailing party, if the case is found to be exceptional;

cease the manufacture, use or sale of the infringing offerings or processes;

discontinue the use of the infringing technology;

expend significant resources to design around patented technology and develop non-infringing technology; and

license patented technology from the third party claiming infringement, which license may not be available on commercially reasonable terms, or may not be available at all.

In addition, our customers products may be subject to claims of intellectual property infringement and such claims could materially affect our business if their products cease to be manufactured and they have to discontinue the use of the infringing technology which we may provide. Further, depending on the particular circumstances of any given claim, it may be the case that we may be responsible for indemnifying our customers for a claim of intellectual property infringement.

If we were to assert any of our own intellectual property against third parties and the third parties were found not to infringe our intellectual property or our intellectual property was found to be invalid, and/or unenforceable, we would lose the opportunity to leverage our own intellectual property, for example, through licensing of our technology to others, collection of damages and/or royalty payments based upon successful assertion of our intellectual property rights or market exclusivity via enjoining others from practicing the technology at issue.

Any of the foregoing could affect our ability to compete or have a material adverse effect on our business, financial condition and results of operations.

***The expiration of certain patents related to the Novasome® technology could negatively impact our ability to generate income from the Novasome products.***

We license certain patents related to the Novasome® technology platform pursuant to a license agreement. Many of the patents under this license have expired and more will expire before this license terminates on December 11, 2015. The loss of patent protection could allow additional competition. To the extent such competition develops, it could negatively impact the income we generate from the Novasome® technology platform.

***Economic conditions could severely impact us.***

Current economic conditions may cause a decline in business and consumer spending which could adversely affect our business and financial performance. Our operating results are impacted by the health of the North American economies. Our business and financial performance, including collection of our accounts receivable, realization of inventory, recoverability of assets including investments, may be adversely affected by current and future economic conditions, such as a reduction in the availability of credit, financial market volatility and recession.

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***Adverse conditions in the economy and disruption of financial markets could negatively impact our customers and therefore our results of operations.***

An economic downturn in the businesses or geographic areas in which we sell our products could reduce demand for these products and result in a decrease in sales volume that could have a negative impact on our results of operations. Volatility and disruption of financial markets could limit our customers ability to obtain adequate financing or credit to purchase and pay for our products in a timely manner, or to maintain operations, and result in a decrease in sales volume that could have a negative impact on our results of operations. Additionally, economic conditions and market turbulence may also impact our suppliers causing them to be unable to supply in a timely manner sufficient quantities of product components, thereby impairing our ability to manufacture on schedule and at commercially reasonable costs.

If the U.S. economy rapidly contracts or expands, we may have difficulty quickly scaling our operations in response, which may negatively impact our business and financial position.

***If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.***

We will need to hire additional qualified personnel with expertise in nonclinical testing, government regulation, formulation and manufacturing, sales and marketing and finance. We compete for qualified individuals with numerous pharmaceutical and consumer products companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

***Our ability to market products successfully depends, in part, upon the acceptance of the products not only by consumers, but also by independent third-parties.***

Our ability to market generic pharmaceutical products successfully depends, in part, on the acceptance of the products by independent third-parties (including pharmacies, government formularies, managed care providers, insurance companies and retailers), as well as patients. In addition, unanticipated side effects or unfavorable publicity concerning any of our products, or any brand-name product of which our generic product is the equivalent, could have an adverse effect on our ability to achieve acceptance by managed care providers, pharmacies and other retailers, customers and patients.

***Risks Related to Our Securities***

***Shares of our common stock are relatively illiquid which may affect the trading price of our common stock.***

For the twelve months ended December 31, 2013, the average daily trading volume of our shares of common stock on the NYSE MKT was approximately 78,000 shares. As a result of our relatively small public float, our shares of common stock may be less liquid than the stock of companies with broader public ownership. Among other things, trading of a relatively small volume of our shares of common stock may have a greater impact on the trading price for our shares than would be the case if our public float were larger.

***We have not paid dividends to our common stockholders in the past nor do we expect to pay dividends in the foreseeable future, and any return on investment may be limited to potential future appreciation on the value of our common stock.***

We currently intend to retain any future earnings to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board of Directors after taking into account various factors, including without limitation, our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. To the extent we do not pay dividends, our stock may be less valuable because a return on investment will only occur if and to the extent our stock price appreciates, which may never occur. In addition, investors must rely on sales of their common stock after price appreciation as the only way to realize their investment, and if the price of our stock does not appreciate, then there will be no return on investment. Investors seeking cash dividends should not purchase our common stock.

***If we fail to comply with the reporting obligations of the Securities Exchange Act of 1934 (the Exchange Act ) and Section 404 of the Sarbanes-Oxley Act of 2002, or if we fail to achieve and maintain adequate disclosure controls and procedures and internal control over financial reporting, our business results of operations and financial condition, and investors' confidence in us, could be materially adversely affected.***

As a public company, we are required to comply with the periodic reporting obligations of the Exchange Act including preparing annual reports, quarterly reports and current reports. Our failure to prepare and disclose this information in a timely manner could subject us to penalties under federal securities laws, expose us to lawsuits and restrict our ability to access financing. In addition, we are required under applicable law and regulations to integrate our systems of disclosure controls and procedures and internal control over financial reporting. Our management assessed our existing disclosure controls and procedures as of December 31, 2013 and December 31, 2012, and our management concluded that our disclosure controls and procedures were effective as of such times.

If we fail to achieve and maintain the adequacy of our disclosure controls and procedures and internal control over financial reporting, we may not be able to ensure that we can conclude that we have effective disclosure controls and procedures and internal control over financial reporting in accordance with the Sarbanes-Oxley Act of 2002. Moreover, effective disclosure controls and procedures and internal control over financial reporting are necessary for us to produce reliable financial reports and are important to help prevent fraud. As a result, our failure to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 on a timely basis could result in the loss of investor confidence in the reliability of our financial statements, which in turn could harm our business and negatively impact the trading price of our common stock.

***If we fail to meet the continued listing standards of the NYSE MKT our common stock could be delisted and our liquidity and stock price could suffer.***

Our common stock is listed on the NYSE MKT, a national securities exchange, which imposes continued listing requirements with respect to listed shares. If we fail to meet the continued listing standards of the NYSE MKT, our common stock could be delisted and our stock price could suffer. A delisting of our shares of common stock could negatively impact us by further reducing the liquidity and market price of our shares of common stock and the number of investors willing to hold or acquire our shares of common stock, which could negatively impact our ability to raise equity financing.

***Our principal stockholders, directors and executive officers own a significant percentage of our stock and will be able to exercise significant influence over our affairs.***

Our current principal stockholders, directors and executive officers beneficially own approximately 67.3% of our outstanding capital stock entitled to vote. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock. If such stockholders sold a significant amount of stock it could have an adverse effect on the price of the stock.

***Due to the concentration of common stock owned by significant stockholders, the sale of such stock might adversely affect the price of our common stock.***

Our largest stockholders own shares of common stock that have been registered for resale under the Securities Act of 1933, as amended. The sale of such stock, depending on the interplay of numerous factors, including, without limitation, the method and timing of the sales, could substantially depress the value of the Company s common stock.

***Our stock price is, and we expect it to remain, volatile and subject to wide fluctuations, which may make it difficult for stockholders to sell shares of common stock at or above the price for which they were acquired***.

Our stock price is, and we expect it to remain, volatile, which could limit investors ability to sell stock at a profit. During the last two fiscal years, our stock price has closed at a low of $0.94 in the second quarter of 2012 and a high of $3.29 in the fourth quarter of 2013. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

publicity regarding actual or potential clinical results relating to products under development by our competitors or us;

delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;

achievement or rejection of regulatory approvals by our competitors or us;

announcements of technological innovations or new commercial products by our competitors or us;

developments concerning proprietary rights, including patents;

developments concerning our collaborations;

regulatory developments in the U.S. and foreign countries;

economic or other crises, especially given the recent financial deterioration in the markets in which we compete, and other external factors;

stock market price and volume fluctuations of other publicly traded companies and, in particular, those that are in the cosmetic, pharmaceutical and consumer products industry;

actual or anticipated sales of our common stock, including sales by our directors, officers or significant stockholders;

period-to-period fluctuations in our revenues and other results of operations;

speculation about our business in the press or the investment community;

changes in financial estimates by us or by any securities analysts who might cover our stock; and

sales of our common stock, including sales by our significant holders.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in their stock price. This type of litigation, even if it does not result in liability for us, could result in substantial costs to us and divert management s attention and resources.

**ITEM 1B.**

**UNRESOLVED STAFF COMMENTS**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the Exchange Act ), and are not required to provide the information required under this item.

**ITEM 2.**

**PROPERTIES**

The Company s executive administrative offices are located in Buena, New Jersey, in a 23,000 square foot facility built on 7.3 acres of land in 1995, which the Company owns. This facility is also used for production, product development, marketing and warehousing for the Company s own generic prescription pharmaceutical products and pharmaceutical, cosmeceutical and cosmetic products for their customers. We believe this facility is in good operating condition for adequately serving our needs. The Company also owns four acres of land adjacent to its main facility that can be used for future expansion.

**ITEM 3.**

**LEGAL PROCEEDINGS**

We are involved from time to time in claims which arise in the ordinary course of business. In the opinion of management, we have made adequate provision for potential liabilities, if any, arising from any such matters. However, litigation is inherently unpredictable, and the costs and other effects of pending or future litigation, governmental investigations, legal and administrative cases and proceedings (whether civil or criminal), settlements, judgments and investigations, claims and changes in any such matters, and developments or assertions by or against us relating to intellectual property rights and intellectual property licenses, could have a material adverse effect on our business, financial condition and operating results.

On December 19, 2013, we filed a complaint in the United States District Court for the District of Delaware against Mallinckrodt LLC, Mallinckrodt, Inc. and Nuvo Research Inc. (collectively, Mallinckrodt ) seeking a declaration of non-infringement of United States Patent Nos. 8,217,078 and 8,546,450 so that we can bring our generic diclofenac sodium topical solution 1.5% to market at the earliest possible date under applicable statutory and FDA regulatory provisions.

On January 10, 2014, Mallinckrodt filed an answer and counterclaim alleging that IGI Laboratories, Inc. infringes the patents at issue. On January 28, 2014, we filed a motion to dismiss Mallinckrodt s counterclaim and, on March 5, 2014, Mallinckrodt filed an opposition to such motion. The court has not yet rendered a decision. We believe the complaint has merit and we intend to continue to pursue Mallinckrodt. Based on the early stage of this complaint and counterclaim, we are unable to predict the outcome.

**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**

The principal market for the Company s Common Stock is the NYSE MKT (symbol: IG ).

The following table sets forth the range of high and low closing sales prices for our shares of common stock, as reported by the NYSE MKT for the periods indicated:

| | High | Low |
|---|---|---|
| **2013** | | |
| First quarter | $1.88 | $1.00 |
| Second quarter | 2.25 | 1.32 |
| Third quarter | 2.28 | 1.24 |
| Fourth quarter | 3.29 | 1.82 |
| **2012** | | |
| First quarter | $1.34 | $1.02 |
| Second quarter | 1.12 | 0.94 |
| Third quarter | 1.48 | 0.98 |
| Fourth quarter | 1.30 | 0.98 |

**Stockholders**

The approximate number of holders of record of the Company s shares of common stock outstanding at March 25, 2014 was 492 (not including stockholders for whom shares are held in a nominee or street name).

**Dividends**

The Company has not paid cash dividends to its common stockholders since inception and does not intend to pay cash dividends on its common stock in the foreseeable future. The Company currently intends to retain earnings, if any, to finance growth of the Company.

**Unregistered Sales of Securities**

None.

**Issuer Purchases of Equity Securities**

None.

**ITEM 6.**

**SELECTED FINANCIAL DATA**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the Exchange Act ) and are not required to provide the information required under this item.

**ITEM 7.**

**MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION**

**Forward-Looking Statements**

This Management s Discussion and Analysis of Financial Condition and Results of Operation section and other sections of this Annual Report on Form 10-K contain forward-looking statements that are based on current expectations, estimates, forecasts and projections about the industry and markets in which the Company operates and on management s beliefs and assumptions. In addition, other written or oral statements, which constitute forward-looking statements, may be made by or on behalf of the Company. Words such as expects, anticipates, intends, plans, believes, seeks, estimates, variations of such words and similar expressions are intended to id such forward-looking statements. These statements are not guarantees of future performance, and involve certain risks, uncertainties and assumptions, which are difficult to predict. (See Item 1A: Risk Factors above.) Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in such forward-looking statements. The Company undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law

**Company Overview**

*Strategic Overview*

IGI Laboratories is a developer, manufacturer, and marketer of topical formulations. Our goal is to become a leader in the generic topical pharmaceutical market. Under our IGI label, we sell generic topical pharmaceutical products that are bioequivalent to their brand name counterparts. We also provide development, formulation, and manufacturing services to the pharmaceutical, over-the-counter (OTC), and cosmetic markets.

Our strategy is based on two initiatives:

Manufacturing, developing, and marketing a portfolio of generic pharmaceutical products in our own label in topical dosage forms; and,

Increasing our current contract manufacturing and development business.

In addition, we will look to create unique opportunities through the acquisition of additional intellectual property, and the expansion of the use of our existing intellectual property, including our licensed Novasome® technology.

In December, 2012, we completed the implementation of our commercial infrastructure and launched our first generic topical pharmaceutical products under the IGI label. We have filed fourteen Abbreviated New Drug Applications, or ANDAs, with the United States Food and Drug Administration, or FDA for additional pharmaceutical products. We filed one application in September 2010, January 2011 and December 2011, we filed two applications in November 2011, two applications in June 2012, one in November 2012, one in January 2013, April 2013, September 2013, November 2013 and one in March 2014. All of the submissions are for generic topical prescription drugs. On March 12, 2014, the Company received its first approval from the FDA for an ANDA. The FDA has approved IGI's application for lidocaine hydrochloride USP 4% topical solution. We will continue to expand our presence in the generic topical pharmaceutical market through the filing of additional ANDAs with the FDA and the subsequent launch of products as these applications are approved. Our target is to file ten ANDAs in 2014 through our internal research and development program. We will also seek to license or acquire further products, intellectual property, or ANDAs to expand our portfolio. On February 1, 2013, we acquired assets and intellectual property, including an ANDA, for econazole nitrate cream 1%.

