

IGI LABORATORIES, INC  
Form 10-K  
March 28, 2013

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2012**

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**  
(State or other jurisdiction of  
incorporation or organization)

**105 Lincoln Ave., Buena, NJ**  
(Address of principal executive offices)

**01-0355758**  
(I.R.S. Employer  
Identification No.)

**08310**  
(Zip Code)

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

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
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

Indicate by check if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Yes  No

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  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  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  Smaller reporting company

[Do not check if a smaller  
reporting company]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes  No

The aggregate market value of the 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 30, 2012 was approximately \$23.6 million.

As of March 25, 2013, there were 43,132,745 shares of the registrant's common stock outstanding.

#### **DOCUMENTS INCORPORATE 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 22, 2013.

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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.

Our strategy is based on three initiatives:

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

Increasing our current contract manufacturing and development business; and,

Creating 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 nine 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 six ANDAs per year 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.

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**

During the first six months of 2012, we entered into supply agreements with two new customers. Both agreements call for the Company to manufacture and package topical pharmaceutical products. Under the first agreement with a brand pharmaceutical company, Akorn, Inc., we successfully completed the site transfer of a branded topical drug product, EMLA® Cream (lidocaine 2.5% and prilocaine 2.5%) in 5g and 30g tubes to our facility in Buena, NJ. We are now the sole manufacturing and packaging site for the product. Under the second agreement, we developed generic versions of two topical drug products and in December 2012, we filed two ANDAs on behalf of our pharmaceutical partners. Upon FDA approval, we will manufacture and package the products under the customer's label.

In November 2012, we gained authorization to launch our first IGI label topical prescription products. We also executed an agreement to partner with DDN, under which DDN provides us launch support, logistics support and order to cash services. We launched our first IGI labeled product in December 2012, and we launched two more IGI labeled products in January of 2013.

On December 19, 2012, we appointed Dr. Kenneth Miller as Senior Vice President of Research and Development. Dr. Miller brings over twenty years of topical and transdermal experience in both branded and generic pharmaceutical product development. Prior to joining IGI, Dr. Miller held various leadership positions at Mylan Technologies (formerly Bertek Inc.) eventually rising to Senior Director in 2008. In his role as head of product development, Dr. Miller oversaw the development of Mylan Technologies' topical and transdermal patches including Mylan's Fentanyl Transdermal System which received the DIANA Award for Best New Product Introduction in 2005.





On December 21, 2012, we closed a \$2,000,000 private placement, or the offering, with Amzak Capital Management, LLC, or Amzak. Pursuant to the terms of a securities purchase agreement entered into with Amzak, or the securities purchase agreement, on December 20, 2012, we issued to Amzak (i) 1,965,740 shares of our common stock, par value \$0.01 per share, held in treasury, or the Shares and (ii) a ten-year warrant to purchase up to an aggregate of 387,201 shares of our common stock, with an exercise price of \$0.01 per share, or the warrants. The warrants, which were exercisable immediately, were exercised by Amzak on December 27, 2012. In addition, we executed as of December 31, 2012 a settlement agreement with Amzak Capital Management, LLC in connection with a common stock purchase warrant we issued to Amzak on December 21, 2012 under which we issued a ten-year warrant to purchase up to 427,713 shares of our common stock, with an exercise price of \$0.55 per share. The warrants were exercised in full on February 8, 2013.

On February 1, 2013, we entered into an Asset Purchase Agreement, or the purchase agreement, with Prasco, LLC, an Ohio limited liability company, or Prasco, pursuant to which we purchased from Prasco assets associated with econazole nitrate cream 1% which is available in 15g, 30g, and 85g tubes and 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. In consideration for the purchase of the assets pursuant to the purchase agreement, we paid Prasco \$1.4 million in cash and will be required to pay an additional aggregate of \$400,000 upon the occurrence of certain milestone events, or the milestone payment. The milestone payment is secured by a first-priority security interest in the acquired assets under the purchase agreement. Under and subject to the terms and conditions of the purchase agreement, Prasco will continue to distribute the product during a six-month period following the closing of the purchase agreement or for a shorter period if we have completed the technical transfer of the product and begun manufacturing the product under our own label.

On February 15, 2013, we entered into a three-year agreement with Juventio, LLC 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 for which we currently hold an exclusive license.

## **Our Services and Products**

### *IGI's Generic Pharmaceutical Business*

IGI has been in the contract manufacturing and development business for several years, offering both 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 nine ANDAs, all for further expansion of our generic topical pharmaceutical portfolio of prescription products.

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 our state licensing requirements, implemented our procedures with our third-party logistics partner, designed our sales order to cash administrative processes and added of 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. To date, we have three products in our generic portfolio which are being manufactured, marketed and distributed by IGI.

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 15 g, 30 g, and 85 g tubes, and 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. Upon approval from the FDA of the manufacturing site transfer, we intend to manufacture the product at our Company's facility in Buena, NJ, and distribute the product in an IGI label. There is no assurance that the FDA will approve the manufacturing site transfer.

Our strategy is focused on the growth of our generic pharmaceutical business. We have filed nine ANDAs to date, and we have a number of additional product candidates in various stages of development. The addressable market, based on November 2012 IMS Health Reports data for the products we have pending at the FDA, totals approximately \$280 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 six ANDAs per year 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 2,500 applications. The Generic Drug User Fee Amendment (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. IMS Health reports the US topical pharmaceutical market at \$9 billion in annual sales, of which generics make up \$2.5 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.

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. However the ANDA sponsor must demonstrate bioequivalence to the innovator drug product. For topical drugs there are two means of addressing bioequivalence: by requesting a waiver from the FDA for certain older products and solutions, or by performing comparative clinical trials against the innovator products. Over time, we intend to develop and submit ANDAs, and eventually market bioequivalent topical drugs by other means.

#### *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 addition, 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 quality contract manufacturing and development business provides a consistent and reliable source for products and services 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 can be highly hydrophobic or 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.

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.

### **Our Competitive Strategy**

Our goal is to become a leading provider and developer of generic topical prescription drug products. 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 devoted to 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 manufacturing to expand our own generic topical prescription drug portfolio. Through the ANDA process, we target to develop at least six topical products annually for the foreseeable future and ultimately 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 the flexibility to manufacture 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.

*Diversify our Revenues.* In 2012, the majority of our revenue is generated from our contract services and licensing of the Novasome® technology platform. We intend to diversify the sources of our income by increasing our focus on the identification, development, manufacturing and sales of our own generic topical prescription products. We believe that growth of the pharmaceutical market and the relatively few competitors in the topical generic market, present attractive revenue growth and diversification opportunities for us.

