IGI LABORATORIES, INC Form 10-K March 25, 2011

### **UNITED STATES**

### SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FO	D	NΙ	11	)-K
ГV	ĸ	IVI	- 11	7- N

(M	Mark One)			
X	ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  For the fiscal year ended December 31, 2010			
	OR			
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  For the transition period fromto			

# $Commission\ file\ number\ 001\text{-}08568$

### 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:**

# Title of each class

Name of each exchange on which registered

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 x

Indicate by check if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes "No x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes "No"

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

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

Large accelerated filer " Accelerated filer " Non-accelerated filer " Smaller reporting company x

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

The aggregate market value of the registrant's voting common equity held by non-affiliates of the registrant on June 30, 2010 was approximately \$6,620,000. 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, 2010.

As of March 23, 2011, there were 41,397,173 shares of the registrant s common stock outstanding.

1

# TABLE OF CONTENTS

Part I.	<u>Page</u>
Item 1. Business.	3
Item1A. Risk Factors.	8
Item1B. Unresolved Staff Comments.	16
Item 2. Property.	16
Item 3. Legal Proceedings.	16
Item 4. (Removed and Reserved)	16
Part II.	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.	17
Item 6. Selected Financial Data.	17
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.	17
Item 7A. Quantitative and Qualitative Disclosures About Market Risk.	24
Item 8. Financial Statements.	24
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.	24
Item 9A. Controls and Procedures.	24
Item 9B. Other Information.	25
Part III.	
Item 10. Directors, Executive Officers and Corporate Governance.	26
Item 11. Executive Compensation.	29
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.	33
Item 13. Certain Relationships and Related Transactions and Director Independence.	37
Item 14. Principal Accountant Fees and Services.	38

# Part IV.

Item 15. Exhibits and Financial Statement Schedules.

39

#### PART I

ITEM 1.
BUSINESS
Overview
IGI Laboratories, Inc. is a Delaware corporation formed in 1977. 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
Contract Services Business
We provide contract services to marketers of topical formulations. These customers contract with us for formulation development and/or manufacturing of products which are marketed in the customer s brand. These products range from pure cosmetic formulations sold by retail to the public, to prescription formulations promoted to physicians.

Our development and manufacturing capabilities encompass product formulation, scale-up, regulatory, quality assurance and in-house validation, as well as commercial manufacture. We formulate products in a broad range of topical semi-solid and liquid dosage forms, including: creams, ointments, gels, liquids, lotions and solutions for dermatologic and cosmetic applications. In addition to customer-requested formulation work, we have the capability to utilize our proprietary encapsulation delivery system in either the development of new products or the reformulation of existing products for our partners.

We offer our customers full turnkey manufacturing services, from ordering raw materials and packaging components to compounding, filling and packaging. We offer flexibility in manufacturing, from pilot batches to large commercial batches, from simple liquid solutions to challenging cream formulations; and in packaging, with high-speed filling and

packaging of bottles, jars, pumps and tubes. We also assist customers in package design and selection of the appropriate container and secondary packaging based upon the product s intended use and target audience. We supply our customers with fully-packaged and tested, ready-for-sale finished products.

We believe that contract services will continue to be crucial to our success. The customer base for these services are pharmaceutical companies, as well as cosmetic, cosmeceutical and over-the-counter, or 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. We intend to continue to create niche opportunities by providing high quality, customer-oriented service.

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.

In May 2010, we entered into a product development and supply agreement with Impax Laboratories of Hayward, CA, a leading marketer of prescription pharmaceutical products. Under the agreement, we will be responsible for developing two topical drug product candidates, obtaining U.S. Food and Drug Administration, or FDA, marketing approvals and manufacturing the commercial products for Impax.

In August 2010, we entered into a Turnkey Manufacturing Services Agreement with The NeoStrata Company. NeoStrata, headquartered in Princeton, NJ, is an internationally-recognized leader in skin care products. Its products, which are primarily cosmeceutical products, are marketed worldwide through consumer outlets, physician s offices and spas. Under the terms of the agreement, IGI is responsible for supplying NeoStrata fully-packaged, ready-for-sale product.

In September 2010, we entered into a product development agreement to provide formulation and development for a New Drug Application, or NDA topical product for a specialty pharmaceutical company. Under the arrangement, we are responsible for product formulation, stability, the manufacture of clinical materials, scale up and preparation of regulatory filings.

IGI s 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 ANDA route. 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. Our second ANDA was filed on December 30, 2010. We have a number of additional product candidates in various stages of development. We anticipate filing 4 to 6 ANDAs per year on an ongoing basis, assuming sufficient financial resources to support these product development plans.

We believe the topical market to be an attractive one. The U.S. market for topical drug products is estimated at \$8-10 billion by IMS Health, a small segment of the estimated \$300 billion pharmaceutical market. Topical drugs are defined as those intended for local external application, meaning used on the skin, scalp, eyes, ears, and outer areas of the vagina and anus. They come in a variety of dosage forms: creams, ointments, lotions, gels, solutions and suspensions. Topical drugs are unique in that they are not intended to enter the bloodstream.

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

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.

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.

### **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 3 customers has increased 254% 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 a 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 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. In 2009, three (3) major customers accounted for 52% of revenue from product sales. Although we are beginning to focus on entering the topical generic drug market, we have not earned any revenue from this line of business to date.

#### **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.

In 2010, we doubled our investment into R&D from \$740,000 in 2009 to \$1,510,000 to support ANDA development activities.

#### 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 by carefully-selected established partners. These partners will be responsible for sales and marketing of our manufactured generic products. We are also evaluating the timing for launching our own sales force for marketing our own generic pharmaceutical products. To date, we have filed two 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 inspection took place in March 2011.

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, 2010.

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 24 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 23,042 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, 2010 we had a total of 34 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**

In May 2010, we entered into a product development and supply agreement with Impax Laboratories of Hayward, CA ( Impax ), a leading marketer of prescription pharmaceutical products. Under the agreement, we will be responsible for developing two topical drug product candidates, obtaining FDA marketing approvals and manufacturing the commercial products for Impax.