IGI also develops, manufactures, fills, and packages topical semi-solid and liquid products for branded and generic pharmaceutical customers as well as the OTC and cosmetic markets. These products are used in a wide range of applications from cosmetics and cosmeceuticals to the prescription treatment of conditions like dermatitis, psoriasis, and eczema.

IGI has structured a new management team to implement this plan, including a recent President and CEO, director of business development, director of operations and development and a manager of national accounts to head up the sales efforts for the newly launched IGI label products. The team brings a wealth of experience in the generic pharmaceutical industry to IGI. IGI s facilities and manufacturing equipment have been designed to produce topical and liquid products and support the Company s target prescription dosage forms.

Contract manufacturing services will continue to be crucial to IGI s success. The customer base for these services is pharmaceutical companies as well as cosmetic, cosmeceutical, and OTC product marketers who require product development/manufacturing support. This is a highly-competitive market with a number of larger, greater-resourced companies offering similar services. IGI looks to create niche opportunities for itself by providing high quality, customer-oriented service.

IGI has exclusive rights for the use of Novasome® technology in topical formulations and intends to pursue collaboration opportunities with established pharmaceutical companies seeking to develop topical products with unique properties. In addition, the Company will explore line extension opportunities through innovative packaging or alternate dosage forms of existing pharmaceutical molecules.

**Results of Operations**

***Fiscal Year 2013 Compared to Fiscal Year 2012***

We had a net loss of $84,000 in 2013 compared to $3,927,000 in 2012. Net loss applicable to common stockholders was $1,392,000 or ($0.03) per share in 2013 and $3,927,000, or $(0.10) per share in 2012:

**Revenues (in thousands):**

| | Year Ended December 31, | | Increase/(Decrease) | |
|---|---|---|---|---|
| **Components of Revenue:** | **2013** | **2012** | **$** | **%** |
| **Product sales** | $ 16,981 | $ 6,545 | $ 10,436 | 159 % |
| **Research and development income** | 1,094 | 1,931 | (837) | (43)% |
| **Licensing, royalty, and other income** | 149 | 87 | 62 | 71 % |
| **Total Revenues** | $ 18,224 | $ 8,563 | $ 9,661 | 113 % |

The increase in product sales for the year ended December 31, 2013 as compared to the same period in 2012 was primarily due to the launch of our own generic pharmaceutical product line, in addition to increased product sales to five of our pharmaceutical customers and one of our cosmetic customers, which was only partially offset by decreased sales to one of our pharmaceutical customers. Research and development income will not be consistent and will vary, from period to period, depending on the required timeline of each development project. The decrease in research and

development income during 2013 as compared to the same period in 2012 is attributable primarily to three new customer relationships with pharmaceutical partners established at the end of 2011 and the beginning of 2012. We completed several site transfers, formulation services, 510 (k) submissions for medical devices and filing of two ANDAs for these customers in 2012. In December 2013, we executed a license, development, supply and marketing agreement with a large multi-national pharmaceutical company under which we filed an ANDA in December 2013, and recorded research and development income in accordance with the agreement. Licensing, royalty and other revenue increased slightly due to an increase in other revenue while licensing and royalty revenue remained the same.

**Costs and expenses (in thousands):**

| | Year Ended December 31, | | Increase/(Decrease) | |
|---|---|---|---|---|
| | 2013 | 2012 | $ | % |
| **Cost of sales** | $ 12,079 | $ 5,787 | $ 6,292 | 109 % |
| **Selling, general and administrative** | 3,484 | 3,078 | 406 | 13 % |
| **Product development and research** | 2,743 | 2,834 | (91) | (3)% |
| **Totals costs and expenditures** | $ 18,306 | $ 11,699 | $ 6,607 | 56 % |

Cost of sales increased for the year ended December 31, 2013 as a result of the increase in total revenue. Cost of sales as a percentage of total revenue was 66% for the year ended December 31, 2013 as compared to 68% for 2012. The decrease in cost of sales as a percentage of product sales for 2013 was attributable to increased revenue from the launch of our first four IGI label products, which have higher margins, and a shift in the mix of our product sales to include greater higher margin pharmaceutical products. During 2013, approximately 61% of our revenue from contract and formulation services came from pharmaceutical customers as compared to 48% in 2012. Our research and development income results primarily from services rendered under contractual agreements, and therefore cost of sales as a percentage of our research and development income is relatively low. Consistent with our strategy, we expect cost of sales as a percentage of total revenue to decline over time.

Selling, general and administrative expenses for the year ended December 31, 2013 increased by $406,000 as compared to the same period in 2012 as a result of increases in salaries, bonuses and employee related costs of $444,000, an increase of $30,000 in professional fees, an increase of $156,000 in the expense from the issuance of stock based compensation related to options and restricted stock, amortization of product acquisition costs of $60,000. These increases were only partially offset by a decrease as a result of the severance agreement with our former President and CEO of $150,000 in 2012, a decrease of $214,000 in recruiting fees and a decrease of $35,000 in commissions.

Product development and research expenses for the year ended December 31, 2013 decreased by $91,000 as compared to the same period in 2012. Consistent with our strategy to expand our portfolio of generic prescription topical pharmaceutical products, we increased headcount, which resulted in an increase of $226,000 in salaries and employee related costs. This increase was partially offset by a decrease of $326,000 in spending on clinical studies, outside testing, pilot batch expense and supplies.

**Interest Expense and Other Income (Expense), net (in thousands):**

| | Year Ended December 31, | | Increase/(Decrease) | |
|---|---|---|---|---|
| | 2013 | 2012 | $ | % |
| **Interest Expense and other income (expense) net** | $ (199) | $ (975) | $ (776) | (80)% |

Interest expense decreased for the year ended December 31, 2013 as compared to the same period in 2012 primarily due to the inclusion in 2012 of approximately $848,000 of amortization of debt issuance costs related to the Note Payable Related Party that was paid in full and terminated on August 31, 2012. In addition to the lower interest rate on the Note Payable Bank (see Note 6 to the Company s Consolidated Financial Statements) that was outstanding for 2013 as compared to the interest rate on the Notes Payable that was outstanding in the comparable period in 2012, which was partially offset by the increase in Note payable in 2013.

We also recorded a tax benefit of $197,000 in 2013 and $184,000 in 2012 as a result of a sale of a portion of the Company s state tax operating loss carry forwards to a third party, pursuant to a program run by the State of New Jersey. There can be no assurance we will continue or be able to continue to sell these operating loss carry forwards.

**Net loss**:

| | Year Ended December 31, | | Increase/(Decrease) | |
|---|---|---|---|---|
| | 2013 | 2012 | $ | % |
| **Net loss** | $ (84) | $ (3,927) | $ (3,843) | (98)% |

The decrease in net loss for the year ended December 31, 2013 as compared to the same period in 2012 is due to the increase in revenues partially offset by the increases in costs and expenses noted above.

**Net loss attributable to common stockholders (in thousands, except per share numbers):**

| | Year Ended December 31, | | Increase/(Decrease) | |
|---|---|---|---|---|
| | 2013 | 2012 | $ | % |
| **Net loss attributable to common stockholders** | $ (1,392) | $ (3,927) | $ (2,535) | (65)% |
| **Net loss per share** | $ (0.03) | $ (0.10) | $ (0.07) | (70)% |

The decrease in net loss attributable to common stockholders for the year ended December 31, 2013 as compared to the same period in 2012 is due to the increase in revenues partially offset by the increases in costs and expenses noted above, which was partially offset by the preferred stock dividend recorded on December 6, 2013, in connection with the mandatory conversion of our Series C Preferred Common Stock. This dividend of $1,308,000 was recorded upon conversion of our Series C preferred stock into common stock.

**Liquidity and Capital Resources**

The Company s business operations have been primarily funded over the past three years through private placements of our capital stock. In 2012, we entered into a new $3 million line of credit, which we expanded to $5 million in December 2013, after our compliance with certain covenants contained in the loan and security agreement related to the line of credit. To date we have drawn down $3 million of this facility. We may require additional funding and this funding will depend, in part, on the timing and structure of potential business arrangements. If necessary, we may continue to seek to raise additional capital through the sale of our equity or through a strategic alliance with a third party. There may also be additional acquisition and growth opportunities that may require external financing. There can be no assurance that such financing will be available on terms acceptable to us, or at all. We believe that our existing capital resources including the recently completed line of credit and private placement detailed below will be sufficient to support our current business plan and operations beyond March 2015.

Our operating activities used $0.6 million and $2.4 million of cash during the years ended December 31, 2013 and 2012, respectively. The use of cash for the years ended December 31, 2013 and 2012 was substantially a result of the net loss for the period offset by non-cash expense items. Our net loss for the year ended December 31, 2013 was $0.1 million, which included $2.7 million of research and development costs.

Our investing activities used $2.1 million of cash in the year ended December 31, 2013 compared to $0.3M of cash used in investing activities in the comparable period of 2012. In 2013, we used $1.8 million to acquire econazole nitrate cream 1%, which we launched in September 2013. The remaining funds used in both years were for additional equipment and related services for the analytical and compounding area, packaging and filling lines.

Our financing activities generated $2.3 million of cash in the years ended December 31, 2013 and 2012. The cash provided for the year ended December 31, 2013 was primarily related to the $2.0 million we drew down on our existing credit line in 2013. The cash provided for the year ended December 31, 2012 was primarily the proceeds of the sale of our treasury stock as more fully described in Note 17 to our Consolidated Financial Statements, in addition to the $1.0 million of proceeds from the drawdown of our credit facility, which was offset by the repayment of the Note Payable Related Party of $0.5 million as a result of the termination of the existing credit facility.

Our principal sources of liquidity are cash and cash equivalents of approximately $2.1 million at December 31, 2013, the $2.0 million available on the $5.0 million credit facility and future cash from operations. We had working capital of $5.3 million at December 31, 2013.

**Recent Pronouncements**

In July 2013, the FASB issued ASU No. 2013-11, Presentation of an Unrecognized Tax Benefit When A Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists ( ASU 2013-11 ), which provides guidance on the presentation of unrecognized tax benefits when net operating loss carryforwards, similar tax losses, or tax credit carryforwards exist. The amendments in this update are effective for fiscal years (and interim periods within those years) beginning after December 15, 2013. The amendments should be applied prospectively to all unrecognized tax benefits that exist at the effective date. Retrospective application is permitted. The Company does not expect ASU 2013-11 to have a material effect on its financial condition, results of operation or cash flows. This update will be effective for the Company for the year beginning January 1, 2014.

**Critical Accounting Policies and Estimates**

The SEC defines critical accounting policies as those that require application of management s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods.

Our significant accounting policies are described in Note 1 to our Consolidated Financial Statements. Not all of these significant accounting policies require management to make difficult, subjective or complex judgments or estimates. However, the following policies could be deemed to be critical within the SEC definition.

Revenue Recognition

The Company considers revenue realized or realizable and earned when it has persuasive evidence of an arrangement, delivery has occurred or contractual services rendered, the sales price is fixed or determinable, and collection is reasonably assured in conformity with ASC 605, *Revenue Recognition*.

The Company derives its revenues from three basic types of transactions: sales of manufactured product, licensing of technology, and research and product development services performed for third parties. Due to differences in the substance of these transaction types, the transactions require, and the Company utilizes, different revenue recognition policies for each.

Product Sales: Product Sales includes IGI Product Sales and Contract Manufacturing Sales.

IGI Product Sales: The Company records revenue from IGI product sales when title and risk of ownership have been transferred to the customer, which is typically upon delivery of products to the customer.

Revenue and Provision for Sales Returns and Allowances

As customary in the pharmaceutical industry, the Company s gross product sales from IGI label products are subject to a variety of deductions in arriving at reported net product sales. When the Company recognizes revenue from the sale of products, an estimate of sales returns and allowances ( SRA ) is recorded, which reduces product sales. Accounts receivable and/or accrued expenses are also reduced and/or increased by the SRA amount. These adjustments include estimates for chargebacks, rebates, cash discounts and returns and other allowances. Currently these provisions are based on industry standards and current contract sales terms with direct and indirect customers. Over time, these provisions will be adjusted as estimates will be based on historical payment experience, historical relationship to revenues, estimated customer inventory levels and current contract sales terms with direct and indirect customers. The estimation process used to determine our SRA provision has been applied on a consistent basis and no material adjustments have been necessary to increase or decrease our reserves for SRA as a result of a significant change in underlying estimates. The Company will use a variety of methods to assess the adequacy of our SRA reserves to ensure that our financial statements are fairly stated. These will include periodic reviews of customer inventory data, customer contract programs and product pricing trends to analyze and validate the SRA reserves.

The provision for chargebacks is our most significant sales allowance. A chargeback represents an amount payable in the future to a wholesaler for the difference between the invoice price paid to the Company by our wholesale customer for a particular product and the negotiated contract price that the wholesaler s customer pays for that product. The Company s chargeback provision and related reserve varies with changes in product mix, changes in customer pricing and changes to estimated wholesaler inventories. The provision for chargebacks also takes into account an estimate of the expected wholesaler sell-through levels to indirect customers at contract prices. The Company will validate the chargeback accrual quarterly through a review of the inventory reports obtained from our largest wholesale customers. This customer inventory information is used to verify the estimated liability for future chargeback claims based on historical chargeback and contract rates. These large wholesalers represent 90% - 95% of the Company s chargeback

payments. The Company continually monitors current pricing trends and wholesaler inventory levels to ensure the liability for future chargebacks is fairly stated.