## **Our Customers**

We have successfully broadened our customer base for our contract manufacturing and development business to increase our revenue growth. In 2012, we significantly 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 of 2012 we filed two ANDAs on behalf of one of these pharmaceutical partners. Under our agreement, if and when the ANDAs are approved by the FDA we will be the manufacturer of those topical pharmaceutical products.

Our customers in the contract manufacturing business are pharmaceutical companies cosmetic, cosmeceutical and OTC product marketers who require product development/manufacturing support. In 2012, approximately forty-seven percent of our revenue was derived from pharmaceutical customers, as compared to thirty-seven percent of total contract manufacturing revenue in 2011. We are focused on adding products and customers for our contract services business with a specific emphasis on pharmaceutical products and partners. As we launched our first IGI labeled product in December 2012, sales of our products were not significant for the year ended December 31, 2012, however we do expect sales of our generic prescription drug products to be a more significant portion of our revenue in 2013.

## **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, from simple solutions to complex creams, lotions and gels. All ANDA development is conducted in-house except for bioequivalence testing, which is performed by qualified contract research organization.

In December 2012, we appointed Dr. Kenneth Miller as Senior Vice President of Research and Development. Dr. Miller brings over twenty years of topical and transdermal experience in both branded and generic pharmaceutical product development.

We have been steadily increasing our investment in R&D as we believe that R&D is the future of IGI. We spent \$2.8 million and \$2.1 million on R&D expenses in 2012 and 2011, respectively.

### **Sales and Marketing**

Our generic topical prescription drug products are marketed to national chain drug stores and drug wholesalers and distributors. In the second half of 2012, we established our commercial infrastructure that allows us to make, sell, distribute and market our IGI label generic products. This included our finalization of all our state licensing requirements, the implementation of our procedures with our third-party logistics partner, the design of our sales order to cash administrative processes and the addition of our first 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 seventy percent (70%) of the generic topical market by value. 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 Group Inc. (formerly Harmony Labs, Inc.) Although this market is competitive, the competition is somewhat 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 skills and technology for development of 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, but unscheduled FDA inspection to assure our facilities, procedures, raw materials and finished products remain in compliance with cGMP regulations. In addition to these general inspections, 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 March 2011 and February 2012.

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.

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 have outpaced inflation.

## **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.

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 2.8 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 ointments, creams, lotions, gels and liquids. 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 as both a drug and medical device manufacturer. We believe that our facility and equipment are in good condition, are well maintained and are able to operate at planned 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, 2012, we had a total of 41 full-time employees. In addition, as the need arises, we occasionally utilize short-term, part-time employees who are paid on an hourly basis. 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, 2012, our stockholders' equity was \$6.4 million and we had an accumulated deficit of \$43.4 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.

***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 will 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 us 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 had \$2.0 million available funds under an existing line of credit at December 31, 2012. We drew down an additional \$1.0 million in principal amount in February of 2013.

***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 three months ended December 31, 2012 and 2011, three of our customers accounted for 74% and three of our customers accounted for 70% of our revenue, respectively. For the year ended December 31, 2012 and 2011, two of our customers accounted for 54% of our revenue, respectively. The loss of one or more of these customers could have a significant impact on our revenues and harm our business and results of operations.

***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.

***We face increased financial risk from the inaccurate pricing of our agreements.***

Since our product development agreements are often structured as fixed-price agreements, we bear the financial risk if we initially under-price our agreements or otherwise over-run our cost estimates. Such under-pricing or significant cost overruns could have a material adverse effect on our business, results of operations, financial condition, and cash flows. Further, the period of revenue recognition under such agreements are based upon the timing of work performed or completed.

***Lack of availability of, 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, bulk tablets 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, bulk tablets 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. Any future recall or removal would result in additional costs to us, and may give rise to product liability 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 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 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 \$25,000 remains accrued as of December 31, 2012. The remediation and disposal on the second facility was completed in 2011 at a cost of approximately \$61,000. We received a No Further Action Letter from the New Jersey Department of Environmental Protection on May 23, 2011. 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 listed 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 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 facilities, maintenance, 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 or receipt of raw materials, 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, particularly the FDA. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, injunctive 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 generic pharmaceutical product may be marketed, it must be approved by the FDA, 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 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, 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.

***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, 2012, the average daily trading volume of our shares of common stock on the NYSE MKT was approximately 13,402 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 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, 2012 and December 31, 2011, 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 64.7% 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.

***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 \$1.80 in the first quarter of 2011. 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.

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.

***If the holders of our Series A Convertible Preferred Stock, Series C Convertible Preferred Stock, options and warrants to purchase common stock exercise their conversion rights, our common stock will be diluted.***

We have outstanding shares of Series A Convertible Preferred Stock and Series C Convertible Preferred Stock, as well as outstanding options and warrants to purchase shares of our common stock. If all or any number of these holders of derivative securities were to exercise their conversion rights, our common stock would be substantially diluted, which could negatively impact our stock price.

*Our shares of preferred stock have preferences over our shares of common stock under certain circumstances.*

In the event of our liquidation, dissolution or winding up, including a change in control of our company, the holders of our shares of Series A Preferred Stock then outstanding shall be entitled to receive an amount equal to \$10,000 per share of the Series A Preferred Stock before any payment shall be made or any assets distributed to the holders of our common stock. In addition, upon a liquidation event (such as the liquidation, dissolution or winding up of our affairs, whether voluntary or involuntary, or a consolidation or merger of us with or into any other corporation or corporations, or a sale of all or substantially all of our assets, or the effectuation by us of a transaction or series of transactions in which more than 50% of our voting shares are disposed of or conveyed), the holders of our shares of Series C Convertible Preferred Stock then outstanding shall be paid out of our assets available for distribution to stockholders, an amount equal to the greater of (i) \$1,000 per share (subject to appropriate adjustment to reflect any stock split, stock dividend, reverse stock split or similar corporate event affecting the Series C Convertible Preferred Stock) plus any accrued but unpaid dividends, whether or not declared, and any other declared but unpaid dividends and (ii) such amount per share of Series C Convertible Preferred Stock as would have been payable had each share been converted to common stock pursuant immediately prior to the Liquidation Event, before any payment shall be made to the holders of common stock or any other junior stock but after any payment has been made to the holders of Series A Preferred Stock or any other senior stock.

**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 2.8 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.

**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: IGI ).

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

	<u>High</u>	<u>Low</u>
<b><u>2012</u></b>		
First quarter	\$1.34	\$1.02
Second quarter	1.12	0.94
Third quarter	1.48	0.98
Fourth quarter	1.30	0.98
<b><u>2011</u></b>		
First quarter	\$1.80	\$1.50
Second quarter	1.54	0.99
Third quarter	1.15	0.85
Fourth quarter	1.20	0.97

**Stockholders**

The approximate number of holders of record of the Company's 43,132,745 shares of common stock outstanding at March 22, 2013 was 582 (not including stockholders for whom shares are held in a nominee or street name).