In May 2010, we were notified by NYSE Amex that we were below certain of the NYSE Amex continued listing standards. On June 24, 2010, we submitted a plan to NYSE Amex for compliance with the continued listing standards. 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. 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.

In August 2010, we entered into a Turnkey Manufacturing Services Agreement with The NeoStrata Company. NeoStrata, headquartered in Princeton, NJ, is an internationally-recognized leader in skin care products. Its products, which are primarily cosmeceutical products, are marketed worldwide through consumer outlets, physician s offices and spas. Under the terms of the agreement, we are responsible for supplying NeoStrata fully-packaged, ready-for-sale products.

In August 2010, all of the issued and outstanding shares of our Series B-1 Convertible Preferred Stock, par value \$0.01 per share automatically converted into an aggregate of 15,692,824 shares of our 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.

In September 2010, we entered into a product development agreement to provide formulation, development and manufacturing for a NDA, topical product for a specialty pharmaceutical company. Under the arrangement, we are responsible for product formulation, stability, the manufacture of clinical materials, scale up and preparation of regulatory filings.

In December 2010, we completed a \$6,500,000 private placement for the sale of 5,909,087 shares of the Company s common stock resulting in net proceeds of approximately \$5,696,000 as more fully described in Note 10 to our Consolidated Financial Statements.

In December 2010, we entered into a credit agreement for a \$3,000,000 credit facility as more fully described in Note 6 to our Consolidated Financial Statements. To secure payment of amounts financed, we have granted to the lender a security interest in and against, generally, all of our tangible and intangible assets, except intellectual property.

#### 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, 2010, our stockholders—equity was \$10.4 million and we had an accumulated deficit of \$37 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 rely on a limited number of customers for a large portion of our revenues.

We depend on a limited number of customers for a large portion of our revenue. For the year ended December 31, 2010 two of our customers accounted for 55% and for the year ended December 31, 2009 three of our customers accounted for 52% of our product sales revenue. 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 of such facilities are \$676,000 and \$65,000, respectively, of which \$24,000 and \$10,000 remain accrued as of December 31, 2010. 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 were 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.

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 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 claim 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, 2010 and December 31, 2009, 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 is necessary for us to produce reliable financial reports and is 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, 2010, the average daily trading volume of our Common Stock on the NYSE Amex was approximately 9,900 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 out 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 will be 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 63% 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 the last two fiscal years, our stock price has closed at a low of \$0.55 in the first quarter of 2009 and a high of \$1.74 in the fourth quarter of 2010. 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 estimate	s by us or by aı	ny securities analysts w	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.

#### **PROPERTY**

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.

# **Removed and Reserved**

16

#### **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: IG).

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

	<u>High</u>	Low
<u>2010</u>		
First quarter	\$ .83	\$ .65
Second quarter	1.14	.68
Third quarter	1.57	.99
Fourth quarter	1.90	1.42
<u>2009</u>		
First quarter	\$ .92	\$ .17
Second quarter	1.60	.68
Third quarter	1.50	.82
Fourth quarter	1.25	.21

The approximate number of holders of record of the Company s Common Stock at March 23, 2011 was 625 (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 it 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 - 24 months. The Company plans to submit multiple ANDAs each year.

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.

## Recent Events

In December 2010, we completed a \$6,500,000 private placement for the sale of 5,909,087 shares of the Company s common stock resulting in net proceeds of approximately \$5,696,000 as more fully described in Note 10 to our Consolidated Financial Statements.

In December 2010, we entered into a credit agreement for a \$3,000,000 credit facility as more fully described in Note 6 to our Consolidated Financial Statements. To secure payment of amounts financed, we have granted to the lender a security interest in and against, generally, all of our tangible and intangible assets, except intellectual property.

## **Results of Operations**

2010 Compared to 2009

The Company had a net loss attributable to common stockholders of \$4,707,000, or \$(0.20) per share, in 2010 compared to a net loss of \$7,408,000, or \$(0.46) per share, in 2009 which resulted from the following:

	For the year			
<u>Revenues</u>	December 31, 2010	December 31, 2010 December 31, 2009		<u>% change</u>
	ands)			
Product Sales, net	\$ 5,163	\$ 3,203	\$ 1,960	61 %
Research and Development Income	666	281	385	137 %
Licensing and Royalty Income	248	294	(46)	(16)%
Other Income	17		17	100 %
Total Revenues	\$ 6,094	\$ 3,778	\$ 2,316	61 %

The increase in product sales for the year ended December 31, 2010 as compared to the same period in 2009 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, 2010 as compared to the same period in 2009 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>For the years ended</u>				
Costs of Sales	<u>December 31, 2010</u>	December 31, 2009	<u>\$ change</u>	<u>% change</u>	
	(in thous	ands)			
Cost of Sales	\$ 4,989	\$ 3,527	\$ 1,462	41%	

Cost of sales increased by approximately \$1,292,000 for the year ended December 31, 2010 as a result of the increase in product sales by 61%. We also had an increase of approximately \$170,000 due to reserves for products that the Company is no longer producing and obsolete and expired inventory for the year ended December 31, 2010. Cost of sales as a percentage of product sales was 97% for the year ended December 31, 2010 as compared to 110% for the year ended December 31, 2009.

	For the years ended			
Operating Expenses	<u>December 31, 2010</u>	<u>December 31, 2009</u>	<u>\$ change</u>	<u>% change</u>
	(in thou			
Selling General and Administrative Expenses	\$ 3,226	\$ 3,602	\$ (376)	(10)%
Product Development and Research Expense	\$ 1,510	\$ 740	\$ 770	104 %

Selling, general and administrative expenses for the year period ended December 31, 2010 decreased as compared to the same period in 2009 as the prior period included a severance expense of \$341,000 for our former President and Chief Executive Officer per his 2009 separation agreement, a decrease of \$338,000 in professional and consulting fees and a decrease of \$62,000 in expense from the issuance of stock options, offset by an increase of \$262,000 in salaries and related expenses, an increase in directors fees of \$51,000 and an increase of \$46,000 in travel related expenses.