Contract Manufacturing Sales: The Company recognizes revenue when title transfers to its customers, which is generally upon shipment of products. These shipments are made in accordance with sales commitments and related sales orders entered into with customers either verbally or in written form. The revenues associated with these transactions, net of appropriate cash discounts, product returns and sales reserves, are recorded upon shipment of the products.

Licensing and Royalty Income: Revenues earned under licensing or sublicensing contracts are recognized as earned in accordance with the terms of the agreements. The Company recognizes royalty revenue based on royalty reports received from the licensee. We do not have current plans to have meaningful revenue from licensing and royalty agreements in 2013.

Research and Development Income*:* The Company establishes agreed upon product development agreements with its customers to perform product development services. Product development revenues are recognized in accordance with the product development agreement upon the completion of the phases of development and when we have no future performance obligations relating to that phase of development. Revenue recognition requires the Company to assess progress against contracted obligations to assure completion of each stage. These payments are generally non-refundable and are reported as deferred until they are recognizable as revenue. If no such arrangement exists, product development fees are recognized ratably over the entire period during which the services are performed.

In making such assessments, judgments are required to evaluate contingencies such as potential variances in schedule and the costs, the impact of change orders, liability claims, contract disputes and achievement of contractual performance standards. Changes in total estimated contract cost and losses, if any, are recognized in the period they are determined. Billings on research and development contracts are typically based upon terms agreed upon by the Company and customer and are stated in the contracts themselves and do not always align with the revenues recognized by the Company.

Stock-based Compensation

ASC 718-10 defines the fair-value-based method of accounting for stock-based employee compensation plans and transactions used by the Company to account for its issuances of equity instruments to record compensation cost for stock-based employee compensation plans at fair value as well as to acquire goods or services from non-employees. Transactions in which the Company issues stock-based compensation to employees, directors and advisors and for goods or services received from non-employees are accounted for based on the fair value of the equity instruments issued. The Company utilizes pricing models in determining the fair values of options and warrants issued as stock-based compensation. These pricing models utilize the market price of the Company s common stock and the exercise price of the option or warrant, as well as time value and volatility factors underlying the positions.

Accounts Receivable and Allowance for Doubtful Accounts

The Company extends credit to its contract services customers, based upon credit evaluations, in the normal course of business, primarily with 30-day terms. The Company does not require collateral from its customers. Bad debt provisions are provided for on the allowance method based on historical experience and management s evaluation of outstanding accounts receivable. The Company reviews the allowance for doubtful accounts regularly, and past due balances are reviewed individually for collectability. The Company charges off uncollectible receivables against the allowance when the likelihood of collection is remote.

The Company extends credit to wholesaler and distributor customers and national retail chain customers, based upon credit evaluations, in the normal course of business, primarily with 60-day terms. The Company maintains customer-related accruals and allowances that consist primarily of chargebacks, rebates, sales returns, shelf stock allowances, administrative fees and other incentive programs. Some of these adjustments relate specifically to the generic prescription pharmaceutical business. Typically, the aggregate gross-to-net adjustments related to these customers can exceed 50% of the segment's gross sales. Certain of these accruals and allowances are recorded in the balance sheet as current liabilities and others are recorded as a reduction in accounts receivable.

Inventory Reserves

The Company periodically reviews its raw material and finished goods inventories for expiry as well as obsolescence and creates reserves to the extent such inventories do not lend themselves to either extending their period of useful life or use in the manufacture of alternative products. Inventory reserves thus created also include inventories relating to

products that are recalled.

Long-Lived Assets

The Company s long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. The recoverability of assets to be held and used is measured by a comparison of the carrying amount of the asset to future net undiscounted cash flows expected to be generated by the asset. If the assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount exceeds the fair value of the assets.

Deferred Tax Valuation Allowance

Deferred taxes arise due to temporary differences in the bases of assets and liabilities and from net operating losses and credit carry forwards. In general, deferred tax assets represent future tax benefits to be received when certain expenses previously recognized in the Company's statement of operations become deductible expenses under applicable income tax laws or loss or credit carry forwards are utilized. Accordingly, realization of deferred tax assets is dependent on future taxable income against which these deductions, losses and credits can be utilized. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. Management considers historical operating losses, scheduled reversals of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. As a result, the Company concluded that it was more likely than not that it will be unable to realize the gross deferred tax assets in the foreseeable future and established a valuation reserve for all such deferred tax assets.

Market Risk

The Company does not use derivative instruments.

Off-Balance Sheet Arrangements

As of December 31, 2013, we had no off-balance sheet arrangements.

**ITEM 7A.**

**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

**ITEM 8.**

**FINANCIAL STATEMENTS**

The Company s Consolidated Financial Statements and Notes thereto begin on page F-1 of this report and are incorporated herein by reference.

**ITEM 9.**

**CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A.**

**CONTROLS AND PROCEDURES**

*(a) Evaluation of Disclosure Controls and Procedures.*

As of the end of the period covered by this Annual Report on Form 10-K, our management conducted an evaluation, with the participation of our President and Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the Exchange Act )). Based on this evaluation, our President and Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms and that such information is accumulated and communicated to management, including our President and Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

*(b) Management's Report on Internal Control over Financial Reporting.*

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of its management, including our President and Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Because of its inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Based on the Company s processes and assessment, as described above, management has concluded that, as of December 31, 2013, the Company s internal control over financial reporting was effective. The Company s assessment

included documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

This Annual Report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report is not subject to attestation by the Company's registered public accounting firm pursuant to Item 308(b) of Regulation S-K.

*(c) Changes in Internal Control over Financial Reporting*

There was no change in our internal control over financial reporting during our fourth quarter ended December 31, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B.**

**OTHER INFORMATION**

None.

**PART III**

**ITEM 10.**

**DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

A portion of the information required by this item will be contained in the Company's Proxy Statement for the Company's 2014 Annual Meeting of Stockholders (the "2014 Proxy Statement") under the captions "Proposal No. 1 Election of Directors , Structure and Practices of the Board of Directors - Committees of the Board of Directors Audit Committee , "Section 16(a) Beneficial Ownership Reporting Compliance", and Executive Compensation , which are incorporated herein by this reference.

The Company has adopted a written code of ethics that applies to all directors, officers and employees of the Company and its subsidiaries. The Company s code of ethics is available at its web site at www.igilabs.com posted as 2012 Standard of Business Conduct . Any amendments to the code of ethics or waivers from the provisions of the code of ethics for the Company s principal executive officer and principal financial and accounting officer will be disclosed on the Company s Internet website within four business days following the date of such amendment or waiver.

**ITEM 11.**

**EXECUTIVE COMPENSATION**

The information required by this item will be contained in the Company's 2014 Proxy Statement under the captions Executive Compensation , and Structure and Practices of the Board of Directors Director Compensation and is incorporated herein by this reference.

**ITEM 12.**

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this item will be contained in the Company's 2014 Proxy Statement under the caption "Security Ownership of Certain Beneficial Owners and Management" and is incorporated herein by this reference.

**Securities Authorized For Issuance Under Equity Compensation Plans**

The information required by this item will be contained in the Company's 2014 Proxy Statement under the captions Securities Authorized for Issuance Under Equity Compensation Plans" and is incorporated herein by this reference.

**ITEM 13.**

**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this item will be contained in the Company's 2014 Proxy Statement under the captions Proposal 1 Election of Directors Independence of Directors , Structures and Practices of the Board of Directors Committees of the Board of Directors and "Certain Relationships and Related Transactions" and is incorporated herein by this reference.

**ITEM 14.**

**PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item will be contained in the Company s 2014 Proxy Statement under the caption Relationship with Independent Public Accountants and is incorporated herein by this reference.

## PART IV

**ITEM 15.**

**EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) (1) Financial Statements

The Consolidated Financial Statements and related Notes filed as part of this Annual Report on Form 10-K are listed on the Index to Consolidated Financial Statements on page F-1.

(a) (2) Financial Statement Schedules

Financial Statement Schedules have been omitted because they are either not applicable or the required information is included in our Consolidated Financial Statements or Notes thereto.

(a) (3) List of Exhibits

See the following list of exhibits below which exhibits are filed as part of this Annual Report on Form 10-K. We are incorporating by reference to our previous SEC filings certain exhibits filed as part of this Annual Report on Form 10-K. The location of each such exhibit in the previous filing is indicated in parentheses.

(b) Exhibits

| **Exhibit Number** | **Description** |
|---|---|

| | |
|---|---|
| (3.1) | Amended and Restated Certificate of Incorporation of IGI Laboratories, Inc., dated May 7, 2008 (incorporated by reference to Exhibit 3.1 to the Company s Report on Form 8-K, filed May 12, 2008). |
| (3.2) | Amended and Restated Bylaws of IGI Laboratories, Inc., effective May 7, 2008 (incorporated by reference to Exhibit 3.2 to the Company s Report on Form 8-K, filed May 12, 2008). |
| (3.3) | Certificate of Designation of the Relative Rights and Preferences of the Series C Convertible Preferred Stock of IGI Laboratories, Inc. (incorporated by reference to Exhibit 3.1 to the Company s Report on Form 8-K, filed March 30, 2010 (the March 2010 8-K )). |
| (4.1) | Specimen stock certificate for shares of Common Stock, par value $.01 per share (incorporated by reference to Exhibit 4 to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2000, filed March 28, 2001 ( the 2000 Form 10-K )). |
| (4.2) | Form of Preferred Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the March 2009 8-K). |
| (4.3) | IGI Laboratories, Inc. Common Stock Purchase Warrant in favor of Rockport Venture Securities, LLC, dated March 13, 2009 (incorporated by reference to Exhibit 4.3 to the March 2009 8-K). |
| (4.4) | Form of IGI Laboratories, Inc. Amended and Restated Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Company s Report on Form 8-K, filed December 8, 2010). |
| (4.5) | IGI Laboratories, Inc. Common Stock Purchase Warrant in favor of Amzak Capital Management, LLC, dated December 21, 2010 (incorporated by reference to Exhibit 4.1 to the Company s Report on Form 8-K, filed December 22, 2010). |
| (4.6) | IGI Laboratories, Inc. Securities Purchase Agreement in favor of Amzak Capital Management, LLC, dated December 20, 2012 (incorporated by reference to Exhibit 4.6 to the Company s Annual Report on Form 10-K, filed March 28, 2013). |
| (10.1)# | IGI, Inc. 1998 Directors Stock Plan, as amended (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 (Registration No. 333-160342), filed June 30, 2009). |
| (10.2)# | IGI, Inc. 1999 Director Stock Option Plan, as amended (incorporated by reference to Exhibit 4.2 to the Company s Registration Statement on Form S-8 (Registration No. 333-160342, filed June 30, 2009). |
| (10.3) | Manufacturing and Supply Agreement dated as of February 14, 2001 among IGI, Inc., IGEN, Inc., Immunogenetics, Inc. and Genesis Pharmaceutical, Inc. (incorporated by reference to Exhibit 10.59 to the 2000 Form 10-K). |

| | |
|---|---|
| (10.4) | License Agreement by and between Micro-Pak, Inc. (now known as Novavax, Inc.) and IGEN, Inc. effective as of December 13, 1995 (incorporated by reference to Exhibit (10) (v) to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 1995, filed March 29, 1996). |
| (10.5) | Sublicense Agreement between IGI, Inc. and Tarpan Therapeutics, Inc. dated April 19, 2004 (incorporated by reference to Exhibit 10.109 to the Company s Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, filed May 14, 2004). |
| (10.6) | Amendment of the supply and license agreement between IGI, Inc. and Estée Lauder, Inc. (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K filed November 24, 2004). |
| (10.7)# | Form of Stock Option Award Agreement under the 1999 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.4 to the Company s Report on Form 10-Q filed November 14, 2008). |
| (10.8) | Securities Purchase Agreement, by and among IGI Laboratories, Inc. and the purchasers set forth on Schedule A thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.1 to the March 2009 8-K). |
| (10.9) | Voting Agreement by and among IGI Laboratories, Inc., Signet Healthcare Partners, G.P. and the stockholders of the Company set forth on Schedule A thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.2 to the March 2009 8-K). |
| (10.10) | Registration Rights Agreement by and among IGI Laboratories, Inc., the purchasers set forth on Schedule A thereto and the placement agent set forth on Schedule B thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.3 to the March 2009 8-K). |
| (10.11) | Guaranty Agreement by Immunogenetics, Inc. in favor of the parties listed on Schedule A thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.4 to the March 2009 8-K). |
| (10.12) | Security Agreement by and among IGI Laboratories, Inc., Immunogenetics, Inc. and the secured parties listed on the signature page thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.5 to the March 2009 8-K). |
| (10.13) | Intellectual Property Security Agreement by and among IGI Laboratories, Inc., Immunogenetics, Inc. and the secured parties listed on the signature page thereto, dated March 13, 2009 (incorporated by reference to Exhibit 10.6 to the March 2009 8-K). |
| (10.14) | Intercreditor Agreement by and among Life Sciences Opportunities Fund II, L.P., Life Sciences Opportunities Fund (Institutional) II, L.P., Pinnacle Mountain Partners, LLC and IGI Laboratories, Inc., dated March 13, 2009 (incorporated by reference to Exhibit 10.7 to the March 2009 8-K). |
| (10.15)# | Indemnification Agreement by and between IGI Laboratories, Inc. and Joyce Erony, dated March 13, 2009 (incorporated by reference to Exhibit 10.10 to the March 2009 8-K). |
| (10.16)# | Form of Indemnification Agreement for Certain Directors (incorporated by reference to Exhibit 10.11 to the March 2009 8-K). |
| (10.17)# | IGI, Inc. 1999 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration No. |

