

IGI LABORATORIES, INC  
Form 10-K  
March 28, 2012

**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, 2011**

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 Amex  |

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.

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Large accelerated filer  Accelerated filer  Non-accelerated filer  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 equity held by non-affiliates of the registrant on June 30, 2011 was approximately \$14,070,000. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the NYSE Amex on June 30, 2011.

As of March 21, 2012, there were 39,511,596 shares of the registrant's common stock outstanding.

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## PART I

### ITEM 1.

#### BUSINESS

##### Overview

IGI Laboratories, Inc. is a Delaware corporation formed in 1977. As used in this report, the terms the Registrant, the Company, IGI Laboratories and IGI refer to IGI Laboratories, Inc. unless the context requires otherwise. We develop, manufacture, fill and package topical semi-solid and liquid products for cosmetic, cosmeceutical and pharmaceutical customers. Our products are used for a variety of skin conditions, including the treatment of symptoms of dermatitis, acne, psoriasis and eczema. We are building upon this foundation by filing our own Abbreviated New Drug Applications, or ANDAs, and continuing to expand into the prescription pharmaceutical arena. Our strategy is based upon three initiatives: increasing the current contract services business, developing a portfolio of prescription generic formulations in topical dosage forms and creating unique opportunities around our licensed Novasome® technology. All of our product development and manufacturing is performed at our 23,000 sq.ft. facility in Buena, NJ.

##### Our Services and Products

We have two major sources of revenue; our contract services business and development of prescription pharmaceutical products. Our expertise is specific to topical formulations; creams, ointments, lotions, gels, and topical liquids. The customer base for our contract services business is comprised of companies engaged in marketing topical preparations to the pharmaceutical, cosmetic, and cosmeceutical markets. Our prescription pharmaceutical development business is focused on in-house development of generic versions of approved topical drug products.

##### *Contract Services Business*

Our contract services business includes two services: contract formulation and contract manufacturing. These services are offered to pharmaceutical, over-the-counter ( OTC ), and cosmetic customers. 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 services products are produced in our customer's label.

Contract formulation involves developing topical formulations to satisfy a customer's product request. Our experienced formulators can replicate an existing formula through reverse engineering or develop one from scratch. 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.

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

We believe that our contract services business will continue to be crucial to our success. The fact that we specialize in dermatologic product forms and offer high-quality formulation capabilities, we believe, sets us apart from others in this competitive market space.

We will continue to seek out strategic partnerships with prestigious companies like The NeoStrata Company, Inc. (NeoStrata) and Medimetriks Pharmaceuticals, Inc. (Medimetriks), as we further establish ourselves in the dermatology marketplace.

Our contract services customers include pharmaceutical companies, for whom we formulate, test and/or manufacture prescription pharmaceutical products and medical devices.

An integral part of our strategy is to partner with leading pharmaceutical and skin care companies. We intend to assist our partners in developing and manufacturing products for sale in the pharmaceutical and OTC markets.

On January 10, 2011, we submitted our second ANDA with the United States Food and Drug Administration (US FDA or FDA). We have successfully integrated the development of ANDA products into our ongoing contract services business.

On October 24, 2011, we were acknowledged as the 23<sup>rd</sup> ranked company on Deloitte and Touche's 2011 Greater Philadelphia Fast 50 Ranking of the 50 Fastest Growing companies.





On November 21, 2011, we announced the submission of two more ANDAs to the US FDA. These submissions were further additions to the development of our portfolio of topical drug products,

On December 8, 2011, we entered into a long term strategic partnership with Medimetriks. This strategic partnership designates us as the developer and manufacturer of a family of prescription topical drug products owned by Medimetriks. In addition, as part of this long term relationship, Medimetriks has appointed us as Medimetriks` authorized generic distributor of certain products in this line. Medimetriks expects to launch its new line of prescription topical brands during the second quarter of 2012. IGI Laboratories is expected to begin the authorized generic distribution of certain of those products shortly thereafter.

On December 22, 2011, we extended our turnkey supply agreement with NeoStrata for three years. Under the extension, we will continue to supply NeoStrata with fully packaged market-ready skin care products that will be available worldwide through consumer outlets, physician s offices and spas.

On December 29, 2011, we announced the submission of our fifth ANDA with US FDA. The latest submission remains consistent with our portfolio of topical products.

#### *IGI s Prescription Pharmaceutical Business*

We are leveraging our expertise in pharmaceutical formulation and manufacturing to expand our own product offerings. We are focused on developing a portfolio of topical generic drug products via the submission of ANDAs with the US FDA. 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.

In September 2010, we filed our first ANDA with the FDA in our own name. We have filed five ANDAs to date, and we have a number of additional product candidates in various stages of development. We continue to anticipate filing four to six ANDAs per year on an ongoing basis, assuming sufficient financial resources to support these product development plans. Our entry into the market is subject to approval of our ANDA applications by the US FDA. The FDA reports that its current average review time is about 30 months and that there is a backlog of more than 2,500 applications. A proposed Generic Drug User Fee program could reduce review times and the backlog.

We believe the topical market to be an attractive one. Topical drugs are defined as those intended for local external application, meaning used on the skin, scalp, eyes, and ears. We believe that this market segment is an attractive niche

due to a number of factors, including the aging of the US population. IMS Health reports the US dermatology market at \$8.7 billion, with generics representing 25.9%, leaving significant room for growth by generic companies. The market for prescription generic topical products is dominated by a few large marketers. We believe that there is room for IGI to compete in selected product areas.

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

*Novasome® Technology Platform*

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

Improved product stability;

Reduced skin irritation;

Extended release of active ingredients;

Improved skin permeation;

Improved product aesthetics; and

Allowance of novel product forms.

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

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 implement our new strategy, 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 of contract service solutions for topical cosmetic, cosmeceutical and pharmaceutical products and to become a leading developer of generic topical, semi-solid and liquid cosmetic, cosmeceutical and pharmaceutical products. The key elements of our strategy include:

*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. Revenue from our top two customers has increased 71% over the past two years. We intend to continue to capitalize on our strong customer relationships to increase our contract services 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.

*Develop Generic Pharmaceuticals.* We intend to continue to develop topical generic products and utilize our expertise in pharmaceutical formulation and manufacture to expand our own product offerings. Through the ANDA process, we intend to develop several topical products and then leverage our internal research and development, or R&D, licensing and other business development relationships to market these products through sales partners.

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

*Diversify our Revenues.* Currently, all of our revenue comes 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 generic topical 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 services business to increase our revenue growth. Our customers in the contract services business generally consist of pharmaceutical companies as well as cosmetic, cosmeceutical and OTC product marketers who require product development/manufacturing support. Based on product sales in our contract services business, we have two (2) major customers. Major customers are defined as having sales for the latest fiscal year equal to or greater than 10% of that year's total gross product sales. The loss of any of these customers would have a material adverse effect on us. In 2011, the Company had sales to two customers which individually accounted for more than 10% of the Company's product sales. These customers had sales of \$2,813,000 and \$1,106,000, respectively, and aggregately represented 58% of revenues from product sales. In 2010,

two customers individually accounted for more than 10% of product sales. These customers had purchases of \$2,288,000 and \$580,000, in aggregate representing 55% of revenue from product sales.

## **Research and Development**

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

We have been steadily increasing our investment in R&D as we believe that R&D is the future of IGI. We spent \$2.1 million and \$1.5 million in 2011 and 2010, respectively.

## **Sales and Marketing**

Our sales and marketing activities are currently focused on increasing our contract development and manufacturing activities. We currently have an experienced senior executive leading this effort. We offer our contract manufacturing services directly to our customer base of cosmetic and OTC customers. These products are sold to the public under the brand of our customer.

The initial group of prescription ANDAs will be marketed to national chain drug stores and drug wholesalers. We are evaluating the timing for launching our own sales force for marketing our own generic pharmaceutical products. Depending on the timing of the approval of our submissions, we may market our new portfolio through our own sales force or we may elect to use carefully-selected established partners. These partners could be responsible for sales and marketing of our manufactured generic products. To date, we have filed five ANDAs with the FDA in our own name.

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 technology.

## **Competition**

The contract manufacturing services market is highly competitive and includes larger organizations with substantially greater resources than us. Many of our competitors are those 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 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 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.

With respect to our development of pharmaceutical and cosmetic products, once we launch our first generic product, we will 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 three dominant companies in the topical generic drug market consist of Taro Pharmaceutical Industries, Ltd., Nycomed International Management GmbH and Perrigo Company. Collectively, these three competitors control approximately fifty percent (50%) of the generic topical market. 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.

#### **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 Company time and resources in the areas of production and quality control.

We are subject to the periodic inspection of our facilities, procedures and operations and/or the testing of our products by the FDA and other authorities, which conduct periodic inspections to ensure that our facilities remain in compliance with cGMP regulations. In addition, in connection with its review of our applications for new products, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes comply with cGMP and other FDA regulations. Our last FDA inspections took place in March 2011 and February 2012.

The two most frequently used applications seeking FDA approval to market and sell a drug product in the United States are:

1)

NDA. Generally, the NDA procedure is required for drugs with active ingredients and/or with a dosage form, dosage strength or delivery system of an active ingredient not previously approved by the FDA. We do not have any NDAs pending approval with the FDA as of December 31, 2011.

2)

ANDA. The Hatch-Waxman Act established a statutory procedure for submission of ANDAs to the FDA covering generic equivalents of previously approved brand-name drugs. Under the ANDA procedure an applicant is required to provide data illustrating that the generic drug formulation is bio-equivalent to a previously approved drug.

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 18 to 36 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. Generic drug manufacturers currently rebate an applicable percentage of calculated average manufacturer price ( AMP ) marketed under ANDAs. We believe that the federal and state governments may continue to enact measures in the future aimed at reducing the cost of drugs and devices to the public. We cannot predict the nature of such measures or their impact on our profitability.

### **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 are currently undergoing remediation of environmental contamination. See Note 15 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 also used for production, product development, marketing and warehousing for our pharmaceutical, cosmeceutical and cosmetic products. Our manufacturing capabilities encompass a full suite of competencies including regulatory, quality assurance and in-house validation.

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

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

### **Employees**

On December 31, 2011, we had a total of 36 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.