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, 2010 increased as compared to the same period for 2009 as follows. Salaries and related costs increased \$419,000 due to establishing a fully staffed Quality Analytical Department, clinical studies expense of \$131,000 was incurred in 2010, supplies and outside testing increased by \$110,000 and the expense from the issuance of stock options increased by \$64,000.

Interest income (expense), net	For the years ended  December 31, 2010 December 31, 2009  (in thousands)			<u>% change</u>	
Interest Income	\$ 3	\$ 19	\$ (16)	(84)%	
Interest Expense	\$ 13	\$ 957	\$ 944	99 %	

Interest expense decreased for the year ended December 31, 2010 as compared to the same period in 2009 due to approximately \$943,000 of accrued interest and amortization of debt discount and debt issuance costs related to the convertible notes payable issued in connection with the Offering (see Note 8 to the Company s Consolidated Financial Statements) that were included in interest expense in 2009. Interest income decreased for the year ended December 31, 2010 as compared to the same period in 2009 due to lower average cash balances in 2010.

<u>For the year</u>	<u>rs ended</u>		
December 31, 2010	December 31, 2009	<u>\$ change</u>	<u>% change</u>

(in thousands)

Income Taxes \$ 217 \$ 108 \$ 109 101%

The tax benefit of \$222,000 in 2010 and \$108,000 in 2009 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.

Net loss attributable to common stockholders	For the year December 31, 2010 (in thousands, except	<u>December 31, 2009</u>	<u>\$ change</u>	<u>% change</u>
Net loss attributable to common stockholders	\$ (4,707)	\$ (7,408)	\$ (2,701)	(36)%
Net loss per share	\$ (0.20)	\$ (0.46)	\$ (0.26)	(57)%

The decrease in net loss attributable to common stockholders for the year ended December 31, 2010 as compared to the same period in 2009 is due to approximately \$943,000 of accrued interest and amortization of debt discount and debt issuance costs related to the convertible notes payable issued in connection with the 2009 Offering (see Note 8 to our Consolidated Financial Statements) that were included in interest expense and the dividend accreted for beneficial conversion features of \$2,488,000 for 2009, as well as the items noted above, offset by the preferred stock dividends of \$1,284,000 in 2010.

## **Liquidity and Capital Resources**

The Company s business operations have been primarily funded over the past two 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 2012.

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).

On March 13, 2009, the Company completed a \$6,000,000 private placement, resulting in net proceeds of approximately \$5,279,000, with certain investment funds affiliated with Signet Healthcare Partners, G.P., which we

refer to as the Offering, as more fully described in Note 8 to our Consolidated Financial Statements. As a condition to the consummation of the Offering, on March 13, 2009, the Company and Pinnacle entered the Third Amendment to Loan and Security Agreement pursuant to which the parties agreed to change the final payment date of the amounts borrowed under the line of credit from July 31, 2009 to instead provide that 50% of the amount of all loans and advances made by Pinnacle under the line of credit will become due and payable on July 31, 2010 and the remaining outstanding loans and advances, together with interest thereon, will become due and payable on July 31, 2011.

In addition, as a condition to the consummation of the Offering, the Company and Pinnacle entered into a note conversion agreement dated March 13, 2009, pursuant to which Pinnacle agreed to convert the principal amount outstanding under the Third Amended and Restated Revolving Note, which we refer to as the Note Payable into shares of the Company s common stock at a conversion rate of \$0.41 per share upon receipt of stockholder approval by the Company of such conversion, which we refer to as the Note Conversion. For additional information relating to the Note Conversion, see Note 6 to our Consolidated Financial Statements. For additional information relating to the Offering, see Note 8 to our Consolidated Financial Statements.

In connection with the Offering, certain holders of our capital stock, representing approximately 51.7% of the voting power of the outstanding shares of our capital stock entitled to vote to approve the Offering, entered into a voting agreement, pursuant to which such holders agreed to vote or execute and deliver a written consent in favor of approving the Offering. At the Company s 2009 annual meeting of stockholders held on May 15, 2009, the Company s stockholders approved the Offering and Note Conversion. Immediately upon stockholder approval, the \$4,782,600 aggregate principal amount of promissory notes issued in the Offering by the Company to the investment funds affiliated with Signet Healthcare Partners, G.P., together with accrued and unpaid interest, were converted into an aggregate of approximately 804 shares of the Company s Series B-1 Convertible Preferred Stock and the warrants to purchase shares of the Company s Series B-2 Preferred Stock issued to these investment funds were cancelled. Additionally, the \$500,000 principal amount outstanding under the Pinnacle Note Payable was converted into 1,219,512 shares of the Company s common stock.

On January 29, 2009, the secured line of credit with Pinnacle Mountain Partners, LLC, which we refer to as Pinnacle, a company owned by Dr. Edward and Jane Hager, significant stockholders of the Company, and in the case of Mrs. Hager, a director of the Company, was amended and extended for a term of six months, which we refer to as the Second Amendment to Loan and Security Agreement, as more fully described in Note 6 to our Consolidated Financial Statements. The Company had an outstanding principal balance under the Second Amendment to Loan and Security Agreement with a face value of \$500,000 as of May 15, 2009 and interest expense related to this line of credit was \$14,065 for the period January 1, 2009 to May 15, 2009 (date of conversion).

The Company's operating activities used \$3,013,000 of cash during the year ended December 31, 2010 compared to \$3,619,000 used in the comparable period of 2009. The use of cash for the year ended December 31, 2010 and for the same period of 2009 was substantially a result of the net loss for the period offset by non-cash expense items.