| | |
|---|---|
| | 333-160342), filed June 30, 2009). |
| (10.18)# | IGI Laboratories, Inc. 2009 Equity Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K filed May 24, 2010). |
| (10.19)# | Form of Non-Qualified Stock Option Agreement under the IGI Laboratories, Inc. 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company s Report on Form 8-K filed July 2, 2009). |
| (10.20)# | Form of Award Agreement for Restricted Shares under the IGI Laboratories, Inc. 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company s Report on Form 8-K filed July 2, 2009). |
| (10.21)# | Amended and Restated Employment Agreement dated April 1, 2010 between IGI Laboratories, Inc. and Charles Moore (incorporated by reference to Exhibit 10.4 to the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2010, filed May 17, 2010). |
| (10.22) | Form of Securities Purchase Agreement, by and among IGI Laboratories, Inc. and the purchasers thereto, dated March 29, 2010 (incorporated by reference to Exhibit 10.1 to the March 2010 8-K). |
| (10.23) | Registration Rights Agreement by and among IGI Laboratories, Inc., the purchasers set forth on Schedule A thereto, dated March 29, 2010 (incorporated by reference to Exhibit 10.2 to the March 2010 8-K). |

| | |
|---|---|
| (10.24) | Registration Rights Agreement by and among IGI Laboratories, Inc. and certain investors, dated December 8, 2010 (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K filed December 8, 2010). |
| (10.25) | Credit Agreement dated as of December 21, 2010 by and between IGI Laboratories, Inc. and Amzak Capital Management, LLC (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K filed December 22, 2010 (the December 2010 8-K ) |
| (10.26) | Pledge and Security Agreement dated as of December 21, 2010 by and between IGI Laboratories, Inc. and Amzak Capital Management, LLC (incorporated by reference to Exhibit 10.2 to the December 2010 8-K). |
| (10.27) | Registration Rights Agreement dated as of December 21, 2010 by and between IGI Laboratories, Inc. and Amzak Capital Management, LLC (incorporated by reference to Exhibit 10.3 to the December 2010 8-K). |
| (10.28) | Registration Rights Agreement dated as of December 21, 2010 by and between IGI Laboratories, Inc. and Amzak Capital Management, LLC (incorporated by reference to Exhibit 10.3 to the December 2010 8-K). |
| (10.29)# | Employment Agreement dated July 14, 2011 between IGI Laboratories, Inc. and Jenniffer Collins (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K filed July 20, 2011). |
| (10.30)# | Form of Stock Option Award Agreement under the IGI Laboratories, Inc. 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company s Report on Form 8-K filed July 20, 2011). |
| (10.31)# | Employment Agreement dated July 30, 2012 between IGI Laboratories, Inc. and Jason Grenfell-Gardner (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K filed July 30, 2012). |
| (10.32)# | Separation of Employment Agreement and General Release dated August 14, 2012 between IGI Laboratories, Inc. and Charles Moore (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K filed August 14, 2012). |
| (10.33) | Loan and Security Credit Agreement dated as of August 31, 2012 by and among IGI Laboratories, Inc., Igen, Inc. and IGI Labs, Inc. as Borrower and Square 1 Bank as Bank (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K filed September 6, 2012) |
| (10.34) | Registration Rights Agreement dated as of December 20, 2012 by and between IGI Laboratories, Inc. and Amzak Capital Management, LLC (incorporated by reference to Exhibit 10.34 to the Company s Annual Report on Form 10-K, filed March 28, 2013). |
| (10.35)+ | Purchase and Sale Agreement between the Company and Prasco, LLC for the purchase of econazole nitrate cream 1%, dated February 1, 2013, (incorporated by reference to Exhibit 10.1 to the Company s Report on Form 8-K, filed August 9, 2013). |
| (21) | List of Subsidiaries (incorporated by reference to Exhibit 21 to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 1999, filed April 14, 2000). |
| (23.1)* | Consent of EisnerAmper LLP. |
| (31.1)* | Certification of the President and Chief Executive Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| (31.2)* | Certification of the Principal Financial and Accounting Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |

| | |
|---|---|
| (32.1)** | Certification of the President and Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| (32.2)** | Certification of the Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| (101)* | The following financial information from this Annual Report on Form 10-K for the year ended December 31, 2013, formatted in XBRL (Extensible Business Reporting Language) and furnished electronically herewith: (i) the Consolidated Statements of Operations; (ii) the Consolidated Balance Sheets; (iii) the Consolidated Statements of Cash Flows; and (iv) the Notes to Consolidated Financial Statements, tagged as blocks of text. |

*

Filed herewith.

**

Furnished herewith.

#

Indicates management contract or compensatory plan.

+

Portions of this Exhibit were omitted and filed separately with the Secretary of the SEC pursuant to a request for confidential treatment that has been filed with the SEC.

**SIGNATURES**

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

| | | |
|---|---|---|
| Date: | | IGI Laboratories, Inc. |
| March 31, 2014 | By: | /s/ Jason Grenfell-Gardner<br>Jason Grenfell-Gardner<br>President and Chief Executive Officer |

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

| Signatures | Title | Date |
|---|---|---|
| /s/ Jason Grenfell-Gardner<br>Jason Grenfell-Gardner | Director, President and Chief Executive Officer<br>(Principal Executive Officer) | March 31, 2014 |
| /s/ Jenniffer Collins<br>Jenniffer Collins | Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 31, 2014 |
| /s/ Joyce Erony<br>Joyce Erony | Director | March 31, 2014 |
| /s/ James Gale<br>James Gale | Director | March 31, 2014 |
| /s/ Michael Hemric<br>Michael Hemric | Director | March 31, 2014 |
| /s/ Narendra Borkar<br>Narendra Borkar | Director | March 31, 2014 |
| /s/ Bhaskar Chaudhuri<br>Bhaskar Chaudhuri | Director | March 31, 2014 |

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**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**


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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders

IGI Laboratories, Inc.

We have audited the accompanying consolidated balance sheets of IGI Laboratories, Inc. and subsidiaries (the Company ) as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders equity, 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 consolidated 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 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of IGI Laboratories, Inc. and subsidiaries 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

Iselin, New Jersey

March 31, 2014

**IGI LABORATORIES, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**(in thousands, except share and per share information)**

| | December 31, 2013 | December 31, 2012 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 2,101 | $ 2,536 |
| Accounts receivable, net | 4,947 | 1,577 |
| Inventories | 2,869 | 1,773 |
| Prepaid expenses and other receivables | 641 | 253 |
| Total current assets | 10,558 | 6,139 |
| Property, plant and equipment, net | 2,623 | 2,691 |
| Product acquisition costs, net | 1,766 | |
| Restricted cash, long term | 54 | 54 |
| License fee, net | 200 | 300 |
| Debt issuance costs, net | 69 | 100 |
| Other | 157 | 143 |
| Total assets | $ 15,427 | $ 9,427 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,523 | $ 1,091 |
| Accrued expenses | 2,915 | 820 |
| Deferred income, current | 768 | 48 |
| Capital lease obligation, current | 15 | 17 |
| Total current liabilities | 5,221 | 1,976 |
| Note payable, bank | 3,000 | 1,000 |
| Deferred income, long term | 4 | 20 |
| Capital lease obligation, long term | 11 | 4 |
| Total liabilities | 8,236 | 3,000 |
| Commitments and contingencies | | |
| Stockholders equity: | | |
| Series A Convertible Preferred stock, $0.01 par value, 100 shares authorized; 0 and 50 shares issued and outstanding as of December 31, 2013 and 2012, respectively; liquidation preference - $0 at December | | 500 |

| | | |
|---|---|---|
| 31, | | |
| 2013 and $500,000 at December 31, 2012 | | |
| Series C Convertible Preferred stock, $0.01 par value, 1,550 shares | | |
| authorized; 0 and 1,550 shares issued and outstanding as of | | |
| December 31, | | |
| 2013 and 2012, respectively; liquidation preference - $0 at December | | |
| 31, | | |
| 2013 and $1,764,240 at December 31, 2012 | | 1,517 |
| Common stock, $0.01 par value, 60,000,000 shares authorized; | | |
| 46,748,575 | | |
| and 42,705,032 shares issued and outstanding as of December 31, | | |
| 2013 | | |
| and 2012, respectively | 487 | 446 |
| Additional paid-in capital | 51,541 | 47,409 |
| Accumulated deficit | (44,837) | (43,445) |
| Total stockholders equity | 7,191 | 6,427 |
| Total liabilities and stockholders' equity | $ 15,427 | $ 9,427 |

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

**IGI LABORATORIES, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**For the years ended December 31, 2013 and 2012**

**(in thousands, except shares and per share information)**

| | 2013 | 2012 |
|---|---|---|
| Revenues: | | |
| Product sales, net | $ 16,981 | $ 6,545 |
| Research and development income | 1,094 | 1,931 |
| Licensing, royalty and other income | 149 | 87 |
| Total revenues | 18,224 | 8,563 |
| Costs and Expenses: | | |
| Cost of sales | 12,079 | 5,787 |
| Selling, general and administrative expenses | 3,484 | 3,078 |
| Product development and research expenses | 2,743 | 2,834 |
| Total costs and expenses | 18,306 | 11,699 |
| Operating loss | (82) | (3,136) |
| Interest expense and other income (expense), net | (199) | (975) |
| Loss before benefit from income taxes | (281) | (4,111) |
| Benefit from income taxes, principally sale of New Jersey net operating losses | 197 | 184 |
| **Net loss** | (84) | (3,927) |
| Deemed dividend upon mandatory conversion of preferred stock into common stock | (1,308) | |
| **Net loss attributable to common stockholders** | $ (1,392) | $ (3,927) |
| **Basic and diluted loss per common share** | $ (0.03) | $ (0.10) |
| **Weighted average shares of common stock outstanding** | | |
| Basic and diluted | 43,517,640 | 39,786,446 |

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

**IGI LABORATORIES, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**For the years ended December 31, 2013 and 2012**

**(in thousands)**

| | 2013 | 2012 |
|---|---|---|
| **Cash flows from operating activities:** | | |
| Net loss | $ (84) | $ (3,927) |
| Reconciliation of net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 375 | 357 |
| Amortization of license fee | 100 | 100 |
| Provision for write down of inventory | 110 | 138 |
| Stock-based compensation expense | 536 | 378 |
| Amortization of debt issuance costs | 31 | 862 |
| Amortization of product acquisition costs | 60 | |
| Loss on abandonment of property | | 9 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (3,370) | (369) |
| Inventories | (1,206) | (716) |
| Prepaid expenses and other current assets | (402) | 119 |
| Accounts payable and accrued expenses | 2,528 | 671 |
| Deferred income | 704 | 5 |
| Net cash used in operating activities | (618) | (2,373) |
| **Cash flows from investing activities:** | | |
| Capital expenditures | (287) | (342) |
| Product acquisition costs | (1,826) | |
| Net cash used in investing activities | (2,113) | (342) |
| **Cash flows from financing activities:** | | |
| Proceeds from note payable, net of debt issuance costs | 2,000 | 886 |
| Repayment of note payable, related party | | (500) |
| (Expenses of) proceeds from sale of treasury stock, net of expenses | (63) | 1,963 |
| Proceeds from exercise of common stock options and warrants | 376 | 39 |
| Principal payments on capital lease obligation | (17) | (51) |
| Net cash provided by financing activities | 2,296 | 2,337 |
| Net decrease in cash and cash equivalents | (435) | (378) |
| Cash and cash equivalents at beginning of year | 2,536 | 2,914 |

| | | | | |
|---|---|---|---|---|
| Cash and cash equivalents at end of year | $ | 2,101 | $ | 2,536 |
| | | | | |
| Supplemental cash flow information: | | | | |
| Cash payments for interest | $ | 142 | $ | 99 |
| Cash receipt from taxes, net | | (194) | | (184) |
| | | | | |
| Non cash transactions: | | | | |
| Conversion of Series A Convertible Preferred Stock into Common Stock | | 500 | | |
| Conversion of Series C Convertible Preferred Stock and accrued dividends into Common Stock | | 2,825 | | |
| Equipment financed through capital lease | | 20 | | 30 |
| Issuance of restricted stock | | 3 | | 1 |
| Forfeiture of restricted stock | | | | (2) |
| Issuance of warrants | | | | 209 |

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

**IGI LABORATORIES, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY**

**For the years ended December 31, 2013 and 2012**

**(in thousands, except share information)**

| | Series A Preferred Stock | | Series C Convertible Preferred Stock | | Common Stock | | Additional Paid-In | Accumulated | Treasury | Total Stockholders |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | Capital | Deficit | Stock | Equity |
| Balance, December 31, 2011 | 50 | $ 500 | 1,550 | $ 1,517 | 41,463,836 | $ 415 | $ 46,246 | $(39,518) | $(1,395) | $ 7,765 |
| Stock based compensation expense stock options | | | | | | | 156 | | | 156 |
| Stock based compensation expense restricted stock | | | | | | | 222 | | | 222 |
| Restricted stock issuance | | | | | 109,748 | 1 | (1) | | | |
| Restricted stock forfeited | | | | | (177,084) | (2) | 2 | | | |
| Stock options exercised | | | | | 40,000 | | 26 | | | 26 |
| Warrants exercised | | | | | 1,268,532 | 13 | | | | 13 |
| Sale of treasury stock, net of expenses of $36 | | | | | | 19 | 549 | | 1,395 | 1,963 |
| Fair value of warrants issued | | | | | | | 209 | | | 209 |
| Net loss | | | | | | | | (3,927) | | (3,927) |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Balance, December 31, 2012 | 50 | $ 500 | 1,550 | $ 1,517 | 42,705,032 | $ 446 | $ 47,409 | $(43,445) | $ | $ 6,427 |
| Stock based compensation expense stock options | | | | | | | 207 | | | 207 |
| Stock based compensation expense restricted stock | | | | | | | 329 | | | 329 |
| Restricted stock issuance | | | | | 325,000 | 3 | (3) | | | |
| Stock warrants exercised | | | | | 427,713 | 5 | 231 | | | 236 |
| Stock options exercised | | | | | 129,336 | 1 | 138 | | | 139 |
| Costs related to stock issuance | | | | | | | (63) | | | (63) |
| Common stock issued for Series A Convertible Preferred stock | (50) | (500) | | | 500,000 | 5 | 495 | | | |
| Common stock issued for Series C Convertible Preferred stock including deemed dividend of $1,308 | | | (1,550) | (1,517) | 2,661,494 | | 2,798 | (1,308) | | |
| Net loss | | | | | | | | (84) | | (84) |
| Balance, December 31, 2013 | | $ | | $ | 46,748,575 | $ 487 | $ 51,541 | $(44,837) | $ | $ 7,191 |

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

**IGI LABORATORIES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## 1. Summary of Significant Accounting Policies

*Nature of the Business*

IGI Laboratories, Inc. is a Delaware corporation formed in 1977. On May 7, 2008, the stockholders of IGI, Inc. approved the name change of the Company from IGI, Inc. to IGI Laboratories, Inc. The Company s office, laboratories and manufacturing facilities are located at 105 Lincoln Avenue, Buena, New Jersey. The Company is a developer, manufacturer, and marketer of topical formulations. The Company s goal is to become a leader in the generic topical pharmaceutical market. In its own label, the Company sells generic topical pharmaceutical products that are bioequivalent to their brand name counterparts. The Company also provides development, formulation, and manufacturing services to the pharmaceutical, over-the-counter (OTC), and cosmetic markets.