**Dividend**

The Company never paid cash dividends to its 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**

We executed as of December 31, 2012 a settlement agreement with Amzak Capital Management, LLC in connection with a common stock purchase warrant we issued to Amzak on December 21, 2010 under which we issued a ten-year warrant to purchase up to 427,713 shares of our common stock, with an exercise price of \$0.55 per share. The warrants were exercised in full on February 8, 2013.

### **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 identify 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 three initiatives:

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

Increasing our current contract manufacturing and development business; and,

Creating 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 nine 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, and one in January 2013. All of the submissions are for generic topical prescription drugs. 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 six ANDAs per year 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 new President and CEO, Senior Vice President of Research 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 2012 Compared to Fiscal Year 2011*

We had a net loss of \$3,927,000, or \$(0.10) per share, in 2012 compared to a net loss of \$3,007,000, or \$(0.08) per share, in 2011 which resulted from the following:

<u>Revenues</u>	<u>For the years ended</u>		<u>\$ change</u>	<u>% change</u>
	<u>December 31, 2012</u>	<u>December 31, 2011</u>		
	<i>(in thousands)</i>			
Product sales, net	\$6,545	\$6,729	\$ (184)	(3)%
Research and development income	1,931	921	1,010	110 %
Licensing, royalty and other income	87	156	(69)	(44)%
Total Revenues	\$8,563	\$7,806	\$ 757	10 %

The decrease in product sales for the year ended December 31, 2012 as compared to the same period in 2011 was primarily due to decreased annual product sales to one of our major cosmetic customers, which was only partially offset by increased sales to two of our new major 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 increase in research and development income during the year ended December 31, 2012 as compared to the same period in 2011 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. Licensing and royalty income decreased due to the decrease in sales of Novasome® based products marketed by our licensees. We believe the loss of certain royalties is related to the normal life cycle of the products and that certain royalties of the Company

may continue to decline.

<u>Cost of Sales</u>	<u>For the years ended</u>		<u>\$ change</u>	<u>% change</u>
	<u>December 31, 2012</u>	<u>December 31, 2011</u>		
	<i>(in thousands)</i>			
Cost of Sales	\$5,787	\$5,546	\$241	4%

Cost of sales increased for the year ended December 31, 2012 as a result of the increase in total revenue of 10%. Cost of sales as a percentage of total revenue was 68% for the year ended December 31, 2012 as compared to 71% for the year ended December 31, 2011. Cost of sales as a percentage of total revenue declined as a result of a shift in the mix of our product sales to include greater higher margin pharmaceutical products, and our increase in revenue from research and development services rendered in 2012. We expect cost of sales as a percentage of revenue to decline over time.

<u>Operating Expenses</u>	<u>For the years ended</u>		<u>\$ change</u>	<u>% change</u>
	<u>December 31, 2012</u>	<u>December 31, 2011</u>		
	<i>(in thousands)</i>			
Selling, general and administrative expenses	\$3,078	\$3,078	\$ 0	0%
Product development and research expense	\$2,834	\$2,151	\$683	32%

Selling, general and administrative expenses for the year ended December 31, 2012 remained unchanged as compared to the same period in 2011. There were increases in severance payments of \$150,000 and recruiting fees of \$152,000 in 2012 as compared to 2011 due to the changes to the executive and senior management team in 2012. These increases were partially offset by a decrease of \$124,000 in the allocation of overhead costs due to the increases in headcount in the departments outside of the selling and administrative functions, a decrease in consulting fees of \$60,000, a decrease in our listing fee of \$12,000 and a \$100,000 decrease in professional fees, as a result of decreased transactions requiring outside counsel.

As we created our pharmaceutical foundation, transitioning from a contract manufacturer to a generic topical pharmaceutical company, product development and research expenses for the year ended December 31, 2012 increased as compared to the same period for 2011. Consistent with our strategy to expand our portfolio of generic prescription topical pharmaceutical products, we increased spending on clinical studies, outside testing and supplies by \$0.2 million, and increased headcount, which resulted in an increase of \$0.1 million in salaries and related costs. In addition we incurred approximately \$0.3 million in fees related to the Generic Drug User Fee Act, of which approximately \$50,000 were reimbursed by our customer in 2013.

<b><u>Interest income (expense), net</u></b>	<b><u>For the years ended</u></b>		<b><u>\$ change</u></b>	<b><u>% change</u></b>
	<b><u>December 31, 2012</u></b>	<b><u>December 31, 2011</u></b>		
	<i>(in thousands)</i>			
Interest income and other income (expense), net	\$ (13)	\$ 17	\$ (30)	(176)%
Interest expense	\$962	\$281	\$681	242 %

Other income and expense decreased for the year ended December 31, 2012 as compared to the same period in 2011 due to decreased interest income of \$14,000 as a result of reduced average cash balances in 2012 and approximately \$11,000 of other expenses incurred in 2012 related to the write off of some capital equipment. Interest expense increased for the year ended December 31, 2012 as compared to 2011 due to the inclusion in 2012 of approximately \$545,000 of amortization of debt issuance costs related to the Note Payable Related Party that was paid in full and terminated on August 31, 2012 and \$209,000 of expense in 2012 related to the issuance to Amzak conditional warrants to purchase 427,713 shares of our common stock. On the same day, we entered into a Loan and Security Agreement with Square 1 Bank pursuant to which the Lender agreed to extend credit facilities to the Company, not to exceed total borrowings of \$3.0 million. The interest rate in effect for the new line of credit at December 31, 2012 was 6.15%, compared to the interest rate on the terminated facility of 14%.

<b><u>Income Taxes</u></b>	<b><u>For the years ended</u></b>		<b><u>\$ change</u></b>	<b><u>% change</u></b>
	<b><u>December 31, 2012</u></b>	<b><u>December 31, 2011</u></b>		
	<i>(in thousands)</i>			
Income Taxes	\$184	\$226	\$ (42)	(19)%

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The tax benefit of \$184,000 in 2012 and \$226,000 in 2011 was the 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.

<u>Net loss</u>	<u>For the years ended</u>		<u>\$ change</u>	<u>% change</u>
	<u>December 31, 2012</u>	<u>December 31, 2011</u>		
	<i>(in thousands, except per share numbers)</i>			
Net loss	\$ (3,927)	\$ (3,007)	\$ 920	31%
Net loss per share	\$ (0.10)	\$ (0.08)	\$0.02	25%

The increase in net loss attributable to common stockholders for the year ended December 31, 2012 as compared to the same period in 2011 is primarily due to the increased research and development expenses and non-cash interest charges incurred related to the Note Payable - Related Party noted above.