The Company s investing activities used \$195,000 of cash in the year ended December 31, 2010 compared to \$736,000 of cash used in investing activities in the comparable period of 2009. The funds used for the year ended December 31, 2010 were for additional equipment and related services for the analytical area, and the funds used for the year ended December 31, 2009 were for additional equipment and improvements for the packaging and filling lines.

The Company's financing activities provided \$7,200,000 of cash in the year ended December 31, 2010 compared to \$5,308,000 provided in the year ended December 31, 2009. The cash provided for the year ended December 31, 2010 is 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 Company s Consolidated Financial Statements. The cash provided for the year ended December 31, 2009 is mainly from the proceeds of the Series B-1 Convertible Preferred Stock financing and the Note Payable as more fully described in Note 8 to the Company s Consolidated Financial Statements.

The Company s principal sources of liquidity are cash and cash equivalents of approximately \$5,116,000 at December 31, 2010, the \$3,000,000 credit facility detailed above and future cash from operations. The Company had working capital of \$6,264,000 at December 31, 2010.

#### **Recent Pronouncements**

In April 2010, the Financial Accounting Standards Board, or FASB, provided guidance under ASC 605 on defining a milestone and determining when it is appropriate to apply the milestone method of revenue recognition for research and development transactions. Vendors can recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period the milestone is achieved if the milestone meets all the criteria stated in the guidance to be considered substantive and must be considered substantive in its entirety. The Company adopted this standard for the three month period ended June 30, 2010 and the adoption is not expected to 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 April 6, 2000, officials of the New Jersey Department of Environmental Protection, which we refer to as DEP, inspected the Company s leased storage site in Buena, New Jersey, and issued Notices of Violation, which we refer to as NOVs, relating to the storage of waste materials in a number of trailers at the site. The Company established a disposal and cleanup schedule and completed the removal of materials from the site. In March 2006, the Company received a judge s decision from the Office of Administrative Law, which we refer to as OAL, of a fine in the amount of \$35,000 in respect to the NOVs the Company received from the DEP. Due to the criminal settlement that was reached between the Company and the DEP in 2002, the Company had a credit of \$40,000 to be used against any fines determined as a result of the civil matter, therefore, the Company did not have to pay any money to the DEP for the settlement amount. The DEP subsequently issued a final decision, which accepted the violation findings but rejected the OAL Judge s penalty recommendation, reinstituting a previously proposed penalty by the DEP of \$215,000, less the \$40,000 credit previously mentioned or \$175,000. The Company appealed this to the Superior Court of the NJ Appellate Division, which determined that the Commission s decision was reasonable thus affirming the DEP Commissioner s decision. This amount of \$175,000 was accrued for in the fourth quarter of 2007. The Company reached a settlement with DEP Commissioner and agreed to pay the above amount in six equal installments. The final installment was paid on June 30, 2009.

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 \$676,000, of which \$24,000 remains accrued as of December 31, 2010. 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 estimated cost for the remediation is \$65,000, of which \$10,000 remains accrued as of December 31, 2010. 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.

#### **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.

<u>Product Sales</u>: 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.

<u>Licensing and Royalty Income</u>: 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, 2010, 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

On August 16, 2010, the Company was notified that Amper, Politziner and Mattia, LLP ( Amper ), the Company s independent registered public accounting firm, combined its practice with that of Eisner LLP ( Eisner ) and the name of the combined practice operates under the name EisnerAmper LLP. The Audit Committee of the Company s board of directors subsequently engaged EisnerAmper LLP to serve as the Company s new independent registered public accounting firm.

Prior to engaging EisnerAmper LLP, the Company did not consult with Eisner regarding any of the matters or reportable events set forth in Item 304(a)(2)(i) and (ii) of Regulation S-K.

In connection with the audit of the Company s consolidated financial statements for the fiscal year ended December 31, 2009 and through the date of engagement of EisnerAmper LLP, there were (i) no disagreements between the Company and Amper on any matters of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of Amper, would have caused Amper to make reference to the subject matter of the disagreement in their report on the Company s financial statements for such year or for any reporting period since the Company s last fiscal year end and (ii) no reportable events within the meaning set forth in item 304(a)(1)(v) of Regulation S-K.

T	$\mathbf{T}$	$\mathbf{E}$	M	9	A.

#### 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 Acting 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 Acting 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 Acting 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 Acting 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, 2010, 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, 2010 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

## **Identification of Directors**

The following table sets forth information regarding each of our current directors according to the information furnished to us by each such director:

Name	Age	Positions Currently held with IGI	Committee Membership		or of IGI nce
Jane E. Hager	65	Director	A, N	1982	2003
				2007	Present
James C. Gale (1)	61	Director	N	2009	Present
Charles Moore	62	Director, President and Chief Executive Officer		2010	Present
Narendra N. Borkar	70	Director	С	2009	Present
Michael Hemric	58	Director	A	2009	Present
Joyce Erony (2)	51	Director, Acting Chief Financial Officer	N	2009	Present
Bhaskar Chaudhuri	56	Director	C	2010	Present

(1)

Mr. Gale was initially appointed to our Board of Directors on May 15, 2009 as a designee of the holders of Series B-1 Convertible Preferred Stock.

(2)

Ms. Erony was initially appointed to our Board of Directors on March 13, 2009 as a designee of the holders of Series B-1 Convertible Preferred Stock. Ms. Erony has served as our Acting Chief Financial Officer since January 2011 and she will remain in this position while the Company conducts its search for a replacement.