Currently, we have two platforms for growth:

Manufacturing, developing, and marketing a portfolio of generic pharmaceutical products in our own label in topical dosage forms; and,

Increasing our current contract manufacturing and formulation services business.

In addition, we will continue to explore ways to accelerate our growth through the creation of unique opportunities from the acquisition of additional intellectual property, and the expansion of the use of our existing intellectual property, including our licensed Novasome® technology.

To date, we have filed fourteen Abbreviated New Drug Applications, or ANDAs, with the United States Food and Drug Administration, or FDA for additional pharmaceutical products. We expect to continue to expand our presence in the generic topical pharmaceutical market through the filing of additional ANDAs with the FDA and the subsequent launch of products as these applications are approved. Our target is to file at least ten ANDAs in 2014 through our internal research and development program. On March 12, 2014, the Company received our first approval from the FDA for an ANDA. The FDA has approved IGI's application for lidocaine hydrochloride USP 4% topical solution. We will also seek to license or acquire further products, intellectual property, or ANDAs to expand our portfolio. On February 1, 2013, we acquired assets and intellectual property, including an ANDA, for econazole nitrate cream 1%, which we launched in September 2013.

IGI also develops manufactures, fills, and packages topical semi-solid and liquid products for branded and generic pharmaceutical customers as well as the OTC and cosmetic markets. These products are used in a wide range of applications from cosmetics and cosmeceuticals to the prescription treatment of conditions like dermatitis, psoriasis, and eczema.

*Principles of Consolidation*

The consolidated financial statements include the accounts of IGI Laboratories, Inc. and its wholly owned and majority-owned subsidiaries. All inter-company accounts and transactions have been eliminated.

*Cash Equivalents*

Cash equivalents consist of short-term investments, which have original maturities of 90 days or less.

*Fair Value of Financial Instruments*

The carrying amounts of cash and cash equivalents, trade receivables, restricted cash, notes payable, accounts payable, capital leases and other accrued liabilities at December 31, 2013 approximate their fair value for all periods presented.

*Accounts Receivable and Allowance for Doubtful Accounts*

The Company extends credit to its contract services customers, based upon credit evaluations, in the normal course of business, primarily with 30-day terms. The Company does not require collateral from its customers. Bad debt provisions are provided for on the allowance method based on historical experience and management s evaluation of outstanding accounts receivable. The Company reviews the allowance for doubtful accounts regularly, and past due balances are reviewed individually for collectability. The Company charges off uncollectible receivables against the allowance when the likelihood of collection is remote.

The Company extends credit to wholesaler and distributor customers and national retail chain customers, based upon credit evaluations, in the normal course of business, primarily with 60-day terms. The Company maintains customer-related accruals and allowances that consist primarily of chargebacks, rebates, sales returns, shelf stock allowances, administrative fees and other incentive programs. Some of these adjustments relate specifically to the generic prescription pharmaceutical business. Typically, the aggregate gross-to-net adjustments related to these customers can exceed 50% of the gross sales through this distribution channel. Certain of these accruals and allowances are recorded in the balance sheet as current liabilities and others are recorded as a reduction in accounts receivable.

*Concentration of Credit Risk*

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and accounts receivable.

The Company maintains its cash in accounts with quality financial institutions. Although the Company currently believes that the financial institutions with whom the Company does business will be able to fulfill their commitments to us, there is no assurance that those institutions will be able to continue to do so.

In 2013, the Company had sales to three customers which individually accounted for more than 10% of the Company s total revenue. These customers had sales of $2.8 million, $2.2 million and $2.1 million, respectively, and aggregately represented 39% of total revenues. Accounts receivable related to the Company s major customers comprised 11% of all accounts receivable as of December 31, 2013.

In 2012, the Company had sales to two customers which individually accounted for more than 10% of the Company s total revenue. These customers had sales of $2.8 million and $1.8 million, respectively, and aggregately represented 54% of total revenues. Accounts receivable related to the Company s major customers comprised 59% of all accounts receivable as of December 31, 2012.

*Inventories*

Inventories are valued at the lower of cost, using the first-in, first-out ( FIFO ) method, or market. The company records an inventory reserve for losses associated with dated and expired raw materials. This reserve is based on management s current knowledge with respect to inventory levels, planned production, and extension capabilities of materials on hand. Management does not believe the Company s inventory is subject to significant risk of obsolescence in the near term. Reserve for obsolescence included in inventory at December 31, 2013 and 2012 were $0.2 million and $0.1 million respectively.

*Property, Plant and Equipment*

Depreciation and amortization of property, plant and equipment is provided for under the straight-line method over the assets estimated useful lives as follows:

| | **Useful Lives** |
|---|---|
| Buildings and improvements | 10 - 30 years |
| Machinery and equipment | 3 - 10 years |

Repair and maintenance costs are charged to operations as incurred while major improvements are capitalized. When assets are retired or disposed, the related cost and accumulated depreciation thereon are removed and any gains or losses are included in operating results.

*Intangible Assets*

Intangible assets consist of the cost of an acquired product and product rights. Intangible assets are amortized over fifteen years (the asset s estimated useful life).

*Long-Lived Assets*

In accordance with the provisions of ASC 360-10-55, the Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. In performing such review for recoverability, the Company compares expected future cash flows of assets to the carrying value of the long-lived assets and related identifiable intangibles. If the expected future cash flows (undiscounted) are less than the carrying amount of such assets, the Company recognizes an impairment loss for the difference between the carrying value of the assets and their estimated fair value, with fair values being determined using projected discounted cash flows at the lowest level of cash flows identifiable in relation to the assets being reviewed. As of December 31, 2013, no impairments existed.

*Accrued Expenses*

Accrued expenses represent various obligations of the Company including certain operating expenses and taxes payable. For the fiscal year ended December 31, 2013, the largest component of accrued expenses was accrued royalties of $945,000, accrued payroll of $704,000, accrued wholesaler fees of $624,500 and accrued directors fees of $214,500. For the fiscal year ended December 31, 2012, the largest component of accrued expenses was accrued payroll of $256,700, accrued directors fees of $209,900 and accrued consulting fees of $60,000.

*License Fee*

License fees are amortized on a straight-line basis over the life of the agreement (10 years).

*Accounting for Environmental Costs*

Accruals for environmental remediation are recorded when it is probable a liability has been incurred and costs are reasonably estimable. The estimated liabilities are recorded at undiscounted amounts. Environmental insurance recoveries are included in the statement of operations in the year in which the issue is resolved through settlement or other appropriate legal process.

*Income Taxes*

The Company records income taxes in accordance with ASC 740-10, Accounting for Income Taxes, under the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred income taxes are recognized for the tax consequences of temporary differences by applying enacted statutory tax rates applicable to future years to operating loss and tax credit carry forwards and differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded based on a determination of the ultimate realizability of future deferred tax assets. A valuation allowance equal to 100% of the net deferred tax assets has been recognized due to uncertainty regarding the future realization of these assets.

The Company complies with the provisions of ASC 740-10-25 that clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements in accordance with ASC 740-10, Accounting for Income Taxes, and prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. Additionally, ASC 740-10 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. There were no unrecognized tax benefits as of the date of adoption. As such, there are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

*Revenue Recognition*

The Company considers revenue realized or realizable and earned when it has persuasive evidence of an arrangement, delivery has occurred or contractual services rendered, the sales price is fixed or determinable, and collection is reasonably assured in conformity with ASC 605, *Revenue Recognition*.

The Company derives its revenues from three basic types of transactions: sales of its own generic pharmaceutical topical products, sales of manufactured product for its customers, and research and product development services performed for third parties. Due to differences in the substance of these transaction types, the transactions require, and the Company utilizes, different revenue recognition policies for each.

Product Sales: Product Sales includes IGI Product Sales and Contract Manufacturing Sales.

IGI Product Sales: The Company records revenue from IGI product sales when title and risk of ownership have been transferred to the customer, which is typically upon delivery of products to the customer.

*Revenue and Provision for Sales Returns and Allowances*

As customary in the pharmaceutical industry, the Company s gross product sales from IGI label products are subject to a variety of deductions in arriving at reported net product sales. When the Company recognizes revenue from the sale of products, an estimate of sales returns and allowances ( SRA ) is recorded, which reduces product sales. Accounts receivable and/or accrued expenses are also reduced and/or increased by the SRA amount. These adjustments include estimates for chargebacks, rebates, cash discounts and returns and other allowances. Currently these provisions are based on industry standards and current contract sales terms with direct and indirect customers. Over time, these provisions will be adjusted as estimates will be based on historical payment experience, historical relationship to revenues, estimated customer inventory levels and current contract sales terms with direct and indirect customers. The estimation process used to determine our SRA provision has been applied on a consistent basis and no material adjustments have been necessary to increase or decrease our reserves for SRA as a result of a significant change in underlying estimates. The Company will use a variety of methods to assess the adequacy of our SRA reserves to ensure that our financial statements are fairly stated. These will include periodic reviews of customer inventory data, customer contract programs and product pricing trends to analyze and validate the SRA reserves.

The provision for chargebacks is our most significant sales allowance. A chargeback represents an amount payable in the future to a wholesaler for the difference between the invoice price paid to the Company by our wholesale customer for a particular product and the negotiated contract price that the wholesaler s customer pays for that product. The Company s chargeback provision and related reserve varies with changes in product mix, changes in customer pricing and changes to estimated wholesaler inventories. The provision for chargebacks also takes into account an estimate of the expected wholesaler sell-through levels to indirect customers at contract prices. The Company will validate the chargeback accrual quarterly through a review of the inventory reports obtained from our largest wholesale customers. This customer inventory information is used to verify the estimated liability for future chargeback claims based on historical chargeback and contract rates. These large wholesalers represent 90% - 95% of the Company s chargeback payments. The Company continually monitors current pricing trends and wholesaler inventory levels to ensure the liability for future chargebacks is fairly stated.

Net revenues and accounts receivable balances in the Company s consolidated financial statements are presented net of SRA estimates. Certain SRA balances are included in accounts payable and accrued expenses.

**Gross-To-Net Sales Deductions**

| | Twelve Months Ended December 31, | | | |
|---|---|---|---|---|
| | 2013 | | 2012 | |
| | (in thousands) | | | |
| Gross IGI product sales | $ | 15,001 | $ | 18 |
| Reduction to gross product sales: | | | | |
| Chargebacks and billbacks | | (6,050) | | |
| Sales discounts and other allowances | | (1,593) | | (1) |
| Total reduction to gross product sales | $ | (7,643) | $ | (1) |
| Net IGI product sales | $ | 7,358 | $ | 17 |

Accounts receivable are presented net of SRA balances of $1.9 million and $0 at December 31, 2013 and 2012, respectively. Accounts payable and accrued expenses include $0.6 million and $0 at December 31, 2013 and 2012, respectively, for certain fees related to services provided by the wholesalers. Wholesale fees of $0.9 million and $0 for the twelve month periods ended December 31 for 2013 and 2012, respectively, were included in cost of goods sold. In addition, in connection with three of the four products the Company currently manufactures, markets and distributes in its own label, in accordance with an agreement entered into in December of 2011, the Company is required to pay a royalty calculated based on net sales to one of its pharmaceutical partners. The royalty is calculated based on contracted terms of 40% of net sales for the three products which is to be paid quarterly to the pharmaceutical partner. In accordance with the agreement, net sales excludes fees related to services provided by the wholesalers. Accounts payable and accrued expenses include $0.9 million and $0 at December 31, 2013 and 2012, respectively, related to these royalties. Royalty expense of $2.6 million and $0 was included in cost of goods sold for the twelve months ended December 31 for 2013, and 2012 respectively. The Company includes significant estimates to arrive at net product sales arising from wholesaler chargebacks, Medicaid and Medicare rebates, allowances and other pricing and promotional programs.

Contract Manufacturing Sales: The Company recognizes revenue when title transfers to its customers, which is generally upon shipment of products. These shipments are made in accordance with sales commitments and related sales orders entered into with customers either verbally or in written form. The revenues associated with these transactions, net of appropriate cash discounts, product returns and sales reserves, are recorded upon shipment of the products.

Research and Development Income*:* The Company establishes agreed upon product development agreements with its customers to perform product development services. Product development revenues are recognized in accordance with the product development agreement upon the completion of the phases of development and when the Company has no future performance obligations relating to that phase of development. Revenue recognition requires the Company to assess progress against contracted obligations to assure completion of each stage. These payments are generally non-refundable and are reported as deferred until they are recognizable as revenue. If no such arrangement exists, product development fees are recognized ratably over the entire period during which the services are performed.

In making such assessments, judgments are required to evaluate contingencies such as potential variances in schedule and the costs, the impact of change orders, liability claims, contract disputes and achievement of contractual performance standards. Changes in total estimated contract cost and losses, if any, are recognized in the period they are determined. Billings on research and development contracts are typically based upon terms agreed upon by the Company and customer and are stated in the contracts themselves and do not always align with the revenues recognized by the Company.