## 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. As described more fully in the Notes to our Consolidated Financial Statements appear elsewhere in this Annual Report on Form 10-K, we raised an aggregate of approximately \$2,000,000 through private placements of equity with accredited investors in 2012. The use of proceeds was intended for general working capital needs as well as the acquisition of econozale nitrate cream 1% which was purchased February 1, 2013. In 2012, we also entered into a new \$3,000,000 line of credit, of which we drew down \$1,000,000 in 2012 and have subsequently drawn down an additional \$1,000,000 in February of 2013. 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 2014.

On August 31, 2012, we entered into a Loan and Security Agreement with Square 1 Bank pursuant to which Square 1 Bank agreed to extend credit facilities to us. We drew down \$1,000,000 in principal amount on August 31, 2012, and we drew down an additional \$1,000,000 in principal amount in February of 2013, primarily to finance the working capital requirements of our recent IGI product launch.

On December 21, 2012, we closed a \$2,000,000 private placement, or the offering, with Amzak Capital Management, LLC, or Amzak. The use of proceeds was intended for general working capital needs as well as the acquisition of econozale nitrate cream 1% which was purchased February 1, 2013. Pursuant to the terms of a securities purchase agreement entered into with Amzak, or the securities purchase agreement, on December 20, 2012, we issued to Amzak (i) 1,965,740 shares of our common stock, par value \$0.01 per share, held in treasury, or the Shares and (ii) a ten-year warrant to purchase up to an aggregate of 387,201 shares of our common stock, with an exercise price of \$0.01 per share, or the warrants. The warrants, which were exercisable immediately, were exercised in full by Amzak on December 27, 2012. In addition, we executed as of December 31, 2012 a settlement agreement with Amzak Capital Management, LLC in connection with a common stock purchase warrant we issued to Amzak on December 21, 2012 under which we issued a ten-year warrant to purchase up to 427,713 shares of our common stock, with an exercise price of \$0.55 per share. The warrants were exercised in full on February 8, 2013.

Our operating activities used \$2.4 million of cash during the years ended December 31, 2012 and 2011. The use of cash for the years ended December 31, 2012 and 2011 was substantially a result of the net loss for the period offset by non-cash expense items. Our cash used in operating activities included \$2.8 million of research and development efforts.



Our investing activities used \$342,000 of cash in the year ended December 31, 2012 compared to \$350,000 of cash used in investing activities in the comparable period of 2011. The 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 year ended December 31, 2012 compared to \$542,000 generated in the year ended December 31, 2011. 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 18 to our Consolidated Financial Statements, in addition to the \$1.0 million of proceeds from the drawdown of our new 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. The cash provided for the year ended December 31, 2011 was mainly the proceeds from the drawdown of the Note Payable - Related Party as more fully described in Note 7 to our Consolidated Financial Statements.

Our principal sources of liquidity are cash and cash equivalents of approximately \$2.5 million at December 31, 2012, the \$2.0 million available on the \$3.0 million credit facility and future cash from operations. We drew down an additional amount of principal of \$1.0 million from the credit facility in February of 2013. We had working capital of \$4.2 million at December 31, 2012.

## Recent Pronouncements

There were no new accounting pronouncements for the twelve months ended December 31, 2012 that have a material impact on the Company's consolidated financial statements.

## 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: 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. Sales of the IGI labeled products were not significant in 2012, however in the future we expect to have significant estimates to arrive at net product sales arising from wholesaler chargebacks, Medicaid rebates, allowances and other pricing and promotional programs.

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.

Environmental Remediation Liability

On March 2, 2001, the Company became aware of environmental contamination resulting from an unknown heating oil leak at its Companion Pet Products manufacturing facility. The Company immediately notified the New Jersey Department of Environmental Protection and the local authorities, and hired a contractor to assess the exposure and required clean up costs. The total estimated costs for the clean-up and remediation is \$739,000, of which approximately \$25,000 remains accrued as of December 31, 2012. 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.

In response to an observation by the New Jersey DEP of pesticide contamination in a portion of its property located at 105 Lincoln Avenue in Buena, Atlantic County, New Jersey, the Company contracted with an environmental and remediation firm to complete soil delineation of the pesticide contamination, its remediation and disposal. The remediation and disposal was completed in 2011 at a cost of approximately \$61,000. The Company received a No Further Action Letter from the New Jersey Department of Environmental Protection on May 23, 2011.

### 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, 2012, 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, 2012, 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, 2012 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 2013 Annual Meeting of Stockholders (the "2013 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](http://www.igilabs.com). 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 2013 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**

A portion of the information required by this item will be contained in the Company's 2013 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 following table includes information as of December 31, 2012 relating to the Company's 1999 Stock Incentive Plan, as amended, the 1999 Director Stock Option Plan, as amended, and the 2009 Equity Incentive Plan, as amended, which comprises all of the equity compensation plans of the Company. The table provides the number of securities to be issued upon the exercise of outstanding options under such plans, the weighted-average exercise price of such outstanding options and the number of securities remaining available for future issuance under such equity compensation plans:

<b>Plan category</b>	<b>Number of securities to be issued upon exercise of outstanding options (a)(1)</b>	<b>Weighted-average exercise price of outstanding options (b)(1)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) (c)(2)</b>
Equity compensation plans approved by security holders	2,581,500	\$ 1.10	2,130,260
Equity compensation plans not approved by security holders	0		
Total	2,581,500	1.10	2,130,260

(1)

Includes information with respect to the 1999 Stock Incentive Plan, as amended, the 1999 Director Stock Option Plan, as amended and the 2009 Equity Incentive Plan, as amended.

(2)

Includes information with respect to the 1999 Director Stock Option Plan and the 2009 Equity Incentive Plan, as amended. As of December 31, 2012, we had 522,984 shares available for issuance pursuant to the 1999 Director Stock Option Plan, as amended, and 1,196,172 shares available for issuance pursuant to the 2009 Equity Incentive Plan, as amended.



**ITEM 13.**

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

The information required by this item will be contained in the Company's 2013 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 2013 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) |  |

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- 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.
- (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)#



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- (10.19)# 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).  
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).

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- (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.
- (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)\*

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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, 2012, 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.

**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 28, 2013 By: /s/ Jason Grenfell-Gardner  
 Jason Grenfell-Gardner  
 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.