## Recent Developments

On January 10, 2011, we submitted our second ANDA with the US FDA. We have successfully integrated the development of ANDA products into our ongoing contract services business.

On October 24, 2011, we were acknowledged as the 23rd ranked company on Deloitte and Touche's 2011 Greater Philadelphia Fast 50 Ranking of the 50 Fastest Growing companies.

On November 21, 2011, we announced the submission of two more ANDAs to the US FDA. These submissions were further additions to the development of our portfolio of topical drug products.

On December 8, 2011, we entered into a long term strategic partnership with Medimetriks. This strategic partnership designates us as the developer and manufacturer of a family of prescription topical drug products owned by Medimetriks. In addition, as part of this long term relationship, Medimetriks has appointed us as Medimetriks' authorized generic distributor of certain products in this line. Medimetriks expects to launch its new line of prescription topical brands during the second quarter of 2012. IGI Laboratories is expected to begin the authorized generic distribution of certain of those products shortly thereafter.

On December 22, 2011, we extended our turnkey supply agreement with NeoStrata for three years. Under the extension, we will continue to supply NeoStrata with fully packaged market-ready skin care products that will be available worldwide through consumer outlets, physician's offices and spas.

On December 29, 2011, we announced the submission of our fifth ANDA with US FDA. The latest submission remains consistent with our portfolio of topical products.

**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, and as a result, we may have to cease operations and liquidate our business.*

Our expenses have exceeded our revenue in each of the last seven years, and no net income has been available to common stockholders during each of these years. As of December 31, 2011, our stockholders' equity was \$7.8 million and we had an accumulated deficit of \$39.5 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.

***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 currently have \$2.5 million available funds under an existing line of credit at December 31, 2011.

***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. In 2011, the Company had sales to two customers which individually accounted for more than 10% of the Company's product sales. These customers had sales of \$2,813,000 and \$1,106,000, respectively, and aggregately represented 58% of revenues from product sales. 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.

***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.



***We rely on third parties for raw materials used in our contract manufacturing services business.***

We currently rely on several third party suppliers to provide us with the raw materials necessary to manufacture cosmetic and over-the-counter products. The loss of one or more of these suppliers, the non-performance of one or more of their materials or the lack of availability of raw materials could suspend our manufacturing process related to these products. This interruption of the manufacturing process could impair our ability to fill our customers' orders as they are placed, which could put our business at a competitive disadvantage. In addition, while we have processes intended to reduce volatility in component and material pricing, we may not be able to successfully manage price fluctuations which may have an adverse effect on our results of operations.

***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 \$63,000 remains accrued as of December 31, 2011 for one facility. The remediation and disposal on the second facility 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. 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 the Company's 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, the Company manufactures and markets certain of its products in accordance with standards set by organizations, such as the United States Pharmacopeial Conventions ( 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 ( ANDA ) process and thus demonstrate to the FDA that each generic product candidate is bioequivalent to a drug previously approved by the FDA through the new drug approval process, known as an innovator, or brand-name reference drug. Bioequivalency may be demonstrated by comparing the generic product to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. However, if the FDA determines that an ANDA for a generic drug product is not adequate to support approval, it could deny our application or request additional information, including preclinical and clinical trials, which could delay approval of the product and impair our ability to compete with other versions of the generic drug product.



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

***We 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.***

## Edgar Filing: IGI LABORATORIES, INC - Form 10-K

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 customer 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.

***If we fail to comply with the reporting obligations of 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, 2011 and December 31, 2010, and our management concluded that our disclosure controls and procedures were effective as of such time.

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.

***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 ( R&D ) 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.

***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 year ended December 31, 2011, the average daily trading volume of our Common Stock on the NYSE Amex was approximately 16,000 shares. As a result of our relatively small public float, our 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 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 meet the continued listing standards of the NYSE Amex our Common Stock could be delisted and our stock price could suffer.***

On May 6, 2008, we were notified by NYSE Amex that we were below certain of the NYSE Amex continued listing standards. Specifically, we are required to reflect income from continuing operations and/or net income in one of our five most recent fiscal years and a minimum of \$6 million in stockholders' equity to remain listed on the exchange. We had net income from continuing operations in our 2002 fiscal year, but had net losses and losses from continuing operations in each of our 2003, 2004, 2005, 2006, 2007, 2008 and 2009 fiscal years. Our stockholders' equity at June 30, 2010 was \$4.9 million.

On June 8, 2008, we submitted a plan to NYSE Amex for compliance with the continued listing standards. On July 15, 2008, NYSE Amex notified us of its acceptance and granted us an extension until May 6, 2009 to regain compliance subject to periodic review by NYSE Amex during the extension period.



On March 13, 2009, we completed a \$6,000,000 private placement offering with certain investment funds affiliated with Signet Healthcare Partners, G.P. In recognition of our efforts in connection with the offering, NYSE Amex granted us an extension from May 6, 2009 until May 31, 2009 to regain compliance with these continued listing standards.

On June 19, 2009, we were notified by NYSE Amex that we had resolved its continued listing deficiencies and would retain our status as a listed issuer on NYSE Amex. However, as of March 31, 2010, our stockholders equity had again fallen below the \$6 million threshold.

On May 25, 2010, we were notified by NYSE Amex that we were below certain of the NYSE Amex continued listing standards. Specifically, we are required to reflect a minimum of \$6 million in stockholders equity to remain listed on the exchange. On June 24, 2010, we submitted a plan to NYSE Amex for compliance with the continued listing standards, which included our plan to increase our stockholders equity through additional offerings.

On August 6, 2010, NYSE Amex notified us that it accepted our plan of compliance and granted us an extension until February 25, 2011 to regain compliance with the continued listing standards. We were subject to periodic review by NYSE Amex Staff during the extension period. On December 10, 2010, NYSE Amex notified us that we had resolved our continued listing deficiencies referenced in its May 2010 letter, and that we were in compliance with the NYSE Amex alternative listing standards, which require at least a \$50 million market capitalization.

If we fail to meet the continued listing standards, our Common Stock could be delisted and our stock price could suffer. A delisting of our Common Stock could negatively impact us by further reducing the liquidity and market price of our Common Stock and the number of investors willing to hold or acquire our 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 68% 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 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 2011, our stock closed at a low of \$0.85 and a high of \$1.80. 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.

**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 pharmaceutical, cosmeceutical and cosmetic products. 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 Company has never paid cash dividends on its common stock (\$.01 par value) and does not intend to pay cash dividends on its common stock in the foreseeable future. Additionally, the Company's Credit Agreement with Amzak Capital Management, LLC (as described below) prohibits the Company from declaring cash dividends with respect to its capital stock, except as otherwise required by the Company's existing organizational documents. The principal market for the Company's Common Stock is the NYSE Amex (symbol: IGI).

The following table shows the range of high and low prices on the NYSE Amex for the periods indicated:

|                    | <b><u>High</u></b> | <b><u>Low</u></b> |
|--------------------|--------------------|-------------------|
| <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              |
| <b><u>2010</u></b> |                    |                   |
| First quarter      | \$0.83             | \$0.65            |
| Second quarter     | 1.14               | 0.68              |
| Third quarter      | 1.57               | 0.99              |
| Fourth quarter     | 1.90               | 1.42              |

The approximate number of holders of record of the Company's Common Stock at March 21, 2012 was 610 (not including stockholders for whom shares are held in a nominee or street name).

**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.

## **Company Overview**

### *Strategic Overview*

IGI is engaged in the formulation, development, manufacture and packaging of topical semi-solid and liquid products for pharmaceutical, cosmeceutical and cosmetic customers. The Company's strategic plan is to build upon this foundation by expanding into the prescription pharmaceutical arena. This strategy will be based upon three initiatives: increasing the current contract manufacturing services business, developing a generic portfolio of formulations in topical dosage forms, and creating unique opportunities around the Company's licensed Novasome® technology and novel dosage forms.

The Company has structured a new management team to implement this plan. 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 plans to build a prescription pharmaceutical portfolio in the specialty areas of topical dosage forms. This will be accomplished through in-house formulation and development, and submission of ANDAs to the FDA. The entire approval process can take 3-5 years before a product is approved, of which the FDA approval portion is approximately 18 - 36 months. The Company plans to submit multiple ANDAs each year. To date, IGI has submitted five ANDAs. We filed one application in September 2010, January 2011 and December 2011, and we filed two applications in November 2011. All of the submissions are for generic topical prescription drugs.

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**

**2011 Compared to 2010**

The Company had a net loss of \$3,007,000, or \$(0.08) per share, in 2011 compared to a net loss attributable to common stockholders of \$4,707,000, or \$(0.20) per share, in 2010 which resulted from the following:

| <u>Revenues</u>                 | <u>For the years ended</u> |                          | <u>\$ change</u> | <u>% change</u> |
|---------------------------------|----------------------------|--------------------------|------------------|-----------------|
|                                 | <u>December 31, 2011</u>   | <u>December 31, 2010</u> |                  |                 |
|                                 | <i>(in thousands)</i>      |                          |                  |                 |
| Product Sales, net              | \$ 6,729                   | \$ 5,163                 | \$ 1,566         | 30 %            |
| Research and Development Income | 921                        | 666                      | 255              | 38 %            |
| Licensing and Royalty Income    | 100                        | 248                      | (148)            | (60)%           |
| Other Income                    | 56                         | 17                       | 39               | 229 %           |
| Total Revenues                  | \$ 7,806                   | \$ 6,094                 | \$ 1,712         | 28 %            |

The increase in product sales for the year ended December 31, 2011 as compared to the same period in 2010 was primarily due to increased annual product sales to the Company's major customers and product sales to new 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, 2011 as compared to the same period in 2010 is attributable to new customer relationships and their desire to have the Company develop, manufacture and package their new products or line extensions and the continued strong relationships with our current customer base. Licensing and royalty income decreased due to the decrease in sales of Novasome based products marketed by our licensees. The Company believes 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, 2011</u>   | <u>December 31, 2010</u> |                  |                 |
|                      | <i>(in thousands)</i>      |                          |                  |                 |
| Cost of Sales        | \$ 5,546                   | \$ 4,989                 | \$ 557           | 11%             |

Cost of sales increased by approximately \$557,000 for the year ended December 31, 2011 as a result of the increase in product sales by 30%. We also had a decrease of approximately \$179,000 in the reserves for products that the Company is no longer producing and obsolete and expired inventory for the year ended December 31, 2011. Cost of sales as a percentage of product sales was 82% for the year ended December 31, 2011 as compared to 97% for the year ended December 31, 2010. 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, 2011</u>   | <u>December 31, 2010</u> |                  |                 |
|   | <i>(in thousands)</i>      |                          |                  |                 |
| Selling General and Administrative Expenses | \$ 3,078                   | \$ 3,226                 | \$(148)          | (5)%            |
| Product Development and Research Expense    | \$ 2,151                   | \$ 1,510                 | \$ 641           | 42 %            |

Selling, general and administrative expenses for the year ended December 31, 2011 decreased as compared to the same period in 2010 due to a decrease of \$120,000 in salaries and related costs, a decrease of \$69,000 in employees compensation payable in stock, a decrease of \$115,000 in professional fees, a decrease in travel related expenses of \$97,000 and a decrease of \$21,000 in listing fees, offset by an increase in consulting fees of \$173,000, an increase of \$30,000 in recruiting fees, an increase of \$23,000 in the expense from the issuance of stock options and an increase of \$23,000 in board fees. As we continue to increase our development activities and prepare to market our own products, we would expect operating expenses to increase over time.