*Stock-Based Compensation*

ASC 718-10 defines the fair-value-based method of accounting for stock-based employee compensation plans and transactions used by the Company to account for its issuances of equity instruments to record compensation cost for stock-based employee compensation plans at fair value as well as to acquire goods or services from non-employees. Transactions in which the Company issues stock-based compensation to employees, directors and advisors and for goods or services received from non-employees are accounted for based on the fair value of the equity instruments issued. The Company utilizes pricing models in determining the fair values of options and warrants issued as stock-based compensation. These pricing models utilize the market price of the Company s common stock and the exercise price of the option or warrant, as well as time value and volatility factors underlying the positions. Stock-based compensation expense is recognized over the vesting period of the grant.

*Debt Issuance Costs*

Expenses related to debt financing activities are capitalized and amortized on a straight-line basis, which approximates the effective interest method, over the term of the loan. On August 1, 2012, the Company paid-off its existing credit facility with Amzak Capital Management, LLC, and wrote-off the unamortized debt issuance costs to interest expense. The Company entered into a new loan agreement with Square 1 Bank, and in connection with this financing the Company incurred and recorded debt issuance costs in the amount of $114,000, which will be amortized over the remaining life of the loan, 42 months.

*Product Development and Research*

The Company's research and development costs are expensed as incurred.

*Advertising Costs*

Advertising costs are expensed as incurred. Such expenses for the years ended December 31, 2013 and 2012 were $3,500 and $3,600, respectively.

*Shipping and Handling Costs*

Costs related to shipping and handling is comprised of outbound freight and the associated labor. These costs are recorded in costs of sales.

*Net Loss per Common Share*

Basic net loss per share of common stock is computed based on the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share of common stock is computed using the weighted average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period. Potential dilutive common stock equivalents include shares issuable upon the exercise of options and warrants and the conversion of preferred stock. Due to the net loss for the years ended December 31, 2013 and 2012, the effect of the Company s potential dilutive common stock equivalents was anti-dilutive for each year; as a result, the basic and diluted weighted average number of common shares outstanding and net loss per common share are the same. Potentially dilutive common stock equivalents, which were excluded from the net loss per share calculations due to their anti-dilutive effect amounted to 2,998,046 for 2013 and 6,445,628 for 2012.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (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 amounts of revenues and expenses during the reporting period. Significant estimates include allowances for excess and obsolete inventories, allowances for doubtful accounts, provisions for income taxes and related deferred tax asset valuation allowances, stock based compensation and accruals for environmental cleanup and remediation costs. Actual results could differ from those estimates.

*Recent Accounting Pronouncements*

In July 2013, the FASB issued ASU No. 2013-11, Presentation of an Unrecognized Tax Benefit When A Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists ( ASU 2013-11 ), which provides guidance on the presentation of unrecognized tax benefits when net operating loss carryforwards, similar tax losses, or tax credit carryforwards exist. The amendments in this update are effective for fiscal years (and interim periods within those years) beginning after December 15, 2013. The amendments should be applied prospectively to all unrecognized tax benefits that exist at the effective date. Retrospective application is permitted. The Company does not expect ASU 2013-11 to have a material effect on its financial condition, results of operation or cash flows. This update will be effective for the Company for the year beginning January 1, 2014.

**2. Liquidity**

The Company s principal sources of liquidity are cash and cash equivalents of approximately $2,101,000 at December 31, 2013, the $2,000,000 available under the $5,000,000 credit facility detailed below and cash from operations. The Company sustained net losses attributable to common stockholders of $1,392,000 and $3,927,000 for the years ended December 31, 2013 and 2012, respectively, and had working capital of $5,337,000 at December 31, 2013.

The Company s business operations have been primarily funded over the past five years through private placements of its capital stock. The Company raised an aggregate of $2,000,000 through private placements of equity with accredited investors in 2012, $7,213,000 in 2010 and $5,304,000 in 2009 principally from private equity investors. The use of proceeds was intended for general working capital needs as well as the acquisition of econazole nitrate cream 1% which was purchased on February 1, 2013 and launched in November 2013. In August 2012, the Company also entered into a $3,000,000 line of credit. On July 26, 2013, the Company entered into an amendment to the loan and security agreement. The amendment increased the line of credit to $5,000,000 on December 31, 2013 upon the Company s compliance with certain covenants (See Note 6). As of December 31, 2013 the outstanding balance on the line of credit was $3,000,000. The Company may require additional funding and this funding will depend, in part, on the timing and structure of potential business arrangements. If necessary, the Company may continue to seek to raise additional capital through the sale of its equity. It may be accomplished via a strategic alliance with a third party. There may also be additional acquisition and growth opportunities that may require external financing. There can be no assurance that such financing will be available on terms acceptable to the Company, or at all. The Company also has the ability to defer certain product development and other programs, if necessary. The Company believes that our existing capital resources will be sufficient to support its current business plan and operations beyond March 2015.

**3. License Fee**

On December 12, 2005, the Company extended its license agreement for an additional ten years with Novavax, Inc. for $1,000,000. This extension entitles the Company to exclusive use of the Novasome® lipid vesicle encapsulation and certain other technologies in the fields of (i) animal pharmaceuticals, biologicals and other animal health products; (ii) foods, food applications, nutrients and flavorings; (iii) cosmetics, consumer products and dermatological over-the-counter and prescription products (excluding certain topically delivered hormones); (iv) fragrances; and (v) chemicals, including herbicides, insecticides, pesticides, paints and coatings, photographic chemicals and other specialty chemicals, and the processes for making the same through 2015. This payment is being amortized ratably over the ten-year period. For the years ended, December 31, 2013 and 2012, the Company recorded a $100,000 expense in each year related to the amortization of the license. Amortization of this license fee will amount to $100,000 per year for 2014 and 2015.

**4. Inventories**

Inventories as of December 31, 2013 and 2012 consisted of:

| | 2013 | 2012 |
|---|---|---|
| | (in thousands) | |

| | | | | |
|---|---|---|---|---|
| Raw materials | $ | 2,172 | $ | 1,673 |
| Work in progress | | 271 | | 26 |
| Finished goods | | 426 | | 74 |
| | $ | 2,869 | $ | 1,773 |

**5. Property, Plant and Equipment**

Property, plant and equipment, at cost, as of December 31, 2013 and 2012, consisted of:

| | | 2013 | | 2012 |
|---|---|---|---|---|
| | | (in thousands) | | |
| Land | $ | 257 | $ | 257 |
| Building and improvements | | 3,599 | | 3,552 |
| Machinery and equipment | | 3,375 | | 3,120 |
| Construction in progress | | 128 | | 123 |
| | | 7,359 | | 7,052 |
| Less accumulated depreciation and amortization | | (4,736) | | (4,361) |
| Property, plant and equipment, net | $ | 2,623 | $ | 2,691 |

The Company recorded depreciation and amortization expense of $375,000 and $357,000 in 2013 and 2012, respectively.

**6. Note Payable**

On August 31, 2012, IGI Laboratories, Inc. and its subsidiaries entered into a Loan and Security Agreement (the *Loan and Security Agreement*) with Square 1 Bank (the *Lender*) pursuant to which the Lender agreed to extend credit facilities to the Company (the *Financing*). The Company drew down $1,000,000 in principal amount on August 31, 2012, $1,000,000 in principal amount on February 5, 2013 and $1,000,000 in principal amount on August 2, 2013. At December 31, 2013, $3,000,000 was outstanding.

To secure payment of the amounts financed under the Loan and Security Agreement, the Company has granted to the Lender a continuing security interest in and against, generally, all of its tangible and intangible assets, except intellectual property.

Under the Loan and Security Agreement, the Company can request revolving loan advances under (a) the Formula Revolving Line and (b) the Non-Formula Revolving Line, and term loan advances under the term loans. The aggregate total borrowings under the facilities cannot exceed the total borrowing limit of $3,000,000 at any one time outstanding. Formula Revolving Line advances shall bear interest, on the outstanding balance thereof, at a variable rate equal to the greater of (A) 1.9% above the prime rate then in effect, and (B) 5.65%. Non-Formula Revolving Line advances shall bear interest, on the outstanding balance thereof, at a variable rate equal to the greater of (A) 2.15% above the prime rate then in effect, and (B) 5.9%. Term loan advances shall bear interest, on the outstanding balance thereof, at a variable rate equal to the greater of (A) 2.4% above the prime rate then in effect, and (B) the rate in effect at December 31, 2013, which was 6.15%.

The term of the Formula Revolving Line and the Non-Formula Revolving Line is one year from the date of the Loan and Security Agreement and can be extended by mutual agreement of the parties. The term of the term loans is 42 months from the date of the Loan and Security Agreement, but term loan advances are available to the Company only until February 28, 2014.

In accordance with the Loan and Security Agreement, the Company had to maintain a liquidity ratio of at least 1.25 to 1.00 (the LQR Threshold), provided that the LQR Threshold was reduced to 1.00 so long as the Company had achieved minimum Revenue, measured monthly on a trailing three month basis, of at least the amounts listed in the document for the corresponding reporting periods. To further clarify, if at any time the Company is not in compliance with the minimum revenue amounts set forth below, the LQR Threshold would be increased to 1.25 to 1.00. Liquidity means the sum of: (i) unrestricted cash in bank plus (ii) the Borrowing Base (the amount drawn to date). In accordance with the Loan and Security Agreement, liquidity ratio means the ratio of Liquidity to all Indebtedness to the Lender (but excluding any Indebtedness to the Lender which is secured by cash held in a segregated deposit account at the

Lender). As of December 31, 2013, the Company was in compliance with the LQR Threshold required under the Loan and Security Agreement.

On July 26, 2013, the Company entered into an Amendment to the Loan and Security Agreement (the Amendment ). In accordance with the Amendment, notwithstanding the existing LQR Thresholds, for so long as the Company is in compliance with the minimum revenue requirements established in this Amendment, the Company shall be permitted to maintain a liquidity ratio of not less than .90 to 1.00 for a continuous 60 day period every 12 months. In connection with the lower liquidity ratio, in accordance with the Amendment, under the Formula Revolving Line advances shall bear interest, on the outstanding balance thereof, at a variable rate equal to the greater of (A) 4.9% above the prime rate then in effect, and (B) 8.65%. Non-Formula Revolving Line advances shall bear interest, on the outstanding balance thereof, at a variable rate equal to the greater of (A) 5.15% above the prime rate then in effect, and (B) 8.9%, until such time that the lower liquidity ratio is no longer in place. The Company remained in compliance through the end of December of 2013, and as such the aggregate borrowing amount was increased from $3,000,000 to $5,000,000.

In connection with the Financing, the Company paid in full its existing credit facility with Amzak Capital Management, LLC (see Note 7 below) and executed a Release and Termination Note and Credit Agreement with Amzak Capital Management, LLC to release the Company from any future obligations under the Credit Agreement executed on December 21, 2010 (the *Amzak Credit Facility* ).

**7. Note Payable Related Party**

On December 21, 2010, the Company entered into a Credit Agreement with Amzak Capital Management, LLC (the *Lender* ) pursuant to which Amzak extended a $3,000,000 credit facility to the Company (the *Credit Agreement* ).

On August 31, 2012, the Company paid in full its existing credit facility with the Lender and executed a Release and Termination Note and Credit Agreement to release the Company from any future obligations under the Credit Agreement executed on December 21, 2010. In addition, the Company received the discharge of mortgage notification indicating the mortgage related to this credit agreement was satisfied and discharged. In connection with the release and termination agreement, the Company recorded amortization expense in the amount of $545,000 to write-off the remaining unamortized debt issuance costs.

Under the Credit Agreement the Company had agreed to certain covenants customarily found in such agreements including, but not limited to, a covenant prohibiting the Company from entering into a merger or acquisition of the Company without the prior consent of the Lender if any advances remain outstanding and a covenant requiring the Company to maintain a certain loan to collateral ratio.

The interest rate applicable to each promissory note was 14% per annum and interest payments were due on each March 31, June 30, September 30 and December 31 during the term of the Credit Agreement.

In addition, as consideration for entering into the Credit Agreement, on December 21, 2010, the Company issued to the Lender a ten-year warrant to purchase certain shares of the Company s common stock, at an exercise price of $0.01 per share (the *Warrant* ). The Warrant was immediately exercisable for 881,331 shares of Common Stock (the *Initial Warrant Shares* ) with the remaining shares of Common Stock representing 1% of the Fully Diluted Shares (as defined therein) as of the Conditional Warrant Exercise Date (as defined therein) (the *Conditional Warrant* ) became exercisable on July 1, 2012 if the Company had not achieved certain milestones related to the Company s product development or financial growth. The Warrant was accounted for as an equity instrument. The fair value of the Initial Warrant of $724,000 was recorded as debt issuance costs and amortized on a straight-line basis, which approximated the effective interest method, over the stated term of the Credit Agreement of five years. Amortization expense of $639,000 was recognized for the year ended December 31, 2012. In August of 2012, upon termination of the credit agreement, the unamortized portion of the initial warrant of $545,000 was recognized as interest expense.

The Initial Warrant for 881,331 shares was exercised on September 28, 2012. On December 21, 2010, the fair value of the Conditional Warrant was not considered to be material. As of December 31, 2012, the Company executed a settlement agreement with Amzak Capital Management, LLC in connection with the Conditional Warrant and issued to Amzak on December 21, 2010 a ten-year warrant to purchase up to 427,713 shares of its common stock, with an exercise price of $0.55 per share. The warrants were exercised in full on February 8, 2013. The Company recorded the fair value of the Conditional Warrant of $209,000 as debt issuance costs which was included in interest expense in 2012.

The Lender is a shareholder of the Company and participated in the private placement on December 8, 2010.