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
/s/ Jason Grenfell-Gardner Jason Grenfell-Gardner	Director, President and Chief Executive Officer (Principal Executive Officer)	March 28, 2013
/s/ Jenniffer Collins Jenniffer Collins	Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2013
/s/ Joyce Erony Joyce Erony	Director	March 28, 2013
/s/ James Gale James Gale	Director	March 28, 2013
/s/ Michael Hemric Michael Hemric	Director	March 28, 2013
/s/ Narendra Borkar Narendra Borkar	Director	March 28, 2013
/s/ Bhaskar Chaudhuri Bhaskar Chaudhuri	Director	March 28, 2013



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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, 2012 and 2011, 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, 2012. The financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of IGI Laboratories, Inc. and subsidiaries as of December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

Edison, New Jersey

March 28, 2013



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**IGI LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

(in thousands, except share and per share information)

	<b>December 31, 2012</b>	<b>December 31, 2011</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,536	\$ 2,914
Accounts receivable, less allowance for doubtful accounts of \$16 in 2012 and in 2011	1,577	1,208
Inventories	1,773	1,195
Other receivables	5	239
Prepaid expenses	248	130
Total current assets	6,139	5,686
Property, plant and equipment, net	2,691	2,800
Restricted cash	54	54
License fee, net	300	400
Debt issuance costs, net	100	639
Other	143	57
Total assets	\$ 9,427	\$ 9,636
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,091	\$ 629
Accrued expenses	820	611
Deferred income, current	48	38
Capital lease obligation, current	17	38
Total current liabilities	1,976	1,316
Note payable, bank	1,000	
Note payable, related party		500
Deferred income, long term	20	25
Capital lease obligation, long term	4	30
Total liabilities	3,000	1,871
Commitments and contingencies		
Stockholders equity:		
Series A Convertible Preferred stock, liquidation preference - \$500,000 at December 31, 2012 and December 31, 2011	500	500

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Series C Convertible Preferred stock, liquidation preference - \$1,764,240 at		
December 31, 2012 and \$1,686,527 at December 31, 2011	1,517	1,517
Common stock, authorized 50,000,000 shares, par value \$0.01	446	415
Additional paid-in capital	47,409	46,246
Accumulated deficit	(43,445)	(39,518)
Less treasury stock, 1,965,740 common shares at cost at December 31, 2011		(1,395)
Total stockholders' equity	6,427	7,765
Total liabilities and stockholders' equity	\$ 9,427	\$ 9,636

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

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**IGI LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS****For the years ended December 31, 2012 and 2011****(in thousands, except shares and per share information)**

	<b>2012</b>	<b>2011</b>
Revenues:		
Product sales, net	\$ 6,545	\$ 6,729
Research and development income	1,931	921
Licensing, royalty and other income	87	156
Total revenues	8,563	7,806
Costs and Expenses:		
Cost of sales	5,787	5,546
Selling, general and administrative expenses	3,078	3,078
Product development and research expenses	2,834	2,151
Total costs and expenses	11,699	10,775
Operating loss	(3,136)	(2,969)
Interest expense	(962)	(281)
Interest and other income (expense), net	(13)	17
Loss before benefit from income taxes	(4,111)	(3,233)
Benefit from income taxes, principally sale of New Jersey net operating losses	184	226
<b>Net loss</b>	<b>\$ (3,927)</b>	<b>\$ (3,007)</b>
<b>Basic and diluted loss per common share</b>	<b>\$ (.10)</b>	<b>\$ (.08)</b>
<b>Weighted average shares of common stock outstanding</b>		
Basic and diluted	39,786,446	39,448,706

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

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**IGI LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****For the years ended December 31, 2012 and 2011****(in thousands)**

	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (3,927)	\$ (3,007)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation	357	319
Amortization of license fee	100	100
Bad debt expense	6	6
Provision for write down of inventory	138	180
Stock-based compensation expense	378	351
Amortization of debt issuance costs	862	161
Loss on abandonment of property	9	
Changes in operating assets and liabilities:		
Accounts receivable	(369)	(399)
Inventories	(716)	(559)
Prepaid expenses and other current assets	119	55
Accounts payable and accrued expenses	671	424
Deferred income	5	(25)
Net cash used in operating activities	(2,373)	(2,394)
<b>Cash flows from investing activities:</b>		
Capital expenditures	(342)	(350)
Net cash used in investing activities	(342)	(350)
<b>Cash flows from financing activities:</b>		
Proceeds from note payable, net of debt issuance costs	886	
Proceeds from (repayment of) note payable, related party	(500)	500
Proceeds from sale of treasury stock, net of expenses	1,963	
Proceeds from exercise of common stock options and warrants	39	74
Principal payments on capital lease obligation	(51)	(32)
Net cash provided by financing activities	2,337	542
Net decrease in cash and cash equivalents	(378)	(2,202)
Cash and cash equivalents at beginning of year	2,914	5,116
Cash and cash equivalents at end of year	\$ 2,536	\$ 2,914

Supplemental cash flow information:

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Cash payments for interest	\$	99	\$	120
Cash receipt from taxes, net		(184)		(226)
Non cash transactions:				
Equipment financed through capital lease		30		
Issuance of restricted stock		1		2
Forfeiture of restricted stock		(2)		(1)
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, 2012 and 2011**

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

	<b>Series A</b>		<b>Series C</b>		<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Treasury</b>	<b>Total</b>
	<b>Preferred</b>	<b>Stock</b>	<b>Convertible</b>	<b>Preferred</b>	<b>Stock</b>	<b>Shares</b>	<b>Paid-In</b>	<b>Deficit</b>	<b>Stock</b>	<b>Stockholders</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Amount</b>	<b>Amount</b>	<b>Capital</b>	<b>Deficit</b>	<b>Stock</b>	<b>Equity</b>
Balance, December 31, 2010	50	\$ 500	1,550	\$ 1,517	41,288,199	\$ 413	\$ 45,823	\$(36,511)	\$(1,395)	\$10,347
Stock based compensation expense stock options							125			125
Stock based compensation expense restricted stock							226			226
Restricted stock forfeiture					(106,672)	(1)	1			
Stock options exercised					81,663	1	73			74
Cashless exercise of warrants					200,646	2	(2)			
Net loss								(3,007)		(3,007)
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
							222			222



Stock based compensation expense								
restricted stock								
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

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. The Company's strategy is based on three initiatives:

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

Increasing the Company's current contract manufacturing and development business; and,

Creating unique opportunities through the acquisition of additional intellectual property, and the expansion of the use of the Company's existing intellectual property, including its licensed Novasome® technology.