- A Audit Committee
- C Organization and Compensation Committee
- N Nominating and Corporate Governance Committee

#### **Name**

## Principal Occupation, Other Business Experience and Other Directorships

Jane E. Hager

President of Prescott Investment Corp., since 1991 and Pinnacle Mountain Partners, LLC since 2002; Managing Member of Gulf Coast Investment Partners, LLC since 2003 and Angelfish Investments, LLC since 2004, all of which are real estate development and/or investment companies. She is a founder and past director of IGI Laboratories, Inc. from 1982 to 2003 and Novavax, Inc. [NASDAQ] from 1995 to 2002. Mrs. Hager is also a founding director and Chair of the Audit Committee of Centrix Bank & Trust, Bedford, NH [OTCBB] since 1999 and a director of ZSGenetics, Stoddard, NH since 2006, a gene expression and sequencing company. Founding Partner of Signet Healthcare Partners. Prior to founding Signet, Mr. Gale was head of principal investment activities and investment banking at Gruntal & Co., LLC. Prior to joining Gruntal, Mr. Gale originated and managed private equity investments for Home Insurance Co., Gruntal s parent. Earlier in his career, Mr. Gale was a senior Investment Banker at E.F. Hutton & Co.

James C. Gale

Mr. Gale is currently the Chairman of the Board of Alpex Pharma S.A. and Cydex Inc. and also serves on the Board of Directors of Anteis SA, Octoplus BV, Pfenex Inc., Spepharm BV and Paladin Laboratories. Mr. Gale holds a Masters of Business Administration from the University of Chicago.

26

#### Name

## Principal Occupation, Other Business Experience and Other Directorships

Narendra N. Borkar

Chief Executive Officer of Aurobindo Pharma USA (2004-2006), Chief Executive Officer of Caraco Pharmaceutical Laboratories (1997-2003), various senior roles for Novartis (formerly Ciba-Geigy) (1981-1997), General Manager of Apte Amalgamation (1979-1981), Works Engineer for Hoffman La Roche (1976-1979), Project Manager for Union Carbide Corp. and Merck & Company, Inc. (1966-1976). Executive with Alcon Laboratories (1980-2008), including Area President/Far East (2007-2008), Vice President/General Manager Pharmaceutical Division (2002-2006), Vice President/Area Manager for Southeast Asia (1999-2002), Vice President/General Manager - Consumer Products Division (1997-1999). Earlier in his career, Mr. Hemric was involved in Sales at Alcon Laboratories and other companies, including The Gillette Company

Charles Moore

Michael Hemric

Mr. Moore served as our Vice President of Technical Operations from February 2010 until March 2010 and has served as our President and Chief Executive Officer since April 1, 2010. Prior to joining the Company, from March 2008 to February 2010, Mr. Moore was Vice President of Business Development for Infa Inc., where he was responsible for development of the North American business of the Infa Group, an Italian-based Active Pharmaceutical Ingredient (API) manufacturer. From March 2006 to February 2008, Mr. Moore served as Director of Business Development for VinChem Inc., a pharmaceutical outsourcing solutions provider. From 1980 to 2006, Mr. Moore served in various senior management roles for Altana Inc. (now Nycomed) including being the Head of the Product Development Task Force. He was responsible for researching the U.S. dermatology market, selecting the product candidates for in-house development, and overseeing the development process through ANDA approval and launch. Mr. Moore received his BSBA from Thomas A. Edison College.

Joyce Erony

Managing Director of Signet Healthcare Partners. Prior to joining Signet, Ms. Erony spent 14 years (1991-2004) at Salomon Brothers Inc., Salomon Smith Barney, Inc. and ultimately Citigroup, which acquired the former companies, most recently as Managing Director responsible for Citigroup s activities in Specialty Pharmaceuticals. Prior to joining Citigroup, Ms. Erony worked as an economist (1983-1991), primarily at the World Bank and International Finance Corporation advising various international development agencies and multilateral organizations. Since January 2011, Ms. Erony has served as our Acting Chief Financial Officer while the Company conducts a search for a permanent replacement.

Ms. Erony has served as a director of Dow Pharmaceutical Sciences, Inc., Control Delivery Systems, Inc., Anteis, S.A., ORBIS International and Atlantis Components, Inc. She currently serves as a director of Peak Surgical and Cedarburg Pharmaceuticals Inc. Ms. Erony holds a Diploma in International Law and Economics from the London School of Economics and Political Science (1982) and a BS in Management from Case Western Reserve University (1981).

Bhaskar Chaudhuri

Mr. Chaudhuri has more than 20 years experience in pharmaceutical management, research and development. Mr. Chaudhuri served as President of Valeant Pharmaceuticals International until September 2010. Prior to joining Valeant, upon Valeant s acquisition of Dow Pharmaceutical Sciences, Inc. in 2008, Mr. Chaudhuri served for seven years as Dow s President and Chief Executive Officer and a member of Dow s Board of Directors from 2003 to 2008. Prior to that, Mr. Chaudhuri served

as Executive Vice President of Scientific Affairs at Bertek Pharmaceuticals, a subsidiary of Mylan Laboratories. Prior to his positions at Bertek, Mr. Chaudhuri served as the General Manager of the Dermatology Division of Mylan Laboratories. Mr. Chaudhuri joined Mylan through the acquisition of Penederm, Inc., where he worked from 1992 to 1998 in a number of senior positions before becoming the Vice President of R&D. Mr. Chaudhuri holds a Doctorate in Physical Pharmacy from the University of Louisiana, a Masters of Science in Industrial Pharmacy and a Bachelors of Science in Pharmacy from India.

When considering whether nominees for director have the experience, qualifications, attributes and skills, taken as a whole, to enable the Board of Directors to satisfy its oversight responsibilities effectively in light of our business and structure, the Nominating and Corporate Governance Committee of the Board of Directors and the Board of Directors focused primarily on the information discussed in each of the directors individual biographies set forth above. In particular, with regard to Ms. Hager, the Board considered her investment experience and familiarity with our company. With regard to Mr. Gale, the Board considered his investment experience, his role as the head of principal investment activities at Gruntal & Co., LLC, as well as his experience as a director with other pharmaceutical companies. With regard to Mr. Borkar, the Board considered his over forty years of experience in the pharmaceutical industry including having held various senior executive positions within the brand and generic segments of major pharmaceutical companies. With regard to Mr. Hemric, the Board considered his over twenty-five years experience with Alcon Laboratories. With regard to Mr. Moore, the Board considered his experience as a pharmaceutical executive with a successful track record in bringing over 50 generic topical products from development to approval. With regard to Ms. Erony, the Board considered her investment experience, her role as managing director of Citigroup s activities in specialty pharmaceuticals, as well as her experience as a director with other pharmaceutical companies. With regard to Mr. Chaudhuri, the Board considered his over twenty years of experience in the pharmaceutical industry, including having held senior executive positions with major pharmaceutical companies.