**8. Series A Convertible Preferred Stock**

On December 5, 2007, pursuant to a subscription agreement entered into with an accredited investor, the Company sold (i) 50 shares of Series A Convertible Preferred Stock with a liquidation preference of $10,000 per share, with each share of preferred stock, convertible into 10,000 shares of common stock of the Company, subject to customary adjustments; and (ii) a warrant to purchase 175,000 shares of common stock at an exercise price of $1.25 per share that expired on December 5, 2009, two years from issuance, for aggregate consideration of $500,000. A summary of significant terms is as follows:

Dividends- Series A Convertible Preferred Stock holders are not entitled to a dividend unless the Company declares and pays a cash dividend on the Common Stock. In that event, the holders of shares of Series A Preferred Stock shall be entitled to share in such dividends on a pro rata basis, as if their shares had been converted into shares of Common Stock.

Conversion- The Series A Convertible Preferred Stock is convertible, at the option of the holders, into shares of the Company s common stock at a conversion price of $1.00 per share. Based on the original purchase price of $10,000 per share of preferred, each share of Series A Convertible Preferred Stock is convertible into 10,000 shares of common stock. The Series A Convertible Preferred Stock also contains an automatic conversion wherein the shares will automatically convert into common shares when the closing price of the Company s common stock is $2.50 for ten (10) consecutive trading days.

Liquidation preference- The liquidation preference is $10,000 per share for a total of $500,000.

The Company has accounted for the Series A Convertible Preferred Stock in accordance with the provisions of ASC 815-10, Accounting for derivative instruments and hedging activities, and ASC 470-20, Accounting for debt instruments with specific conversion features . The Company has allocated the value received between the preferred stock and the related warrants. The allocated value for the preferred stock and the related warrants was approximately $475,000 and $25,000, respectively. In addition, the Company evaluated the shares and determined a beneficial conversion feature existed within this transaction, which totaled $55,000; the preferred stock was further discounted by this amount. The beneficial conversion amount related to the value of the preferred stock and the associated warrant was then accreted back to the preferred stock in accordance with the conversion provision, which allowed for 100% to be converted immediately. The accretion was reflected as an expense in 2007. The warrants have been classified as an equity instrument.

The Company has a total of 1,000,000 of authorized shares of preferred stock par value $0.01, including a total of 100 authorized shares of Series A Convertible Preferred Stock.

On September 5, 2013, at the option of the holder, all of the issued and outstanding shares of the Series A Convertible Preferred Stock, par value $0.01 per share, of the Company were converted into 500,000 shares of the Company s common stock, at a conversion price of $1.00 per share.

**9. Series C Convertible Preferred Stock 2010 Offering**

On March 29, 2010, the Company completed a $1,550,000 private placement with certain investors, including investment funds affiliated with Signet Healthcare Partners, G.P. and Jane E. Hager (the Series C Offering ). As part of the Series C Offering, the Company issued 1,550 shares of Series C Convertible Preferred Stock. The Series C Convertible Preferred Stock has a par value of $0.01 per share and the holders are entitled to quarterly dividends at an annual rate of 5%, when and if declared by the Board of Directors. Furthermore each share of Series C Convertible Preferred Stock is convertible into shares of common stock equal to (i) 1,000 plus any accrued and unpaid dividends, divided by (ii) $0.69 (the closing price of the Company s common stock on the date of issuance of the Series C Convertible Preferred Stock).

The Company has a total of 1,000,000 shares of authorized shares of preferred stock par value $0.01, including a total of 1,550 of the Series C Convertible Preferred Stock.

On December 6, 2013, the Company recognized a deemed dividend as a component of net loss attributable to common stockholders for the fair value of the additional shares issued to the former preferred stockholders, 415,118 shares of common stock at the conversion date or $1,308,000. All of the issued and outstanding shares of the Series C Convertible Preferred Stock, par value $0.01, of the Company, as well as accrued dividends of $1,308,000 automatically converted into an aggregate of 2,661,494 shares of the Company s common stock, par value $0.01 per share, in accordance with the terms and conditions set forth in the original Certificate of Designation of the Rights and Preferences of Series C Convertible Preferred Stock (the Certificate of Designation ), which specified a $0.69 conversion ratio.

Pursuant to the terms of the Certificate of Designation, the shares of Series C Preferred Stock automatically convert into shares of the Company s Common Stock upon the date that the closing price of the Company s Common Stock shall have exceeded three times the Closing Price on the Issuance Date for a period of twenty-five consecutive trading days immediately preceding such date. Accordingly, on December 6, 2013 all of the shares of Series C Convertible Preferred Stock automatically converted into shares of the Company s Common Stock.

**10. Stock Based Compensation**

The 1999 Director Stock Option Plan, as amended (the Director Plan ), provides for the grant of stock options to non-employee directors of the Company at an exercise price equal to the fair market value per share on the date of the grant. An aggregate of 1,975,000 shares have been approved and authorized for issuance pursuant to this plan. A total of 2,179,798 options have been granted to non-employee directors through December 31, 2013 and 727,782 of those have been forfeited through December 31, 2013 and returned to the option pool. The options granted under the Director Plan vest in full one year after their respective grant dates and have a maximum term of ten years.

The 1999 Stock Incentive Plan, as amended ( 1999 Plan ), replaced all previously authorized employee stock option plans, and no additional options may be granted under those previous plans. Under the 1999 Plan, options or stock awards may be granted to all of the Company's employees, officers, directors, consultants and advisors to purchase a maximum of 3,200,000 shares of common stock. However, pursuant to the terms of the 1999 Plan, no awards may be granted after March 16, 2009. A total of 2,892,500 options, having a maximum term of ten years, have been granted at 100% of the fair market value of the Company's common stock at the date of grant. Options outstanding under the 1999 Plan are generally exercisable in cumulative increments over four years commencing one year from date of grant.

On June 26, 2009, the Board of Directors adopted, and the Company s stockholders subsequently approved by partial written consent, the IGI Laboratories, Inc. 2009 Equity Incentive Plan (the 2009 Plan ). The 2009 Plan became effective on July 29, 2009. The 2009 Plan allows the Company to continue to grant options and restricted stock, as under the 1999 Plan, but also authorizes the Board of Directors to grant a broad range of other equity-based awards, including stock appreciation rights, restricted stock units and performance awards. The 2009 Plan has been created, pursuant to and consistent with the Company s current compensation philosophy, to assist the Company in attracting, retaining and rewarding designated employees, directors, consultants and other service providers of the Company and its subsidiaries and affiliates, in a manner that will be cost efficient to the Company from both an economic and financial accounting perspective. On April 12, 2010, the Board of Directors adopted, and the Company s stockholders subsequently approved, an amendment and restatement of the 2009 Plan to increase the number of shares of Common Stock available for grant under such plan by adding 2,000,000 shares of Common Stock. The 2009 Plan, as amended on May 19, 2010, authorizes up to 4,000,000 shares of the Company s common stock for issuance pursuant to the terms of the 2009 Plan. The maximum number of shares that may be subject to awards made to any individual in any single calendar year under the 2009 Plan is 1,000,000 shares. As of December 31, 2013, options to purchase 1,919,500 shares of common stock were outstanding under the 2009 Plan. As of December 31, 2013, 1,473,748 shares of restricted stock had been granted under the 2009 Plan and 230,420 of those have been forfeited through December 31, 2013 and returned to the pool.

In summary, there are 2,643,500 options outstanding under the 1999 Plan, The Director Plan and the 2009 Plan, collectively as of December 31, 2013.

Stock Options

There are 1,323,000 options available for issusance under the 1999 Plan, the Director Plan, and the 2009 Plan collectively as of December 31, 2013.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing formula that uses assumptions noted in the following table. Expected volatilities and risk-free interest rates are based upon the expected life of the grant.

| **Assumptions** | **2013** | **2012** |
|---|---|---|
| Dividend yield | 0% | 0% |
| Risk free interest rate | 0.48% | 0.39% |
| Estimated volatility factor | 36.9% 43.1% | 54.5% |
| Expected life | 3.2 3.3 years | 3.2 years |

Estimated volatility was calculated using the historical volatility of the Company s stock over the expected life of the options. The expected life of the options was estimated based on the Company s historical data. The forfeiture rates are estimated based on historical employment/directorship termination experience. The risk free interest rate is based on U.S. Treasury yields for securities with terms approximating the terms of the grants. The assumptions used in the Black-Scholes option valuation model are highly subjective, and can materially affect the resulting valuation.

Stock option transactions in each of the past two years under the aforementioned plans in total were:

| | Shares | Exercise Price Per Share | Weighted Average Exercise Price |
|---|---|---|---|
| January 1, 2012 shares issuable | | | |
| Under options | 1,448,016 | .55 - 1.74 | 1.16 |
| Granted | 1,551,000 | 1.02 - 1.18 | 1.05 |
| Exercised | (40,000) | .65 | 0.65 |
| Expired | (15,000) | .65 | 0.65 |
| Forfeited | (337,516) | .55 - 1.52 | 1.22 |
| December 31, 2012 shares issuable | | | |
| Under options | 2,606,500 | .55 - 1.74 | 1.10 |
| Granted | 247,000 | 1.04 - 3.03 | 1.35 |
| Exercised | (129,336) | 1.02 - 1.27 | 1.08 |
| Expired | | | |
| Forfeited | (80,664) | 1.10 - 1.74 | 1.30 |
| December 31, 2013 shares issuable | | | |
| Under options | 2,643,500 | .55 - 3.03 | 1.12 |
| Exercisable options at: | | | |
| December 31, 2013 | 1,452,496 | | $1.13 |
| December 31, 2012 | 951,001 | | $1.19 |

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2013:

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Price | Number of Options | Weighted Average Remaining Life (Years) | Weighted Average Exercise Price | Number of Options | Weighted Average Exercise Price |
| $ .55 to $1.00 | 218,000 | 4.83 | $ .76 | 214,000 | $ .75 |
| 1.01 to 2.00 | 2,418,000 | 7.90 | 1.14 | 1,238,496 | 1.19 |
| 2.01 to 3.03 | 7,500 | 9.87 | 2.83 | | |
| $ .55 to $3.03 | 2,643,500 | 7.65 | $1.12 | 1,452,496 | $1.13 |

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2012:

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Price | Number of Options | Weighted Average Remaining Life (Years) | Weighted Average Exercise Price | Number of Options | Weighted Average Exercise Price |
| $ .55 to $1.00 | 218,000 | 5.83 | $ .76 | 212,000 | $ .75 |
| 1.01 to 1.50 | 2,213,500 | 8.43 | 1.09 | 564,001 | 1.21 |
| 1.51 to 1.74 | 175,000 | 8.01 | 1.68 | 175,000 | 1.68 |
| $ .55 to $1.74 | 2,606,500 | 8.19 | $1.10 | 951,001 | $1.19 |

The Company has recorded an aggregate of $206,500 and $156,000 related to its stock option based expenses in cost of sales and selling, general and administrative expenses on the accompanying Statement of Operations for the years ended December 31, 2013 and 2012, respectively.

The aggregate intrinsic value of options outstanding was $5,109,925 at December 31, 2013 and $82,270 at December 31, 2012. The aggregate intrinsic value of the options exercisable was $2,789,901 at December 31, 2013 and $62,410 at December 31, 2012. The total intrinsic value of the options exercised during 2013 and 2012 was $254,779 and $15,600, respectively.

A summary of non-vested options at December 31, 2013 and changes during the year ended December 31, 2013 is presented below:

| | Options | Weighted Average Grant Date Fair Value |
|---|---|---|
| Non-vested options at January 1, 2013 | 1,655,499 | $ 0.32 |
| Granted | 247,000 | 0.38 |
| Vested | (656,831) | 0.33 |
| Forfeited | (54,664) | 0.37 |
| Non-vested options at December 31, 2013 | 1,191,004 | $ 0.32 |

As of December 31, 2013, there was $280,000 of total unrecognized compensation cost related to non-vested share-based compensation arrangements under the Plan. The costs will be recognized through November 2016.

Restricted Stock

The Company periodically grants restricted stock awards to certain officers and other employees that typically vest one to three years from their grant date. On December 30, 2013, in accordance with the terms of the employment agreement between Jason Grenfell-Gardner, President and CEO, and the Company excecuted on July 30, 2012, a restricted stock award in the amount of 325,000 shares was granted to Jason Grenfell-Gardner, with one third of the shares of restricted stock vested on December 30, 2013, and the remaining two thirds of the shares of restricted stock vesting in equal amounts on July 30, 2014 and July 30, 2015. The Company recognized $329,400 and $222,000, respectively, of compensation expense during the years ended December 31, 2013 and 2012 related to restricted stock awards. Stock compensation expense is recognized over the vesting period of the restricted stock. At December 31, 2013, the Company had approximately $621,300 of total unrecognized compensation cost related to non-vested restricted stock, all of which will be recognized through December 2015.

| | Number of Restricted Stock | Weighted Average Exercise Price |
|---|---|---|
| Non-vested balance at January 1, 2012 | 626,000 | $ 0.71 |
| Changes during the period: | | |
| Shares granted | 109,748 | 1.00 |
| Shares vested | (529,330) | 0.76 |
| Shares forfeited | (177,084) | 0.70 |
| Non-vested balance at January 1, 2013 | 29,334 | $ 1.00 |
| Changes during the period: | | |
| Shares granted | 325,000 | 2.86 |
| Shares vested | (108,333) | 2.86 |
| Shares forfeited | | |
| Non-vested balance at December 31, 2013 | 246,001 | $ 2.64 |

**11. Stock Warrants**

Stock Warrants as of December 31, 2013 and 2012 consisted of:

| | 2013 | | 2012 | |
|---|---|---|---|---|
| | Warrants | Weighted Average Exercise Price | Warrants | Weighted Average Exercise Price |
| Beginning balance | 782,259 | $0.85 | 1,235,877 | $0.35 |
| Stock warrants granted | | | 814,914 | 0.29 |
| Stock warrants expired | | | | |
| Stock warrants exercised | (427,713) | 0.55 | (1,268,532) | 0.01 |
| Ending balance | 354,546 | $1.21 | 782,259 | $0.85 |

In connection with the private placement of the Company s Common Stock on December 8, 2010, the Company granted common stock warrants to purchase 338,182 and 16,364 shares, respectively, to each of its two placement agents for $1.21 per share which expire on December 8, 2015.