As the Company created its pharmaceutical foundation, transitioning from a contract manufacturer to a generic topical pharmaceutical company, product development and research expenses for the year ended December 31, 2011 increased as compared to the same period for 2010 as follows. Consistent with our strategy to create our pharmaceutical foundation, we increased spending on clinical studies, outside testing and supplies by \$458,000, increased the headcount in the Quality Analytical Department, which resulted in an increase of \$171,000 in salaries and related costs and increased consulting fees by \$100,000. These increases were partially offset by a decrease in a decrease in compensation payable in stock of \$84,000 and a decrease in professional fees of \$38,000.

| <u>Interest income (expense), net</u> | <u>For the years ended</u> |                          | <u>\$ change</u> | <u>% change</u> |
|---------------------------------------|----------------------------|--------------------------|------------------|-----------------|
|                                       | <u>December 31, 2011</u>   | <u>December 31, 2010</u> |                  |                 |
|                                       | <i>(in thousands)</i>      |                          |                  |                 |
| Interest Income and Other Income, net | \$ 17                      | \$ 4                     | \$ 13            | 325%            |
| Interest Expense                      | \$281                      | \$13                     | \$268            | 2062%           |

Interest income increased for the year ended December 31, 2011 as compared to the same period in 2010 due to higher average cash balances in 2011. Interest expense increased for the year ended December 31, 2011 as compared to the same period in 2010 due to amortization of debt issuance costs of \$161,000 and interest expense of \$110,000 for the year ended December 31, 2011 and the fact that \$500,000 of the Notes Payable Related Party (See Note 6 to our Consolidated Financial Statements) was drawn down in March 2011, and there was no debt outstanding during the year ended December 31, 2010.

| <u>Income Taxes</u> | <u>For the years ended</u> |                          | <u>\$ change</u> | <u>% change</u> |
|---------------------|----------------------------|--------------------------|------------------|-----------------|
|                     | <u>December 31, 2011</u>   | <u>December 31, 2010</u> |                  |                 |
|                     | <i>(in thousands)</i>      |                          |                  |                 |
| Income Taxes        | \$ 226                     | \$ 217                   | \$ 9             | 4%              |

The tax benefit of \$226,000 in 2011 and \$217,000 in 2010 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 of continuation.

| <u>Net loss attributable to common stockholders</u> | <u>For the years ended</u>                      |                          | <u>\$ change</u> | <u>% change</u> |
|---|---|--------------------------|------------------|-----------------|
|   | <u>December 31, 2011</u>                        | <u>December 31, 2010</u> |                  |                 |
|   | <i>(in thousands, except per share numbers)</i> |                          |                  |                 |
| Net loss attributable to common stockholders        | \$(3,007)                                       | \$(4,707)                | \$(1,700)        | (36)%           |
| Net loss per share                                  | \$ (0.08)                                       | \$ (0.20)                | \$ (0.12)        | (60)%           |

The decrease in net loss attributable to common stockholders for the year ended December 31, 2011 as compared to the same period in 2010 is due to the preferred stock dividends of \$1,284,000 in 2010, which did not occur in 2011 offset by the increase in Revenues and the increase in Costs and expenses and Interest Expense 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 Notes 6, 8, 9 and 10 to our Consolidated Financial Statements, we raised an aggregate of \$7,213,000 through private placements of equity with accredited investors in 2010 and \$5,304,000 in 2009 principally from private equity investors. In 2010, we also entered into a \$3,000,000 line of credit. 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 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 the Company, 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 beyond March 2013.

On December 21, 2010, we entered into a Credit Agreement with Amzak Capital Management, LLC pursuant to which Amzak has agreed to extend a \$3,000,000 credit facility to the Company. The Company had no amounts outstanding under the facility at December 31, 2010. The Company drew down \$500,000 in principal amount in March 2011. To secure payment of the amounts financed under the Credit Agreement, the Company has granted to the Lender a security interest in and against, generally, all of its tangible and intangible assets, except intellectual property, pursuant to that certain Pledge and Security Agreement with the Lender dated December 21, 2010. In addition, the Company has pledged to the Lender its equity interests in IGEN, Inc., one of the Company's wholly-owned subsidiaries.

On December 8, 2010, we completed the sale of 5,909,087 shares of the Company's common stock, \$0.01 par value per share, to several accredited investors, as defined in Rule 501 of Regulation D under the Securities Act of 1933, as amended at a price of \$1.10 per share, or an aggregate of approximately \$6,500,000. The Company paid placement agent fees of \$650,000 and issued warrants to purchase 354,546 shares of Common Stock at \$1.21 per share. The Common Stock and the warrants were issued in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act and Rule 506 promulgated thereunder.

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, which we refer to as 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 Preferred Stock is convertible into shares of common stock equal to (i) 1,000 plus any accrued and unpaid dividends, divided by (ii) \$0.69 (the closing price of the Company's common stock on the date of issuance of the Series C Convertible Preferred Stock).

The Company's operating activities used \$2,394,000 of cash during the year ended December 31, 2011 compared to \$3,013,000 used in the comparable period of 2010. The use of cash for the year ended December 31, 2011 and for the same period of 2010 was substantially a result of the net loss for the period offset by non-cash expense items.

The Company's investing activities used \$350,000 of cash in the year ended December 31, 2011 compared to \$195,000 of cash used in investing activities in the comparable period of 2010. The funds used for the year ended December 31, 2011 were for additional equipment and related services for the analytical and production area, and the funds used for the year ended December 31, 2010 were for additional equipment and related services for the analytical area.

The Company's financing activities provided \$542,000 of cash in the year ended December 31, 2011 compared to \$7,200,000 provided in the year ended December 31, 2010. 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 6 to our Consolidated Financial Statements. The cash provided for the year ended December 31, 2010 was primarily the proceeds of the sale of the Company's common stock as more fully described in Note 10 to our Consolidated Financial Statements and the Series C Convertible Preferred Stock financing as more fully described in Note 9 to the our Consolidated Financial Statements.



The Company's principal sources of liquidity are cash and cash equivalents of approximately \$2,914,000 at December 31, 2011, the \$2,500,000 available on the \$3,000,000 credit facility detailed in Note 6 and future cash from operations. The Company had working capital of \$4,370,000 at December 31, 2011.

### **Recent Pronouncements**

There were no new accounting pronouncements for the twelve months ended December 31, 2011 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.

#### 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 DEP 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 \$63,000 remains accrued as of December 31, 2011. 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.

### 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.

Licensing and Royalty Income: Revenues earned under licensing or sublicensing contracts are recognized ratably over the life of the agreements. Advance payments by customers are initially recorded as deferred income on the Consolidated Balance Sheet and then recognized ratably over the life of the agreement or as contract obligations are completed.

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. Payments under these arrangements are generally non-refundable and are reported as deferred until they are recognized 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 product 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. On occasions when revenue recognized exceeds the milestone or progress billed to our customer, an unbilled receivable is recorded on our Consolidated Balance Sheet.

### 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.

### Market Risk

The Company does not use derivative instruments.

### 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.

Accounts Receivable and Allowance for Doubtful Accounts

The Company extends credit to its 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.

Off Balance Sheet Arrangements

As of December 31, 2011, 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 report, 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 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 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 rule 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, 2011, 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, 2011 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 2012 Annual Meeting of Stockholders (the "2012 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 2012 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 2012 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, 2011 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<br/>(a)(1)</b> | <b>Weighted-average exercise price of outstanding options<br/>(b)(1)</b> | <b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))<br/>(c)(2)</b> |
|--|--|--|--|
| Equity compensation plans approved by security holders     | 1,448,016  | \$ 1.16  | 2,970,304  |
| Equity compensation plans not approved by security holders | (3)  | -  | -  |
| Total  | 1,448,016  | \$ 1.16  | 2,970,304  |

(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, 2011, we had 445,968 shares available for issuance pursuant to the 1999 Director Stock Option Plan, as amended, and 2,524,336 shares available for issuance pursuant to the 2009 Equity Incentive Plan, as amended.

(3)

Under the terms of his employment agreement, Hemanshu Pandya received a grant of (i) 975,000 shares of restricted stock and (ii) an option to purchase 530,145 shares of our common stock. On March 23, 2010, the Company announced in a Form 8-K filed with the Securities and Exchange Commission that on March 19, 2010, Hemanshu Pandya, the President and Chief Executive Officer of the Company, resigned as an employee of the Company and as a member of the board of directors, effective April 1, 2010. Upon the effective date of his resignation, Mr. Pandya retained the 324,968 restricted shares of common stock that were vested and forfeited the 650,032 restricted shares of common stock that were not vested per his Restricted Stock Agreement. Additionally, Mr. Pandya had 90 days from April 1, 2010 to exercise his 176,718 vested stock options, and he forfeited 353,427 stock options that were not vested per his Option Agreement.