#### **Identification of Executive Officers**

In addition to Charles Moore whose biography is set forth above in Identification of Directors the following people served as our executive officers in 2010:

<u>Name</u> <u>Title</u>

Nadya Lawrence Executive Vice President of Sales and Marketing Philip Forte Former Chief Financial Officer

Nadya Lawrence (42) has served as our Executive Vice President of Sales and Marketing since April 2010. From 2006 to April 2010, Ms. Lawrence served as our Executive Vice President of Operations and from 2001 to 2006 she served as our Vice President of Operations. Previously, Ms. Lawrence served as our R&D Technical Director and R&D Manager from 1995 to 2001.

Philip Forte (58) served as our Chief Financial Officer from February 2010 to January 2011 and he served as our Controller from May 2009 until February 2010. Previously, Mr. Forte served as the Senior Director of Finance at Teva Specialty Pharmaceuticals Industries, Ltd., a generic pharmaceutical company. Prior to Teva Specialty Pharmaceuticals, Mr. Forte held various financial roles in corporate and public accounting including Bristol Myers Squibb and Aventis. Mr. Forte received his BBA in Accounting from Bernard M Baruch and his MBA in accounting and finance from Fairleigh Dickinson University. Please see the section entitled Separation Agreements below for more details regarding Mr. Forte s resignation.

None of our directors or executive officers is related by family to any other director or executive officer.

#### **Audit Committee of the Board of Directors**

The Company s Board of Directors has a standing Audit Committee. The members of the Audit Committee are Jane E. Hager (Chair) and Michael Hemric. The Company believes that the composition and functioning of the Audit Committee complies with all applicable requirements of the Sarbanes-Oxley Act of 2002, NYSE Amex and SEC rules and regulations, including those regarding the independence of the Audit Committee members. The Board of Directors has determined that Jane E. Hager, one of its independent directors, is an audit committee financial expert as currently defined under the SEC s rules implementing Section 407 of the Sarbanes-Oxley Act of 2002.

#### **Code of Ethics**

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. 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.

## Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and holders of more than 10% of our common stock, which we refer to as Reporting Persons, to file with the SEC and the NYSE Amex initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. SEC regulations also require such persons to furnish us with copies of all such reports. Based solely on our review of copies of reports filed by Reporting Persons and furnished to us, we believe that, except as set forth below, during 2010 our officers, directors and holders of more than 10% of our common stock complied with all Section 16(a) filing requirements. During 2010, Bhaskar Chaudhuri filed one late Form 3 relating to two transactions, Nadya Lawrence filed one late Form 4 relating to three transactions, James Gale filed one late Form 4 relating to two transactions, Narendra Borkar filed one late Form 4 relating to one transaction, Michael Hemric filed one late Form 4 relating to one transaction, and Joyce Erony filed one late Form 4 relating to one transaction.

ITEM 11.

EXECUTIVE COMPENSATION

## 2010 Summary Compensation Table

The following table sets forth the cash and non-cash compensation for the previous two fiscal years, which was earned by each of our former President and Chief Executive Officer and our former Chief Financial Officer who served during 2010, our current President and Chief Executive Officer, who also served during 2010, and our other most highly compensated executive officer who received compensation in excess of \$100,000 during 2010. We refer to these people in this Annual Report as our Named Executive Officers.

Name and Principal Position (1)	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$) (2)	Option Awards (\$) (3)	All Other Compensation (\$) (4)	Total (\$)
Hemanshu Pandya Former President and Chief Executive Officer	2010 2009	83,740 125,000	15,000	1,043,250 (5)	347,750 (6)	4,641 3,518	88,381 1,534,518
Philip Forte Former Chief Financial Officer	2010 2009	185,000 88,827	0 19,000	60,000 (7) 75,200 (7)	68,124(8)	28,538 11,632	273,538 262,783
Charles Moore President and	2010 2009	222,326	48,000	665,050		12,706	948,082

Chief Executive Officer(9)

 Nadya Lawrence
 2010
 144,200
 27,177
 171,377

 Executive Vice
 2009
 140,000
 25,947
 165,947

President of

Sales and Marketing

(1)

Lists the principal positions held as of December 31, 2010. On June 29, 2009, Hemanshu Pandya assumed the position as our President and Chief Executive Officer. Mr. Pandya resigned from our Board of Directors and as our President and Chief Executive Officer on March 19, 2010, effective April 1, 2010. On May 29, 2009, Philip Forte assumed the position of our Controller and was later promoted to serve as our Chief Financial Officer. Mr. Forte resigned as our Chief Financial Officer, effective January 11, 2011. On February 12, 2010, Charles Moore assumed the position of our Executive Vice President Technical Operations and was later promoted to serve as our President and Chief Executive Officer.

(2)

The amounts shown in this column represent the fair value of the awards on the date of grant, as computed in accordance with FASB ASC Topic 718.

(3)

The amounts reflected in this column represent the fair value of the awards on the date of grant, as computed in accordance with FASB ASC Topic 718. We valued these options using a Black-Scholes model. In the model, we used an expected life of five and one-half (5.5) years to value the ten year options that we issued. We used an interest rate equal to the yield on the treasury bonds that have approximately five and one-half years remaining until maturity and used the volatility of our stock price over a period that is approximately five and one-half years prior to the grant date.