In December, 2012, the Company completed implementation of its commercial infrastructure and launched its first generic topical pharmaceutical products under the IGI label. The remainder of product sales are private labeled under contract manufacturing agreements. The Company has filed nine Abbreviated New Drug Applications, or ANDAs, with the United States Food and Drug Administration, or FDA. As discussed in Note 19, the Company acquired product rights to econozale nitrate cream 1%. The Company performs all of its product development and manufacturing at its 25,000 square foot facility in Buena, New Jersey.

*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 and other accrued liabilities at December 31, 2012 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 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.

#### *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 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.

In 2011, 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 \$1.3 million, respectively, and aggregately represented 54% of total revenues. Accounts receivable related to the Company's major customers comprised 48% of all accounts receivable as of December 31, 2011.

The Company operates in the United States with a concentration of its customers located in the Northeastern United States.

#### *Inventories*

Inventories are valued at the lower of cost, using the first-in, first-out ( FIFO ) method, or market.

*Property, Plant and Equipment*

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

	<b><u>Useful Lives</u></b>
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.

### *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, 2012, 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, 2012, the largest component of accrued expenses was accrued payroll of \$256,694, accrued directors' fees of \$209,870 and accrued consulting fees of \$60,000. For the fiscal year ended December 31, 2011, the largest component of accrued expenses was accrued payroll of \$150,000, accrued directors' fees of \$165,000 and accrued consulting fees of \$90,000.

### *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 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: 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. Sales of the IGI labeled products were not significant in 2012, however the Company expects to have significant estimates to arrive at net product sales arising from wholesaler chargebacks, Medicaid and Medicare rebates, allowances and other pricing and promotional programs.

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. The Company does 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 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*

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. At December 31, 2011, the Company's expenses incurred related to the credit facility with Amzak Capital Management, LLC are being amortized to interest expense over the five year term of the credit facility. On August 1, 2012, the Company paid-off its existing credit facility, 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, 2012 and 2011 were \$3,600 and \$4,400, 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, 2012 and 2011, 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 6,445,628 for 2012 and 5,628,135 for 2011.

### *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*

There were no new accounting pronouncements for the year ended December 31, 2012 that have a material impact on the Company's consolidated financial statements.

## 2. Liquidity

The Company's principal sources of liquidity are cash and cash equivalents of approximately \$2,536,000 at December 31, 2012, the \$2,000,000 available under the \$3,000,000 credit facility detailed below and cash from operations. In February 2013, the Company drew down an additional \$1,000,000 from the available credit facility. The Company sustained net losses of \$3,927,000 and \$3,007,000 for the years ended December 31, 2012 and 2011, respectively, and had working capital of \$4,163,000 at December 31, 2012.

The Company's business operations have been primarily funded over the past four 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 is intended for general working capital needs as well as the acquisition of econozale nitrate cream 1% which was purchased on February 1, 2013. In August 2012, the Company also entered into a \$3,000,000 line of credit (See Note 6). As of December 31, 2012 the outstanding balance on the line of credit was \$1,000,000. In February 2013, the Company purchased an asset expected to provide contribution to its gross profit in 2013 (See Note 19). 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 2014.

### 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, 2012 and 2011, 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 2013-2015.

### 4. Inventories

Inventories as of December 31, 2012 and 2011 consisted of:

	<b>2012</b> <b>(in thousands)</b>		<b>2011</b> <b>(in thousands)</b>
Raw materials	\$ 1,673	\$	1,070
Work in progress	26		16
Finished goods	74		109
	\$ 1,773	\$	1,195

### 5. Property, Plant and Equipment

Property, plant and equipment, at cost, as of December 31, 2012 and 2011, consisted of:

<b>2012</b> <b>(in thousands)</b>	<b>2011</b> <b>(in thousands)</b>
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Land	\$	257	\$	257
Building and improvements		3,552		3,526
Machinery and equipment		3,120		2,900
Construction in progress		123		123
		7,052		6,806
Less accumulated depreciation		(4,361)		(4,006)
Property, plant and equipment, net	\$	2,691	\$	2,800

The Company recorded depreciation expense of \$357,000 and \$319,000 in 2012 and 2011, respectively.

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## 6. Note Payable

On August 31, 2012, IGI Laboratories, Inc. and its subsidiaries, Igen, Inc. and IGI Labs, Inc., 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 in on August 31, 2012.

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, 2012, 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 must maintain a liquidity ratio of at least 1.25 to 1.00 (the *LQR Threshold*), provided that the LQR Threshold shall be reduced to 1.00 to 1.00 so long as Borrower has achieved minimum Revenue, measured monthly on a trailing 3 month basis, of at least the amounts listed in the document for the corresponding reporting periods. To further clarify, if at any time Borrower is not in compliance with the minimum revenue amounts set forth below, the LQR Threshold shall 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).

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* ). The Company had \$500,000 outstanding under the facility at December 31, 2011.

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 was approximately \$160,000 per year for five years. Amortization expense of \$639,000 and \$161,000 was recognized for each of the years ended December 31, 2012 and 2011, respectively. 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 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, or 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.

#### **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). Liquidation preference is the original cost less fees associated with the transaction plus undeclared dividends of \$214,240 and amounted to \$1,764,240 at December 31, 2012.

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.

#### **10. Stock Based Compensation**

Under the 1998 Directors Stock Plan, as amended, 600,000 shares of the Company's Common Stock are authorized under the plan and reserved for issuance to non-employee directors, in lieu of payment of directors' fees in cash. In November 2009, the Company's Board of Directors approved the elimination of payment of directors' fees in stock under this plan beginning in the fourth quarter of 2009.

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 2,049,798 options have been granted to non-employee directors through December 31, 2012 and 727,782 of those have been forfeited through December 31, 2012 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, 2012, options to purchase 1,991,000 shares of common stock were outstanding under the 2009 Plan. As of December 31, 2012, 1,148,748 shares of restricted stock had been granted under the 2009 Plan and 230,420 of those have been forfeited through December 31, 2012 and returned to the pool.

## Stock Options

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.