Pursuant to the terms of his employment agreement, Mr. Forte received two grants of 80,000 shares of restricted stock and (ii) an option to purchase 110,000 shares of our common stock. On January 11, 2011 Philip S. Forte, the Chief Financial Officer of the Company, resigned from employment with the Company. Upon the effective date of his resignation, Mr. Forte retained the 53,328 restricted shares of common stock that were vested and forfeited the 106,672 restricted shares of common stock that were not vested per his Restricted Stock Agreement. Additionally, Mr. Forte had 90 days from January 11, 2011 to exercise his 36,663 vested stock options, and he forfeited 73,337 stock options that were not vested per his Option Agreement.

The above option grants will have an exercise price equal to the closing price of the Company's common stock on the date of grant. The above equity grants will be granted as an employment inducement award pursuant to the executive's employment agreement and will be issued without stockholder approval pursuant to Rule 711 of the NYSE Amex Company Guide.

### **ITEM 13.**

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

The information required by this item will be contained in the Company's 2012 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 2012 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

| <b>Exhibit Number</b> | <b>Description</b>   |
|-----------------------|--|
| (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)                 |  |

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- Amended and Restated Bylaws of IGI Laboratories, Inc., effective May 7, 2008 (incorporated by reference to Exhibit 3.2 to the Company's Report on Form 8-K, filed May 12, 2008).
- (3.3) Certificate of Designation of the Relative Rights and Preferences of the Series B-1 Convertible Preferred Stock and Series B-2 Preferred Stock of IGI Laboratories, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Report on Form 8-K filed March 19, 2009 (the March 2009 8-K)).
- (3.4) Certificate of Correction to Correct a Certain Error in the Certificate of Designation of the Relative Rights and Preferences of the Series B-1 Convertible Preferred Stock and Series B-2 Preferred Stock (incorporated by reference to Exhibit 3.2 to the March 2009 8-K).
- (3.5) 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 Secured Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to the March 2009 8-K).
- (4.3) Form of Preferred Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the March 2009 8-K).
- (4.4) 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).
- (4.5) 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).
- (4.6) 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).

- (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) Manufacturing and Supply Agreement dated May 31, 2002 between IGI, Inc. and IGEN, Inc. (collectively Suppliers) and Vetoquinol, USA, Inc. (Purchaser) (incorporated by reference to Exhibit 10.93 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002, filed March 10, 2003 (the 2002 Form 10-K)).
- (10.5) Technological Rights Agreement dated May 31, 2002 between IGI, Inc. and IGEN, Inc. (collectively Sellers) and Vetoquinol, USA, Inc. (Purchaser) (incorporated by reference to Exhibit 10.94 to the 2002 Form 10-K).
- (10.6) Supplemental Agreement dated May 31, 2002 between IGI, Inc. (Seller) and Vetoquinol, USA, Inc. (Buyer) (incorporated by reference to Exhibit 10.95 to the 2002 Form 10-K).
- (10.7) Amendment dated March 19, 2002, to License Agreement by and among Ethicon, Inc. and IGI, Inc., IGEN, Inc. and Immunogenetics, Inc. (incorporated by reference to Exhibit 10.98 to the 2002 Form 10-K).
- (10.8) Product Development Agreement dated November 10, 2003, between Pure Energy Corporation d/b/a/ Pure Energy of America, Inc. and IGI, Inc. (incorporated by reference to Exhibit 10.99 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, filed April 14, 2004 (the 2003 Form 10-K)).
- (10.9) License Agreement effective December 24, 2003, by and among Michael F. Holick, MD, PhD, A&D Bioscience, Inc. and IGI, Inc. (incorporated by reference to Exhibit 10.103 to the 2003 Form 10-K).
- (10.10) License Agreement dated February 9, 2004, between Universal Chemical Technologies, Inc. and IGI, Inc. (incorporated by reference to Exhibit 10.104 to the 2003 Form 10-K).
- (10.11) 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).
- (10.12) Agreement for Development Services dated March 27, 2003, between Chattem, Inc. and IGI, Inc (incorporated by reference to Exhibit 10.107 to the 2003 Form 10-K).
- (10.13) 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).
- (10.14) 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).
- (10.15) License Agreement dated October 11, 2006 between IGI, Inc. and Dermworx Inc. (incorporated by reference to Exhibit 10.51 to the Company's Form 10-KSB filed on April 2, 2007).
- (10.16) Loan and Security Agreement dated, January 29, 2007, in favor of Pinnacle Mountain Partners LLC (incorporated by reference to Exhibit 10.54 to the Company's Form 10-KSB filed on April 2, 2007).
- (10.17) First Amendment to Loan and Security Agreement, dated July 29, 2008, between IGI, Laboratories, Inc. and Pinnacle Mountain Partners LLC (incorporated by reference to Exhibit

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- 10.1 to the Company's Report on Form 8-K filed August 1, 2008).
- (10.18) Second Amendment to Loan and Security Agreement, dated January 26, 2009, between IGI, Laboratories, Inc. and Pinnacle Mountain Partners LLC (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed January 29, 2009).
- (10.19) Third Amendment to Loan and Security Agreement by and between IGI Laboratories, Inc. and Pinnacle Mountain Partners, LLC, dated March 13, 2009 (incorporated by reference to Exhibit 10.8 to the March 2009 8-K).
- (10.20) Second Amended and Restated Revolving Note, dated January 26, 2009, of IGI Laboratories, Inc., made in favor of Pinnacle Mountain Partners LLC (incorporated by reference to Exhibit 10.2 to the Company's Report on Form 8-K filed January 29, 2009).
- (10.21) Third Amended and Restated Revolving Note in favor of Pinnacle Mountain Partners, LLC, dated March 13, 2009 (incorporated by reference to Exhibit 4.4 to the March 2009 8-K).
- (10.22) Note Conversion Agreement by and between IGI Laboratories, Inc. and Pinnacle Mountain Partners, LLC, dated March 13, 2009 (incorporated by reference to Exhibit 10.9 to the March 2009 8-K).



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- (10.23)+ Agreement dated August 21, 2007 between Pharmachem Laboratories and IGI, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form-10QSB filed on November 14, 2007).
- (10.24)+ Agreement dated August 23, 2007 between Dermworx, Inc. and IGI, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Form-10QSB filed on November 14, 2007).
- (10.25)# Separation Agreement and Release dated September 16, 2008 between IGI Laboratories, Inc. and Carlene Lloyd (incorporated by reference to Exhibit 10.3 to the Company's Report on Form 8-K filed September 22, 2008).
- (10.26)# 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).
- (10.27) 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).
- (10.28) 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).
- (10.29) 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).
- (10.30) 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).
- (10.31) 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).
- (10.32) 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).
- (10.33) 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).
- (10.34)# 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).
- (10.35)# Form of Indemnification Agreement for Certain Directors (incorporated by reference to Exhibit 10.11 to the March 2009 8-K).
- (10.36)# 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).
- (10.37)# Employment Agreement dated May 29, 2009 between IGI Laboratories, Inc. and Hemanshu Pandya (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed May 29, 2009).
- (10.38)# Amended and Restated Employment Agreement dated February 18, 2010 between IGI Laboratories, Inc. and Philip S. Forte (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2010, filed May 17, 2010).
- (10.39)# Non-Qualified Stock Option Award Agreement dated May 29, 2009 between IGI Laboratories, Inc. and Philip S. Forte (incorporated by reference to Exhibit 10.3 to the Company's Report on

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- Form 8-K filed May 29, 2009).
- (10.40)# Separation of Employment Agreement and General Release between IGI Laboratories, Inc. and Rajiv Mathur dated May 28, 2009 (incorporated by reference to Exhibit 10.4 to the Company's Report on Form 8-K filed May 29, 2009).
- (10.41)# IGI Laboratories, Inc. 2009 Equity Incentive Plan, as amended and restated (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed May 24, 2010).
- (10.42)# 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).
- (10.43)# Form of Award Agreement for Restricted Shares under the IGI Laboratories, Inc. 2009 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Report on Form 8-K filed July 2, 2009).
- (10.44)# IGI Laboratories, Inc. Form of Award Agreement for Restricted Shares between IGI Laboratories, Inc. and Philip S. Forte (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-8 (No. 333-160341) filed June 30, 2009).

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- (10.45)# IGI Laboratories, Inc. Non-Qualified Stock Option Award Agreement dated June 29, 2009 between IGI Laboratories, Inc. and Hemanshu Pandya (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-8 (No. 333-160341) filed June 30, 2009).
- (10.46)# IGI Laboratories, Inc. Form of Award Agreement for Restricted Shares between IGI Laboratories, Inc. and Hemanshu Pandya (incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-8 (No. 333-160341) filed June 30, 2009).
- (10.47)# 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).
- (10.48) 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).
- (10.49) 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).
- (10.50) 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).
- (10.51) 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 )
- (10.52) 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).
- (10.53) 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).
- (10.54) 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).
- (10.55)# Separation of Employment Agreement and General Release dated January 14, 2011 between IGI Laboratories, Inc. and Philip S. Forte (incorporated by reference to Exhibit 10.1 to the Company's Report on Form 8-K filed January 18, 2011).
- (10.56)# 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).
- (10.57)# 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).
- (21) List of Subsidiaries (incorporated by reference to Exhibit 21 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1999, filed April 14, 2000).
- (23.1)\* Consent of EisnerAmper LLP.
- (31.1)\* Certification of the President and Chief Executive Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- (31.2)\* Certification of the Principal Financial and Accounting Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- (32.1)\*

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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, 2011, 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.

#

Indicates management contract or compensatory plan.

+

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

**SIGNATURES**

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

Date: IGI Laboratories, Inc.  
 March 28, 2012 By: /s/ Charles E. Moore  
 Charles E. Moore  
 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/ Charles E. Moore<br>Charles E. Moore   | Director, President and Chief Executive Officer<br>(Principal Executive Officer) | March 28, 2012 |
| /s/ Jenniffer Collins<br>Jenniffer Collins | Chief Financial Officer<br>(Principal Financial and Accounting Officer)          | March 28, 2012 |
| /s/ Joyce Erony<br>Joyce Erony             | Director   | March 28, 2012 |
| /s/ Jane E. Hager<br>Jane E. Hager         | Director   | March 28, 2012 |
| /s/ James Gale<br>James Gale               | Director   | March 28, 2012 |
| /s/ Michael Hemric<br>Michael Hemric       | Director   | March 28, 2012 |
| /s/ Narendra Borkar<br>Narendra Borkar     | Director   | March 28, 2012 |
| /s/ Bhaskar Chaudhuri<br>Bhaskar Chaudhuri | Director   | March 28, 2012 |



**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

IGI Laboratories, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of IGI Laboratories, Inc. and Subsidiaries (the Company ) as of December 31, 2011 and 2010, 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, 2011. 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, 2011 and 2010, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2011, in conformity with accounting principles generally accepted in the United States of America.