(4)

The amounts shown in this column represent premiums for group life insurance, medical, and dental insurance paid by us, and contributions made by us to the executive s account under our 401(k) Plan. The amounts shown include \$12,847 in automobile reimbursements made to Mr. Forte in 2010 and \$9,022 in automobile reimbursements made to Ms. Lawrence in 2010. In 2010, we paid \$4,245, \$15,214, \$12,569 and \$692 for medical, dental, vision and group life insurance for Mr. Moore, Mr. Forte, Ms. Lawrence and Mr. Pandya, respectively. We also made contributions to the 401(k) Plan accounts of Mr. Pandya, Mr. Forte, Ms. Lawrence and Mr. Moore in the amounts of \$3,950, \$477, \$5,586 and \$8,461, respectively. The amounts shown include \$2,905 in automobile reimbursements made to Mr. Forte in 2009 and \$9,022 in automobile reimbursements made to Ms. Lawrence. In 2009, we paid \$318, \$6,818 and \$11,339 for medical, dental and group life insurance for Mr. Pandya, Mr. Forte and Ms. Lawrence, respectively. We also made contributions to the 401(k) Plan accounts of Mr. Pandya, Mr. Forte and Ms. Lawrence in the amounts of \$3,200, \$1,908 and \$5,586, respectively.

(5)

The unvested portion of \$695,535 of this stock award was forfeited on April 1, 2010 upon the resignation of Mr. Pandya.

(6)

This award was for options to purchase 530,145 shares, of which 176,718 options were vested on April 1, 2010 (date of Mr. Pandya s resignation) and 353,427 were unvested and forfeited. Mr. Pandya forfeited the vested portion of his options when he did not exercise them before their expiration date.

(7)

Mr. Forte resigned as of January 11, 2011, and at this time, 53,328 shares of these stock awards vested and the unvested portion of 106,672 stock awards was forfeited.

(8)

This award was for options to purchase 110,000 shares, of which 36,663 were vested on January 11, 2011 (date of Mr. Forte s resignation) and 73,337 were unvested and forfeited.

(9)

Mr. Moore is also a member of our Board and he did not receive any compensation as a director in 2010.

## Outstanding Equity Awards at 2010 Fiscal Year-End

The following table sets forth certain information concerning outstanding option awards as of December 31, 2010.

	Number of	Option Av Number of	wards	Stock A	<b>Awards</b>	
<u>Name</u>	Securities Underlying Unexercised Options (#) Exercisable	Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration <u>Date</u>	Number of Shares or Units of Stock That Have Not <u>Vested (#)</u>	Market Value of Shares or Units of Stock That Have Not Vested(1)(\$)
Hemanshu Pandya	176,718 (2)	353,427(2)	\$1.07	06/29/19	650,032 (3)	1,092,054
Philip Forte	36,663 (4)	73,337 (4)	\$1.01	05/29/19	106,672 (5)	179,209
Charles Moore						
Nadya Lawrence	5,000 30,000 40,000 100,000 30,000 40,000		\$ .52 \$ .80 \$ .65 \$1.07 \$1.27 \$ .76	12/27/11 05/16/11 05/23/12 05/20/13 12/20/14 12/09/15		

(1)

The market value is based upon the closing price of our common stock on December 31, 2010 (\$1.68).

(2)

These shares were scheduled to vest as follows: one-twelfth vested on June 29, 2009; one-twelfth vested on September 30, 2009; one-twelfth vested on December 31, 2009; one-twelfth vested on March 31, 2010; one-third will vest on June 29, 2011; and one-third will vest on June 29, 2012. This award was for options to purchase 530,145 shares, of which 176,718 options were vested on April 1, 2010 (date of Mr. Pandya s resignation) and 353,427 were unvested and forfeited.

(3)

These shares were scheduled to vest as follows: 325,000 shares were to vest on June 29, 2011 and 325,000 shares were to vest on June 29, 2012. These shares were forfeited on April 1, 2010 upon the resignation of Mr. Pandya.

(4)

Pursuant to the option agreements, these shares vest as follows: one-twelfth vested on June 1, 2009; one-twelfth vested on September 30, 2009; one-twelfth vested on December 31, 2009; one-twelfth vested on March 31, 2010; one-third will vest on June 1, 2011; and one-third will vest on June 1, 2012. Mr. Forte has 90 days from January 11, 2011 (date of Mr. Forte s resignation) to exercise his 36,663 vested stock options, and he forfeited the remaining 73,337 stock options that were not vested per his option agreement.

(5)

These shares were scheduled to vest as follows: 26,664 shares were to vest on June 29, 2011; 26,672 shares were to vest on June 29, 2012; 26,664 were to vest on February 12, 2011 and 26,672 were to vest on February 12, 2012. These shares were forfeited on January 11, 2011 upon the resignation of Mr. Forte.

## **Employment Agreements**

Charles E. Moore. Charles Moore commenced services as our Executive Vice President of Technical Operations effective February 12, 2010. Mr. Moore was promoted to serve as our President and Chief Executive Officer on March 19, 2010, effective April 1, 2010. Mr. Moore receives an annual salary of \$265,000. Pursuant to the terms of his employment agreement, Mr. Moore also received a grant of 379,000 shares of restricted stock, one-third of which vested on January 4, 2011, one-third of which will vest on January 4, 2012 and one-third of which will vest on January 4, 2013. In connection with his promotion to serve as our President and Chief Executive Officer, Mr. Moore also received an additional grant of 560,000 restricted shares of common stock. These shares had a grant date of April 1, 2010 and will vest over three years, in one-third increments beginning after Mr. Moore s first year of service as our President and Chief Executive Officer.

In addition, Mr. Moore is entitled to participate in certain of our benefit programs on the same terms and conditions generally provided by us to our executive employees. Mr. Moore will also be eligible to receive an annual performance bonus for each calendar year during the term of his employment, which may be payable in either cash, stock options and/or restricted stock. Mr. Moore s target bonus will be equal to 40% of his base salary for the applicable fiscal year. All performance targets pursuant to such plan shall be determined by our Compensation Committee.