<u>Assumptions</u>	<u>2012</u>	<u>2011</u>
Dividend yield	0%	0%
Risk free interest rate	0.39%	0.76%
Estimated volatility factor	54.5%	58%
Expected life	3.2 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:

	<u>Shares</u>	<u>Exercise Price Per Share</u>	<u>Weighted Average Exercise Price</u>
January 1, 2011 shares issuable			
Under options	1,298,516	.52 - 1.52	1.09
Granted	370,000	1.04 - 1.74	1.29
Exercised	(81,663)	.52 - 1.03	0.91
Expired	(15,000)	.80	0.80
Forfeited	(123,837)	.76 - 1.03	1.02
December 31, 2011 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

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Forfeited	(337,516)	.55 - 1.52	1.22
December 31, 2012 shares issuable			
Under options	2,606,500	.55 - 1.74	1.10
Exercisable options at:			
December 31, 2012	951,001		\$1.19
December 31, 2011	1,103,016		\$1.13

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

<b><u>Range of Exercise Price</u></b>	<b>Options Outstanding</b>			<b>Options Exercisable</b>	
	<b><u>Number of Options</u></b>	<b><u>Weighted Average Remaining Life (Years)</u></b>	<b><u>Weighted Average Exercise Price</u></b>	<b><u>Number of Options</u></b>	<b><u>Weighted Average Exercise Price</u></b>
\$ .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	2,605,500	8.19	\$1.10	951,001	\$1.19

The following table summarizes information concerning outstanding and exercisable options as of December 31, 2011:

<b><u>Range of Exercise Price</u></b>	<b>Options Outstanding</b>			<b>Options Exercisable</b>	
	<b><u>Number of Options</u></b>	<b><u>Weighted Average Remaining Life (Years)</u></b>	<b><u>Weighted Average Exercise Price</u></b>	<b><u>Number of Options</u></b>	<b><u>Weighted Average Exercise Price</u></b>
\$ .55 to \$1.00	307,000	5.61	\$ .71	307,000	\$ .71
1.01 to 1.50	909,000	6.47	1.20	684,000	1.25
1.51 to 1.74	232,016	7.29	1.64	112,016	1.59
\$ .55 to \$1.74	1,448,016	6.42	\$1.16	1,103,016	\$1.13

The Company has recorded an aggregate of \$156,000 and \$125,000 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, 2012 and 2011, respectively.

The aggregate intrinsic value of options outstanding was \$82,270 at December 31, 2012 and \$130,250 at December 31, 2011. The aggregate intrinsic value of the options exercisable was \$62,410 at December 31, 2012 and \$15,750 at December 31, 2011. The total intrinsic value of the options exercised during 2012 and 2011 was \$15,600 and \$13,250,

respectively.

A summary of non-vested options at December 31, 2012 and changes during the year ended December 31, 2012 is presented below:

	<b>Options</b>	<b>Weighted Average Grant Date Fair Value</b>
Non-vested options at January 1, 2012	345,000	\$ 0.25
Granted	1,551,000	0.11
Vested	(220,001)	0.41
Forfeited	(20,500)	0.56
Non-vested options at December 31, 2012	1,655,499	\$ 0.14

As of December 31, 2012, there was \$391,031 of total unrecognized compensation cost related to non-vested share-based compensation arrangements under the Plan. The costs will be recognized through December 2015.

## 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. The Company recognized \$222,000 and \$226,000, respectively, of compensation expense during the years ended December 31, 2012 and 2011 related to restricted stock awards. Stock compensation expense is recognized over the vesting period of the restricted stock. At December 31, 2012, the Company had approximately \$21,186 of total unrecognized compensation cost related to non-vested restricted stock, all of which will be recognized through January 2014.

	<b>Number of Restricted Stock</b>	<b>Weighted Average Exercise Price</b>
Non-vested balance at January 1, 2011	939,000	\$ 0.71
Changes during the period:		
Shares granted		
Shares vested	(206,328)	0.71
Shares forfeited	(106,672)	
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 December 31, 2012	29,334	\$ 1.00

**11. Stock Warrants**

Stock Warrants as of December 31, 2012 and 2011 consisted of:

	<b>2012</b>		<b>2011</b>	
<b><u>Warrants</u></b>	<b><u>Weighted Average Exercise Price</u></b>		<b><u>Warrants</u></b>	<b><u>Weighted Average Exercise Price</u></b>



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Beginning balance	1,235,877	\$0.35	1,498,377	\$0.36
Stock warrants granted	814,914	0.29		
Stock warrants expired				
Stock warrants exercised	(1,268,532)	0.01	(262,500)	0.41
Ending balance	782,259	\$0.85	1,235,877	\$0.35

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 private placement of the Company's Common Stock (see Note 18) in 2012, the Company granted common stock warrants to purchase 387,201 shares for \$0.01 per share, which expire December 2022.

In connection with the Credit Agreement with Amzak Capital Management, LLC as more fully described in Note 7, on December 21, 2010, the Company issued a ten-year warrant to purchase 881,331 shares of the Company's Common Stock for \$.01 per share.

In addition, the Company executed as of December 31, 2012 a settlement agreement with Amzak Capital Management, LLC in connection with a common stock purchase warrant we 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 warrants were 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.

In connection with the private placement offering to certain investment funds affiliated with Signet Healthcare Partners, G.P. (the Offering) on March 13, 2009, the Company granted its placement agent for the Offering a Common Stock Warrant to purchase 350,000 shares of common stock for \$0.41 per share, which expired on March 13, 2012. Until stockholder approval of the Offering was obtained, this Common Stock Warrant was exercisable for no more than 88,550 shares. At the Company's 2009 annual meeting of stockholders held on May 15, 2009, the Company's stockholders approved the Offering and accordingly, all shares under the warrant became issuable. The fair value of the Common Stock Warrant of approximately \$102,000 was determined using the Black-Scholes model. The factors used in the calculation are as follows: expected volatility of 66.8%, expected term of 3 years and risk-free interest rate of 1.36%. Expected volatility and risk-free interest rates are based upon the expected life of the warrant. The interest rates used are the yield of a 3-year U.S. Treasury Note as of March 13, 2009. Of this amount, \$82,000 was deemed to be attributable to the issuance of debt and was capitalized as debt issuance costs. On December 2, 2009, the Common Stock Warrant was amended to include a partial transfer for 87,500 shares of common stock. On December 2, 2009, the warrant to purchase 87,500 was exercised using the cashless exercise provision and 51,681 shares of common stock were issued. On February 25, 2011, the warrant to purchase the remaining 262,500 shares of common stock was exercised using the cashless exercise provision and 200,646 shares of common stock were issued.