/s/ EisnerAmper LLP

Edison, New Jersey

March 28, 2012



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

(in thousands, except share and per share information)

|   | <b>December 31,<br/>2011</b> | <b>December 31,<br/>2010</b> |
|---|------------------------------|------------------------------|
| <b>ASSETS</b>   |                              |                              |
| Current assets:   |                              |                              |
| Cash and cash equivalents   | \$ 2,914                     | \$ 5,116                     |
| Accounts receivable, less allowance for doubtful accounts of \$16 in 2011 and \$10 in 2010                          | 1,197                        | 794                          |
| Licensing and royalty income receivable   | 11                           | 21                           |
| Inventories   | 1,195                        | 816                          |
| Other receivables   | 239                          | 234                          |
| Prepaid expenses  | 130                          | 190                          |
| Total current assets  | 5,686                        | 7,171                        |
| Property, plant and equipment, net  | 2,800                        | 2,769                        |
| Restricted cash, long term  | 54                           | 54                           |
| License fee, net  | 400                          | 500                          |
| Debt issuance costs, net  | 639                          | 800                          |
| Other   | 57                           | 57                           |
| Total assets  | \$ 9,636                     | \$ 11,351                    |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>  |                              |                              |
| Current liabilities:  |                              |                              |
| Accounts payable  | \$ 629                       | \$ 341                       |
| Accrued expenses  | 611                          | 476                          |
| Deferred income, current  | 38                           | 58                           |
| Capital lease obligation, current   | 38                           | 32                           |
| Total current liabilities   | 1,316                        | 907                          |
| Note payable, related party   | 500                          | -                            |
| Deferred income, long term  | 25                           | 29                           |
| Capital lease obligation, long term   | 30                           | 68                           |
| Total liabilities   | 1,871                        | 1,004                        |
| Commitments and contingencies   |                              |                              |
| Stockholders equity:  |                              |                              |
| Series A Convertible Preferred stock, liquidation preference - \$500,000 at December 31, 2011 and December 31, 2010 | 500                          | 500                          |

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|  |          |           |
|--|----------|-----------|
| Series C Convertible Preferred stock, liquidation preference -<br>\$1,686,527 at<br>December 31, 2011 and \$1,609,027 at December 31, 2010 | 1,517    | 1,517     |
| Common stock   | 415      | 413       |
| Additional paid-in capital   | 46,246   | 45,823    |
| Accumulated deficit  | (39,518) | (36,511)  |
| Less treasury stock, 1,965,740 common shares at cost   | (1,395)  | (1,395)   |
| Total stockholders' equity   | 7,765    | 10,347    |
| Total liabilities and stockholders' equity   | \$ 9,636 | \$ 11,351 |

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

**IGI LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS****For the years ended December 31, 2011 and 2010****(in thousands, except shares and per share information)**

|  | <b>2011</b>       | <b>2010</b>       |
|--|-------------------|-------------------|
| Revenues:  |                   |                   |
| Product sales, net   | \$ 6,729          | \$ 5,163          |
| Research and development income                            | 921               | 666               |
| Licensing and royalty income                               | 100               | 248               |
| Other revenue  | 56                | 17                |
| Total revenues   | 7,806             | 6,094             |
| Costs and Expenses:  |                   |                   |
| Cost of sales  | 5,546             | 4,989             |
| Selling, general and administrative expenses               | 3,078             | 3,226             |
| Product development and research expenses                  | 2,151             | 1,510             |
| Total costs and expenses                                   | 10,775            | 9,725             |
| Operating loss   | (2,969)           | (3,631)           |
| Interest expense   | (281)             | (10)              |
| Interest and other income, net                             | 17                | 1                 |
| Loss before benefit from income taxes                      | (3,233)           | (3,640)           |
| Benefit from income taxes                                  | 226               | 217               |
| <b>Net loss</b>  | <b>(3,007)</b>    | <b>(3,423)</b>    |
| Preferred stock dividends                                  | -                 | (1,284)           |
| <b>Net loss attributable to common stockholders</b>        | <b>\$ (3,007)</b> | <b>\$ (4,707)</b> |
| <b>Basic and diluted loss per common share</b>             | <b>\$ (.08)</b>   | <b>\$ (.20)</b>   |
| <b>Weighted average shares of common stock outstanding</b> |                   |                   |
| Basic and diluted  | 39,448,706        | 23,822,167        |

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



**IGI LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS****For the years ended December 31, 2011 and 2010****(in thousands)**

|  | <b>2011</b> | <b>2010</b> |
|--|-------------|-------------|
| <b>Cash flows from operating activities:</b>                         |             |             |
| Net loss   | \$ (3,007)  | \$ (3,423)  |
| Reconciliation of net loss to net cash used in operating activities: |             |             |
| Depreciation   | 319         | 276         |
| Amortization of license fee  | 100         | 100         |
| Bad debt expense   | 6           |             |
| Provision for write down of inventory                                | 180         | 430         |
| Stock-based compensation expense                                     | 351         | 501         |
| Amortization of debt issuance costs                                  | 161         | 4           |
| Changes in operating assets and liabilities:                         |             |             |
| Accounts receivable  | (409)       | (53)        |
| Licensing and royalty income receivable                              | 10          | 46          |
| Inventories  | (559)       | (372)       |
| Prepaid expenses and other current assets                            | 55          | (291)       |
| Accounts payable and accrued expenses                                | 424         | (147)       |
| Deferred income  | (25)        | (84)        |
| Net cash used in operating activities                                | (2,394)     | (3,013)     |
| <b>Cash flows from investing activities:</b>                         |             |             |
| Capital expenditures   | (350)       | (158)       |
| Deposit for capital lease  |             | (37)        |
| Net cash used in investing activities                                | (350)       | (195)       |
| <b>Cash flows from financing activities:</b>                         |             |             |
| Proceeds from note payable, related party                            | 500         |             |
| Sale of common stock, net of expenses                                |             | 5,696       |
| Sale of Series C Convertible Preferred Stock, net of expenses        |             | 1,517       |
| Proceeds from exercise of common stock options and warrant           | 74          | 12          |
| Principal payments on capital lease obligation                       | (32)        | (25)        |
| Net cash provided by financing activities                            | 542         | 7,200       |
| Net increase (decrease) in cash and cash equivalents                 | (2,202)     | 3,992       |
| Cash and cash equivalents at beginning of year                       | 5,116       | 1,124       |
| Cash and cash equivalents at end of year                             | \$ 2,914    | \$ 5,116    |

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Supplemental cash flow information:

|                              |    |       |    |       |
|------------------------------|----|-------|----|-------|
| Cash payments for interest   | \$ | 120   | \$ | 8     |
| Cash receipt from taxes, net |    | (226) |    | (222) |

Non cash transactions:

|  |    |  |     |       |
|--|----|--|-----|-------|
| Conversion of Series B-1 Convertible Preferred Stock and accrued dividends into Common Stock | \$ |  | \$  | 7,136 |
| Equipment financed through capital lease   |    |  |     | 122   |
| Issuance of common stock warrant related to credit facility                                  |    |  |     | 723   |
| Issuance of restricted stock   |    |  | 2   | 10    |
| Forfeiture of restricted stock   |    |  | (1) | (7)   |
| Debt issuance costs accrued  |    |  |     | 74    |

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

**IGI LABORATORIES, INC. AND SUBSIDIARIES**

**CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY**

**For the years ended December 31, 2011 and 2010**

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

|  | <b>Series A</b>  |               | <b>Series B-1<br/>Convertible</b> |               | <b>Series C<br/>Convertible</b> |               | <b>Common Stock</b> |               | <b>Additional</b> | <b>Accumulated</b> | <b>Treasu</b> |
|--|------------------|---------------|-----------------------------------|---------------|---------------------------------|---------------|---------------------|---------------|-------------------|--------------------|---------------|
|  | <b>Preferred</b> | <b>Stock</b>  | <b>Preferred</b>                  | <b>Stock</b>  | <b>Preferred</b>                | <b>Stock</b>  | <b>Shares</b>       | <b>Amount</b> | <b>Paid-In</b>    | <b>Deficit</b>     | <b>Stock</b>  |
|  | <b>Shares</b>    | <b>Amount</b> | <b>Shares</b>                     | <b>Amount</b> | <b>Shares</b>                   | <b>Amount</b> |                     |               | <b>Capital</b>    |                    |               |
| Balance,<br>December 31,<br>2009   | 50               | \$ 500        | 1,007                             | \$ 5,852      |                                 |               | \$ 19,302,987       | \$ 193        | \$ 31,975         | \$(31,804)         | \$(1,39       |
| Issuance of<br>preferred<br>stock pursuant<br>to a private<br>placement, net<br>of<br>associated<br>fees of \$33                   |                  |               |                                   |               | 1,550                           | 1,517         |                     |               |                   |                    |               |
| Conversion of<br>Series B-1<br>Convertible<br>Preferred<br>Stock and<br>accrued<br>dividends of<br>\$1,284 into<br>Common<br>Stock |                  |               | (1,007)                           | (5,852)       |                                 |               | 15,692,824          | 157           | 6,979             | (1,284)            |               |
| Issuance of<br>common stock<br>pursuant to a<br>private<br>placement, net<br>of<br>associated<br>fees of \$804                     |                  |               |                                   |               |                                 |               | 5,909,087           | 59            | 5,637             |                    |               |
| Issuance of<br>warrant to  |                  |               |                                   |               |                                 |               |                     |               | 723               |                    |               |