Mr. Moore is also subject to certain restrictive covenants as set forth in his employment agreement, including confidentiality, non-solicitation and non-competition. Further, Mr. Moore is entitled to payment of six months of severance plus a pro-rata portion of his bonus, if he is terminated without cause. Mr. Moore s employment agreement further provides for payments upon certain other types of employment termination events as further set forth in his employment agreement.

#### Former Executive Officers

Philip Forte. Philip Forte commenced service as our controller effective May 26, 2009. Mr. Forte was promoted to serve as our Chief Financial Officer in 2010. Mr. Forte resigned as our Chief Financial Officer effective January 11, 2011 and entered into a Separation of Employment Agreement and General Release with the Company in connection with his resignation. Mr. Forte s Separation Agreement provides that we 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. 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.

Under the terms of his employment agreement, Mr. Forte received an annual salary of \$185,000. Mr. Forte also received a grant of (i) 80,000 shares of restricted stock and (ii) an option to purchase 110,000 shares of our common stock. In connection with his promotion to our Chief Financial Officer, on February 18, 2010, the Company further granted Mr. Forte 80,000 shares of restricted stock. Upon the effective date of his resignation, Mr. Forte retained the 53,328 shares of restricted stock that were vested and forfeited the remaining 106,672 shares of restricted stock that were not vested per his restricted stock agreement. Additionally, Mr. Forte has 90 days from January 11, 2011 to exercise his 36,663 vested stock options, and he forfeited the remaining 73,337 stock options that were not vested per his option agreement. In addition, Mr. Forte was entitled to participate in certain of our benefit programs on the same terms and conditions generally provided by us to our executive employees.

Mr. Forte was also eligible to receive an annual performance bonus for each calendar year during the term of his employment. For 2010, Mr. Forte s target bonus was \$46,250.

Hemanshu Pandya. Effective June 29, 2009, Mr. Pandya commenced service as our President and Chief Executive Officer. Mr. Pandya resigned from our Board of Directors and as our President and Chief Executive Officer on March 19, 2010, effective April 1, 2010. Under the terms of his employment agreement, Mr. Pandya received an annual salary of \$260,000. Mr. Pandya also received a grant of (i) 975,000 shares of restricted stock and (ii) an option to purchase 530,145 shares of our common stock. The foregoing equity grants had vested as to one-third of the shares as of the date of his termination. The remaining two-thirds of such grant terminated without vesting. Mr. Pandya was also eligible to receive an annual performance bonus for each calendar year during the term of his employment, which he did not attain in 2010 given his resignation. Mr. Pandya was also subject to certain restrictive covenants as set forth in his employment agreement, including confidentiality, non-solicitation and non-competition.

#### **Oversight of Risk Management**

We are exposed to a number of risks and we regularly identify and evaluate these risks and develop plans to manage them effectively. Our Chief Executive Officer and Chief Financial Officer are directly responsible for our risk management function and report to our Board and Audit Committee in this regard. In fulfilling their risk management responsibilities, our CEO and CFO work closely with members of senior management, including our accounting staff.

On behalf of the Board of Directors, the Audit Committee plays a key role in the oversight of our risk management policy. In that regard, the CFO meets with the Audit Committee at least four times a year to discuss the risks facing us, highlighting any new risks that may have arisen since they last met. The Audit Committee reports to the Board of Directors on a regular basis to apprise them of their discussions with the CFO. Finally, the CFO and CEO report directly to the Board of Directors on at least an annual basis to apprise them directly of our risk management efforts.

Director Options. In September 1999, our Board of Directors adopted the 1999 Director Stock Option Plan, which we refer to as the 1999 Plan. Under the 1999 Plan, on January 2 of each year, (i) each non-employee director is granted a stock option to purchase 15,000 shares of our common stock; and (ii) each of the Chairmen of the Audit Committee and the Organization and Compensation Committee is granted additional stock options to purchase 15,000 and 10,000 shares of our common stock, respectively. Additionally, under the 1999 Plan, each newly elected director will receive a stock option grant to purchase 15,000 shares of our common stock at the time of his or her election. All of such options will be granted at an exercise price equal to the closing price of our common stock on the NYSE Amex on the date of grant. All options granted under the 1999 Plan become 100% vested 12 months after the date of grant.

Director Fees. During 2009, the directors unanimously adopted a non-employee director compensation program which provides for equity grants to our non-employee directors under, pursuant to and in the amounts that were provided for in the original 1999 Plan as set forth above. The board of directors also approved the payment of an annual cash retainer of \$25,000, payable quarterly, to each non-employee director and a one-time grant of an option to purchase an additional 15,000 shares of our common stock to a non-employee director when he or she joins the Board of Directors (in addition to the similar 15,000 share grant pursuant to the 1999 Plan) pursuant to such program. This one-time award is granted to non-employee directors who join the Board of Directors after April 7, 2010. Ms. Erony, Ms. Hager and Mr. Gale have indicated that they will voluntarily defer any cash compensation otherwise due to them on account of director fees unless, until and only in the event that we return to profitability. In 2010, the board of

directors reduced the annual grant to the Chairman of the Audit Committee from an option to purchase 15,000 shares of common stock to an option to purchase 10,000 shares of common stock.

## **2010 DIRECTOR COMPENSATION**

Name of Director	Fees Earned or Paid in Cash (\$)	<b>Stock Awards</b> (\$) (1) (2)	Option Awards (\$) (1) (3) (4)	Total (\$)
Jane E. Hager	25,000 (5)		9,013	34,013 (5)
James C. Gale	25,000 (5)		9,013	34,013 (5)
Narendra N. Borkar	25,000		9,013	34,013
Michael Hemric	25,000		5,408	30,408
Hemanshu Pandya (6)				
Joyce Erony	25,000 (5)		5,408	30,408 (5)