In connection with the Credit Agreement with Amzak Capital Management, LLC as more fully described in Note 7, on December 10, 2010, the Company issued a ten-year warrant to purchase 881,331 shares of the Company s Common Stock for $0.01 per share. The warrant was exercised in full on September 28, 2012.

In connection with the private placement of the Company s common stock in 2012, the Company granted common stock warrants to purchase 387,201 shares for $0.01 per share, which expire December 2022. The warrants were exercised in full on December 27, 2012.

The Company executed as of December 31, 2012 a settlement agreement with Amzak Capital Management, LLC ( Amzak ) in connection with a common stock purchase warrant issued to Amzak on December 21, 2012 under which the Company issued a ten-year warrant to purchase up to 427,713 shares of the Company s common stock, with an exercise price of $0.55 per share. The warrant was exercised in full on February 8, 2013. The amount of the fair value of the warrant issued was $209,000, and included as interest expense in 2012, as it related to the credit agreement

which was terminated in August of 2012.

**12. Income Taxes**

The Company s current tax benefit was $197,000 and $184,000 for the year ended December 31, 2013 and 2012, respectively. The (benefit) from income taxes attributable to loss from continuing operations before (benefit) from income taxes for the years ended December 31, 2013 and 2012 is as follows:

| | 2013 | 2012 |
|---|---|---|
| | (in thousands) | |
| Current tax expense (benefit): | | |
| Federal | $ | $ |
| State and local | (197) | (184) |
| Total current tax expense (benefit) | (197) | (184) |
| Deferred tax expense | | |
| Federal | | |
| State and local | | |
| Total deferred tax expense | | |
| Total expense (benefit) from income taxes | $ (197) | $ (184) |

The Company sold some of its New Jersey operating loss carry forwards under a program of the New Jersey Economic Development Authority (NJEDA) in exchange for net proceeds of $197,000 and $189,000 in 2013 and 2012 respectively. In order to realize these benefits, the Company must apply to the NJEDA each year and must meet various requirements for continued eligibility. In addition, the program must continue to be funded by the state of New Jersey, and there are limitations based on the level of participation by other companies. Since these specific sale transactions are subject to approval by the NJEDA, the Company recognizes the associated tax benefits in the financial statements as they are approved.

The (benefit) from income taxes differed from the amount of income taxes determined by applying the applicable federal tax rate (34%) to pretax loss from continuing operations as a result of the following:

| | 2013 | 2012 |
|---|---|---|
| | (in thousands) | |
| Statutory benefit | $ (95) | $ (1,381) |
| Other non-deductible expenses | 2 | 1 |
| Increase in federal valuation allowance | 30 | 1,317 |
| Sale of New Jersey net operating loss carry forward | (197) | (189) |
| Federal tax impact of state tax benefit, net | 63 | 68 |
| | $ (197) | $ (184) |

Deferred tax assets included in the Consolidated Balance Sheets as of December 31, 2013 and 2012 consisted of the following:

| | 2013 | 2012 |
|---|---|---|
| | (in thousands) | |
| Current Assets | | |
| Allowance for doubtful accounts | $ 6 | $ 6 |
| Inventory reserve | 115 | 45 |
| Other | 161 | 151 |
| Total Current Assets | 282 | 202 |
| | | |
| Long Term Assets (Liabilities) | | |
| Property, plant and equipment | 209 | 203 |
| Deferred royalty payments | 5 | 10 |
| Tax operating loss carry forwards | 10,672 | 11,101 |
| Tax credit carry forwards | 217 | 225 |
| Non-employee stock options | 685 | 625 |

| | | |
|---|---|---|
| Other | (8) | (8) |
| Total Long Term Assets (Liabilities) | 11,780 | 12,156 |
| Gross Deferred Tax Asset (Liability) | 12,062 | 12,358 |
| Less: valuation allowance | (12,062) | (12,358) |
| Deferred taxes, net | $ | $ |

The Company evaluates the recoverability of its deferred tax assets based on its history of operating earnings, its plan to sell the benefit of certain state net operating loss carry forwards, its expectations for the future, and the expiration dates of the net operating loss carry forwards. The Company has concluded that it is more likely than not that it will be unable to realize the gross deferred tax assets in the immediate future and has established a valuation allowance for all such deferred tax assets. Accordingly, the Company has provided a valuation allowance of $12.1 million and $12.4 million for the years ended December 31, 2013 and 2012, respectively, on the deferred tax assets relating to these net operating loss carry forwards.

Operating loss and tax credit carry forwards for tax reporting purposes as of December 31, 2013 were as follows:

| | (in thousands) |
|---|---|
| Federal: | |
| Operating losses (expiring through 2032) | $ 31,308 |
| Research tax credits (expiring through 2025) | 168 |
| Alternative minimum tax credits (available without expiration) | 28 |
| State: | |
| Net operating losses Tennessee (expiring in 2027) | 425 |
| Alternative minimum assessment New Jersey (available without expiration) | 21 |

Federal net operating loss carry forwards that expire through 2032 have significant components expiring in 2020 (21%), 2029 (11%), 2030 (11%), 2031 (9%) and 2032 (12%).

The Company s ability to use net operating loss carry forwards may be subject to substantial limitation in future periods under certain provisions of Section 382 of the Internal Revenue Code, which limit the utilization of net operating losses upon a more than 50% change in ownership of the Company s stock that is held by 5% or greater stockholders. The Company examined the application of Section 382 with respect to an ownership change that took place during 2009 and 2010, as well as the possibility of such limitation having any material effect on the application of net operating loss carry forwards in the immediate future. The Company believes that it is likely that a change in ownership took place and that the net operating loss carry forwards will be limited.

The Company complies with ASC 740-10-25 and there was no effect on the Company s consolidated financial position and results of operations. Accordingly, there is no interest and penalties recorded on the balance sheet for such reserves. The Company is currently open to audit under the statute of limitations by the Internal Revenue Service and the appropriate state income taxing authorities for the tax years 2009 to 2012 due to the net loss carry forwards from those years.

**13. Lease Commitments**

The Company s commitments and contingencies consisted of operating leases for warehouse space and equipment of $95,800 for 2014, $97,200 for 2015, $98,700 for 2016, $98,700 for 2017 and $34,200 for 2018. Rent expense was $121,700 and $66,900 for the years ended December 31, 2013 and 2012, respectively.

**14. Legal and U.S. Regulatory Proceedings**

On March 2, 2001, the Company became aware of environmental contamination resulting from an unknown heating oil leak at its former manufacturing facility. The Company immediately notified the New Jersey Department of Environmental Protection (NJ DEP) and the local authorities, and hired a contractor to assess the exposure and required clean up. The total estimated costs for the clean-up and remediation is $739,000, of which approximately $6,000 remains accrued as of December 31, 2013. Based on information provided to the Company from its environmental consultant and what is known to date, the Company believes the reserve is sufficient for the remaining remediation of the environmental contamination. There is a possibility, however, that the remediation costs may exceed the Company s estimates.

The restricted cash on the Consolidated Balance Sheet of $54,000 as of December 31, 2013 and 2012 represents a restricted escrow account set up on the requirement of the NJ DEP for the soil remediation work. These funds will be released to the Company upon the DEP approval when the remediation is completed.

On December 19, 2013, we filed a complaint in the United States District Court for the District of Delaware against Mallinckrodt LLC, Mallinckrodt, Inc. and Nuvo Research Inc. (collectively, Mallinckrodt ) seeking a declaration of non-infringement of United States Patent Nos. 8,217,078 and 8,546,450 so that we can bring our generic diclofenac sodium topical solution 1.5% to market at the earliest possible date under applicable statutory and FDA regulatory provisions.

On January 10, 2014, Mallinckrodt filed an answer and counterclaim alleging that the Company infringes the patents at issue. On January 28, 2014, we filed a motion to dismiss Mallinckrodt s counterclaim and, on March 5, 2014, Mallinckrodt filed an opposition to such motion. The court has not yet rendered a decision. The Company believes the complaint has merit, and the Company intends to continue to pursue Mallinckrodt. Based on the early stage of this complaint and counterclaim the Company is unable to predict the outcome.

**15. Employee Benefits**

The Company has a 401(k) contribution plan, pursuant to which employees may elect to contribute to the plan, in whole percentages, up to 100% of compensation. Employees contributions are subject to a minimum contribution by participants of 1% of compensation and a maximum contribution of $17,500 for 2013 and $17,000 for 2012, plus a catch-up contribution of up to $5,500 for 2013 and 2012, if a participant qualifies. The Company matches 100% of the first 3% of compensation contributed by participants and 50% of the next 2% of compensation contributed by participants. The Company contribution is in the form of cash, which is vested immediately. The Company has recorded charges to expense related to this plan of approximately $93,000 and $71,000 in 2013 and 2012, respectively.

**16. Related Party Transactions**

For a description of the Company s Private Placement and Credit Agreement with Amzak Capital Management, LLC, the related party, see Notes 7 and 17.

**17. 2012 Private Placement**

On December 21, 2012, the Company, closed a $2,000,000 private placement (the ***Offering*** ) with Amzak Capital Management, LLC (the ***Investor*** ). Pursuant to the terms of a Securities Purchase Agreement entered into with the Investor (the ***Purchase Agreement*** ) on December 20, 2012, the Company issued to the Investor (i) 1,965,740 shares of the Company common stock, held in treasury (the ***Shares*** ), and (ii) a ten-year warrant to purchase up to an aggregate of 387,201 shares of the Company common stock, with an exercise price of $0.01 per share (the ***Warrants*** ). The Warrants are exercisable immediately. The Company used the proceeds from this Offering to for general working capital as well as the acquisition of econozale nitrate cream 1% which was purchased on February 1, 2013.

In connection with the Offering, the Company also entered into a registration rights agreement (the ***Registration Rights Agreement*** ), dated as of December 20, 2012, with the Investor, relating to the registration of the Shares, the Warrants and the shares of common stock issuable upon the exercise of the Warrants, issued in connection with the Offering (the ***Registrable Shares*** ). The Registration Rights Agreement provides that the Company will file a resale registration statement (the ***InitialRegistration Statement*** ) covering all of the Registrable Shares within six months of the date of the Registration Rights Agreement and that such Initial Registration Statement shall be declared effective within nine months of the date of the Registration Rights Agreement, subject to certain limitations. Further, the Company has agreed to pay the Investor specified cash payments as partial liquidated damages in the event the Initial Registration Statement is not declared effective by the Securities and Exchange Commission (the ***SEC*** )within the

specified timeframe. The Initial Registration Statement was filed with the SEC on May 9, 2013, within six months of the date of the Registration Rights Agreement and became effective on May 13, 2013, within nine months of the date of the Registration Rights Agreement.

**18. Asset Purchase Agreement**

On February 1, 2013, the Company entered into an Asset Purchase Agreement (the ***Purchase Agreement***) with Prasco, LLC, an Ohio limited liability company (***Prasco***), pursuant to which the Company purchased from Prasco assets associated with econazole nitrate cream 1% (the ***Product***), which is available in 15g, 30g, and 85g tubes has United States Food and Drug Administration approved indications for the treatment of tinea pedis, tinea cruris, and tinea corporis as well as the treatment of cutaneous candidiasis and tinea versicolor.

In consideration for the purchase of the assets pursuant to the Purchase Agreement, the Company paid Prasco $1.4 million in cash and paid an additional aggregate of $400,000 upon the occurrence of the milestone events (the ***Milestone Payment***). The Milestone Payment is secured by a first-priority security interest in the acquired assets under the Purchase Agreement. The transaction is accounted for as a purchase of the product and product rights, and as such the initial payment, milestone payment and related costs to acquire the asset are included as part of product acquisition costs totaling $1.8 million. The Company capitalized and amortized the costs over fifteen years, the useful life of the acquired product and product rights.

Under and subject to the terms and conditions of the Purchase Agreement, Prasco continued to distribute the Product during a six-month period following the closing of the Purchase Agreement, and the Company completed the technical transfer of the Product and begun manufacturing the Product under its own label during the third quarter of 2013. The Company s product sales in the third quarter included sales of the product.

In addition, the Purchase Agreement contains certain non-compete restrictions preventing Prasco from selling the Product in United States for a period of seven years.

On October 23, 2013, the Company announced that it had received formal approval from the U.S. Food and Drug Administration (FDA) for the CBE-30 supplemental filing to approve the site transfer of the Econazole nitrate cream 1%, to the Company s manufacturing facility in Buena, NJ.

**19. Subsequent Events**

On March 3, 2014, the Company submitted its ANDA in 2014 to the FDA, which brings the Company s total number of ANDA submissions to fourteen.

On March 12, 2014, the Company received its first approval from the FDA for an ANDA. The FDA has approved IGI's application for lidocaine hydrochloride USP 4% topical solution. Lidocaine hydrochloride USP 4% topical solution is indicated for the production of topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract.

On March 25, 2014, the Board of Directors of the Company, at the recommendation of its Organization and Compensation Committee, resolved to award a cash bonus in the amount of $75,000 to its President and Chief Executive Officer, Jason Grenfell-Gardner. Mr. Grenfell-Gardner is also a director of the Company.

On March 31, 2014, the Company filed a Form 8-K disclosing that on March 25, 2014, Joyce Erony, a director and the chairperson of the IGI Laboratories, Inc. s Board of Directors, advised us that she will not stand for re-election as a director at the Company s annual meeting to be held on May 27, 2014. Also included in the 8-K, was the announcement that on March 28, 2014, Michael B. Hemric advised the Company that he will be resigning as a director of the Company s Board of Directors effective April 1, 2014. We have begun the interview process to appoint new directors to the Company s Board.