|   |    |        |    |       |           |            |        |           |  |  |            |         |
|---|----|--------|----|-------|-----------|------------|--------|-----------|--|--|------------|---------|
| purchase<br>common stock<br>pursuant to a<br>credit facility  |    |        |    |       |           |            |        |           |  |  |            |         |
| Stock based<br>compensation<br>expense stock<br>options       |    |        |    |       |           |            |        |           |  |  | 193        |         |
| Stock based<br>compensation<br>expense<br>restricted<br>stock |    |        |    |       |           |            |        |           |  |  | 308        |         |
| Restricted<br>stock issuance                                  |    |        |    |       | 1,019,000 |            | 10     |           |  |  | (10)       |         |
| Restricted<br>stock<br>forfeiture                             |    |        |    |       | (650,032) |            | (7)    |           |  |  | 7          |         |
| Stock options<br>exercised                                    |    |        |    |       | 14,333    |            | 1      |           |  |  | 11         |         |
| Net loss  |    |        |    |       |           |            |        |           |  |  | (3,423)    |         |
| Balance,<br>December 31,<br>2010                              | 50 | \$ 500 | \$ | 1,550 | \$ 1,517  | 41,288,199 | \$ 413 | \$ 45,823 |  |  | \$(36,511) | \$(1,39 |
| Stock based<br>compensation<br>expense stock<br>options       |    |        |    |       |           |            |        |           |  |  | 125        |         |
| Stock based<br>compensation<br>expense<br>restricted<br>stock |    |        |    |       |           |            |        |           |  |  | 226        |         |
| Restricted<br>stock<br>forfeiture                             |    |        |    |       |           | (106,672)  | (1)    |           |  |  | 1          |         |
| Stock options<br>exercised                                    |    |        |    |       |           | 81,663     | 1      |           |  |  | 73         |         |
| Cashless<br>exercise of<br>warrants                           |    |        |    |       |           | 200,646    | 2      |           |  |  | (2)        |         |
| Net loss  |    |        |    |       |           |            |        |           |  |  | (3,007)    |         |
| Balance,<br>December 31,<br>2011                              | 50 | \$ 500 | \$ | 1,550 | \$ 1,517  | 41,463,836 | \$ 415 | \$ 46,246 |  |  | \$(39,518) | \$(1,39 |

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

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**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. IGI develops, manufactures, fills and packages topical semi-solid and liquid products for cosmetic, cosmeceutical and pharmaceutical customers. The Company's products are used for cosmetic, cosmeceutical and prescription applications for the treatment of symptoms of dermatitis, acne, psoriasis and eczema. The Company is building upon this foundation by filing its own Abbreviated New Drug Applications ( ANDAs ) and continuing to expand into the prescription pharmaceutical arena. The Company's strategy is based upon three initiatives: increasing the current contract services business, developing a portfolio of generic formulations in topical dosage forms and creating unique opportunities around its licensed Novasome® technology. All of its product development and manufacturing is performed at its 25,000 sq.ft. facility in Buena, NJ.

*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, notes payable, accounts payable and other accrued liabilities at December 31, 2011 approximate their fair value for all periods presented.

*Accounts Receivable and Allowance for Doubtful Accounts*

The Company extends credit to its 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. When determining the allowances, a number of factors are considered including the length of time the receivable is past due, past loss history, the customer's current ability to pay and the general condition of the economy. The allowance requirements are based on the best information available to the Company and are reevaluated and adjusted as additional information is received. The Company charges off uncollectible receivables to the allowance when the likelihood of collection is remote.

*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 high quality financial institutions. Although we currently believe that the financial institutions with whom we do 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 2011, the Company had sales to two customers which individually accounted for more than 10% of the Company's product sales. These customers had sales of \$2,813,000 and \$1,106,000, respectively, and aggregately represented 58% of revenues from product sales. Accounts receivable related to the Company's major customers comprised 42% of all accounts receivable as of December 31, 2011.

In 2010, the Company had sales to two customers which individually accounted for more than 10% of the Company's product sales. These customers had sales of \$2,288,000 and \$579,000, respectively, and aggregately represented 55% of revenues from product sales.

The Company received royalty revenue in 2011 and 2010 from one customer, which accounted for approximately 95% of royalty revenue.

The Company operates in the United States with a concentration of our 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:

|                            | <u>Useful Lives</u> |
|----------------------------|---------------------|
| 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, 2011, 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, 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. For the fiscal year ended December 31, 2010, the largest component of accrued expenses was accrued payroll of \$154,000 and accrued legal and audit of \$154,000.

*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.

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.

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*

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 over the term of the loan. 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 a straight-line basis.

*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, 2011 and 2010 were \$4,400 and \$3,700, 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, 2011 and 2010, 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 include options and warrants to purchase the Company's common stock and the conversion of preferred stock, which were excluded from the net (loss) per share calculations due to their anti-dilutive effect amounted to 5,628,135 for 2011 and 5,628,817 for 2010.

#### *Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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, 2011 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 \$2,914,000 at December 31, 2011, the \$2,500,000 available on the \$3,000,000 credit facility detailed below and cash from operations. The Company sustained net losses of \$3,007,000 and \$3,423,000 for the years ended December 31, 2011 and 2010, respectively, and had working capital of \$4,370,000 at December 31, 2011.

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 Notes 6, 8, 9 and 10, we raised an aggregate of \$7,213,000 through private placements of equity with accredited investors in 2010 and \$5,304,000 in 2009 principally from private equity investors. In 2010, we also entered into a \$3,000,000 line of credit (See Note 6). As of December 31, 2011 the outstanding balance on the line of credit was \$500,000. The Company may require additional funding and this funding will depend, in part, on the timing and structure of potential business arrangements. If necessary, the Company may continue to seek to raise additional capital through the sale of its equity. It may be accomplished this 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. We also have the ability to defer certain product development and other programs, if necessary. We believe that our existing capital resources will be sufficient to support our current business plan beyond March 2013.

### 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 thru 2015. This payment is being amortized ratably over the ten-year period. For the years ended, December 31, 2011 and 2010, 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 2012-2015.

### 4. Inventories

Inventories as of December 31, 2011 and 2010 consisted of:

|                  | <b>2011</b><br><b>(in thousands)</b> | <b>2010</b><br><b>(in thousands)</b> |
|------------------|--------------------------------------|--------------------------------------|
| Raw materials    | \$ 1,070                             | \$ 759                               |
| Work in progress | 16                                   | 10                                   |

|                |    |       |    |     |
|----------------|----|-------|----|-----|
| Finished goods |    | 109   |    | 47  |
|                | \$ | 1,195 | \$ | 816 |

## 5. Property, Plant and Equipment

Property, plant and equipment, at cost, as of December 31, 2011 and 2010 consisted of:

|                                    |    | <b>2011</b>           |    | <b>2010</b>           |
|------------------------------------|----|-----------------------|----|-----------------------|
|                                    |    | <b>(in thousands)</b> |    | <b>(in thousands)</b> |
| Land                               | \$ | 257                   | \$ | 257                   |
| Building and improvements          |    | 3,526                 |    | 3,440                 |
| Machinery and equipment            |    | 2,900                 |    | 2,632                 |
| Construction in progress           |    | 123                   |    | 127                   |
|                                    |    | 6,806                 |    | 6,456                 |
| Less accumulated depreciation      |    | (4,006)               |    | (3,687)               |
| Property, plant and equipment, net | \$ | 2,800                 | \$ | 2,769                 |

The Company recorded depreciation expense of \$319,000, and \$276,000 in 2011 and 2010, respectively.

## 6. 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 has agreed to extend 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. The Company drew down \$500,000 in principal amount in March 2011.

To secure payment of the amounts financed under the Credit Agreement, the Company has granted to the Lender a security interest in and against, generally, all of its tangible and intangible assets, except intellectual property, pursuant to that certain Pledge and Security Agreement with the Lender dated December 21, 2010. In addition, the Company has pledged to the Lender its equity interests in IGEN, Inc., one of the Company's wholly-owned subsidiaries.

Under the Credit Agreement the Company has 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. Upon the breach of a covenant, without cure, the Lender will have certain remedies customarily found in such agreements including, but not limited to, the ability to cause all of the loans outstanding to be immediately due and payable and to terminate the Credit Agreement.

Upon funding of each Advance (as defined therein), the Company shall make payments of accrued interest on the unpaid Accreted Principal Amount (as defined therein) of each promissory note. The interest rate applicable to each promissory note shall be 14% per annum and interest payments are due on each March 31, June 30, September 30 and December 31 during the term of the Credit Agreement, commencing March 30, 2011. The Company may prepay any Advance in connection with the consummation of a Liquidity Event (as defined therein) or at any time subsequent to December 21, 2012.

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 is 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 Shares*) becoming exercisable July 1, 2012 if the Company has achieved certain milestones related to the Company's product development or financial growth. The Warrant is accounted for as an equity instrument. The fair value of the initial Warrant of \$723,541 will be recorded as debt issuance costs and amortized on a straight-line basis over the stated term

of the Credit Agreement which is five years. Amortization expense of \$161,000 and \$4,000 was recognized for the years ended December 31, 2011 and 2010, respectively. The Company anticipates amortization expense to be approximately \$160,000 for the years 2012 to 2016. On December 21, 2010, the fair value of the Conditional Warrant is not considered to be material. The fair value of the Conditional Warrant will be recognized as additional expense when and if it becomes exercisable.

The complete statement of the parties' rights and obligations under the Credit Agreement, the Pledge and Security Agreement, the Warrant and the Registration Rights Agreements is qualified in its entirety by reference to the terms and conditions of such documents which are filed as exhibits to the Company's Current Report on Form 8-K filed on December 22, 2010.

The Lender is a shareholder of the Company and participated in the private placement previously disclosed in a Current Report on Form 8-K filed with the Securities and Exchange Commission on December 8, 2010.

## **7. 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 our 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 a dividend expense in 2007. The warrants have been classified as an equity instrument.

## **8. Series B-1 Convertible Preferred Stock and Convertible Promissory Notes**

On March 13, 2009, the Company completed a \$6,000,000 private placement with certain investment funds affiliated with Signet Healthcare Partners, G.P. (the 2009 Offering). As part of the 2009 Offering, the Company issued 202.9 shares of Series B-1 Preferred Stock, with an ascribed value of \$1,218,000, \$4,782,600 in Secured Convertible Promissory Notes (Promissory Notes), Preferred Stock Purchase Warrants to purchase 797.1 shares of non-voting Series B-2 Preferred Stock (Preferred Stock Warrants), a Common Stock Purchase Warrant to purchase 350,000 shares of common stock (Common Stock Warrant) and amended its line of credit with Pinnacle. In connection with the 2009 Offering, the Company incurred placement and legal fees of approximately \$721,000, resulting in net proceeds of \$5,279,000. These fees were recorded as debt issuance costs in the amount of \$577,000 and paid-in capital in the amount of \$144,000.