## 12. Income Taxes

The (benefit) from income taxes attributable to loss from continuing operations before (benefit) from income taxes for the years ended December 31, 2012 and 2011 is as follows:

	<b>2012</b>	<b>2011</b>
	<b>(in thousands)</b>	
Current tax expense (benefit):		

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Federal	\$		\$	
State and local		(184)		(226)
Total current tax expense (benefit)		(184)		(226)
Deferred tax expense				
Federal				
State and local				
Total deferred tax expense				
Total expense (benefit) from income taxes	\$	(184)	\$	(226)

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 \$189,000 and \$231,000 in 2012 and 2011 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:

	<b>2012</b>		<b>2011</b>
	<b>(in thousands)</b>		
Statutory benefit	\$	(1,381)	\$ (1,097)
Other non-deductible expenses		1	1
Increase in federal valuation allowance		1,317	1,019
Sale of New Jersey net operating loss carry forward		(189)	(231)
Federal tax impact of state tax benefit, net		68	82
	\$	(184)	\$ (226)

Deferred tax assets included in the Consolidated Balance Sheets as of December 31, 2012 and 2011 consisted of the following:

	<b>2012</b>		<b>2011</b>
	<b>(in thousands)</b>		
<b>Current Assets</b>			
Allowance for doubtful accounts	\$	6	\$ 4
Inventory reserve		45	66
Other		151	91
Total Current Assets		202	161
<b>Long Term Assets (Liabilities)</b>			
Property, plant and equipment		203	170
Deferred royalty payments		10	12
Tax operating loss carry forwards		11,101	9,899
Tax credit carry forwards		225	335
Non-employee stock options		625	560
Other		(8)	(8)
Total Long Term Assets (Liabilities)		12,156	10,968
Gross Deferred Tax Asset (Liability)		12,358	11,129
Less: valuation allowance		(12,358)	(11,129)
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 \$12.4 million and \$11.1 million for the years ended December 31, 2012 and 2011, respectively, on the deferred tax assets relating to these net operating loss carry forwards.

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Operating loss and tax credit carry forwards for tax reporting purposes as of December 31, 2012 were as follows:

**(in thousands)**

Federal:

Operating losses (expiring through 2032)	\$ 31,584
Research tax credits (expiring through 2025)	168
Alternative minimum tax credits (available without expiration)	28

State:

Net operating losses - New Jersey (expiring through 2017)	4,030
Alternative minimum assessment - New Jersey (available without expiration)	29

Federal net operating loss carry forwards that expire through 2032 have significant components expiring in 2020 (24%), 2029 (12%), 2030 (12%), 2031 (10%) and 2032 (11%).

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 equipment of \$11,200 for 2013 and \$9,400 for 2014. Rent expense was \$66,900 for the years ended December 31, 2012 and 2011.

#### **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 \$25,000 remains accrued as of December 31, 2012. 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, 2012 and 2011 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.

In response to an observation by the NJ DEP of pesticide contamination in a portion of its property located at 105 Lincoln Avenue in Buena, New Jersey, the Company contracted with an environmental and remediation firm to complete soil delineation of the pesticide contamination, its remediation and disposal. The remediation and disposal was completed in 2011 at a cost of approximately \$61,000. The Company received a "No Further Action Letter" from the New Jersey Department of Environmental Protection on May 23, 2011.

## **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 \$17,000 for 2012 and \$16,500 for 2011, plus a catch-up contribution of up to \$5,500 for 2012 and 2011, 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 \$71,000 and \$72,000 in 2012 and 2011, 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 18.

## **17. Changes in Management**

On December 19, 2012, the Company announced that Dr. Kenneth Miller has been appointed Senior Vice President of R&D at IGI Laboratories, Inc. effective December 17, 2012. Dr. Miller brings over twenty years of topical and transdermal experience in both branded and generic pharmaceutical product development.

On July 30, 2012, the Company announced that Jason Grenfell-Gardner has been appointed the Company's new President and Chief Executive Officer, effective July 30, 2012. Charles E. Moore left his employment with the Company and resigned as a member of the Company's board of directors (the Board), effective July 30, 2012. The Board appointed Mr. Grenfell-Gardner to fill the vacant Board seat created by Mr. Moore's resignation, effective July 30, 2012.

The Company entered into an employment agreement with Mr. Grenfell-Gardner, effective as of July 30, 2012. Under the terms of such employment agreement, Mr. Grenfell-Gardner will receive an annual salary of \$315,000. Mr. Grenfell-Gardner has received an option to purchase 975,000 shares of the Company's common stock (the Primary



Option ) and a supplemental option to purchase 25,000 shares of the Company's common stock (the Supplemental Option ), the vesting terms of which are explained below. In addition, Mr. Grenfell-Gardner will receive an award of 325,000 shares of restricted stock and an option to purchase 25,000 shares of the Company's common stock, as soon as practicable. In addition, Mr. Grenfell-Gardner will be entitled to participate in certain of the Company's benefit programs on the same terms and conditions generally provided by the Company to its executive employees. Mr. Grenfell-Gardner will also be eligible to receive an annual performance bonus for each calendar year during the term of his employment, which may be payable in either, cash, stock options and/or restricted stock. Mr. Grenfell-Gardner's target bonus will be equal to 70% of his base salary for the applicable fiscal year. All performance targets pursuant to such plan shall be determined by the Board's Compensation Committee. Mr. Grenfell-Gardner is also subject to certain restrictive covenants as set forth in his employment agreement, including confidentiality, non-solicitation and non-competition covenants. Mr. Grenfell-Gardner's employment agreement further provides for payments upon certain types of employment termination events as further set forth in his employment agreement.

The above referenced stock option grants have an exercise price equal to the closing price of the Company's common stock on the date of grant, and the Primary Option and the restricted stock will become fully vested over a period of three years as follows: (i) one-third shall vest on the first anniversary of the date of the grant; (ii) one-third shall vest on the second anniversary of the date of the grant and (iii) one-third shall vest on the third anniversary of the date of the grant. One-half of the shares subject to the Supplemental Option shall become fully vested immediately upon their grant and the remaining one-half of the shares subject to such award shall vest on the first anniversary of the effective date of Mr. Grenfell-Gardner's employment. In addition, any options or restricted stock that remain unvested immediately prior to a change in control will become vested, provided that the executive remains in continuous service with the Company through the consummation of the change in control.

On April 25, 2012, Jane E. Hager notified the Company and its Board of Directors of her decision to retire from the Board of Directors and not to stand for re-election at the Company's 2012 annual meeting of stockholders (the Annual Meeting). Ms. Hager continued to serve as a director until the Annual Meeting that was held on May 22, 2012.

## 18. 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, par value \$0.01 per share, 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 econazole 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 *Initial Registration 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 within the specified timeframe.

## 19. Subsequent Event

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 will be required to pay an additional aggregate of \$400,000 upon the occurrence of certain milestone events (the *Milestone Payment* ). The Milestone Payment is secured by a first-priority security interest in the acquired assets under the Purchase Agreement.

Under and subject to the terms and conditions of the Purchase Agreement, Prasco will continue to distribute the Product during a six-month period following the closing of the Purchase Agreement or for a shorter period if the Company has completed the technical transfer of the Product and begun manufacturing the Product under its own label.

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.