The Series B-1 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 the Series B-1 Preferred Stock is convertible into 14,634 shares of common stock for an implied common stock conversion price of

\$0.41 per share, subject to certain adjustments and any accrued and unpaid dividends. At the time of issuance, the market price of the common stock into which the Series B-1 Preferred Stock is convertible was greater than the conversion price. The embedded beneficial conversion feature is being accounted for in accordance with ASC 470 relating to *Debt with Conversions and Other Options*. Accordingly, the beneficial conversion feature on the Series B-1 Preferred Stock is approximately \$505,000, which represents the amount by which the estimated fair value of the common stock issuable upon conversion exceeds the proceeds from such issuance and was treated as a deemed dividend on the date of the 2009 Offering.

The Promissory Notes had a maturity date of July 31, 2009 and an annual interest rate of 5%. On May 15, 2009, the \$4,782,600 aggregate principal amount of Promissory Notes issued in the 2009 Offering, together with accrued and unpaid interest, were converted into an aggregate of 803.979 shares of the Company's Series B-1 Preferred Stock and the Preferred Stock Warrants issued in the 2009 Offering became null and void.

The Company granted its placement agent for the 2009 Offering a Common Stock Warrant to purchase 350,000 shares of common stock for \$0.41 per share, which expires on March 13, 2012, as described more fully in Note 12.

In connection with the 2009 Offering, the Company and Pinnacle entered into the Third Amendment to Loan and Security Agreement. Pinnacle agreed to change the terms of repayment such that 50% of the amount borrowed under the line of credit, or \$500,000 as of March 31, 2009, would be payable on July 31, 2010 and the remaining balance would be payable on July 31, 2011. On May 15, 2009, the \$500,000 principal amount outstanding under the Note Payable was converted into 1,219,512 shares of the Company's common stock.

Debt discounts and debt issuance costs were amortized using the effective interest method and were fully amortized as of December 31, 2009.



On August 20, 2010, all of the issued and outstanding shares of the Series B-1 Convertible Preferred Stock, as well as accrued dividends of \$1,284,000 automatically converted into an aggregate of 15,692,824 shares of the Company's common stock, in accordance with the terms and conditions set forth in the Certificate of Designation of the Rights and Preferences of Series B-1 Convertible Preferred Stock and Series B-2 Preferred Stock (the Certificate of Designation).

Pursuant to the terms of the Certificate of Designation, the shares of Series B-1 Preferred Stock automatically convert into shares of the Company's Common Stock upon the date that the closing price of the Company's Common Stock shall have exceeded \$1.20 for a period of twenty-five (25) consecutive trading days immediately preceding such date. On August 19, 2010, the closing price of the Company's Common Stock was \$1.29, which was the twenty-fifth consecutive trading day for which the closing price of such Common Stock exceeded \$1.20. Accordingly, on August 20, 2010 all of the shares of Series B-1 Preferred Stock automatically converted into shares of the Company's Common 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 \$136,527 and amounted to \$1,686,527 at December 31, 2011.

#### **10. Private Placement**

On December 8, 2010, the Company, consummated the sale of 5,909,087 shares of the Company's common stock, \$0.01 par value per share (the *Common Stock*), to several accredited investors (collectively, the *Investors*), as defined in Rule 501 of Regulation D under the Securities Act of 1933, as amended (the *Securities Act*) at a price of \$1.10 per share, or an aggregate of approximately \$6,500,000. The sale of Common Stock was conditioned upon Investors purchasing not less than \$2,200,000 of Common Stock and the Company may accept subscriptions for not more than \$6,600,000 of Common Stock (the *Common Stock Offering*). In connection with the Common Stock Offering, the Company paid a placement agent fee of \$90,000 to Maxim Group LLC (*Maxim*) and issued Maxim warrants to

purchase 16,364 shares of Common Stock at \$1.21 per share (the *Maxim Warrants* ). The Company paid a placement agent fee of \$560,000 to Sanders Morris Harris Inc. ( *SMHI* ) and issued SMHI warrants to purchase 338,182 shares of Common Stock at \$1.21 per share in the same form of the Maxim Warrants (collectively, with the Maxim Warrants, the *Warrants* ) in connection with Maxim's engagement of SMHI as a selected dealer for the Offering. The Common Stock and the Warrants were issued in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act and Rule 506 promulgated thereunder.

SMHI may be deemed to have an affiliation with the Company. Joyce Erony and James Gale, serve on the Company's board of directors and are associated persons of SMHI. Mr. Gale is the Chief Investment Officer, a manager, and a member of Signet Healthcare Partners, LLC, a Delaware limited liability company ( *Signet Healthcare Partners* ) and Ms. Erony is a managing director and member of Signet Healthcare Partners. Signet Healthcare Partners is the general partner of Life Sciences Opportunities Fund II, L.P. and Life Sciences Opportunities Fund (Institutional) II, L.P. (the *Funds* ), both Delaware limited partnerships. The Funds together represent the largest owner of the Company's Common Stock and Series C Convertible Preferred Stock. As the general partner of the Funds, Signet Healthcare Partners receives a 2% annual management fee and holds a 20% carried interest. SMHI is a member of Signet Healthcare Partners and has a 50% operating profits percentage and a 40% carried interest percentage, but no management rights of Signet Healthcare Partners. SMHI also provides office space and certain accounting and administrative services to Signet Healthcare Partners and the Funds.

## 11. 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 1,939,798 options have been granted to non-employee directors through December 31, 2011. 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 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 time 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, 20 days after the initial mailing of the Company's Information Statement on Schedule 14C to its stockholders. 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, 2011, options to purchase 490,000 shares of common stock were outstanding under the 2009 Plan and 1,039,000 shares of restricted stock had been granted under the 2009 Plan.

### *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. The interest rates used are the U.S. Treasury yield curve in effect at the time of the grant.

| <u>Assumptions</u>          | <u>2011</u> | <u>2010</u> |
|-----------------------------|-------------|-------------|
| Dividend yield              | 0%          | 0%          |
| Risk free interest rate     | 0.76%       | 1.58%       |
| Estimated volatility factor | 58%         | 65%         |
| 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. Through the third quarter of 2009, the expected life of the options was estimated based on the Company's historical data, and prior to that time, the expected life of the options was estimated using the simplified method. The forfeiture rates are estimated based on historical employment/directorship termination experience. The risk free interest rate is based on US 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, 2010 shares issuable   |               |                                 |  |
| Under option                      | 2,014,177     | \$ .50-\$2.75                   | \$1.12                                 |
| Granted                           | 135,000       | .79 - 1.61                      | 0.97                                   |
| Exercised                         | (14,333)      | .50 - 1.00                      | 0.79                                   |
| Expired                           | (65,000)      | 1.88 - 2.75                     | 1.95                                   |
| Forfeited                         | (771,328)     | .50 - 2.75                      | 1.08                                   |
| December 31, 2010 shares issuable |               |                                 |  |
| Under option                      | 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 option                      | 1,448,016     | .55 - 1.74                      | 1.16                                   |
| Exercisable options at:           |               |                                 |  |
| December 31, 2011                 | 1,103,016     |                                 | \$1.13                                 |
| December 31, 2010                 | 1,050,179     |                                 | \$1.12                                 |

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

| Range of Exercise Price | Number of Options | Options Outstanding    |                                 | Options Exercisable |                                 |
|-------------------------|-------------------|------------------------|---------------------------------|---------------------|---------------------------------|
|                         |                   | Remaining Life (Years) | Weighted Average Exercise Price | Number of Options   | Weighted Average Exercise Price |
| \$ .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 following table summarizes information concerning outstanding and exercisable options as of December 31, 2010:

| Range of<br><u>Exercise Price</u> | Number of<br><u>Options</u> | Options Outstanding              |                          | Options Exercisable         |                          |
|-----------------------------------|-----------------------------|----------------------------------|--------------------------|-----------------------------|--------------------------|
|                                   |                             | Remaining<br><u>Life (Years)</u> | Exercise<br><u>Price</u> | Number of<br><u>Options</u> | Exercise<br><u>Price</u> |
| \$ .50 to \$1.00                  | 357,500                     | 5.74                             | \$ .71                   | 252,500                     | \$ .68                   |
| 1.01 to 1.50                      | 854,000                     | 6.76                             | 1.21                     | 740,663                     | 1.23                     |
| 1.51 to 2.00                      | 87,016                      | 5.39                             | 1.55                     | 57,016                      | 1.52                     |
| \$ .50 to \$2.00                  | 1,298,516                   | 6.39                             | \$1.09                   | 1,050,179                   | \$1.12                   |

The Company has recorded an aggregate of \$125,000 and \$193,000 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 year ended December 31, 2011 and 2010, respectively.

The aggregate intrinsic value of options outstanding was \$130,250 at December 31, 2011 and \$761,863 at December 31, 2010. The aggregate intrinsic value of the options exercisable was \$15,750 at December 31, 2011 and \$591,175 at December 31, 2010. The total intrinsic value of the options exercised during 2011 and 2010 was \$13,250 and \$8,600, respectively.

A summary of non-vested options at December 31, 2011 and changes during the year ended December 31, 2010 is presented below:

|   | <b>Options</b> | <b>Weighted Average<br/>Grant Date Fair Value</b> |
|---|----------------|---|
| Non-vested option at January 1, 2011    | 248,337        | \$ 0.49   |
| Granted                                 | 370,000        | 0.29  |
| Vested                                  | (160,000)      | 0.41  |
| Forfeited                               | (113,337)      | 0.56  |
| Non-vested options at December 31, 2011 | 345,000        | \$ 0.25   |

As of December 31, 2011, there was \$88,765 of total unrecognized compensation cost related to non-vested share-based compensation arrangements under the Plan. The costs will be recognized through December 2014.

#### *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 \$225,803 and \$307,488, respectively, of compensation expense during the year ended December 31, 2011 and 2010 related to restricted stock awards. Stock compensation expense is recognized over the vesting period of the restricted stock. At December 31, 2011, the Company had approximately \$257,536 of total unrecognized compensation cost related to non-vested restricted stock, all of which will be recognized through April 2013.

|                                       | <b>Number of<br/>Restricted<br/>Stock</b> | <b>Weighted<br/>Average<br/>Exercise Price</b> |
|---------------------------------------|---|--|
| Non-vested balance at January 1, 2011 | 939,000                                   | \$ 0.71  |

Changes during the period:

|                  |           |      |
|------------------|-----------|------|
| Shares granted   |           |      |
| Shares vested    | (313,000) | 0.71 |
| Shares forfeited |           |      |

|   |         |         |
|---|---------|---------|
| Non-vested balance at December 31, 2011 | 626,000 | \$ 0.71 |
|---|---------|---------|

See Note 18 below regarding restricted stock and stock options for Philip S. Forte, the Company's former Chief Financial Officer, upon his resignation as of January 11, 2011.

## 12. Stock Warrants

Stock Warrants as of December 31, 2011 and 2010 consisted of:

|                          | 2011            |  | 2010            |  |
|--------------------------|-----------------|--|-----------------|--|
|                          | <u>Warrants</u> | <u>Weighted<br/>Average<br/>Exercise Price</u> | <u>Warrants</u> | <u>Weighted<br/>Average<br/>Exercise Price</u> |
| Beginning balance        | 1,498,377       | \$0.36   | 262,500         | \$0.41   |
| Stock warrants granted   |                 |  | 1,235,877       | 0.35   |
| Stock warrants expired   |                 |  |                 |  |
| Stock warrants exercised | (262,500)       | 0.41   |                 |  |
| Ending balance           | 1,235,877       | \$0.35   | 1,498,377       | \$0.36   |



In connection with the private placement of the Company's Common Stock as more fully described in Note 10, the Company granted Common Stock Warrants to purchase 338,182 and 16,364, respectively, to each of its two placement agents for \$1.21 per share which expire on December 8, 2015.

In connection with the Credit Agreement with Amzak Capital Management, LLC as more fully described in Note 6, 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 connection with the private placement offering to certain investment funds affiliated with Signet Healthcare Partners, G.P. (the Offering) on March 13, 2009 (See Note 8 above), 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 expires 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.

### 13. Income Taxes

The (benefit) from income taxes attributable to loss from continuing operations before (benefit) from income taxes for the years ended December 31, 2011 and 2010 is as follows:

|                                | 2011           |       | 2010  |
|--------------------------------|----------------|-------|-------|
|                                | (in thousands) |       |       |
| Current tax expense (benefit): |                |       |       |
| Federal                        | \$             |       | \$    |
| State and local                |                | (226) | (217) |

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|   |          |          |
|---|----------|----------|
| Total current tax expense (benefit)       | (226)    | (217)    |
| Deferred tax expense                      |          |          |
| Federal                                   |          |          |
| State and local                           |          |          |
| Total deferred tax expense                |          |          |
| Total expense (benefit) from income taxes | \$ (226) | \$ (217) |

The Company sold some of its New Jersey operating loss carry forwards in exchange for net proceeds of \$231,000 and \$222,000 in 2011 and 2010 respectively.

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>2011</b>           |    | <b>2010</b> |
|--|-----------------------|----|-------------|
|  | <b>(in thousands)</b> |    |             |
| Statutory benefit                              | \$ (1,097)            | \$ | (1,237)     |
| Other non-deductible expenses                  | 1                     |    | 3           |
| State income taxes, net of valuation allowance | (149)                 |    | (143)       |
| Increase in Federal valuation allowance        | 1,019                 |    | 1,160       |
| Tax benefits expiring                          | \$ (226)              | \$ | (217)       |

Deferred tax assets included in the Consolidated Balance Sheets as of December 31, 2011 and 2010 consisted of the following:

|                                      | <b>2011</b><br><b>(in thousands)</b> |    | <b>2010</b><br><b>(in thousands)</b> |
|--------------------------------------|--------------------------------------|----|--------------------------------------|
| Current Assets                       |                                      |    |                                      |
| Allowance for doubtful accounts      | \$ 4                                 | \$ | 4                                    |
| Inventory reserve                    | 66                                   |    | 78                                   |
| Other                                | 91                                   |    | 49                                   |
| Total Current Assets                 | 161                                  |    | 131                                  |
| Long Term Assets (Liabilities)       |                                      |    |                                      |
| Property, plant and equipment        | 170                                  |    | 139                                  |
| Deferred royalty payments            | 12                                   |    | 14                                   |
| Tax operating loss carry forwards    | 9,899                                |    | 9,069                                |
| Tax credit carry forwards            | 335                                  |    | 335                                  |
| Non-employee stock options           | 560                                  |    | 507                                  |
| Other                                | (8)                                  |    | (8)                                  |
| Total Long Term Assets (Liabilities) | 10,968                               |    | 10,056                               |
| Gross Deferred Tax Asset (Liability) | 11,129                               |    | 10,187                               |
| Less: valuation allowance            | (11,129)                             |    | (10,187)                             |
| 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 \$9,899,000 over the years on the deferred tax assets relating to these net operating loss carryforwards.

Operating loss and tax credit carry forwards for tax reporting purposes as of December 31, 2011 were as follows:

**(in thousands)**

Federal:

|  |           |
|--|-----------|
| Operating losses (expiring through 2031)                       | \$ 28,041 |
| Research tax credits (expiring through 2025)                   | 279       |
| Alternative minimum tax credits (available without expiration) | 28        |

State:

|  |       |
|--|-------|
| Net operating losses - New Jersey (expiring through 2017)                | 3,563 |
| Alternative minimum assessment New Jersey (available without expiration) | 29    |

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

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 is currently examining 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 takes place and that the net operating loss carryforwards 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 2008 to 2011 due to the net loss carry forwards from those years.

#### **14. Lease Commitments**

The Company's commitments and contingencies consisted of operating leases for equipment of \$13,200 for 2012, \$11,200 for 2013 and \$9,400 for 2014. Rent expense was \$66,900 and \$68,700 for the years ended December 31, 2011 and 2010, respectively.

#### **15. 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 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 \$63,000 remains accrued as of December 31, 2011. 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, 2011 and 2010 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 New Jersey 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.

#### **16. 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 \$16,500 for 2011 and 2010, plus a catch-up contribution of up to \$5,500 for 2011 and 2010, 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 \$72,000 and \$61,000 in 2011 and 2010, respectively.

## **17. Related Party Transactions**

For a description of the Company's Credit Agreement with Amzak Capital Management, LLC and the Private Placement with Signet Healthcare Partners, G.P., the related parties, see Notes 6, 8, 9 and 10 above.

## **18. Changes in Management**

On January 11, 2011, Philip S. Forte, the Chief Financial Officer of the Company, resigned from employment with the Company. Joyce Erony, the Company's Chairwoman of the Board, acted as Acting Chief Financial Officer and as the Company's Principal Financial and Accounting Officer until August 15, 2011. In connection with Mr. Forte's departure from the Company, the Company entered into a Separation of Employment Agreement and General Release (the "Separation Agreement") dated January 14, 2011 with Mr. Forte. The Separation Agreement provides that the Company shall pay Mr. Forte \$125,000 as a separation payment, with such amount to be paid ratably over a 6 month period on each regular payroll payment date during such period. Such costs will be recognized in 2011. Also, in the Separation Agreement, Mr. Forte agreed to provide the Company with a general release, and Mr. Forte agreed to certain restrictive covenants, and reconfirmed his agreement to the confidentiality, non-competition and non-solicitation covenants set forth in his employment agreement with the Company, after the Separation Date. Upon the effective date of his resignation, Mr. Forte retained the 53,328 restricted shares of Common Stock that were vested and forfeited the 106,672 restricted shares of Common Stock that were not vested per his Restricted Stock Agreement. Additionally, Mr. Forte had 90 days from January 11, 2011 to exercise his 36,663 vested stock options, and he forfeited 73,337 stock options that were not vested per his Option Agreement. The 36,663 vested stock options were exercised on April 5, 2011. The description of the material terms of the Separation Agreement above is subject to the full terms and conditions of the Separation Agreement, a copy of which is filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 18, 2011.

On July 15, 2011, the Company announced that it had named Jenniffer Collins as its new Chief Financial Officer, effective July 21, 2011. Joyce Erony continued to serve as the Company's Acting Principal Financial and Accounting Officer until August 15, 2011. Under the terms of her employment agreement, Ms. Collins will receive an annual salary of \$210,000. On December 22, 2011, Ms. Collins also received an option to purchase 225,000 shares of Common Stock, the vesting terms of which are explained below. In addition, Ms. Collins 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. Ms. Collins will also be eligible to receive an annual performance bonus for each calendar year during the term of her employment, which may be payable in either, cash, stock options and/or restricted stock. Ms. Collins' target bonus will be equal to 30% of her base salary for the applicable fiscal year. All performance targets pursuant to such plan shall be determined by the Company's Compensation Committee. Ms. Collins is also subject to certain restrictive covenants as set forth in her employment agreement, including confidentiality, non-solicitation and non-competition. Ms. Collins' employment agreement further provides for payments upon certain types of employment termination events as further set forth in her employment agreement.

The above stock option grant has an exercise price equal to the closing price of Common Stock on the date of grant and will become fully vested over a period of three years as follows: (i) one-third of the stock options shall vest on the first anniversary of the date of the grant; (ii) one-third of the stock options shall vest on the second anniversary of the date of the grant and (iii) one-third of the stock options shall vest on the third anniversary of the date of the grant. In addition, any options 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.

**EXHIBIT INDEX**

| <b>Exhibit Number</b> | <b>Description</b>  |
|-----------------------|---|
| 23.1                  | Consent of EisnerAmper LLP  |
| 31.1                  | Certification of the President and Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.  |
| 31.2                  | Certification of the Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.   |
| 32.1                  | Certification of the President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.  |
| 32.2                  | Certification of the Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.   |
| 101                   | The following financial information from this Annual Report on Form 10-K for the year ended December 31, 2011, 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. |